

METHODOLOGICAL PROCEDURES & DOCUMENTS MANUAL

Reducing Maternal Depression and Promoting Infant
Social-Emotional Health & Development

NIH R01 HD086894

NCT03464630

Randomized Controlled Trial Design: Prior to iPhone set up, the Intervention Project Coordinator implements randomization procedures. Using a random number generator, mother-infant dyads were randomized, in a 1:1 allocation, to one of the two parallel interventions: Mom and Baby Net or Depression and Developmental Awareness. The Intervention Project Coordinator notifies the PI to review condition assignment and assigns case to intervention coach. (see pages 26 and 98 in Procedures below)

Objective and Specific Aims:

The objective of this project was to address the problem of silo interventions and to improve accessibility to intervention that both reduces maternal depression and improves infant social emotional and communication development. To achieve this objective the following specific aims were addressed:

1. Embed core components of the Mom-Net Internet intervention into the Internet based virtual coaching intervention, Baby Net, to create Mom and Baby Net, an instructionally sound program geared to reduce the internal demands of depressed mothers postpartum.
2. Evaluate the impact of the Mom and Baby Net (MBN) program, as compared to a parallel Internet remote coaching intervention: Depression and Developmental Awareness (DDAS), via a randomized controlled trial. Depressed mothers during the postpartum period and their infants (N=180 dyads) will be randomized to the MBN or DDAS . Impact will be examined relative to:
 - 2.1 Change in parenting behavior, attitudes, beliefs, knowledge, and stress;
 - 2.2 Infant social-emotional behavior and development change;
 - 2.3 maternal depressive symptoms change; and
 - 2.4 Concomitant change in parenting, infant social-emotional, and maternal depressive symptom outcomes as a result of intervention.
3. Evaluate moderating influences on parent and infant behavior within the context of depression during the post partum period. We will focus on:
 - 3.1 The extent to which maternal depression prior to intervention, including current depression symptoms as well as depressive history and chronicity, relate to dosage within the MBN program;
 - 3.2 How dosage moderates parent and infant behavioral change as well as maternal depressive symptom change; and
 - 3.3 The extent to which contextual risks surrounding mothers (maternal isolation, social support and relationship status and conflict) not only relate to maternal depressive symptoms and MBN program dosage/skill acquisition but also moderate parenting, infant, and maternal depressive symptom change.
4. Assess maintenance of the program effects at 1-, 3- and 6-months after intervention. These trajectories for mothers and infants will allow for building a preliminary view of intervention effects as infants move into the next stage of development to determine if intervention early in infancy produces continued positive effects as these infants age.

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I. Recruitment and Screening

RECRUITMENT & SCREENING PROCEDURES

RECRUITMENT PROCEDURES

Referrals from sites

Referral sites will be given referral materials to distribute to eligible participants. Eligible participants are mothers of babies age 0 – 12 months who live in the metro-Atlanta area, speak English, and meet criteria of depression on approved depression screening. Some sites will refer moms without screening for depression based on mom's age, location, and baby's age eligibility criteria. They will use the parent letter specific to sites that are not screening for depression.

Referral site home visitors will review the parent letter with eligible participants to tell them about the study and give them an interest card and envelope. The participant will complete the card, marking their interest and contact information, place in envelope, and return to their home visitor. The home visitor will write their initials on the outside of the envelope as well as the participant's score on the depression screening (number only) and baby's age. Home visitors will return envelopes to their site supervisor. The assessment coordinator will collect envelopes regularly in a manner agreed upon between the site and recruitment coordinator.

Some sites will also place a locked interest box in their office. The box will have information from the parent letter displayed with interest cards available for moms to read, complete, and place in the locked box. Research staff will check the boxes once a week and collect interest cards.

The assessment coordinator will open envelopes at GSU office. She will immediately shred any interest cards that are marked “not interested” and record the number of “not interested” cards and date collected in the Access database. She will assign an ID number to all “interested” cards and transfer contact information into the Access database.

The assessment coordinator will then contact interested participants and use the screening procedures to determine participants' full eligibility.

Referrals from community events

Research staff will attend community events that they are invited to attend or that they register to attend. As moms approach the project table, research staff will give them a parent letter (see Referral Site Packet) and read it with them. This letter tells them about the project and the eligibility criteria. If mom is interested in hearing more about the project, research staff will give them an ipad to complete the online screening and interest form.. Research staff will look at the screening form to confirm eligibility. If mom is not eligible, research staff will follow script on instructions sheet. If mom is eligible, research staff will tell her that they will call her to tell her more about the study.

Research staff will offer moms who are not eligible for the study a list of local resources (see 'Georgia Resources' section of the Mom & Baby Net handbook) and encourage them to reach out to the project team if needed (contact info on parent letter).

Online Referrals/Interest

Partners may direct eligible moms to the Mom & Baby Net website or moms may come to the website themselves. The website gives information about the program (same information as the parent letter) and includes an online screening and interest form. Moms will first answer 3 eligibility questions (mom age, baby age, and PHQ2 questions). If mom is not eligible based on this info, the form is completed and does not ask mom for contact information. For moms who are eligible, they will continue with the form and complete contact information.

The project coordinator will be notified by email when a form is submitted, go into Qualtrics, retrieve the information to a Recruitment Form, then delete the record from Qualtrics. The project coordinator will then continue with screening procedures below.

SCREENING PROCEDURES

Assessment coordinator will call interested participants. Prior to calling, assessment coordinator should have the participant's interest card, a blank recruitment form (see Recruitment Form) and the RCT consent form handy.

The assessment coordinator will then follow the Screening Call script and procedures to complete the screening call (see Screening Call Script). For referrals coming from sites that have not screened participant for depression, the screening call will include the depression screening as noted in Screening Call Script instructions.

MOM & BABY NET RCT RECRUITMENT CALL

After recording participant's responses to questions on the recruitment form, transfer the information to the Access Database & Matriculation Table

1. **Before the Call**
2. **Project Overview**
3. **Determine Eligibility**
4. **If Participant is Ineligible**
5. **Participant is Eligible**
6. **After the Call**

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1. **BEFORE THE CALL**

- Have mom's interest card available.
- Have recruitment form ready to record mom's responses.
- Have RCT consent form ready to go over.

