Home Visitation Enhancing Linkages Project
NCT03750487

Study Protocol and Statistical Analysis Plan
Document Approved: November 2020

NOTE: This document contains the study protocol and analysis plan for the originally planned pilot RCT. Due to significant delays and recruitment challenges caused by the COVID-19 pandemic, we were unable to complete the RCT as planned. After review by the DSMB and study sponsor, the decision was made to eliminate the randomization and assign all participants to the intervention condition to evaluate feasibility and acceptability of the intervention. Of the 14 enrolled participants, 4 were assigned to the control condition prior to elimination of randomization. The remaining 10 participants were assigned to the intervention condition. Due to the small sample size, planned longitudinal analyses detailed in this protocol were not able to be carried out.

STUDY PURPOSE AND AIMS

Substance use (SU) in the perinatal period is a critical public health challenge that is highly associated with negative birth outcomes, poor maternal and child health, and increased risk for child maltreatment. Rates of SU among pregnant and postpartum women have been on the rise, due to the current opioid epidemic. While effective treatments for SU exist, less than 20% of women who need SU treatment receive it, and this gap is greater for low-income, ethnic minority women. Many pregnant and postpartum women conceal their SU and do not seek treatment for fear of child removal, significantly increasing risk to themselves and their children.

Home visiting (HV), a strategy for delivering voluntary preventive services aimed at optimizing parent and child outcomes across the life course, is the primary supportive intervention offered to at-risk families during the perinatal period. HV represents a promising venue for addressing SU needs in pregnant and postpartum women for several reasons. First, with increased federal support, HV programs have been scaled up nationally, and currently exist in all 50 states, the District of Columbia, and five territories, and serve more than 280,000 of the nation's highest risk families annually. Nearly 40% of HV clients report binge drinking or using drugs in the 3 months prior to HV enrollment. Second, many HV programs aim to enroll women prenatally or shortly after birth, providing an opportunity to intervene early to prevent negative outcomes associated with caregiver SU. The immediate postpartum period is a particularly important time for preventing SU relapse, and HV often represents vulnerable families' only contact with the formal service system during this time. Finally, pregnancy and the postpartum period are times when many women are especially motivated to change behaviors that may negatively impact their baby, such as SU. As a voluntary, strength-based program, HV provides a natural framework for capitalizing on this motivation to change.

Despite the potential of HV as a venue for addressing maternal SU, there is currently no systematic protocol for addressing SU within routine HV, leaving many HV clients with undetected and unmet needs that increase maternal and child risk. Screening, Brief Intervention, and Referral to Treatment (SBIRT), originally designed to reduce gaps in the service continuum from primary care to SU treatment, is strongly supported as a public health model for addressing SU. New recommendations for SBIRT in the perinatal period were recently published by the CDC, and include universal screening, followed by brief intervention (BI) for women at low-to-moderate risk, and referral to specialty SU treatment for those screening as at highest risk. This approach has potential as a framework for addressing SU in HV. While HV clients comprise the full range of SU risk, the vast majority likely fall in the low-to-moderate range, as is common among pregnant and postpartum women in community settings, making them good candidates for BIs. Two significant challenges may preclude the successful installation of traditional SBIRT procedures into HV. First, HV clients are often reluctant to disclose SU to professionals, including home visitors, due to shame, stigma, and fear of child removal. Second, most preventive HV models do not provide intensive skills-based training in SU for home visitors and do not include standardized protocols for identifying and addressing maternal SU. Moreover, most home visitors are paraprofessionals, who lack the advanced

clinical training and skills needed to effectively deliver evidence-based BIs. To overcome these challenges, this study will test an innovative adaptation of the SBIRT framework, *SBI-HV*, that will feature a computerized screening and brief intervention (e-SBI) for SU that has been validated in prior studies of pregnant and postpartum women, and adapted for testing in the context of home visiting services. The primary advantages of the e-SBI are: (1) it screens for SU prior to pregnancy rather than currently, a strategy proven to promote greater openness in responding; (2) it is self-administered, allowing women to complete it without disclosing SU to home visitors; and (3) it provides a fully-automated BI, precluding the need for home visitors to implement complex clinical interventions. The full SBI-HV will include the e-SBI and protocols for home visitors to provide facilitation and support to clients. As the e-SBI can be accessed remotely, via any internet-enabled device, including a smartphone, clients can access the e-SBI independently from their own devices at home. Given the shift to virtual home visiting during the COVID-19 pandemic, the e-SBI will be tested as an enhancement to virtual home visiting, and completed by clients in between home visits, with facilitation and support provided by home visitors during virtual visits. The e-SBI includes two sessions (approximately 20 minutes each) focusing on alcohol and drug use (session 1) and co-occurring problems (session 2). The e-SBI will be compared to a control intervention that will use the same platform but will provide content on nutrition (session 1) and exercise (session 2). Both groups will include home visitor facilitation and support before and after e-SBI sessions, as well as technical support provided by the study researchers.

