Sexual Health Empowerment for Jail-Involved Women's Health Literacy and Prevention

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SHE-WOMEN PROTOCOL

SIGNIFICANCE OF PROJECT

Public health problem and opportunity. On any given day, one million women are under criminal justice supervision in the U.S.[13] Criminal justice policies in the U.S., linked to the 'War on Drugs' initiated nearly 50 years ago, have had a disproportionate impact on poor women, Black and Brown women, and women with complex trauma, mental health, and drug problems.[14] The criminal justice policies themselves result in stark class, race, and gender disparities when it comes to who gets incarcerated. [15] Indeed, the incarceration of women has increased at a rate double that of men for the decades since the War on Drugs was initiated.[16]

Because the U.S. incarcerates the most disenfranchised women in the country, mass incarceration has become a de facto driver of women's health disparities.[17] Women face health disparities related especially to their long trauma histories, ongoing drug use, and participation in the sex trade economy.[18] The U.S. also incarcerates women who, because of their poverty, lack of participation in the formal employment sector, and ongoing stints of incarceration, are least likely to have health insurance, primary care doctors, or usual places for medical care, all predictors of engagement in preventive health services that mitigate women's health problems.[19] Women who become incarcerated also have low levels of educational attainment to begin with, and we have found that their low levels of health literacy, in particular, may explain their health disparities.[3] They simply do not have high levels of women's health knowledge; they have varying beliefs about women's health practices and screening; and they have multiple barriers to self-efficacy for negotiating prevention and getting the health care they need.[3]

Our prior work has focused on addressing these women's health disparities. For example, we work to narrow *cervical cancer disparities,* since women with criminal justice involvement have 4-5 times the rates of cervical cancer compared to the general population.[4-6] Jailed women may also face *breast cancer disparities,* as only 40% of age-eligible jailed women are up to date on breast cancer screening, compared to 79% in the general population.[7-8,20] There are *disparities in unintended pregnancy* as well, with up to 84% of jailed women reporting unintended pregnancy, while only about 49% of women in the general population do so. [21,22] Finally, women with criminal justice histories bear the burden of *sexually transmitted infection (STI) disparities*, with higher rates of HIV, syphilis, Chlamydia, and gonorrhea, compared to the general population.[23,24,25] Our goal is to address these disparities through a comprehensive women's health literacy intervention.

Progress report for this study. To address just one of these women's health disparities, in 2014 we received funding to evaluate the effectiveness of a jail-based cervical health literacy intervention*,* Sexual Health Empowerment (SHE) for Cervical Health Literacy and Cancer Prevention*,* on changing the women's cervical health knowledge, beliefs, and self-efficacy, and confidence for screening and prevention (R01 CA181047, Ramaswamy (PI), 04/01/2014 – 03/31/2019). The first aim of the study was to assess the impact of a sexual health empowerment intervention (SHE Project) on cervical health knowledge, barriers to screening that are related to beliefs about cervical cancer, and self-efficacy for screening and follow-up among women leaving jail. Using a three-year observational design employing both survey and ethnographic methods for follow-up, the second aim of the study was to understand how knowledge, beliefs, self-efficacy, and other factors change post-release cervical health prevention behaviors over time. We published a paper in 2014 that described the need for the intervention and laid out intervention components.[26] We published a paper in 2015 operationalizing a definition for cervical health literacy – that is, women's knowledge, beliefs, and self-efficacy for cervical cancer screening.[3] From September 2014 to March 2016, we consented 261 women to participate in the jail and group-based 10-hour intervention, running 29 separate intervention groups. We followed up with a paper in 2017 showing that among the 182 women who completed the intervention in jail (we lost about one-third of consented women primarily due to jail turnover), cervical health literacy increased in 7/8 domains for participants in the experimental group, compared to the waitlist control group.[4] Our follow-up rates annually over the last three years have averaged an exceptional 85% with this incredibly hard-to-reach group of women. We currently have a paper in press describing our team's outreach and follow-up strategy.[12] Another paper published in 2018 described the rich theoretical framing of our intervention, using both social theory and feminist scholarship to undergird the content.[27] We have also completed our one-year post-intervention outcomes paper that showed that more women were up to date on cervical cancer screenings compared to baseline and that the best predictors for up to date Pap screenings were age, public benefits, medical insurance, along with cervical cancer knowledge, benefits, barriers, seriousness, and susceptibility (i.e., cervical health literacy).[28] Interestingly, we found that women who also went for STI screening after jail had greater increases in cervical health literacy in 5/8 domains, suggesting that components of the original SHE intervention extended to other women's health outcomes.

Women who consented to participate in SHE had several women's health risk factors, as shown in Table 1. During execution of SHE, we observed: 1) the cross-cutting nature of women's health risk factors, i.e. the risks that jailed women faced for cervical cancer also could lead to other women's health problems; and 2) an opportunity for taking a now evidence-based intervention, with a rich theoretical framing, to expand to other women's health issues faced by this group of women, around, not only cervical cancer prevention, but also breast cancer, unintended pregnancy, and STI prevention. *It is this opportunity that is the focus of this study.*

Table 1. Justice-involved women's health risk, N=261	**N (% or SD)**
Cervical cancer risk	
No Pap test in past 3 years	59 (22.6)
Lifetime abnormal Pap test	126 (48.2)
Cervical cancer diagnosis	30 (11.4)
Breast cancer risk	
No mammogram for 50 or older (N=23) in past 2 years	11 (47.8)
Unintended pregnancy risk	
Lifetime unintended pregnancy	207 (79.3)
No past month birth control use (excluding hysterectomy)	76 (29.1)
Sexually transmitted infection risk	
Lifetime STI history	163 (62.4)
No condom use at last sex	196 (75.1)
Ever sold sex	91 (34.8)
Cross-cutting risk factors	
Past month tobacco use	205 (78.5)
Alcohol use problem	132 (50.5)
Past year drug dependence	163 (62.4)
Lifetime mental health diagnosis	191 (73.1)
Past year intimate partner violence	133 (50.9)
Uninsured	160 (61.3)
No primary care doctor	150 (57.4)
No medical home	70 (26.8)
Lifetime months incarcerated, *Mean*	24.2 (45.3)
Race/ethnic group with higher cancer mortality	
e.g. Black	83 (31.8)
e.g. Hispanic	21 (8.0)
Age, *Mean*	33.7 (±9.9)