2. **PROJECT OVERVIEW**

Introduction: *Hello.....my name is _____ and I am calling from Georgia State University about a new research project called Mom & Baby Net.*

You recently said you'd like to hear more about the program to see if you could be included.

Thank you for your interest! I would like to tell you a little more about the project and see if you would be interested in participating and ask you a few questions to see if you are eligible. It will take about 15 – 20 minutes. You can stop the call at any time or tell me if you do not want to answer any questions. Is now a good time?

- If they can't talk now, set up a date and time for you to call again

About the project: *I have a couple of points I'd like to quickly share with you about the Mom & Baby Net project....if you have any questions, feel free to stop me at any time*

- *The purpose of this research project is to test two iPhone-based program for moms who have been feeling down and their babies. We hope to use this information to improve our program in order to help more moms.*
- *Participants in our study will be given an iPhone to access the program during the course of the study. There is no cost to your family for the loan of the iPhone for free data, texting, and phone calls to use while you are participating in the study. Upon completion of the program and assessment visits, participants will be able to keep the iPhone.*
- *Participating in this project will not affect any other services you currently receive.*
- *We have two different programs that provide information to mothers.*

- Both of the programs include 14 sessions with one session to be covered each week. Most moms spend between 40-60 minutes each week using the iPhone to work on the program and you can start and stop as needed. It will save your place. Each mom will be assigned an individual coach who will provide support through a video call each week. The call will involve watching a video that was created during the session. Each call will last about 20-30 minutes.
- Participants will be asked to complete 2 in-home assessments: 1 assessment visit at the beginning of the project and 1 assessment visit at the end. Each assessment visit will last about 1 to 1 ½ hours. If needed, we can split those into multiple visits. At each assessment visit we will make a video of you and your baby playing together and looking at books. We will also complete an online questionnaire that asks questions about you and your baby.
- Once you complete the first assessment, we will schedule one more home visit to give you the iPhone and support you in using it. This visit will last about 1 hour.
- There may be some benefits to mothers who participate in the program.
 - You may find that answering questions about parenting your baby is helpful and interesting.
 - You will have the iPhone with free data, texting, and calls to use during the study.
 - You will be able to keep the iPhone upon completion of the study. Although we will not continue to pay for phone service, you can use the phone through wireless Internet if you have access to it.
 - You will have the videos on the iPhone that you created during on the program.
 - You will be helping researchers to learn whether the program you receive is helpful for mothers of infants.
- There are few risks to being in the program.
 - You may feel uncomfortable answering some of the questions asked today or during the project. You can stop this call at any time and skip any questions during the project that you do not want to answer.
 - All information we collect is stored in a secure, locked office or database that is only accessible by approved research staff. We will use a study number rather than your name on all study records. There is only one code sheet use to identify research participants and it is stored securely in a password-protected file on a locked computer in a locked office.
- If you have any concerns or complaints, you can find IRB contact information at gsu.edu/irb

Does this sound like something you might be interested in hearing more about?

- If no: select DECLINE for final status and Eligibility Status; in the reason box next to Eligibility Status, select TOO BUSY/TIME or NOT INTERESTED
 - Do you have any other questions I could answer for you?
 - Thank you for your time. If you change your mind, feel free to contact me in the future to see if we are still recruiting.
- If yes, continue

3. DETERMINE ELIGIBILITY

Now we need to make sure that you are eligible for the project. There are some requirements for participating. Before spending any more time explaining the program, I would like to ask you a few questions to find out if you can indeed participate in this study. Are you comfortable with that? Your answers will be kept strictly confidential.

Age:

- *Are you 18 years of age or older?*
 - If Yes, continue and record mom's birth date on the recruitment form.
 - If No, **ineligible**. Go to page 5.

Residency

- *Do you live in the metro Atlanta area and plan to stay here during the next year?*
 - If Yes, continue
 - If No, **ineligible**. Go to page 5.

Baby

- *How old is your baby?*
 - Ask mom baby's age and date of birth. Record on recruitment form.
 - If baby is younger than 12 months, continue.
 - If baby is older than 12 months, **ineligible**. Go to page 5.

Stressful Situations

Sometimes families are experiencing stressful situations in their lives that can make it hard for them to be a part of a study such as this, either because the situation makes it burdensome for the family to participate in the study and/or because the family may need help that cannot be provided within the study. I am going to read you a list of some situations that families experience that make it a good idea for them to NOT participate in this study for the reasons that I just mentioned. You don't have to tell me which of these situations apply to you if any do. When I finish reading the list, I'll ask if any of these situations describe you.

- 1) *You have been diagnosed with schizophrenia.*
- 2) *You have received treatment or medication to help with hallucinations or delusions such as seeing or hearing things other people can't see or hear or having ideas that others might think are odd or strange, like people are out to get you or trying to hurt you.*
- 3) *You are currently receiving inpatient substance abuse treatment.*
- 4) *You live in a homeless shelter or domestic violence shelter.*
- 5) *Your infant is currently in intensive treatment for a genetic or health condition.*
- 6) *You do not have permanent legal guardian custody of your infant.*

Again, you don't have to tell me which of those might apply to you. However, please think about the situations I just mentioned, and answer "yes" or "no." Do any of these situations apply to you?

- If YES, **ineligible**. Go to page 5.
- If NO, continue.

Depression Screening (only do if not already completed by referring provider; mark responses on PHQ2 form)

Lastly, since our program is for moms who have been bothered by feeling down, we want to see how you've been feeling over the past 2 weeks. I'm going to read 2 statements with some answer choices for each one.

Over the past 2 weeks, how often have you had little interest or pleasure in doing things? Not at all, several days, more than half the days, or nearly every day?

Over the past 2 weeks, how often have you felt down, depressed or hopeless? Not at all, several days, more than half the days, or nearly every day?

- If score is less than 3, **ineligible**. Go to page 5.
- If score is 3 or higher, continue.