The primary study aim is to conduct a pilot randomized controlled trial (RCT) to (1) assess feasibility, acceptability, and fidelity of SBI-HV, and (2) determine the preliminary impacts of SBI-HV on client symptom reduction (SU, depression, parenting stress), retention in HV, engagement in SU treatment, and alliance between the home visitor and client. The pilot RCT will be conducted in New Jersey, in counties that are implementing the Healthy Families America (HFA) home visiting program. We will enroll 20 home visitors and 40 clients. The pilot RCT will be a cluster-randomized trial, with home visitors randomly assigned to study condition. Feasibility, acceptability, and fidelity will be assessed via home visitor and client interviews and fidelity checklists. Clients will be assessed at baseline, and 3- and 6-month follow-up to track SBI-HV impacts on outcomes.

STUDY PARTICIPANTS

The study will be conducted within New Jersey (NJ)'s HV system within the Healthy Families America (HFA) HV program. Participation will be offered to all HFA home visitors throughout the state

Home Visitors

We will enroll 20 HFA home visitors in the trial. Based on our prior research with this population, we expect the home visitors to have the following demographic characteristics: 100% female, average age 36 years, 25% White, 40% Latina, 30% Black, average 5 years HV experience, and 60% with greater than a high school education.

Clients

We will enroll 40 clients who meet the following study eligibility criteria: (1) speak English or Spanish; (2) age 18 years old or older; (3) pregnant or up to 3 months postpartum; (4) enrolled in HFA with a participating home visitor within the prior six months; (5) reporting binge drinking or illicit drug use in the 3 months prior to their most recent pregnancy and not currently attending substance use treatment; and (6) have access to smartphone or other internet-enabled device with internet connection. Based on prior work with this population, we expect clients to have the following demographic characteristics: 40% Latina, 41% White, 34% Black,

63% single, 22% with a high school education or less, 78% unemployed, 85% on public assistance, and 15% child welfare system-involved.

STUDY CONDITIONS AND HV-SBI COMPONENTS FOR EACH CONDITION

Home visitors will be randomly assigned to Intervention or Control conditions, and clients will be assigned to whichever condition their home visitor is in. SBI-HV components that will be added on to routine HFA services include (1) electronic screening and brief intervention (e-SBI); (2) Home Visitor Facilitation; and (3) Technical Support. Table 1 details which study component clients in each condition will receive. The primary difference between conditions will be in the content of the e-SBI and home visitor facilitation components. A detailed description of each SBI-HV component follows the table.

Table 1. SBI-HV Components by Study Condition

Intervention Condition	Control Condition
Routine HFA Services	Routine HFA Services
e-SBI Session 1: Substance Use e-SBI Session 2: Co-occurring Problems	e-SBI Session 1: Nutrition e-SBI Session 2: Exercise
Home Visitor Facilitation: Introduction and de-brief before and after each e-SBI session (content related to substance use and co-occurring problems)	Home Visitor Facilitation: Introduction and de-brief before and after each e-SBI session (content related to nutrition and exercise)
Technical support provided by research staff	Technical support provided by research staff

Routine HFA Services

HFA is an evidence-based, voluntary, HV program designed to promote positive parenting, enhance child health and development, and prevent child maltreatment in at-risk families that serves families prenatally up to age 5 years. Home visits (approximately 1 hour each) occur weekly for the first 6 months, tapering in frequency over time depending on the family's level of functioning, and follow a structured curriculum. Model implementation follows the HFA Best Practice Standards, operationalized through structured program guidelines that are flexibly tailored to families' needs. HFA mandates a quality assurance and accreditation process for program sites, thus an infrastructure for fidelity monitoring and CQI is already in place. Federally-funded HFA sites are also required to track and report progress on federally-specified benchmarks. All of the NJ HFA sites are accredited and federally-funded and have extensive data tracking and CQI procedures in place. Home visitors and supervisors routinely complete logs after each visit and supervision session and data is maintained in an electronic Management Information System (MIS) managed by PCANJ.

The HFA national model requires a minimum of a high school diploma plus relevant experience for home visitors and a Masters degree or BA with 3 years experience for supervisors. Training is required for home visitors (4 days) and supervisors (2 days) at initial hire with annual refreshers. In NJ, all HFA training is provided by PCANJ. As required by the HFA standards, all full-time home visitors receive 2 hours of individual supervision per week. Per the HFA Standards, each supervision session must include administrative (i.e., oversight of program policies; adherence to standards), clinical (i.e., discussing families' challenges; providing guidance and coaching; evaluating progress), and reflective (i.e., attending to home visitors' emotional reactions) components.

Families are eligible for enrollment in HFA if they are prenatal or within 2 weeks of the baby's birth, and if they have two or more risk factors associated with child maltreatment (e.g., inadequate income, unstable housing, history of substance abuse, no prenatal care, history of depression or psychiatric care). Note that these eligibility criteria pertain to enrollment in the HFA program and are different from eligibility criteria to enroll in the research study described in this protocol (detailed on page 3). Supervisors assign clients to home visitors based on the home visitor's experience and skill, difficulty level of the family, and home visitor's current caseload. Home visitor caseload size is 13-26 families, varying based on the service needs of each family.