We took advantage of a study team that included public health graduate students, medical students, and NIH diversity supplement trainees on SHE to start building out the other intervention components. We also leveraged relationships with local organizations to start piloting intervention content. In SHE, we had already built out the cervical health literacy content. Using the same health literacy framework and theoretical underpinning, we built and integrated components for age and risk appropriate breast cancer, birth control, and STI literacy. With departmental funds, a university fellowship supporting a medical student and funding from NCI through a diversity supplement to the parent SHE grant (R01CA181047-S2, Pickett, Trainee), we have begun piloting the new intervention components. We have run three cycles of the birth control literacy curriculum with women in a local domestic violence shelter. Though the sample size is small (N=25), we showed gains in birth control literacy, and have made necessary changes to the content based on the piloting.[29] We have conducted focus groups with 32 women to help build content for STI literacy. We also developed breast cancer literacy content and have manuscripts under review in each of these three areas.[7,10,28] Most papers describe health risks, while some, like the birth control literacy paper, describes the piloting of our intervention. During summer 2018, while this proposal is under review, one of the diversity supplement trainees (Pickett, an MD who specializes in sexual health) will work with the SHE Project Director (who was the primary SHE health educator) to integrate content for all four areas of our new intervention, SHE-Women (Table 2). SHE-Women will specifically target *cervical, breast cancer, birth control, and STI literacy, screening, and risk reduction.*

Table 2. SHE-Women - A women's health literacy curriculum			
Knowledge of cervical, breast cancer, birth control, and STIs	**Beliefs** about cervical, breast cancer, birth control, and STIs	**Self-Efficacy** for cervical, breast cancer, birth control, and STI screening	**Confidence** navigating health systems for screening and risk reduction
Female body anatomy Medical terminology How stuff works in the body, prevention, and cures Procedures Costs	Beliefs about disease Beliefs about screening Where you learned about sex/health/prevention? What do you share with kids, partners? Romantic/sexual relationship dynamics Experiences with providers Motivations for screening and prevention	What is self-efficacy? Do you know where to go for services/experiences at these places/barriers? Do romantic/sexual partners get in the way/help? How to get results? What makes it easy to get services? Drug use/ homelessness/ transportation/ financial/ other barriers – how to overcome?	Confidence navigating providers given long-term criminal justice involvement? Jail health care and services, trust, cost Outside of jail services, trust, cost, fears Insurance/no insurance Social support for health care seeking Coercion

We hypothesize that SHE-Women, like the original SHE intervention, will be effective at increasing women's health literacy, screening, and risk reduction practices among the vulnerable group of women leaving jail. To test this hypothesis, the first goal of this study is to assess the effectiveness of the broadened SHE-Women intervention. Our study addresses the health disparities faced by women leaving jail, and the relative lack of evidence-based programming for this group of vulnerable women.

A second goal of this study is to test intervention modality. SHE-Women will rely on an integrated, mediated electronic platform to deliver content and engage participants.[30] Delivery of the original SHE intervention required daily entry into the jail for 5 days per intervention cohort. Two health educators needed to be present. While there were advantages to this approach (group context, building rapport, conversation), there were challenges associated with access to the jails, costs for staffing, and replicability across criminal justice facilities. Thus, in this study we will test the effectiveness of an integrated, multimedia electronic women's health literacy intervention delivery program through a text and Web platform.[31] To support a trial of this new modality, our diversity supplement trainee collected data on the feasibility of offering the intervention in a text-Web platform to 32 jailed women. The trainee found that women access the internet daily when in the community and have interest in an electronic women's health platform with access to health professionals via the platform. In another study, we found that 88% of our participants had a mobile phone; 76% sent and received text messages, and 50% accessed the Web on their phones. About 79% of the women said they used internet regularly – with most citing internet use at the public library, home, or from their mobile phones. Seventy percent had Facebook accounts. Many of the participants stayed in touch with our outreach team through text messaging. They texted the PD/former health educator a day or two after their release, suggesting that they knew us, trusted us, and looked to keep in touch after jail.[12] For example, 40% of participants regularly engaged with us through a closed Facebook group, post-intervention. This rapport is reflected in an 85% follow-up rate even three years post-intervention. In this study, our data supported the movement of SHE-Women to an integrated, multimedia electronic women's health literacy intervention delivery program through a text and Web platform. If such an electronic sexual health educational program is effective, for future projects, we can create an intervention model that is replicable across other groups of high-risk women in the community.

It is worth noting that 80% of women with criminal justice involvement are *in the community*, rather than confined. Thus, for the purposes of reducing this population's health disparities, an intervention modality that works for vulnerable women *in the community* has the greatest potential utility. Because of our history of working with women leaving jails, we are also uniquely positioned to conduct a trial that tests the effectiveness of an integrated, multimedia electronic women's health literacy intervention delivery program in this context.

Our third goal is focused on investigating the role and impact of trust and rapport that health educators build with participants during behavioral interventions. Although we did not measure trust and rapport in the original SHE study, we always commented about the "Joi effect" on participants – Joi being the name of our lead health educator, and the ways in which the women responded positively to her. We also realize that although fitness apps and electronic interventions are extremely popular, many miss the potential benefit of integrated human interaction with a health "expert." [31] Thus, our study formalizes the measurement of perception and impact of human interaction in behavioral and electronic interventions. Dr. Shawana Moore has been awarded a diversity supplement (NIH R01CA181047-S1 Ramaswamy). The overall goal will be to develop an electronic literacy intervention focused on the prevention of cervical cancer through implementation of HPV catch-up vaccination among criminal legal system (CLS)-involved women aged 27-45. The aims of this supplement are as follows:

1) Assess the interest and needs for adapting and implementing an HPV catch-up vaccine module for the SHE-WOMEN.

2) Create and pilot an electronic HPV vaccination catch-up module for women with criminal legal system involvement.

3) Evaluate the impact of the electronic HPV vaccination catch-up module in a sample of 25 women.

For this supplement, Dr. Moore will work with Dr. Ramaswamy and the SHE-WOMEN study team to conduct formative interviews (N~40) with women in the target population. Women will be recruited from within the ongoing SHE-WOMEN RCT. Eligibility will be based on age – targeting the 27-45 age group – with a focus on recruiting women who have NOT received HPV vaccine. A

A verbal consent will be read, and an informed consent will be provided if the participant requests. Participants will participate in a 20–30-minute semi-structured interview. Interviews will be recorded with the participant's consent. They will be paid $10 for their participation in interviews. Participants may stop at any time, if they do not want to complete the interview.

To evaluate the impact of the electronic HPV vaccination catch-up module, Dr. Moore will have 25 women look at content for a new HPV vaccine module, then ask questions about their demographics, HPV knowledge, beliefs and vaccination receipt. Participants will be paid $25 for completion of the survey.

Audriana Angeles has been awarded the Clendening Fellowship funded by the KU School of Medicine. The aim of her project is to assess the experiences and perspectives of women who utilized health services in jails and prisons. For the project, Audriana Angeles, will work with Dr. Ramaswamy and the SHE-Women study team to contact 20 current SHE-Women participants by phone or Zoom using a random list. She will ask a set of questions to do more in depth inquiry into jail health care experiences. Each participant will be paid $25 for their interview, which we estimate will last 20-30 minutes each. A verbal consent asking, "Would you be interested in answering a few questions about any health care you received while you were in jail or prison?", will be read before the interview.