❖ **If participant is Eligible go to page 6**

4. IF PARTICIPANT IS INELIGIBLE

Thank the Mom for her time and let her know that she is not eligible (choose the response below that best fits with why the participant is ineligible).

Thank you for taking the time to answer my questions. Unfortunately you are not eligible for the project at this time.

- **Age:** *The project requires that moms be at least 18 years of age*
- **Baby:** *The project requires that babies be younger than 12 months of age at the time we begin the first assessment.*
- **Residency:** *The project requires that moms must live in the metro Atlanta area and remain there for the next year.*
- **Stressful situations:** *We have found that participation in the study is very challenging for those that are dealing with other stressful situations in their life.*
- **Depression screening:** *Based on our brief screening, there are no signs that you are struggling with depression symptoms at this time. But we know these feelings can change. If anything changes we encourage you to follow up with your doctor and or local community program or reach back out to us in a few weeks.*

Update contact and eligibility information in Matriculation Table.

File recruitment form in ‘Not Enrolled’ folder (program coordinator’s office).

5. **PARTICIPANT IS ELIGIBLE**

Based on the information you just gave me, you are eligible to participate in the program at this time. Before finalizing eligibility, we will confirm at our first visit that there is Sprint wireless coverage at your home. If you are interested in participating, the first step will be for us to come to your home to complete the first assessment. During that visit we will also go over the consent form, which will explain all the project details again. It will review exactly what you are being asked to do as well as the risks and benefits of being in this research study. We can answer any questions you have then before continuing.

What questions do you have right now? Answer any questions.

Schedule assessment visit: *I'd like to go ahead and set up a time to come visit for the first assessment. It's possible to finish all of the assessment in one visit, but that really depends on how long it takes for you to complete the questionnaire. We found it's best to block up to 2 hours of time for the visit. Then, we can just play it by ear. If you're not finished after an hour or so, we can schedule a second visit to finish up. Or, if you want to just power through and finish it in one visit, that's your choice as well.*

- *It's important to remember that the assessment visits are VERY different than the intervention. It's about gathering information about you and your baby – as compared to the intervention where you are going through an iPhone app on your own while learning information and watching fun videos of other moms and babies.*
- *When scheduling the 1st visit, it would be best to schedule this visit at a time of day when your baby is usually awake and alert since we will record you and your baby playing together.*
- *When is good for you? Is there a day or time that works best for you? Do you prefer mornings or afternoon?*
 - Record the scheduled appointment time in the Access Database along with any notes
 - Record appointment in the Mom & Baby Net Outlook calendar or other scheduling software

Confirm all the contact and demographic information and edit if necessary in the database:

- **NOTE:** Make sure to confirm if mailing address and physical address are different, confirm spelling of first and last name, and confirm date of birth and name of baby
- *Is this the best number to call to follow-up with you?*
- *Can we leave a message at this number? If it's a cell # - ask if you can text her appointment reminders.*
- *If for some reason I can't get a hold of you, it would be helpful to have some contact names and numbers of people who would be able to reach you. Do you have one or two people who typically stay in touch with you and know how to locate you even if you move or change numbers? Can I get their names and phone numbers?*
 - Record the contact names/numbers on the recruitment form

Recap:

- *I believe I have all the information I need. I'd like to quickly recap a couple of points*
 - *We will want your baby to be at the appointment so we can video tape you while you play and read together for about 10 minutes*
 - *We will need a quiet place for you and your baby to play together without interruptions*
 - *Again, we expect that the first visit will take approximately 1-1½ hours but we ask you to block off up to 2 hours. That way, if you want, you can finish everything in 1 visit and we won't need to schedule a 2nd assessment visit.*
 - *We have found that a lot of new moms worry about their house being messy or have concerns about having other people in their home. We are used to messy. We want you to be comfortable and we understand that with a new baby, there is a lot going on for you.*
- *Do you have any questions about the project in general?*
 - If yes, try and answer any questions they have or let them know you will call back with the answer.
 - If no, continue.
- *Give us a call if you have any questions or concerns before your scheduled appointment. We will also give you a reminder call or text the day before your appointment.*
- *We really want to thank you for your interest in our study and being willing to let us come to your home during this busy time in your life. We look forward to meeting with you on _____ at _____ am/pm.*

❖ **CONTINUE FOR 'AFTER THE INITIAL RECRUITMENT CALL' STEPS**

6. AFTER THE INITIAL RECRUITMENT CALL

- Update Access Database - Tracking Information Form
 - Update/confirm contact, alternate contact, and demographic information
 - Enter phone screen information
 - Enter eligibility information
 - Enter Call Attempt information and enter Call Back Date if needed to call back to schedule preassessment

Mom Baby Net Tracking Information Form

If this is a new Mom, you can click in the Date Received box and start entering data.
If this is an existing Mom, use the drop down box to the right to look up Mom's