The HFA Standards specify that home visitors are not therapists and that their role with regard to maternal behavioral health needs is to link clients to needed services. Use of Motivational Interviewing (MI) strategies is recommended, but programs vary in the extent to which MI training and support is provided. HFA provides a manual for working with families in acute crisis, but SU is not included in the manual. HFA requires maternal depression screening and home visitors are trained in administering screens, talking with families about depression, community resources for depression, and stress-reduction activities. SU training is required and includes content on: etiology of substance abuse, culture of drug use, strategies for working with families with SU, smoking cessation, alcohol use/abuse, fetal alcohol spectrum disorders, street drugs, and referral resources. Specific interventions to address SU, beyond providing referrals, are not included in the HFA model.

Due to the COVID-19 pandemic, HFA services in New Jersey have moved to a virtual model, following guidance from the HFA national model. Virtual home visits are conducted via phone or video-conferencing (Zoom or a similar platform), but otherwise are conducted according to HFA Standards as described above.

Electronic Screening and Brief Intervention (e-SBI)

e-SBI Software and Development

e-SBI content for both conditions was created using Ondersma's Computerized Intervention Authoring System (CIAS), an authoring tool that allows creation or editing of computer-delivered interventions without the need of a programmer. Interventions built using CIAS are compatible with all mobile platforms, and feature a high-quality synthetic text-to-speech engine that reads all questions and speaks aloud to the participant; synchronous interactivity; natural language reflections; branching logic; a clean user interface; and the ability to easily incorporate specific images, graphs, figures, text, or videos. The program is fully automated, completed on a touch-screen tablet with headphones for privacy. A 3-D cartoon character capable of a range of animated actions (i.e., smile, wave, express concern) narrates the e-SBI, reads all items and response choices aloud, and reflects back participant responses. The program is designed to maximize interactivity, with immediate responses to participant input, occasional summaries, and branching based on participant responses and preferences. CIAS has been used with thousands of participants to date, many low-SES, and has consistently received extremely high user satisfaction ratings. CIAS can be run on apple and android devices, and on tablets and smartphones.

e-SBI Session Features

In both study conditions, e-SBI content is tailored to pregnancy status (pregnant vs. postpartum) and in the intervention condition, session 1 content is tailored to the primary substance reported by the participant (alcohol, marijuana, opioids, or other drugs). Participants will complete the e-SBI sessions in between scheduled home visits, with reminders and technical support provided by research staff. The following sections describe the intervention content for each session, for the Intervention and Control groups. All sessions for both groups

include interactivity, branching to specific topics based on selection or responses to questions, narration via the 3-D cartoon character, and reflection of responses. All sessions also include animated videos providing educational content related to the topic of the session. Each session is approximately 20 minutes in length. The purpose of the Control condition e-SBI sessions is to control for time and attention associated with e-SBI completion and technical support provision. Content was selected to be informative and interesting and potentially useful to the participant, but not likely to have an impact on substance use. Nutrition and exercise were selected as topics because while these topics are relevant to the home visiting population, they are not covered in depth as part of the home visiting curriculum, and thus would be of interest and of use to participants.

Intervention Condition Session #1: Substance Use

Session one of the Intervention Condition e-SBI is adapted directly from Ondersma's 20-minute interactive e-SBI for alcohol and drug use, which has been tested extensively in pregnant and postpartum women in delivery hospitals and OB-GYN clinics. Session one begins with *Screening* for substance use. The Screening section consists of a modified version of the Alcohol, Smoking, and Substance Involvement Screening Test (ASSIST), a brief screening tool developed by the WHO that evaluates frequency and consequences of SU, and demonstrated high sensitivity and specificity and strong validity properties. The ASSIST was modified to ask about SU in the three months prior to pregnancy, which has been shown to yield more accurate responses with greater sensitivity for identifying active substance users during pregnancy/postpartum than asking about current use. Based on their responses on the ASSIST, participants will be branched to a brief intervention (BI) that focuses on their primary substance (determined based on their highest scoring substance on the ASSIST): alcohol, marijuana, opioids, or other illicit drugs. Content in the BI section of the e-SBI will be tailored to primary substance and pregnancy status (pregnant or postpartum). The BI applies motivational interviewing principles and the FRAMES (Feedback, Responsibility, Advice, Menu of options, Empathy, and Self-efficacy) BI framework. The BI begins with a brief video providing psychoeducational information about the risks of substance use during pregnancy/postpartum. Following the video, participants are asked about their readiness to quit or cut down their substance use with the following response options: (a) I have already quit or cut down; (b) I would like to quit or cut down right now; (c) I am not sure whether I want to quit or cut down; (d) I am not ready to quit or cut down now. BI content is tailored to the participant's reported level of readiness for change and includes the following MI interventions: (1) Personalized Feedback on participant-reported negative consequences of SU, readiness to change, and how their SU compares to other women; (2) Pros and Cons of SU and behavior change; (3) Menu of Options for things they can try that have helped other women change their SU behavior; and (4) Optional Goal-Setting regarding changing SU behavior for those who report a desire to make a change. Clients who report that they have already quit receive a purely psychoeducational BI. Clients who express limited interest in change receive motivational enhancement interventions and those desiring change receive goal-setting interventions. Home visiting is featured throughout the BI as an important resource, with emphasis on the different ways the home visitor can be helpful to participants in dealing with SU concerns. In addition, information about local and online resources for obtaining SU treatment or self-help groups (such as AA) is also included in the program, so that clients can access that information without the involvement of their home visitor. Session one concludes with a video providing a testimonial from a mother describing her struggles with SU during pregnancy/postpartum and her success at overcoming them. At the end of the session, participants have the option to enter their email address into the program and receive a list of all of the resources described in the program (local SU treatment providers and online resources).