We bring together an exceptional team of researchers and staff to work on this project – most of us have been together since the inception of the original SHE study. Members of the original team include PI Megha Ramaswamy (PhD, MPH with 15 years of work in the criminal justice system; continuous funding for this work from NCI since 2011); PD Joi Wickliffe (MPH, working with Ramaswamy since 2012, and on SHE team as lead health educator, and then PD); Data Manager Molly Allison (MPH, working with Ramaswamy since SHE began in 2014, trained in epidemiology); Co-I/Statistician Jaehoon Lee (PhD, collaborator with Ramaswamy since SHE began in 2014); Consultant Patricia Kelly (PI's main collaborator on jail-based programming for the last eight years); Co-I Michelle Pickett (MD with expertise in STIs and Ramaswamy's diversity supplement trainee). New members of the team include Co-I Kevin Ault (MD and OBGYN, international expert in HPV and cervical cancer screening, collaborator with Ramaswamy on other NCI grants); Co-I Catherine Satterwhite (PhD, MSPH, international STI expert, former CDC employee for over a decade, and collaborator with Ramaswamy on contraceptive research); Co-I Jennifer Klemp (PhD, breast cancer researcher and leader of Cancer Prevention core of NCI-Designated Cancer Center); and Co-I Mugur Geana (MD,PhD, health communications expert and leader of Health Communication Research core at NCI-Designated Cancer Center). This team of collaborators will ensure success at meeting aims and translation of findings.

Scientific premise and significance. This study is premised on an identified public health problem that offers a unique opportunity to build on an evidence-based approach, grounded in a solid and empirically-tested theoretical framework; an empirically-based intervention designed from data our team collected; for a population who despite great health risks, have few intervention options designed to mitigate these risks. To our knowledge, no one is intervening on cervical and breast cancer risk with the group of high risk women with justice involvement, and certainly no one is intervening with women in transition from jails to community (80% of justice-involved women are community-based). We have the knowledge, skills, experience, team, and established relationships with participants to be successful. Although some researchers have worked on birth control and even more have worked on STI screening (with good results), [32,33] no one is working in the domain of women's health literacy when it comes to justice-involved populations. Intervening on health literacy has been cited by the Institute of Medicine as a priority area,[34] and the original PA for which we applied when SHE was funded was health literacy focused.[35] We are expanding and building on our NCI-funded intervention, which was our goal originally. In this study, we are packaging the SHE-Women intervention in such a way as to be a) comprehensive in addressing women's health broadly; and b) translatable to other groups of adult women by testing an integrated, multimedia electronic women's health literacy intervention delivery program. The study is significant because it addresses the health disparities faced by a high-risk population combined with the use of an electronic women's health literacy platform, which, if found effective, increases the potential for adoption and implementation by other groups.

INNOVATION

The primary innovation of our research with women in jails is that for the most part, criminal justice involvement is a negative experience. But our work seeks to shift the paradigm by tying women's criminal justice stays with preventive health opportunities.

While the effectiveness of electronic health communications has been demonstrated in other contexts,[31] few interventions have been designed for the high-risk and hard-to-reach group of adult women leaving jails. [36-38] We are able to design such an intervention given a long track record of work with this group, excellent follow-up records, and thus data to support the feasibility of this intervention. Studying the effectiveness and context in which an electronic women's health literacy intervention works is highly innovative for the field of people working with justice-involved persons, as few have tested this modality in this context.

We also seek to take an active role in shifting the paradigm by undertaking research on integrated, multimedia electronic women's health literacy intervention programs to increase our understanding of how and why electronic interventions work. Much of the work in fitness apps and electronic means of getting people to

change behavior rely on the assumption that electronic engagement is enough. We shift the research by paying explicit attention to the nature of human interaction needed in these intervention models.

A final innovation of our work is that it seeks to shift the paradigm in clinically-relevant research that targets underserved members of our catchment area. Especially when it comes to cancer prevention research, those least likely to be served (the poor, racial/ethnic minorities, the transient) are at the highest risk for cancer morbidity and mortality.[39,40] We are testing an intervention that could potentially be easily disseminated to high-risk populations in our own catchment area, throughout the state and, potentially, even nationally.

Our hypothesis about the potential effectiveness of an electronic women's health literacy intervention is based on "medium theory," that is the idea that new electronic mediums can disrupt conventional thinking in communications and offer new pathways to health education that destabilize power relations in traditional modes of bi-directional health education. If our hypothesis is correct, we will create an innovative approach to reaching disenfranchised and disempowered populations to help promote better health and life outcomes and, potentially, save costs to and pressures on health care systems.

APPROACH

Overview of study. The objective of this study is to expand the reach of SHE to address women's health disparities more broadly, and to create a sustainable model for dissemination of health promotion interventions for vulnerable populations. In the first aim (Year 1), we will run a pilot study to assess feasibility of the expanded content and electronic women's health literacy intervention delivered through text-Web modality with N~10 of our original SHE participants. Feasibility outcomes include uptake of intervention components, barriers and facilitators of implementation, problems with delivery, and necessary modifications. Pilot effectiveness outcomes will include an assessment of women's health literacy, operationalized as knowledge, beliefs, and self-efficacy for screening related to cervical, breast cancer, birth control, and STIs, post-intervention.

In the second aim (Year 2-3), we will conduct an RCT with N~200 newly recruited women to test the effectiveness of the SHE-Women electronic women's health literacy intervention: the intervention arm will get SHE-Women; the control arm will get a standard of care discharge planning session and health education booklet. Assessment of effectiveness will occur on two outcomes: a) Women's health literacy, operationalized as knowledge, beliefs, and self-efficacy for screening related to cervical, breast cancer, birth control, and STIs; and an increase in COVID-19 health literacy and increase in self-efficacy for prevention immediately post-intervention and 1-year post-intervention; b) Screening/ risk reduction for cervical, breast cancer, unintended pregnancy, and STIs at 1, 2, and 3-years post-intervention (follow-up complete by Year 5).

In the third aim (Year 3-5) we will track participants and conduct key stakeholder interviews to better understand the role and impact of human interaction in electronic interventions to answer the question: how much human "touch" is needed to make an intervention effective? Outcomes will include perception and uptake of intervention components, women's health literacy, screening, and risk reduction outcomes. Table 3 describes aims, activities, outcomes, and benchmarks.