Mom ID	(New)	Date Received	Referral Source	Study Enrolled																																													
Study Status		Attrition Reason		Please specify other:																																													
Mom First Name		Mom Last Name		Marital Status		Cell Phone																																											
Street Address		Other Address		Home Phone																																													
City		State		Postal Code		Primary Language		Work Phone																																									
Mom Birthdate		Email																																															
Baby's Name				Baby's Birthdate																																													
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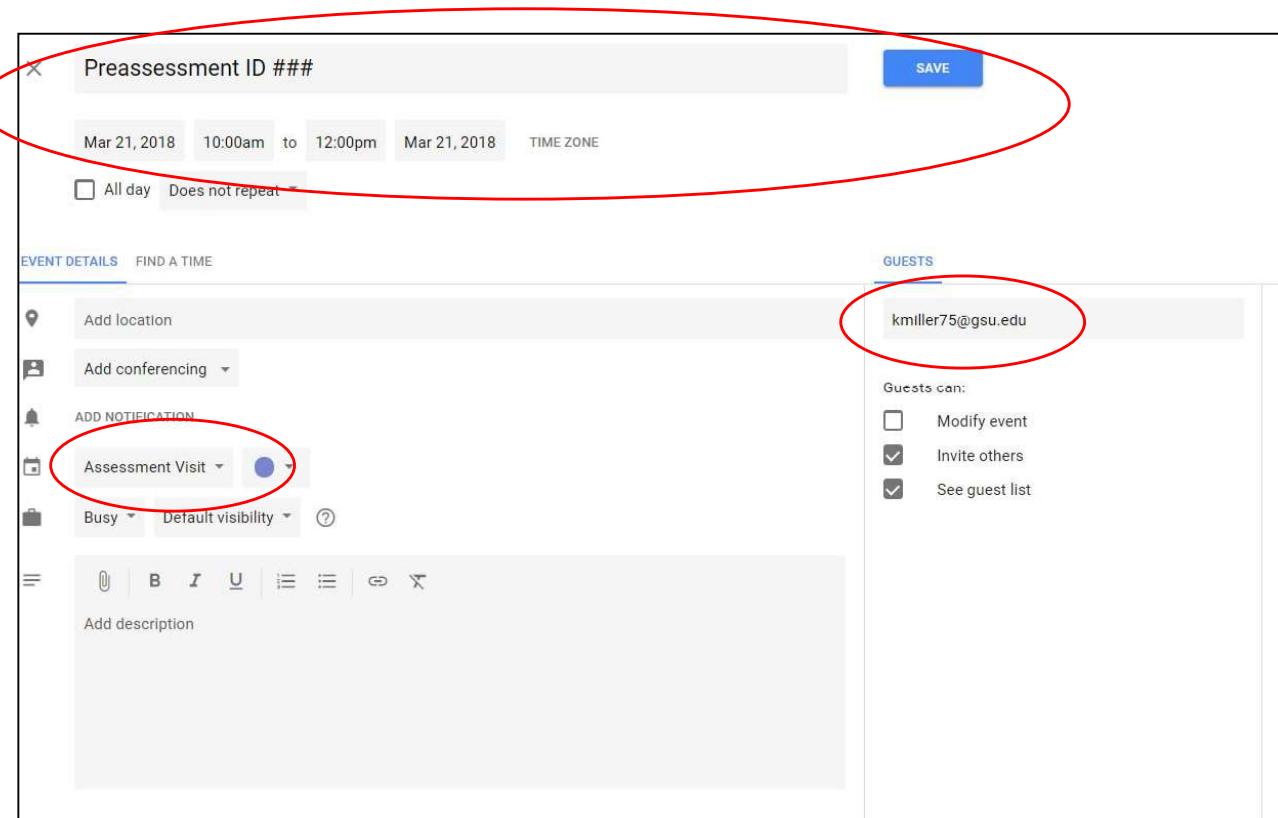
- If applicable, enter Scheduled Appointments information

Scheduled Appointments

Mom ID	Type	Date	Appointment Details			Check the Completed Assessments				
			Time	Assessor	Status	Q1	Q2	Interactions	iPhoneTrain	Notes

- Update Matriculation Table
 - Entire 'Screening' section

- ‘PreAssessment Scheduled’ column of ‘PreAssessment’ section (if scheduled)
- Update Google calendar
 - Add scheduled preassessment on Assessment Visit calendar
 - Add assessor as ‘guest’ when known



MOM & BABY NET RECRUITMENT FORM

Date Interest Card/Email Received: _____ Date/Time of Initial Phone Call: _____

Contact Information

Name: _____

Physical Address: _____

Mailing Address (if different): _____

Cell #: _____ ok to text? Y N

Home #: _____ Work #: _____

Eligibility Status

- Mom age 18 or older
- Baby age under 12 months
- Mom depression screening score
 - PHQ9 \geq 10
 - PHQ2 \geq 3
 - Edinburgh \geq 11

1. Mom's birthdate: _____

2. Metro Atlanta residency for the next year: yes no

3. Baby's birthdate: _____

7. Stressful situations: yes no

- ***Is mom eligible? YES NO***
If NO, reason why: _____
- ***Is mom interested in participating? YES NO***
If NO, reason why: _____
If YES, schedule first assessment

- ***Date First Assessment scheduled:*** _____

Alternate Contacts

Name: _____ Relationship: _____

Address: _____

Phone number: _____ home cell work

Name: _____ Relationship: _____

Address: _____

Phone number: _____ home cell work

II. Consent & Assessment Manual

Mom & Baby Net Consent & Assessment Procedures

- **BEFORE HOME VISIT**
 - RESCHEDULING
- **DAY OF HOME VISIT**
 - BEFORE ARRIVING
 - ARRIVE AT HOME
 - REVIEW CONSENT FORM
 - CHECK FOR SPRINT SIGNAL
 - CONDUCT ASSESSMENT
 - CHECK FOR CRISIS
 - PREPARE FOR VIDEO RECORDING
 - RECORD THE INTERACTIONS
 - BEFORE LEAVING THE HOME
- **AFTER THE HOME VISIT**

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BEFORE HOME VISIT

1. Check Outlook calendar to confirm participant ID#, date, and time of assessment.
2. Look up participant in Access database to confirm names, address, field partner, and check for any notes specific to the assessment.
3. Contact the participant
 - a. Confirm the time and place; see RESCHEDULING below if needed.
 - b. Prepare mom for what to expect during the visit
 - 1-1.5 hour visit duration
 - Prepare mom for video recording. Explain there will be two 5-minute recordings of mom and her baby. Baby needs to be present and awake at some point during the assessment visit. Video can be done whenever is best during the time assessor is there.
 - Visit will go most quickly and smoothly if there is someone in the home who can care for baby and other children; we understand that this is not always possible and we will work with you if this can't happen, but it does make the process go faster during the visit.
 - c. Ask if there are any questions
 - d. Let her know we are looking forward to meeting her and her baby
4. Print out map-quest map/directions or use navigator.
5. If applicable, contact field partner and confirm where/when you will be meeting for the assessment
6. Check that you have all assessment materials:
 - a. 3 assessment board books
 - b. 2 participant board books (to leave with family)
 - c. Project iPhone on Sprint network
 - d. iPad fully charged
 - e. Touch Screen Stylus
 - f. Mapquest directions

- g. Forms
 - i. Assessment Data Checklist
 - ii. iPhone Customization Questionnaire
- h. Resources materials
 - i. Postpartum Depression Facts
 - ii. Crisis Help Card
- i. Safety procedures packets
 - i. Assessment Summary & Risk Identification
 - ii. Safety Monitoring Documents

RESCHEDULING: Tasks to complete for No-Shows, Cancelled or Rescheduled appointments

1. In Access, change appointment status to NO SHOW, CANCELLED or RESCHEDULED, and contact the participant to reschedule the appointment. Create a new line for any new appointment you book.