Intervention Condition Session #2: Co-Occurring Problems

Session two of the Intervention Condition e-SBI is structured similarly to session one, and focuses on behavioral health concerns that often co-occur with substance use in pregnant women and new mothers: smoking and vaping, depression, and intimate partner violence. Participants can choose which of the three topics they are interested in learning more about. They have the option to select one, two, or all three of the topics, and also have the option to select none of them and exit the session. For each of the three topics, the program is based on MI principles and contains the following components: (1) short psychoeducational video; (2) brief question about their own experience followed by a reflection; (3) menu of options that have been helpful to other women (for example, talking to home visitor); (4) links to resources; (5) opportunity to select something from the menu of options that they would like to try; (6) reflection on choice. The sessions ends with a brief recap.

Control Condition Session #1: Nutrition

Session one of the Control Condition e-SBI is focused on nutrition for pregnant and postpartum women. Content was drawn from First Steps Nutrition Trust, Washington State Department of Health First Steps, and Foundations of Maternal and Child Health. Content includes: benefits of proper nutrition and healthy eating habits during pregnancy and postpartum for both mother and baby; weight gain during pregnancy; recommended nutrients and eating habits for pregnancy and postpartum, including while breastfeeding; and advice on reading and understanding nutrition labels. Throughout the session, the narrator emphasizes the importance of talking to a doctor prior to making any decisions about nutrition or diet. The role of the home visitor as a non-judgmental support person who can be helpful is also emphasized.

Control Condition Session #2: Exercise

Session two of the Control Condition e-SBI is focused on exercise and physical activity during pregnancy and postpartum. Content was drawn from the March of Dimes and American College of Obstetricians and Gynecologists recommendations for physical activity in the perinatal period. Content includes: benefits of exercise and physical activity during pregnancy and postpartum for mother and baby; recommendations for amount of physical activity during pregnancy and postpartum; exercising safely; how to motivate yourself to exercise when you may not feel like it; and recommendations for different types of physical activity to engage in at different stages of pregnancy and postpartum. Throughout the session, the narrator emphasizes the importance of talking to a doctor prior to starting any new exercise program. The role of the home visitor as a non-judgmental support person who can be helpful is also emphasized.

Home Visitor Facilitation

We have developed brief home visitor facilitation protocols (5 minutes each) to be implemented during the home visits before and after each e-SBI session is completed. All protocols were designed in the spirit of the strength-based perspective that underpins HV, and aim to leverage the trusting, supportive relationship that is core to effective HV. The goal of the facilitation protocols is to support successful integration of the e-SBI within the HV context; they are not intended to be therapeutic. Protocols are scripted to aid home visitors in delivery. Note that the facilitation protocols will not require clients to disclose SU to the home visitor, though they will not be prevented from doing so, and may do so if they wish to. Protocols include *Introduction* to be delivered in the home visit prior to each e-SBI session, and *Debriefing* to be delivered in the home visit following completion of each e-SBI session. The format of each protocol is consistent across Intervention and Control conditions, but the content is different, reflecting the different e-SBI content depending on study condition.

Technical Support

The Study RAs will provide text- or phone-based technical support to study participants as needed. All text and phone communication with participants will be conducted through Partnership to End Addiction's JITAI Master Platform, described in detail below. The Platform provides a dedicated study phone number, which will be used for all communication with participants. Participants will be sent a personalized link to each e-SBI session via text message, which will allow them to click on the link and access the session. If they have trouble, they can send a text message to the study number and one of the RAs will respond. They can also call the study phone number to reach an RA by phone. RAs will monitor the study number (text and phone) daily and will respond within 24 hours to all technical support requests on weekdays, and by the next business day if the request comes in on a weekend. Participants will also be offered the option to have the RA call them at an agreed upon time and walk them through the process of accessing the e-SBI session on their device.

TRAINING AND FIDELITY MONITORING

Training for home visitors will include a mix of recorded webinars and live trainings over zoom. Home visitors will be trained in procedures for referring clients to the study and in implementation of the facilitation protocols. Some didactic information on perinatal substance use will also be provided, for context. Finally, home visitors will be introduced to the e-SBI so that they are familiar with the content their clients will receive. Training will be conducted separately for home visitors in each study condition, as the content of the e-SBI and facilitation protocols differs by condition.