Table 3. Aims, Activities, Outcomes, and Benchmarks

Activities	Outcomes	Benchmarks for success
Aim 1. Assess feasibility and pilot effectiveness of 'SHE-Women,' an electronic women's health literacy intervention.		
• Finalize IRB protocol/approvals • Finalize build out of expanded intervention content/ text-Web platform • Re-consent N~20 women in original SHE cervix study to participate in SHE-Women via text-Web platform/ deliver SHE-Women • Conduct stakeholder interviews with participants of SHE-Women pilot • Conduct baseline, post-intervention assessment of women's health literacy outcomes • Refine intervention content/text-Web platform for Aim 2 RCT	• Uptake of components • Barriers and facilitators of implementation • Problems with delivery • Modifications needed • Women's health literacy: knowledge, beliefs, self-efficacy for cervical, breast cancer, birth control, STI screening • Increase in health literacy and self-efficacy for avoiding COVID-19	• IRB approval secured prior to study start • Intervention content build out and text-Web platform ready by Y1Q3 • Re-consent and deliver SHE-Women to N~50 original SHE participants from Y1Q3-Y1Q4 • Key stakeholder interviews conducted between Y1Q3-Y1Q4 • Refine intervention content and text-Web platform for Aim 2 RCT by Y1Q4 • Manuscript #1 mixed methods pilot study to modify an electronic intervention for women leaving jail in Y1
Aim 2. Test the effectiveness of SHE-Women on women's health literacy, screening, and risk reduction practices against a standard of care discharge planning session using a randomized controlled trial.		
• Recruit N~200 women leaving jails, women in community organizations that cater to our	• Women's health literacy	• Recruit, consent, and deliver intervention and control arms to N~200 women between Y2Q1-Y3Q4

organizations (i.e. transitional living facilities, DV shelters, social support centers,etc.) • Randomize participants to intervention and control arms • Deliver SHE-Women to N~100 women via text-Web platform; deliver standard of care discharge planning session to N~100 women • Conduct baseline, post-intervention, 1, 2, 3 year assessments of women's health literacy and screening/risk reduction outcomes • Conduct N~30 stakeholder interviews to determine efficacy of COVID-19 module	• Screening/risk reduction for cervical, breast cancer, unintended pregnancy, STIs and COVID-19	• Manuscript #2 strategies for recruiting women leaving jails into health promotion interventions in Y3 • Conduct follow-ups for 3 years from intervention during Y1-Y5/ maintain 75-85% follow-up rate • Manuscript #3 effectiveness of SHE-Women at improving women's health literacy in Y3 • Manuscript #4 effectiveness of SHE-Women at improving women's health screening/risk reduction in Y4 • Placement of SHE-Women on NCI Research-Tested Intervention Programs site in Y5 • Manuscript #5 3-year outcomes of interventions in Y5
Aim 3. Understand the role and impact of human interaction in electronic interventions by tracking participants and interviewing key stakeholders.		
• Collect uptake data on use of text messages with health educator and attendance at community sessions • Track participant use of text-Web components • Conduct N~20 stakeholder interviews with participants to assess perceptions of human interaction in intervention delivery (5 intervention arm; 5 control arm; 10 utilizers of texting with health educator or community sessions)	• Perception and uptake of intervention components, electronic or otherwise • Women's health literacy, screening/ risk reduction outcomes.	• Participant tracking and collection of intervention component uptake data to occur between Y2-Y5 • Key stakeholder interviews conducted between Y3Q4-Y4Q1 • Manuscript #6 perceptions of role of human interaction in intervention delivery in Y4 • Manuscript #7 uptake of text-Web components among high-risk women in Y5 • Manuscript #8 impact of human interaction (uptake of text messaging with health educator and/or attendance at community sessions) on women's health literacy and screening/risk reduction in Y5

Settings, eligibility, recruitment, and sampling. Aim 1 pilot study settings will be in the community. Women will be eligible if currently participating in the original SHE study (85% of whom are in the community), if they volunteer to be re-consented to the pilot study, and if they are not actively intoxicated, so as to provide true consent to participation. For recruitment, we will use a random number generator to generate a random sample of N~30 women from the original SHE study to participate, oversampling to account for attrition, with the goal of ending at N~20 women for participation in the pilot. We will use this same process to generate a sample of N~20 women to pilot the COVID-19 modules. We anticipate that most (N~90%) participants we approach will re-consent to longer participation in the study, based on feedback we have gotten from the women in our 3-year follow-up interviews. For recruitment, we will use phone and Facebook outreach through a closed group to contact participants. These are the same methods we have used for follow-up for the last three years with an average 85% follow-up rate. Sample size is determined by our previous mixed methods pilot studies for feasibility. From this same group of women, we will request participation in stakeholder interviews which will be conducted using Zoom, a web-based video conferencing tool . We anticipate we can recruit the women within a three-month period, but are leaving six months, in case we encounter problems or need to collect additional stakeholder data.

Aim 2 RCT settings will be various locations in the Kansas City metro: two urban city/county jails in Kansas City – one facility on the Missouri side of the state line, and one facility in Kansas. We will also recruit women in various community settings with the women having a release date of five years post incarceration. We will recruit women in social support centers, DV shelters, transitional living facilities and other community organizations where our population may frequent. Our goal is to work with women leaving jail or with recent criminal justice involvement using an electronic women's health literacy intervention modality; volunteer for the study; and do not exhibit psychological distress, which would prohibit informed consent. There are no age or medical study exclusions, since all women could potentially benefit for guidance on cervical, breast, unintended pregnancy, and STI screening. For recruitment in jails, we will work with discharge planners to recruit women scheduled to be released from jail. The jail staff will distribute hygiene packets to women as they are being released while introducing the program. included in these packets, the women will see a business card with our picture and contact info so that if they are interested, they can call us. For sampling, on any given day, about 120 women are incarcerated in the KC, MO facility and 45 women are incarcerated in the KC, KS facility. In local community organizations, we will distribute our 'flyer' that will be placed in the organization, where the population frequents. We will recruit a convenience sample of N~260 women for the RCT, oversampling to account for attrition, with the goal of ending with N~200 women for the RCT. In our previous studies, we have found that in these facilities between 1-4 women are released each day, and that we were

able to recruit about 50% of these women.[3,4,9] Given the sample size of women being released each day, our ability to recruit, and staff schedules, we anticipate that it will take one year to recruit the RCT sample, though we are allowing for a two-year period in case we have challenges. To increase the sample size, respondent-driven sampling (RDS) will be used. The post-intervention survey will ask participants if they have friends who have been in jail or prison within the past 5 years and who would be interested in participating in this study. Participants will have friends contact the study team and can have up to 5 friends complete the baseline survey, earning $20 for each completed baseline survey (with the potential to earn up to $100). Sample seeds will be tracked in Redcap. Because of our relationship with our current population of women (participants in the parent SHE study), we have a unique opportunity to recruit women from our participants in our parent study. These women will receive the same incentive: up to $100 for five friends who consent and complete a baseline survey.

Aim 3 settings will be in the community. We will track participants and interview key stakeholders in the community. All participants, regardless of intervention assignment, will be invited to utilize text messaging with a health educator and attend community sessions. The community sessions will be at two public libraries in neighborhoods where > 50% of participants live.[18] Eligibility for participants will be enrolling in the Aim 2 RCT. Recruitment will be as follows: to assess perceptions of human interaction in intervention delivery, we will recruit for key stakeholder interviews five participants from intervention arm; five participants from control arm; and 10 participants who utilized text messaging with health educator or community sessions. We will ask the first participants we interview for Aim 2 follow-ups if they would like to be interviewed; if they say no, we will move on to the next participant we encounter in follow-up. Sampling will be purposive We will track all participants in the RCT to assess intervention uptake. We will also choose 40 random participants to participate in the COVID-19 module interview. The participants will receive $10 to complete a 20 minute interview. Data collection for this aim will occur throughout the study period, leaving sufficient time for more key stakeholder interviews if needed.