Scheduled Appointments							
Mom ID	Type	Date	Appointment Details	Time	Assessor	Status	Check the Completed Assessments
							Q1 Q2 Interactions iPhoneTrain Notes
101	Pre	4/8/2015		9:00 AM	Sandra	Scheduled	
*	101					Completed	
						Cancelled	
						Rescheduled	

2. Re-file participant materials in Assessor's designated file/storage area until the new appointment.

DAY OF HOME VISIT

BEFORE ARRIVING

1. Call or text (if approved by mom) 30 minutes – 1 hour ahead of time to let mom know your ETA.
2. Prepare yourself mentally: have a cool, calm, and matter-of-fact affect.
3. Arrive at the participant's home at the scheduled time (call or text mom if an earlier assessment is running late and you will not be arriving on time).

ARRIVE AT HOME

1. **Greeting the participant: Politely introduce yourself and establish small talk to “break the ice”**
 - Avoid controversial or uncomfortable topics (politics, religion, moral issues, etc.)
 - The goal is to **begin building rapport**. Try to get mom talking about herself or her interests (How many kids in the home, how long have you lived in the area, etc.)
2. **Review order of events** with the mother so she knows what to expect during the home visit:
 - *Today we will be checking for wireless signal and spending some time getting to know you through a questionnaire.*
 - *We will go over the consent form and answering any questions you have.*

- You will answer questions using the iPad. You and I will begin looking at questions together on the iPad then if you would prefer to continue on your own, you can.
- We will also make a 10-minute video of you and your baby playing together and looking at books.
- We can do the questionnaire first or the video first, depending on the timing for the baby.
- The last thing we will do is discuss when would be a good time to set up the training visit.
- What questions do you have?

*****Note: if baby is awake, suggest doing video recording first after consent form***

CHECK FOR SPRINT SIGNAL

1. Check for Sprint signal with test device.
2. If there appears to be no signal or little signal, test a webpage (open Safari, go to gsu.edu)
3. If phone cannot get a signal, tell mom
 - a. *Unfortunately I cannot find a signal for the network the project phone is on, which means you would not be able to complete the program.*
 - b. *Thank you for your time and I am sorry you are not eligible at this time.*
4. Return to office and update Access database and matriculation table to indicate mom was ineligible due to lack of Sprint signal.

REVIEW CONSENT FORM

1. Take out 2 copies of the consent form and give one to mom
2. Go over each section – you don't have to read word for word but say the main points of each section.
3. Ask mom what questions she has after each section.
4. Have mom complete lines *Print Participant's Name, Child's Name, Participant's Signature, Date*
5. Assessor signs as *Researcher Obtaining Consent and Date*

CONDUCT ASSESSMENT

1. Go to Qualtrics Pre-Assessment on iPad (Qualtrics folder -> MBN part1)
2. Enter the ID #, mom's Initial, Assessor's name and date before mom starts with the questionnaire.
3. Provide mom with the iPad and explain to her how to use the iPad.
4. Sit next to mom if possible, so you can read the questions and/or instructions to her.
5. Help create comfort for moms to opt to have the questions read to them.
 - a. *Some moms prefer to have the questions read to them so that they can relax for a moment and think about the answer without having to read and enter responses. Other moms really prefer reading on their own.*
 - b. *Either way we will start the questions together and go over instructions for each section together. The questionnaires are divided into sections, which are separated by pictures. When we get to those pictures we will stop so that I can review the instructions for each new section with you. Sometimes questions are asked in a way that might be unfamiliar or they might be confusing. At any point that you have a question about what something means, please let me know so that I can address your question. Also, if I notice that you are coming up to a section with items that moms sometimes find confusing, I'll let you know so that we can talk about those and I can explain them up front.*

- c. *We will begin the questionnaire going through questions together.* Start the questions together. Read each question for mom and allow her to choose an answer. Pay attention to how mom is doing comprehending questions and answers.
 - i. If she seems to be comprehending well, find a good point to ask if she would like to continue on her own or continue going through together. If she wants to continue on her own, remind her to stop at the pictures so you can review instructions.
 - ii. If she seems to be comfortable going through questions together, continue that way.
6. When mom reaches STOP sign she will hand iPad back to assessor. Click submit to check for safety concerns and skipped questions.

CHECK QUALTRICS FOR POTENTIAL SAFETY CONCERNS & SKIPPED QUESTIONS

1. When mom hands back the iPad, click 'Next' to see flagged questions related to self-harm.
 - a. If self-harm question(s) are endorsed, use Decision Tree to follow up.
 - i. ATQ #6 – I don't think I can go on
 - responses of moderately often, often, or all the time
 - ii. PHQ9 #9 – Thoughts that you would be better off dead, or of hurting yourself
 - responses of several days, more than half of the days, or nearly every day
 - b. NOTE: If someone is in immediate crisis, call your supervisor. Do not leave the home.
2. Check Qualtrics report for missing or skipped items. Tell mom you want to double check any missing responses and make sure nothing was skipped by mistake.
 - a. If questions were skipped on purpose, leave blank.
 - b. If questions were skipped my mistake, add the mom's new responses (edit survey option).