To monitor home visitor implementation of facilitation protocols (fidelity monitoring), we will develop brief fidelity checklists consisting of 1 or 2 items that can be delivered to home visitors via text message. For example, after a virtual home visit in which a home visitor is expected to deliver the introductory protocol, the home visitor would receive a text message asking "Did you deliver the introductory protocol? Text Yes or No." If the response is "No," the home visitor would receive an additional text message asking for the reason, with a list of reasons to select from: "Text 1 if you forgot, Text 2 if the client was not interested, Text 3 if the visit was devoted to dealing with a crisis, Text 4 for some other reason."

RECRUITMENT, ENROLLMENT AND RANDOMIZATION PROCEDURES

Home Visitors

The PI will schedule a group zoom meeting for all HFA home visitors in New Jersey's HFA network to introduce the study. Following that meeting, home visitors who are interested in possibly participating will be invited to schedule a one-on-one zoom meeting with the PI. During the one-on-one meeting, the PI will explain the study in detail and review the informed consent form. A pdf version of the informed consent form will be sent to the home visitor via email prior to the zoom meeting so that they can follow along as the PI reviews it. Home visitors will be given the opportunity to ask questions about the study and the consent form. Once all questions are answered, the PI will ask the home visitor if they would like to make a decision right then whether to enroll or if they would like to take some time to think about it. If the home visitor would like time to think about it, the PI will call the home visitor back at a later time specified by the home visitor. When a home visitor decides to enroll, he/she will sign the pdf version of the consent form via DocuSign and then email it back to the PI. The PI will sign via DocuSign as well and then email a fully signed copy back to the home visitor for their records. Signing the consent form constitutes enrollment into the study. Following enrollment, the PI will use a computerized randomization program to randomly assign home visitors to study condition (Intervention or Control).

Clients

Clients will be assigned to home visitors according to usual site procedures. Home visitors will introduce the study to all clients who meet eligibility criteria (English or Spanish speaking; 18 or older; pregnant or within 3 months postpartum; enrolled in HFA within the prior 6 months) at the enrollment visit (for newly enrolling clients) or at the next available visit (for clients already enrolled within the prior six months) using a script provided by study staff. Home visitors will ask clients for their permission to provide their contact information to the study team. If permission is granted, the home visitor will provide the client's contact information to a study RA, who will contact the client by phone and conduct a brief eligibility screen (data will be retained anonymously). Home visitors will also give clients the option to contact the study team themselves, if they prefer, rather than having home visitors provide their contact information to the study team. If the client is eligible, the study RA will explain the study in more detail and ask the client if she is interested in enrolling. If the client says yes, the RA will send the client a link to a pdf copy of the informed consent form via email or text (depending on client preference). After giving the client a few minutes to review the consent form, the RA will review the main points in the consent form and ask the client if she has any questions. After answering all questions, the RA will ask the client if she would like to decide now whether or not to enroll, or would like to take more time and receive a call back later from the RA. If the client would like more time, the RA will call the client back at a time specified by the client. Once the client decides to enroll, the RA will ask her to sign the pdf of the consent form using DocuSign and send it back to the RA. The RA will then sign as a witness, and send the pdf to the PI for her signature, also using DocuSign. After obtaining all signatures, the RA will send a final signed pdf of the consent form back to the client for her records. After the informed consent process is complete, the RA will either send the client a link to complete the baseline assessment online (via a Qualtrics survey), or schedule an appointment to complete the baseline assessment with the client via phone or video-conference, depending on the client's preference. Signing informed consent and completing the baseline assessment constitutes enrollment into the study. Clients are assigned to whichever study condition their home visitor is assigned to.

RETENTION STRATEGIES

To maximize retention of home visitors, research staff will conduct monthly check-ins via Zoom at each study site to provide a forum for home visitors and other staff to ask questions about study procedures and express concern with aspects that are not functioning as intended. Ongoing contact with home visitors will allow us to address issues of dissatisfaction as they arise and we expect this to lead to greater retention. We have used similar procedures in other studies. For example, in our prior home visiting study, we retained 21 out of 25 enrolled home visitors for the study duration.

To maximize retention of clients, we will apply published strategies that have been demonstrated effective in samples of substance using adults, accounting for the high rates of mobility that typically characterize this population. These strategies have been applied by Co-I Ondersma in many prior studies of low-income pregnant and postpartum women, and have yielded follow-up rates ranging from 75% to over 95%. We have also used these strategies in several large studies of adolescents and families with substance use and behavior problems, and have consistently achieved follow-up rates of over 90% at one-year. Specifically, at the baseline interview, we will obtain multiple forms of contact information for clients (phone, cell phone, and email). We will maintain contact with clients during the time periods between follow-up interviews by sending regular texts and/or emails (depending on client preference), with reminders about the study and of the next scheduled contact. Follow-up interviews may be conducted either online or by phone or video-conference, depending on client preference. If we

are not able to reach a client directly through these means, we will reach out to home visitors and try to connect with clients through them. Additionally, prior to the Baseline interview, the RA will explain to clients the specific purposes of the study, the nature of their participation, and the timing and content of follow-up interviews, so clients are fully informed and will know when to expect to be contacted next. We will also ensure that clients understand that the research study is separate from the home visiting program, and that they can continue to participate in the research even if they discontinue enrollment in the home visiting program. Information on incentives for completing interviews will also be provided.