Intervention content, theoretical framing, and modality. Table 2, presented earlier, described the core domains of SHE-Women, a comprehensive women's health literacy intervention. As in our original SHE intervention, we operationalized health literacy as knowledge, beliefs, self-efficacy for screening, and confidence navigating health systems (see Table 2).[26] The original SHE intervention focused on cervical health literacy, screening, and prevention. The primary change in this new study is the broadening of scope to include cervical, breast cancer, birth control, and STI literacy, screening, and prevention of unwanted health outcomes. This tying together of women's health issues reflects three important areas: 1) cervical cancer risk does not happen in isolation for risks from other women's health issues; 2) in delivering a cervical health intervention it is impossible not to address broader women's health concerns. In fact, the women probed us about other conditions like breast cancer, birth control, and STIs; 3) age and risk-appropriate screening for multiple women's health conditions is a part of routine clinical practice. The old "well-woman exam" is a jumping off point for comprehensively meeting women's needs. Thus, by tying together women's health issues, women may be empowered to advocate for comprehensive women's health screenings at every encounter with clinicians, rather than focusing on one condition and ignoring others. The health information women will receive will be about breast cancer, cervical cancer, STIs, and birth control. Women will receive information about these health issues, how to get care for these issues, how to prevent health problems, and will be able to review what challenges women face preventing health problems. A module specific to the COVID-19 pandemic will be included in the intervention due to the effect it has had on various health outcomes and media literacy.

The new intervention, SHE-Women, is guided by the theoretical framing of the original SHE intervention, drawing on social and feminist understandings of health[27]: 1) we leverage the participants' own beliefs about health screenings and knowledge about navigating health systems in their communities; 2) we meet the women where they are at, rejecting status quo assumptions about women, the siloing of women's health issues, and the judgment about their social context, which includes long histories of trauma, mental health problems, drug use, and for some, sex work.

A second major change in the intervention for this study is the movement of SHE from a face-to-face, group, and jail-based format, into a community-based electronic women's health literacy intervention platform designed for women *leaving jail*. We have learned a lot during our follow-up of the SHE participants over the last three years about their use of technology[12] – text messages, Web, and Facebook – and operate on the premise that using an electronic platform would be a cost-effective and more easily disseminated way of reaching high-risk women. If successful, this new electronic platform could be highly replicable. We also know that for the high-risk group of women with criminal justice involvement, upwards of 80% are community based, having recently been released from jail, on probation or parole, or in community corrections. Thus, the

community is where most of these women are, and given what we know about how to *find* women after release from jail, we are uniquely poised to test this type of intervention.

We should also note that for this particular group of women we have chosen an integrated, multimedia electronic women's health literacy text-Web platform intervention system, rather than just a smartphone application to deliver content. This is primarily because most women (76%) use text messages, while only 50% browse the internet on their mobile phones, suggesting a lack of data plans needed to utilize an app. We also know from follow-ups, that many women have "burner" type mobile phones, not permanent smart phones.

Intervention software platform. A content management system (CMS) will be the foundation of the software platform that will be developed to support the current study and will provide seamless integration of SMS (text) messaging with the Web-delivered content. As one of the purposes of this research is to be the starting point for wider dissemination of this intervention addressing cancer prevention among this at-risk population, the technology we will implement should also serve as the core for future development. Considering both the characteristics of the target audience as well as the specific requirements of the project, the proposed CMS will 1) allow publication of content in various formats (text, audio, video); 2) asynchronous communication with users using various methods, starting with SMS messaging; 3) synchronous communication with users (e.g., chat); 4) integration with various social media channels (e.g. Facebook); 5) track user interaction with the content and automatically respond to certain user actions (e.g., send SMS reminders if the user does not open the content within a certain period of time), and 6) collect data using automated metrics (e.g., access logs, data usage logs) and survey-like tools. The CMS will be developed by the Health Communication Research core of the University of Kansas Cancer Center, which will also provide know-how and assist with the production of the multimedia content for the Website. In-house development will start from an existing development platform such as Django, Plone, or ModX. This solution uses proven infrastructure to develop a highly customized ecosystem that would be able to combine the above functionality in one integrated software platform and make both problem-solving and future development easy. A dedicated administration page will provide researchers with aggregated as well as individual use, and allow full management of the CMS. User access to content will be PIN-protected, and data transfer will be encrypted. We are leaving nine months to build out the electronic health literacy intervention and six additional months to test it, with additional time if needed.

Intervention arms and procedures. All women will be mailed a SHE-Women booklet with the intervention content. Electronic women's health literacy intervention procedures (intervention arm**).** e will deliver the integrated, multimedia electronic women's health literacy intervention arm of SHE-Women in text-Web format for individuals recently released from jail or have recent involvement with the criminal-legal system (2 years). Two health educators will be responsible for delivering content to participants, with an estimated contact time of ~10 hours pushed to participants over approximately a 5-day period. However, because it is a text-Web intervention, accessing content will be dependent on user engagement with the platform. We will measure uptake of the intervention components as it relates to number of minutes of engagement and length of time (total number of days) that all content was accessed. The lead health educator will describe the study and obtain consent from participants. If participants consent, they will immediately be asked to participate in a baseline survey.

For Aim 1 pilot study participants, this will occur over phone or in person in the community. For Aim 2 RCT participants – all of this will occur at the jail at the participant's time of discharge. Participants will be informed that after consent/ after they leave jail, in order to initiate the program, they should contact the health educator through phone, text message, email, or Facebook message. We estimate that we might lose 30% of women between consent and initiation of the community-based intervention, simply because they do not follow-up with us. Thus, in the Aim 1 pilot study we will over-recruit by 15 women; and in the Aim 2 RCT we will over recruit by 60 women, to make up for potential loss to attrition. To improve rates of follow-up, we will also collect multiple points of expected contact information for the participants: phone numbers, addresses for themselves or family members; usual places of hangout; and Facebook handle. That way, if participants don't reach out to us within three days of consent/release from jail, we can contact them.

Participants who successfully initiate the intervention, over a 5-day period will be sent texts to their mobile phone or messaged through email or Facebook (participant preference) with a link to content on a SHE-Women Website. Content will correspond to Table 2, with tabs for Knowledge, Beliefs, Self-efficacy, Confidence navigating systems, and Wrap-up/review. Content will be delivered through a mix of short videos of the health educators and standardized patient actors discussing content (available in video and audio only format), interactive quizzes, and plain text. Although participants will be able to access content in all five areas, they will receive a daily text message for each area. For example, on Day 1, they will receive a text message to engage in Knowledge content; Day 2, a message to engage in Beliefs content; Day 3, a message to engage in

Self-Efficacy content; Day 4, a message to engage in Confidence navigating health systems content; and on Day 5, a message to complete Wrap-Up content and be invited to complete post-intervention assessments.

A second health educator will monitor whether participants access content after receiving the text messages. If participants have not accessed content within 24 hours of receiving a text message prompt, they will be sent a second text message invitation. If participants still haven't responded, they will receive a phone call from the lead health educator, or a video message through Facebook, that is directly geared toward the participant, re-inviting them to access content for that day.