PREPARE FOR VIDEO RECORDING

1. *Now we are going to make a video of you and your baby as you interact together. There will be two parts to the video. We'll start with whatever you and your baby want to do together, then I'll share some books that you and your baby can look at together.*
2. Setting up for the interactions:
 - o **Setting the Stage:**
 - i. **Let mom know that we need a relatively quiet place with plenty of light.**
 - o The space should be **away from others** so that the interactions will not be interrupted by other people in the home
 - o If possible, pick a room **away from sources of noises** that could be picked up on the camera's microphone (**like a noisy kitchen, television, or street**)
 - ii. Discuss types of possible interruptions and have a discussion about how they can be avoided from the onset; then discuss interruptions that may occur during the recording, how to handle them, and the need to discontinue recording and re-recording if interruptions beyond 30 seconds occur.
 - iii. **Have the mother select a space for conducting the interaction**
 - o **Make sure the television/stereo is off** during the observation period
 - o **Turn on any available lights and Do not film into a bright window.**
 - o **Do not place the iPad next to a return air vent, fan, or aquarium.**

- **How to Shoot the Scene**
 - i. **Make sure both mom's and child's faces are in the frame.**
 - If objects/toys are blocking faces, adjust the angle of the camera.
 - If mom and child have a face-to-face interaction, please adjust the camera angle to view their profiles (**we would rather see part of both of their faces verses all of one of their faces**).
 - ii. **Make sure the camera angle is wide enough to allow mom some space to move around;** however, be prepared to pan /move the camera if needed
 - iii. **If you can't keep mom & baby in the frame** (e.g. mom walks across the room or baby crawls away & mom doesn't follow) focus on mom's face and shift to baby briefly to capture what s/he is doing. Shift back & forth until you can get both in the frame. If mom or baby a changes behavior, try to capture that if possible (e.g., baby was playing with toy but dropped it and is showing nonverbal signs of fussiness).
 - iv. **Follow the mom around to make sure she is being filmed at all times**
 - v. **Pausing for Interruptions**
 - If you must pause, **note the running time on the video before pausing** so as to know how much longer to film once the observation resumes.
 - vi. **Do not engage conversation or shuffle papers next to the camera during the video.**

RECORD THE INTERACTIONS

Avoid giving the appearance of 'reading' the instructions. The activities should be presented in the order that they occur in the protocol. Always begin with free choice interaction and end with looking at books.

1. **FIRST INTERACTION (5 Minute Free Choice Interaction): Instructions**
 - Record giving instructions to mom then stop before beginning interaction recording
 - *Let's get started with the first part of the video by spending five minutes with you and your baby doing something that you enjoy doing together.*
 - *What I'm interested in seeing are things that you and your baby are both comfortable with and used to, and things that your baby loves to do.*
 - *Please feel free to move around as is comfortable for you and your baby. You don't have to sit in one place, but I'll need to know what room you'd like to be in so that I can move along with you.*
 - *Attend to any needs your baby might have during this time just as you normally would.*
- **Note:** The purpose of this activity is to encourage the caregiver and child to engage in whatever activity they enjoy and to be as non-restrictive as possible. It is important not to impose any structure on the caregiver above and beyond the instructions. Therefore, do not restrict the caregiver's and child's movement by asking them to stay in one place.
 - *After these 5 minutes, I will give you the instructions for the second part of the recording which lasts 5 minutes. What questions do you have?*
 - **Begin the first 5 minute interaction**

- Record header: *"This is a Mom & Baby Net interaction with family ID # _____; the mother's initials are _____."*
- Tell the participant that we are now beginning the interaction. *You can begin now.*
- After 5 minutes, stop recording and say *Okay, you have finished the first interaction.*

2. **SECOND INTERACTION (5 Minute Looking at Books): Instructions**

- **Place the books near mom and baby so mom can see/reach them:**
1)Brown Bear; 2) Touch and Feel Puppy; 3)Touch and Feel Farm
- Record giving instructions to mom then stop before beginning interaction recording
- Instructions:
 - *During the next five minutes, you and your baby can spend a little time with these books.*
 - *However you want to use the books with your baby is fine.*
 - *Feel free to attend to whatever needs your baby might have.*
 - *What questions do you have?*
- **Record the second interaction**
 - i. Record header: *"This is a Mom & Baby Net interaction with family ID # _____; the mother's initials are _____."*
 - ii. Tell the participant she can begin. *You can begin now.*
 - iii. After 5 minutes, stop recording and say *Thank you! You have finished the video recording piece of the visit.*
 - iv. *Collect 3 assessment books then give 2 participant board books to leave with family.*

BEFORE LEAVING THE HOME

1. Complete iPhone Customization Form
2. Review the **Data Checklist** to ensure all steps and documentation are complete.
 - a. Sprint signal
 - b. Qualtrics Questionnaire, ASRI
 - c. 2 video recordings
 - d. Confirm Family information and alternative contacts
3. Share materials with mom if necessary per safety decision tree
 - a. Referral to talk with doctor and/or home visitor (if PHQ9 score is 10+)
 - b. Postpartum Depression Facts
 - c. Crisis Help Card (if flagged item(s) on questionnaire were endorsed)
4. Schedule training visit to bring her iPhone to get her started in the program. NOTE: allow more time if she is in crisis or other anomalies arise that may require more time to sort out. She should plan for 1.5 hour for training – preferably when baby is asleep or another adult is at home to help with other children.
 - a. Open Google Calendar on iPad
 - b. Ask mom for best times for future calls or visits. Schedule day and time if possible and add to Google calendar using ID number ('Training Visit ID ####')

c. Confirm with mom the best numbers to call with a visit reminder or to schedule training visit (if unable to schedule now)

AFTER HOME VISIT

1. Update Access Database:

a. If applicable, update “Best times to call” under Notes in the “Tracking Information Form”

If this is a new Mom, you can click in the Date Received box and start entering data.
If this is an existing Mom, use the drop down box to the right to look up Mom's

Mom ID	(New)	Date Received	Referral Source
Study Status		Attrition Reason	Please specify other:
Mom First Name		Mom Last Name	Marital Status
Street Address		Other Address	Cell Phone
City		State	Home Phone
Mom Birthdate		Postal Code	Primary Language
Baby's Name		Baby's Birthdate	Work Phone
Email			
Notes			
Mom Baby Net App Tracking Information			
UserName: <input type="text"/> Password: <input type="password"/>			

b. Update Scheduled Appointments: Change “Status” from “SCHEDULED” to “COMPLETE.” Check the boxes “Q1” and “Interactions” accordingly.