TIMELINE OF STUDY ACTIVITIES

Timeframe	**Activity**	**Person Responsible**
Home Visitor Recruitment, Enrollment, and Training [October 2020-December 2020]		
At Quarterly Supervisors' Meeting in October	HELP staff introduce study to HFA supervisors at Quarterly Supervisors' Meeting (via Zoom)	PI, RAs
Scheduled for Oct-Nov 2020	HELP staff introduce study to home visitors in NJ HFA network (via Zoom)	PI, RAs
	Home visitors sign informed consent and enroll in study via individual Zoom meetings with PI	PI, RAs
	Home visitors are randomized to condition	PI
After home visitors enroll [Dec 2020]	Home visitor training [pre-recorded videos plus live zoom sessions]-intervention and control groups trained separately	PI, RAs, Home visitors
Client Recruitment and Enrollment [January 2021-October 2021]		
At HFA enrollment visit OR next visit after client is identified as eligible	Home visitors introduce study (using script) to all clients meeting eligibility criteria: newly enrolling or enrolled within the last 6 months; speak English or Spanish; 18 years or older; pregnant or within 3 months postpartum.	Home visitors
Weekly	Home visitors provide client contact information to HELP staff	Home visitors
Ongoing	HELP RAs contact client, conduct eligibility screen, and obtain informed consent from eligible clients who are interested in participating.	RAs
Within 1 week of consent	Client completes baseline assessment [either via Qualtrics link or via phone with RA, depending on client preference]	RAs, Clients
Upon completion of baseline	RA informs home visitor that client has enrolled and completed baseline interview and to do Introduction at next home visit (content differs by condition)	RAs
Implementation of HV-SBI Components [January 2021-December 2021]		
At next home visit	Home visitor completes Introduction: Alcohol & Other Drugs (for intervention group) OR Introduction: Nutrition (for control group)	Home visitor
After home visit	RA sends home visitor text-based fidelity checklist to determine whether Introduction was completed	RAs

	Home visitor completes text-based fidelity checklist	Home visitor
Within 2 weeks of baseline	RA prompts client to complete HELP Session 1 (content differs by condition) within 2 weeks of baseline date and provides technical support by phone or text as needed	RAs
Within 2 weeks of baseline	Client completes HELP Session 1	Clients
Upon completion of HELP Session 1	RA informs home visitor that client has completed HELP Session 1 and to do HELP Debrief 1 AND Introduction to session 2 at next home visit (content differs by condition)	RAs
At next home visit	Home visitor completes Debrief: Alcohol & Drugs (for intervention group) OR Debrief: Nutrition (for control group) AND Introduction: Other Concerns (for intervention group) OR Introduction: Exercise (for control group)	Home visitors
After home visit	RA sends home visitor text-based fidelity checklist to determine whether HELP Debrief 1 was completed	RAs
	Home visitor completes text-based fidelity checklist	Home visitors
Within 2 weeks of HELP Session 1	RA prompts client to complete HELP Session 2 (content differs by condition) within 2 weeks after completing HELP Session 1 and provides tech support by phone or text as needed	RAs
Within 2 weeks of HELP Session 1	Client completes HELP Session 2	Clients
Upon completion of HELP Session 2	RA informs home visitor that client has completed HELP Session 2 and to do HELP Debrief 2 at next home visit (content differs by condition)	RAs
At next home visit	Home visitor completes Debrief: Other Concerns (for intervention group) OR Debrief: Exercise (for control group)	Home visitors
After home visit	RA sends home visitor text-based fidelity checklist to determine whether HELP Debrief 2 was completed	RAs
	Home visitor completes text-based fidelity checklist	Home visitors
Follow-Up Interviews [April 2021-March 2022]		
After completion of entire HELP intervention	RA conducts qualitative interviews with home visitors and clients (random sample from intervention condition only) on zoom.	RAs, Clients, Home visitors
3 months after baseline	Client completes 3-month follow-up assessment (either via online survey or phone, depending on client preference)	RAs, Clients
6 months after baseline	Client completes 6-month follow-up assessment (either via online survey or phone, depending on client preference)	RAs, Clients

DATA COLLECTION AND TRACKING PROCEDURES

Data Tracking

We will use Partnership to End Addiction's JITAI Master Platform for tracking participants through the study. This platform has previously been used in NIH and foundation research studies

at Columbia University, New York University, and Northwell Health. The Platform is designed for intervention, adaptability, and customization and can be used to manage multiple forms of participant contact, including email, text, and phone/voice chat. The platform also accommodates linkages to online surveys (such as through Qualtrics) to collect more extensive assessment data. The Platform is hosted in HIPAA-compliant Amazon Web Services, with messsaging triggered through Twilio, and is managed by Partnership to End Addiction's staff of content and programming experts.