The SHE-Women Website will also have a tab available to live-chat with a health educator 5 days a week for 8 hours a day. Participants will be able to send messages to the health educator through the SHE-Women Website, if they are not able to live chat. This feature will be available in addition to standard text-message access to a health educator during business hours. We will add weekend or evening hours if necessary.

Although the text-Web intervention will be designed to be accessed over a continuous 5-day period; participants will be given a three-week window to access all intervention content, to allow for self-directed completion of the text-Web intervention. As soon as participants access all intervention content, the second health educator will be triggered to complete a post-intervention assessment. The post-assessment will be offered to participants over the phone or through an electronic link to the survey.

We will not provide participants equipment or electronic devices. The goal of this project is to assess whether a text-Web intervention is feasible and effective in real life circumstances, thus, with the participants' own devices. We will not pay for any data usage charges to participants. However, because we are compensating participants for study participation, they can use some of the money from study compensation to cover any data usage costs incurred. There are no limitations on what devices can be used. Though participants will have to either receive initial text messages either through a mobile phone or through a private Facebook message. A third option could be through an email address. Participants will then need to be able to access Web content, but they can do that at any place of their choosing: a mobile phone, a home computer, a public library computer, or at some other place.

Standard of care discharge planning session (control arm**).** In the Aim 1 pilot study, participants will only access the intervention arm content. In the Aim 2 RCT, participants will be randomized after consent to the intervention or control arm. The women will be offered a 10-page women's health booklet that utilizes SHE-Women content, but in print form. The booklet will provide simple definitions, screening guidelines, and local health resources for age and risk appropriate cervical, breast cancer, unintended pregnancy, and STI prevention. We will collect multiple points of contact information for the participants: phone numbers, addresses for themselves or family members; usual places of hangout; and Facebook handle, for follow-up. Participants in this arm of the intervention will be contacted 5 days after receiving the standard of care intervention for post-assessment. Similar to the intervention arm, we expect to lose 30% of women to follow-up, thus we will over-recruit by about 30% for the RCT, as described above. Participants will be asked to reach out to us 5 days after or we will contact them for follow-up and to complete the post-assessment over the phone or through an electronic link to the survey.

We wish to note that although we call the control arm the "standard of care," in reality there is no standard discharge planning session in the jails we work with; women are sent out the door with their belongings. But we feel it would be grossly unethical to not provide the control arm with some health information, even if limited.

Opportunities for human interaction – text messaging and community sessions (both arms invited). To develop a more robust measure of the impact of human interaction on intervention outcomes for Aim 3, we will invite participants from both intervention arms to participate in text messaging with a health educator if they have questions *and* with the opportunity for attendance at community-based women's health group sessions. To facilitate access to text messaging with a health educator, all participants will be given the health educator's study cell phone number, which she will respond to during business hours. The health educators will also hold quarterly women's health discussion sessions at two public libraries in the Kansas City neighborhoods in which >50% of our participants live.[18] These are public sites where participants know how and when to access services, per our past experiences with them. All participants will be invited, regardless of randomization.

Compensation and retention**.** Pilot study participants will receive $25 for completing the intervention, and $20 for completing the stakeholder interviews. All participants of the RCT will be offered $50 for completing the intervention. The women in the control arm will receive the same payment to be fair. Participants who complete the COVID-19 interview will receive $10. Compensation will be placed on a debit card. We have used this method and amount of payment successfully in our previous work with these women.[3,5,9]

Retention of participants for the annual follow-ups will be accomplished through effective methods that our research teams have developed and used successfully for the last eight years to achieve excellent follow-up

rates (in our original SHE study, the 3-year follow-up rate is 85%).[12] These methods include supplementing existing participant contact information with names, addresses, phone numbers of participant, family members, friends; places of congregation such as bars, bodegas, street corners, or churches; places for usual drug or mental health treatment (with signed approval to contact facilities), places of previous incarcerations, along with social media hangouts such as Facebook and Snapchat. We will employ previously successful quarterly check-ins during which we verify contact information of participants who will be provided a $10 incentive. These check-ins will last 5 minutes at most. The only topic to be discussed at the check-in is the verification of contact information (have phone numbers changed? Addresses? Or any other contact information change that we should know about?). Check-ins will primarily be conducted over the phone, but could also occur over text message, private Facebook message, email, or by us writing a participant a letter and the participant calling or writing us back. In rare cases we could also conduct check-ins in person, if the participant would prefer to see us in the community.

Participants will receive $50 for each follow-up interview, which both compensates their time and allows us to retain participants over time. In our past studies this dollar amount hits the right balance of providing an incentive of value, but not so high as to coerce participants into meeting with us. It is a reality that only one-third of the women are employed, while the rest scrape money together from benefits, under the table work, or trade of sex.[42,43] Thus, our compensation, while minimal, is a meaningful source of additional income.

Participants will not receive compensation for participation in key stakeholder interviews, since we are only inviting a subsample to participate. We do not want selected participants to be unfairly compensated, when others who were not invited did not receive compensation. In order to not waste participants' time, we will tack on these key stakeholder interviews to regularly scheduled follow-up interviews. Participants will also not receive compensation for communicating with the health educator via text messages or attendance at group sessions, since those are designed to be community-based activities for which participants elect to attend.

Table 4. Expected attrition over study period

	Aim 1 feasibility Target N~20	Aim 2 RCT Target N~200	Aim 3 (same as Aim 2)
Consent and baseline	20	260	--
Intervention initiation	15	220	--
Post-intervention	10	200	--
1 year follow-up	--	170	--
2-year follow-up	--	160	--
3-year follow-up	--	150	--

Table 4 includes estimates of attrition during the study period, which reflect the team's research for the past 20 years with people leaving jails. For Aim 3, we will track all RCT participants for uptake of intervention components, although we will also be studying the acceptance of an invitation for a text messaging with a health educator and attendance at community-based group sessions. When we used a similar design in a jail and community-based intervention in New York City, about half of participants accepted the invitation to work with a community organization.[44] Thus, we expect that about half might also accept an invitation for greater participation. For participation in qualitative interviews in Aim 1 and Aim 3, we expect zero attrition, since we will invite participants for interviews *until* we reach our target sample size.