Scheduled Appointments

Mom ID	Type	Date	Appointment Details	Assessor	Status	Check the Completed Assessments	Notes
101	Pre	4/8/2015	9:00 AM	Sandra	Scheduled	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	
*					Completed	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/>	
*					Cancelled	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	
*					Rescheduled	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	

i. Use “Notes” for things like missing data, etc., NOT safety concerns.

Initial Visit

Mom ID	Initial Visit Date	Assessor	Eligibility Status	Reason	Notes
101					

Scheduled Appointments

Mom ID	Type	Date	Appointment Details	Assessor	Status	Check the Completed Assessments	Notes
101					Scheduled	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	

ii. Complete a new line for the training visit (if scheduled).

3. Update Matriculation Table (on Google docs)

4. Complete Assessment Summary & Risk Identification (ASRI)

a. If any concern may qualify as an Adverse Event (AE) or a Serious Adverse Event (SAE): **contact Kathleen immediately.** The PI needs to be notified immediately. In the event of an SAE, a

letter needs to be sent out within 24 hours of the reported situation. If Kathleen is not in the office, send her a text to (816) 616-6568.

- i. You will need to provide the supervisor with a copy of all related Safety forms
- ii. **If any safety concerns are noted, you will need the supervisor's signature on the ASRI and any and all safety forms prior to scanning**
 1. If the supervisor is not in the office you will need to obtain an electronic signature by emailing the needed documents to the supervisor in Word format.
 - iii. Add the possible AE/SAE to AE SAE Log (on Google docs)
- b. Scan the ASRI in **one PDF file** after needed signatures are obtained.
 - i. ASRIs without potential safety concerns can be scanned without supervisor signature.
 - ii. The scan, with no identifying information, should be emailed to yourself.
 - iii. Save scanned ASRI and all other documentation in the participant's ID folder in this location:
S:\ECSEHP\Projects\Baby-Net Depression NIH R01 2016-2021\Participant Data

Use this naming convention: [ID] PRE/POST [document] mm-dd-yy
Example: 101 PRE ASRI 10-22-17
 - iv. Email scanned ASRI to project coordinator

*** NOTE: If the assessment visit is completed in two visits, one final ASRI will be scanned and saved after the second visit. Be sure to enter both dates of the visits on the ASRI and what was completed by the mom and anything and everything that you responded to at each time point. If there is any concern involving potential harm- self-harm, child maltreatment or other harm, follow the protocol and send an ASRI for each visit.*

5. Project coordinator will export the PDF of mom's questionnaire responses.

- a. Save in the participant's ID folder in this location:
S:\ECSEHP\Projects\Baby-Net Depression NIH R01 2016-2021\Participant Data

Use this naming convention: [ID]-Q PRE/POST mm-dd-yy
Example: 101-Q PRE 10-22-17

6. Upload Observation Data to iCloud

- a. Each participant should have 2 videos: 1 5-minute free play video and 1 5-minute book video.
 - i. Edit videos to combine recordings if more than one recording was necessary to complete one activity
- b. Upload videos to iCloud
 - i. On iPad, open Photos app and go to Videos
 - ii. Tap 'Select' in top right corner and click on both videos
 - iii. Click the Share button in top left corner (box with up arrow)

- iv. Click 'Save to Files' -> select folder 'Assessment Videos' -> click 'Add' in top right corner
- v. Return to home screen and open the Files app to make sure it has uploaded (it may take a little while; will be faster if you connect to wifi)

c. Project coordinator will pull from iCloud and save in the participant's ID folder in this location:

S:\ECSEHP\Projects\Baby-Net Depression NIH R01 2016-2021\Participant Data

Use this naming convention: **[ID] PRE/POST [interaction type] mm-dd-yy**
Example: 101 PRE Free Play 10-22-17

7. Checklist

- a. Use the Data Checklist to ensure you have completed all necessary steps
- b. Give all original paper forms (Data Checklist, ASRI, any safety monitoring forms) to project coordinator for filing in participant folder.

Randomization: Prior to iPhone set up, the Intervention Project Coordinator implements randomization procedures. Using a random number generator, mother-infant dyads were randomized, in a 1:1 allocation, to one of the two parallel interventions: Mom and Baby Net or Depression and Developmental Awareness. The Intervention Project Coordinator notifies the PI to review condition assignment and assigns case to intervention coach.

Georgia State University
Mark Chaffin Center for Healthy Development
School of Public Health
Informed Consent

Title: Mom & Baby Net

Principal Investigator: Kathleen Baggett, Ph.D.

Sponsor: NIH/NICHD

I. PURPOSE

You are invited to participate in a research study. The purpose of this study is to learn about how it works to put two programs together. One program is for helping parents learn how to change thoughts and actions to help themselves feel better. The other program helps parents learn ways to help their babies' development. We want to find out if putting these two programs together and giving moms an iPhone to complete the program helps moms and babies. You are invited to be a part of the study because you have said that you have been feeling down and you want to help your baby grow in a healthy way. A total number of 180 moms will be recruited for this study. The study will take about 27 hours of your time over up to 12 months.

II. PROCEDURES

If you decide to participate, you will be asked to complete the following:

1) Pre-Assessment Calls (2 hours, 20 minutes): You will have calls to complete enrollment in the study:

- Call 1 (20 minutes): A research team member will have a call with you to read the consent form. You will follow along on your own copy. The team member will ask you to say what you understand about the project and allow you to ask questions. The research staff will answer your questions. If you agree to participate, you will be given an iPhone that will be dropped off at your house or mailed.
- Call 2 (split, 1 hour each):
 - Call 2a: The research staff will record a 10-minute video of you and your baby through a video call. The video will be divided into two parts. The first part will be playing with your baby as usual at home. The second part will be looking at a book with your baby. You can ask to stop the video at any time if needed. You will then answer the first part of questions about you and your baby while on a video call. You will be able to answer the questions on your iPhone. Questions can be read aloud to you while you wear ear phones. If you don't want to answer a question, you can skip it.
 - Call 2b: This call will be completed within a few days of the first call. You will continue to answer questions on your iPhone about you and your baby.