All contacts between study staff and participants will go through the Platform. Partnership to End Addiction's IT department will create a Platform account for the study, with a dedicated phone number, that will be accessible only to the PI and study RAs. Upon enrollment into the study, home visitors and clients will be instructed to send a text message to the study phone number, which will enroll them into the Platform. This will allow study staff to send communications via text message. Upon enrollment into the Platform, participants will receive an automated message asking them to select preferences for language (English or Spanish) and correspondence via text or email (with a prompt to enter their email if selected). Communications with home visitors will include (1) reminders to complete study activities; and (2) brief fidelity questionnaires as described above. Communications with clients will include (1) reminders to complete study activities; and (2) scheduling assessments; and (3) technical support requests and responses. Secure links to e-SBI components and online assessments will also be sent at the time when clients should complete them. Home visitors and clients can also text and/or call the study team to ask questions, reschedule assessments, or request technical support. Some messages will be automated (i.e., the welcome and initial introductory messages) and others will be generated in real-time by study RAs, using pre-written text to ensure consistency in messaging across RAs.

Implementation Data Collection

Qualitative feasibility interviews (approx. 30 minutes) will be conducted via zoom with all home visitors and a random sample of 10 clients (balancing on pregnancy status) in the intervention condition during the second half of the pilot RCT to assess feasibility and acceptability of the SBI-HV. We will randomly select 10 clients to participate in the interview. Selection will be random with one exception: we will ensure that the proportion of pregnant women in the interview sample of 10 is representative of the proportion of pregnant women in the overall sample. Thus, if the overall sample of 20 women in the experimental condition includes 8 pregnant women, we will randomly select 6 non-pregnant women and 4 pregnant women to participate in the interviews. All interviews will be one-on-one. Clients and home visitors will be interviewed separately. All qualitative interviews will be recorded and transcribed, in accordance with gold standard procedures for collection and analysis of qualitative interview data. While we prefer that clients and home visitors have their video cameras on during the interview to allow for a more natural conversation, clients and home visitors will have the option to leave their cameras off and join with audio only if they are more comfortable with that. Recordings of qualitative interviews will include audio only, using the setting on Zoom that allows for recording of audio only without video. Thus, no recordings will include video. If a participant is not comfortable being recorded, they can still participate in the interview; the interviewer will take detailed notes on what is said. Clients will also complete a series of quantitative rating scales at the end of each e-SBI session assessing user satisfaction. Home visitor fidelity will be assessed via brief questions delivered via text message following virtual visits in which facilitation protocols are intended to be implemented. Home visitors will also be asked to complete a brief Qualtrics survey prior to SBI-HV training to assess demographics and readiness to implement evidence-based interventions.

Outcome Data Collection

Client outcome data will be collected at baseline, 3- and 6-month follow-up using validated clinical assessment instruments. Assessments will be conducted either via online survey using Qualtrics, or via phone or video-conference with the study RA, depending on the client's preference. Video-conference data collection will be done over Zoom and these sessions will not be recorded. Assessments will be available in English or Spanish. Each assessment will take approximately 40 minutes and clients will receive $25 per interview completed. To maximize our follow-up rates, we will obtain multiple forms of contact information and contact the home visitor when unable to reach clients directly. Strategies proven effective for maximizing honest disclosure of substance use in high-risk populations will be applied, including: option for completing the survey online without the RA, a Certificate of Confidentiality, and numeric ID codes to link within-client data across timepoints without attaching client identifiers to responses.

STUDY MEASURES

Feasibility and Acceptability

Feasibility and acceptability of SBI-HV will be assessed via qualitative interviews with home visitors and clients in the intervention condition, designed based on published guidelines for assessing feasibility and acceptability of new interventions in field settings. Home visitor interviews will assess added burden of the SBI-HV, perceived benefits, and implementation barriers. Client interviews will focus on e-SBI satisfaction, barriers to discussing SU with home visitors, and the impact of the e-SBI on their HV experience. Following completion of the e-SBI sessions, clients will complete several quantitative items assessing different dimensions of user satisfaction. Finally, completion rates for each e-SBI session will be used as indicators of feasibility.

Home Visitor Measures

Prior to SBI-HV training, home visitors in both conditions will complete a brief demographic survey. They will also complete the *Evidence-Based Practice Attitude Scale*, a 15-item measure of provider attitudes towards evidence based practices (EPBs), that generates 4 scales: Appeal of EBPs, Required Use by Organization, Openness to Trying EBPs, Unfavorable Attitudes toward EBPs. Consistent factor structure and good internal consistency have been shown in diverse provider samples. Home visitors will complete 1-2 item brief fidelity checklists after each visit in which a facilitation protocol is intended to be implemented. These items will be sent to home visitors via text message and they will respond via text message.