Power. The sample size for the Aim 1 feasibility study is based on our original SHE study pilot and expanded to allow for rigorous testing and refining of modality.[26] The sample size of N~200 for the Aim 2 RCT was determined to provide satisfactory power (≥80%) for this study in addressing the specific aims, which depends on the following parameters: number of participants (n), number of measurements (t=3 for health literacy for screening; t=4 for screening/risk reduction practices), effect size (f) as group difference in change, correlation between repeated measures (r), and attrition rate. The effect sizes estimated from the original SHE study were in the small to moderate range—for health literacy (8 domains), average f=0.13 at immediately post-intervention and 0.16 at 1-year post-intervention; f=0.17 for cervix screening and 0.12 for condom use during the last intercourse at 1-year post-intervention. Although effect sizes for breast cancer screening and STI screening are not available from the original SHE study, we expect similar, small to moderate effect sizes for these outcomes. Thus, we conservatively assumed the smallest observed effect size of f=0.12 for our power calculation. The correlations between repeated measures observed in the original SHE study were r=0.46 on average, with the range of 0.39-0.75 between baseline and immediately post-intervention and 0.25-0.61 between baseline and 1-year post-intervention. Power analysis of these data (f=0.13, t=3 or 4, r=0.46) and G*Power 3.1.9.2 indicated that a sample of 124 women will produce ≥80% power for both health literacy (80%) and screening/risk reduction behaviors (85%). In our original SHE study, the 3-year follow-up rate was 85%. Conservatively assuming a high attrition rate up to 40%, we will recruit ~200 women at baseline to adequately power the SHE-Women study—i.e., maintain ≥80% power even with a low follow-up rate as small as 60%. As

described above, missing data due to either attrition or nonresponse will be fully recovered via multiple imputation in our intent-to-treat analysis, which will provide additional power and remove any confounding effect of missing data on our statistical power. For Aim 3, the key stakeholder interviews will occur with enough research participants to reach thematic saturation. Based on prior experience with key stakeholder interviews, we believe N~20 interviews will accomplish this goal,[27] but have resources to interview additional participants. Additionally, our COVID-19 module interview suggests N~30 interviews will accomplish the goal of thematic saturation.

Outcomes and instruments. Aim 1 feasibility outcomes include uptake of intervention components, barriers and facilitators of implementation, problems with delivery, and necessary modifications.[45] Pilot effectiveness outcomes will include an assessment of women's health literacy, operationalized as knowledge, beliefs, and self-efficacy for screening related to cervical, breast cancer, birth control, and STIs, post-intervention.[4,26] Aim 2 RCT outcomes include women's health literacy, immediately post-intervention and 1-year post-intervention; and screening/ risk reduction for cervical, breast cancer, unintended pregnancy, and STIs at 1, 2, and 3-years post-intervention. Aim 3 outcomes include perception and uptake of intervention components.[45]

Feasibility and perception of intervention outcomes are defined below and assessed through participant tracking and key stakeholder interviews with a subset of participants.:

- *Uptake of integrated, multimedia electronic women's health literacy intervention*: documentation of number of participants who responded to text messages; clicks on Website; real-time assessment of knowledge; time elapsed between text messages and Website clicks; number of outreach messages (through text, phone, or Facebook); Facebook posts/messages; chats with health educator; total minutes of contact through text, Web, chat, Facebook with each participant; attendance at community sessions
- *Barriers and facilitators of implementation:* problems described by participants in setting up text message platform, Website, closed Facebook group; factors that make set up of text message platform, Website, closed Facebook group ease of use; ease of Website components use (content modules, assessments)
- *Potential problems with delivery of intervention:* number of incorrect phone numbers, changed phone numbers; problems with Website described by participants and staff; description of level of annoyance with outreach messages through text, phone, and Facebook; number of participants re-incarcerated during intervention trial and, thus, resulted in non-completion; problems with chat feature with health educator
- *Modifications needed to maximize implementation:* suggestions from participants about improving multimedia electronic approaches; suggestions about improving real-time assessments of knowledge
- *Perception of human interaction in intervention:* positive and negative aspects of multimedia electronic educational interventions; benefits and disadvantages to offer of community-based sessions; perceived value of human face in video/audio intervention content; advantages/disadvantages of conversation during discharge planning session for control arm

Women's health literacy and screening/risk reduction outcomes are described in Table 5 below. Items will be adapted from scales listed in Table 5.

Table 5. Women's health literacy and screening/risk reduction outcomes and instruments

Women's health literacy (Knowledge, beliefs, self-efficacy, confidence navigating systems)	**Screening/ Risk reduction**
Cervix literacy Pap knowledge scale[46] Health belief model scale for cervical cancer and Pap smear test[47] Self-efficacy for cancer screening scale[48] Confidence navigating health systems scale (cervix, breast, birth control, STI)[4]	**Up-to-date Pap exam or HPV co-testing** **Abnormal Pap follow-up** HINTS cervical cancer screening questions[49] Original SHE HPV co-testing and abnormal Pap follow-up questions[4]
Breast literacy Knowledge, beliefs, self-efficacy items from breast cancer literacy assessment[50]	**Up-to-date screening mammography (biennial) for age 50+** HINTS breast cancer screening questions[49]
Birth control literacy Contraceptive knowledge assessment[51] Beliefs about acquisition and use of contraceptive items from self-efficacy scale[52]	**Current use of hormonal or long-acting reversible birth control method, if no menopause or sterilization** BRFSS birth control questions[53]
Sexually transmitted infection literacy STD knowledge questionnaire[54] Multidimensional condom attitudes scale[55] Condom self-efficacy scale[56]	**Condom use at last sex** **STI treatment** BRFSS condom use and STI treatment questions[53]

Data collection. Aim 1 feasibility data will be collected by study staff who have training and experience conducting qualitative interviews. Staff will conduct 30- to 60-minute key stakeholder interviews with selected

research participants. If the staff collecting data have not reached thematic saturation at a certain time point (after reviewing findings with the PI on a weekly basis), particularly with research participants, they will recruit additional key stakeholders for interviews until saturation is reached.

A record of intervention uptake and outreach using a Redcap relational database system. The project director has been using Redcap to monitor intervention uptake and outreach for the last four years as part of her duties on the original SHE study, and will employ a similar method for the present study. Some elements of data capture will occur through study staff entering data directly into Redcap, as well as auto-population of fields with a connection to the SHE-Women Website.

Aim 1 pilot and Aim 2 RCT effectiveness outcomes data will be collected in surveys at baseline and post-intervention for Aim 1, and then also at 1, 2, and 3 years for Aim 2. For Aim 1, depending on the method of re-consenting original SHE participants (over the phone or in person), study staff will conduct the baseline assessment either over the phone or in person using a Web link on the SHE-Women study Website. The Web link to the survey will utilize audio computer-assisted self-interview (ACASI) technology, where the computer device will read the questions and answer options aloud as participants move through the assessment. Study staff will make themselves available in person or by phone to guide participants through the Web survey, if they desire this service. Participants will have the option to turn off audio if they cannot gain access to headphones or are in a public place. To facilitate use of ACASI, participants will be offered free headphones at study start, and then at quarterly check-ins, or follow-up surveys. We have used ACASI with other hard to reach low literacy populations with success (active drug users and with women leaving corrections in other cities). For the Aim 2 RCT, study staff will conduct the baseline assessment using the same Web link to the SHE-Women study Website so that participants become accustomed to survey administration using a secure Web link. Participants randomized to the control arm will not have access to any intervention content on the Website. All other surveys – post-intervention, and 1-,2-, and 3-year follow-up surveys, will be administered using the same Web link to an ACASI-administered survey. Participants will always be given the option of completing the survey over the phone or in person with a member of the study staff, if that is their preference. If participants become re-incarcerated during the longitudinal follow-up, we can conduct surveys in person or through the mail with paper and pencil copies of the survey – we have previously employed these techniques.

Aim 3 perceptions and uptake data will be collected using the same methods described above for Aim 1.

Validation strategies. Validation of data collected is an important aspect of rigorous outcomes assessment, especially since our primary outcomes of women's health literacy and screening/risk reduction are self-reported (see Table 5). In our original SHE study, we conducted a formalized evaluation of the accuracy of self-reported cancer screening with a subsample of women.[57] We found that 61% of Pap screening self-reports were accurate against medical record review. Importantly, Pap knowledge scores and semi-structured interview assessment of Pap events were statistically significantly associated with accurate Pap screening self-report. Thus, the conclusion of our validation study in SHE, was to analyze self-reported data for a weight for Pap knowledge scores and/or semi-structured interview assessment of Pap events (a total of four questions). For the purposes of the present study, for each outcome variable in Aim 1 (cervical, breast screening, birth control, and STI screening), we will weight self-reported data for knowledge scores in each of the domains of interest (cervix, breast, birth control, and STI knowledge).

To validate data collected in key stakeholder interviews, we will rely on reaching participant or thematic saturation.[58] We will interview a subsample of participants and will continue interviewing until we have reached thematic saturation, which will be determined by the study team and the PI, who has extensive expertise in qualitative methods in both research and implementation studies.

Data analysis. For analyses of qualitative data from key stakeholder interviews in Aim 1 and Aim 3, open coding will be used to delineate conceptual categories for each transcription using an iterative process, initial codes will inform subsequent data analysis.[58] During data review meetings and after collection of data, the research associate and PI will develop a list of preliminary codes to create a codebook for subsequent analyses. Each of these two researchers will read through the rest of the transcripts and open-code each transcript independently. Coded transcripts will be checked for degree of agreement among coders, and disagreements will be resolved through discussion. Dominant themes will be extracted from these coded transcripts and guided by domains of interest in our study of feasibility and perception of human interaction in intervention (barriers and facilitators of implementation, problems with delivery of intervention, modifications needed to maximize implementation, perception of human interaction). For quantitative data in Aim 1 and Aim 3 related to the uptake of intervention components, we will summarize outcome measures with descriptive statistics.

Using quantitative data from the pilot trial of the SHE-Women text-Web intervention, we will conduct descriptive analysis and bivariate tests to explore women's health literacy (knowledge, beliefs, and self-efficacy) for screening related to cervical, breast cancer, birth control, and STIs (Aim 1). The results including effect sizes estimated for the outcome will be utilized for refinement of the intervention content and modality. To test the hypothesis that SHE-Women will be more effective than standard of care at improving outcomes (Aim 2), we will utilize mixed modeling techniques for repeated measures, separately for each outcome variable: health literacy for screening and screening/risk reduction practices. General/generalized models will evaluate the effects of the intervention by estimating overall group difference across measurements (i.e., group effect), change over time (i.e., time effect), and group difference in change (i.e., group-by-time interaction). In other words, we will evaluate whether the intervention vs. control group improves in outcomes over time. The models will account for the impacts of sociodemographic characteristics as well as other cross-cutting risk factors including tobacco use, alcohol use, criminal justice involvement, intimate partner violence, lack of continuous health care coverage or primary care contact, etc. (covariates), thereby providing unbiased estimates of the intervention effects. The models for screening/risk reduction behaviors will also consider knowledge about cervix cancer, breast cancer, birth control, or STI as an additional covariate for the respective outcome variable. Incorporating participant tracking data, descriptive analysis and bivariate tests will demonstrate the pattern and uptake of various intervention components as measured by number of participants who responded to text messages; clicks on the Website; interactive clicks on the Website, e.g. through real-time assessment of knowledge; time elapsed between text messages and Website clicks; number of outreach messages (through text, phone, or Facebook); Facebook posts/messages; chats with health educator; total minutes of contact through text, Web, chat, Facebook with each participant; and attendance at community sessions (Aim 3). General/generalized mixed modeling for repeated measures will assess the impacts of the uptake on each outcome variable of health literacy for screening and screening/risk reduction practices while controlling for the impact of sociodemographic characteristics and other risk factors. A proper covariance structure for repeated measures will be chosen for each outcome variable based on model fit (i.e., likelihood, Akaike Information Criterion, adjusted Bayesian Information Criterion). Statistical significance will be determined at 0.05 alpha level, and all analyses conducted using SAS 9.4[59]

Missing data will be handled by iterative Markov Chain Monte Carlo (MCMC) multiple imputation, in which expectation-maximization (EM) algorithm provides prior estimates of missing values for subsequent MCMC procedure.[60] A large number of (e.g., 200) imputed datasets will be generated and then analysis results from each imputed dataset will be combined together to make valid statistical inference. This approach includes all selected variables (auxiliary variables) into the imputation process, which allows for greater recovery of missing data.[61] It is possible that some women will reenter the jail facility during the recruitment period. To avoid re-randomizing these same participants, we will collect basic identifying information recruitment (name, DOB, race) and double check to see if the participant already is enrolled in our study.

Integration of study aims to meet project objective. Because the objective of this study is to ultimately create a sustainable model for dissemination of health promotion interventions for vulnerable populations, we feel it is important to use a mixed methods approach to understand the relationship between qualitative and quantitative data.[62] Integration of study aims to meet our project objective will primarily occur through the writing of Manuscripts # 1,6 and 8 (see Table 3). In each of these manuscripts we plan to report on both the perceptions of key stakeholders, as well as the effectiveness of the intervention given the electronic modality of delivery. We will take lessons learned to develop subsequent projects that test SHE-Women in diverse groups of high risk women both inside and outside our catchment area.

Strategies for success, alternatives, key findings. Strategies for success include allowing for sufficient time for recruitment early in the study in case recruitment is slow, but we also draw on our successful and effective methods of recruitment, intervention delivery, and retention strategies. The integrated, mediated electronic women's health literacy intervention via text-Web delivery platform is based on carefully collected data over the last three years about use of electronic technologies among women leaving jails and extensive experience among our health communications team of developing electronic interventions. Alternative strategies in case we have problems include: having adequate time for recruitment of more participants. If we have higher than expected rates of attrition, we have adequate time, resources, and partnerships with the jails to recruit more participants. We will also leave sufficient lead time for development of the text-Web modality. We realize our methods may not allow for an ideal unbiased experimental design given convenience sampling; however, we feel that our unique access to a difficult to reach and understudied population of *prisoners* outweighs the pitfalls of utilizing convenience samples. If our hypotheses are not supported, subsequent projects will focus on discharge planning or going back to tried and true methods of face-to-face health education. Key findings from

this study will include whether a women's health literacy intervention is effective at changing intersecting behaviors among women leaving jail; whether an electronic women's health literacy intervention is feasible and effective; and how much human "touch" is ideal in an electronic intervention. Knowledge gained from this study will help develop a new paradigm for mitigating health disparities among vulnerable women.