Client Measures

Clients will complete a battery of assessments at baseline, 3-month, and 6-month follow-up using instruments that have demonstrated strong psychometric properties in similar samples. At baseline, we will administer selected sections of the *Addiction Severity Index (ASI)* to assess basic demographics and lifetime and current problems with physical health, employment and finances, illegal activity, family relationships, and psychiatric symptoms. Trauma history will be assessed at baseline via the *Childhood Trauma Questionnaire-Short Form.* Primary study outcomes (to be assessed at baseline, 3-mo, and 6-mo follow-up) include substance use, depression, and parenting stress. Substance use will be assessed via the *Timeline Follow Back Interview*, a calendar-based method for assessing quantity and frequency of SU. Primary SU outcomes will include seven-day point-prevalence abstinence rates and monthly reported days of use. Depression will be assessed via the *Beck Depression Inventory-II, a 21-item scale* measuring depressive symptoms that is widely used in research and practice with perinatal women. Parenting stress will be assessed using the *Parenting Stress Index-Short Form*, a 36-

item measure of stress associated with parenting that is widely used in longitudinal studies of parenting and HV. Secondary study outcomes (assessed at baseline, 3-mo, and 6-mo follow-up) include home visiting retention, home visitor-client relationship, substance use treatment engagement, child protective services reports, and conversations about substance use during home visits. HV retention, CPS reports, and conversations about SU will be mined from the HFA MIS. SU Treatment Engagement will be assessed at 6-month follow-up via the *Treatment Services Review.* Additional variables that are potential moderators of impact include: motivation to change, intimate partner violence, social support, and stress. Motivation to change substance use will be measured with the Maternal Motivation Scale. Intimate partner violence will be measured with the Composite Abuse Scale. Social support will be measured with the Interpersonal Support Evaluation List (ISEL-12), and stress will be measured with the Perceived Stress Scale. All are validated measures that have been widely used in other studies of pregnant and postpartum women. The strength of the relationship between home visitors and clients will be measured via the Working Alliance Inventory-Short Form, Client Version (WAI-SC). The WAI-SC is a 12-item measure of client perceptions of trust in their provider and of agreement on goals and tasks, and has demonstrated good psychometric properties in the HV context.

DATA ANALYSIS

Feasibility, Acceptability, and Fidelity. We will use thematic content analysis to analyze qualitative data, an approach that applies inductive coding to identify themes within the data, and has been used in other evaluation studies in child welfare, including our prior HV study. Audio-recordings of interviews will be transcribed verbatim and transcripts will be coded by two independent raters. Final themes will be determined via an iterative process of individual rater review and discussion to resolve discrepancies, according to the following steps: (1) independent transcript review by each rater to note general themes and highlight key concepts; (2) generation of list of lower-level sub-themes and collated statements by each rater independently; (3) review of sub-themes by both raters and consensus decisions on final list; (4) sorting of sub-themes into higher-level thematic categories by each rater; (5) raters come together to agree on final thematic map. Quantitative items assessing client satisfaction with the e-SBI will be analyzed using descriptive statistics in SPSS. We will examine descriptive statistics for all fidelity checklist items to determine dose of home visitor facilitation received.

SBI-HV Impacts on Client Outcomes. The study will use a randomized intent-to-treat design, with home visitors randomly assigned to condition (routine HV vs. HV+SBI-HV). Data will have a 3-level nested structure: clients (N=40) within home visitors (N=10-20) within sites. Given the small number of home visitors and sites, modeling each as a random effect would not yield stable estimates. Therefore, we will use the sandwich variance estimator to adjust standard errors as appropriate to account for nesting of clients within home visitors. Site will be included as a fixed covariate in all models. We will conduct ANOVA or chi-square tests to assess group equivalence on home visitor characteristics (demographics, EBP readiness), and client characteristics; those that differ between groups will be included as covariates. We will conduct latent growth curve (LGC) modeling in Mplus to examine the impact of study condition on change over time in primary and secondary outcomes. Mplus provides full information maximum likelihood estimation that produces unbiased parameter estimates under the assumption that the data are missing at random (MAR), and outperforms other missing data approaches even when MAR is not met. Analyses will use a 2 (study condition) X 3 (time) repeated measures intent-to-treat design. First, we will use likelihood ratio difference tests of nested models to determine the overall shape of the individual change trajectories: no change or linear change. Next, we will test unconditional models for all outcomes to obtain the average change effect. Third, we will add study condition to test its impact on initial status and change over time. Model

fit will be evaluated via chi-square, RMSEA, CFI, and TLI, and condition effects will be demonstrated by a statistically significant slope parameter, as tested by the pseudo z test, associated with study condition. For normally distributed outcomes, we will use conventional LGC models, with the appropriate estimator selected based on the distributional properties of the DVs. If client outcomes deviate substantially from normality, we will apply a negative binomial estimator, as recommended for count outcomes (i.e., days of SU) with a distribution that is skewed toward zero. Effect size estimates using Cohen's *d* will be calculated for all condition effects on client outcomes based on published LGC model recommendations.

The LGC modeling described above is our preferred approach for analysis. However, given our small sample, we present an alternative analytic strategy in case the longitudinal models fail to converge. If this occurs, we will conduct a series of ANOVAs to test the difference between study conditions on client outcomes separately at each follow-up time point (3- and 6-month), including the baseline value of the outcome as a covariate. Effect sizes will be calculated using Cohen's *d.*

Exploratory post-hoc analyses using the methods described above will be conducted to examine: (1) condition differences in home visitor-client alliance; and (2) differences in SBI-HV impact based on pregnancy status.