2) Training Call (1.5 hours): You will receive one of two parent programs on the iPhone. Both programs are set up the same way, but have different information. We want to find out which program helps parents and babies the most. We will show you, through a video call, how to use the phone. You don't have to know how to use an iPhone before you start the program.

Also during this call, you will use your iPhone to go to one of two parent program apps. A research staff person will show you how to use the program. You have an equal chance of being in either program. This will help us find out if one program works better than the other. Each program has the same number of sessions and the main activities are the same as described below under weekly program activities.

3) Weekly Program Activities (14 sessions, 1.5 hours each): You will use the iPhone to go through one of the two parent programs. Each program has 14 weekly sessions. You will have up to 8 months to complete the app program to make sure you have plenty of time to complete it. We understand that sometimes things come up and you may not be able work in the program each week.

Each of the 14 sessions will take about an hour to complete. You do not have to complete the activities all at the same time. Instead you can go through each session at your own speed. You can stop and start again when it's best for you. After each session you will have a 30-minute call with your coach.

During each session you will do the following:

- Listen to parent information
- Watch videos of other moms and babies
- Make a plan to use the skills for yourself and your baby
- Make a video of you and your baby
- Have a weekly call with your coach on your iPhone to talk about what you are learning in the program and watch the video that you made with your baby. Calls are recorded for quality assurance.
- Tell us what you think about the program session

During some sessions you will answer questions about how you are feeling. In between sessions, your coach may send messages to check in.

4) Post-Assessment Call (1.5 hours): After you finish the iPhone program, we will schedule a time to have a video call to answer survey questions and record a video of you and your baby. You will keep the iPhone (valued at \$350) at the end of this meeting. If possible, this meeting can be done in person.

5) Follow-Up Questionnaire (10 minutes): At 6 months after the program, you will use your iPhone or other device to answer questions about parenting. You will receive \$10

for completing this.

Moms who are not making progress and cannot be reached after 2 weeks will be sent a letter to confirm their continued participation. All participants will be given the opportunity to complete the post-assessment.

III. Risks

There are possible risks to being involved in any research study. Though we believe these risks to be small, we want you to know what they are and the steps we take to protect against them.

- 1) You will be asked personal information about you and your baby. You should wear headphones during the surveys. Only take the surveys in a private location where others cannot see the device screen. You might feel uncomfortable answering questions about your child or making a video. If you are uncomfortable, you may talk about your concerns with the project staff.
- 2) Everything on the Internet is at risk to be seen by someone unexpected. There is a chance that someone who is not supposed to see information about you will accidentally see it. On our part, any information you give us will not have your name on it, but will be marked by a number instead, and the staff has been trained to keep information private. Although recordings will be labeled by a number, videos are facially identifiable, and someone who views them could recognize you or your baby.
- 3) We will not give information to anyone unless you give us signed permission or unless we observe or you tell us of a concern about: 1) abuse, neglect, or endangerment of a child or elder; or 2) that anyone is in immediate danger of seriously hurting himself/herself or someone else. Such reports will be made, with or without your consent, as required by the law and for the safety of all persons, to the appropriate authorities. If there is a concern about child safety, Child Protection services are called as required by law. If there is concern about the immediate safety of an adult emergency medical services are contacted, as required by law. If any person threatens to harm another, the police are called, as required by law.
- 4) Because you will have an iPhone with Internet access, there is the chance that you or others will be able to see sites that you don't want to. It is your responsibility to use your iPhone safely. We will show you how to lock and use a password to keep your phone safe and to store your phone safely. Don't give your password to anyone.

IV. Benefits

Participation in this study may benefit you personally. Some parents like learning about their baby's development. They sometimes say that they feel better and their relationship with their baby has gotten better. Overall, we hope to gain information to help us make the program better for other mothers and babies in the future.

V. Compensation

You will have the iPhone to use at no cost to you during the study. The cost of the phone is \$350 for the research project to buy it. If the phone breaks, we will have it fixed or replaced. If your phone is stolen, we will file a police report and remotely lock and wipe your phone. If your phone is lost, we will remotely lock and wipe the phone. We may give you a new phone to finish the study after we talk about keeping the phone safe. If you choose to stop being in the study, a member of the research team will retrieve your phone.

You will keep the phone when you complete study activities through visit 3 but we will not continue to pay for phone service. You can use the phone's wireless Internet anywhere that you have Wi-Fi (for example, many coffee shops, parks, libraries, and schools).

You will receive \$10 for completing the Follow-Up Questionnaire.

VI. Voluntary Participation and Withdrawal

Participation in research is voluntary. You do not have to be in this study. If you decide to be in the study and change your mind, you can stop being in the study at any time. You may skip questions or stop being in the study at any time. Whatever you decide, you will not lose any benefits or services that you receive. However, you will have to return the iPhone.

VII. Confidentiality

We will keep your records private as allowed by law. Dr. Baggett and her research team will have access to the information you provide. Information may also be shared with those who make sure the study is done correctly (GSU Institutional Review Board, the Office for Human Research Protection, NIH). We will use a study number rather than your name on all study records. A code sheet will be used to identify research participants. The code sheet will be stored in a password-protected file on a locked computer in a locked office and is destroyed at the end of the study. All information uploaded on the iPhone app is secured and the Internet connections are secured. We use the same approach as banks and online stores (e.g. Amazon.com). Your coach and your coach's supervisor are the only people who will see the weekly session videos that you make and send to your coach. All video recordings are stored on a secure server accessible only by the project director and assigned staff using a special code. You can also ask that the video be deleted after it is sent. Five years after the study is finished, all videos and recordings will be deleted.

Your name and other facts that might identify you will not be used when we present this study or publish its results. The findings will be summarized and reported in group form. You will not be identified personally.

A description of this clinical trial will be available on <http://www.clinicaltrials.gov>, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

VIII. Contact Person

Contact Dr. Baggett at kbaggett@gsu.edu or 404-413-1571 if you have questions, concerns, or complaints about this study. You can also call if you think you have been harmed by the study. Contact Susan Vogtner in the Georgia State University Office of Research Integrity at 404-403-3513 or svogtner1@gsu.edu if you want to talk to someone who is not part of the study team. You can talk about questions, concerns, offer input, obtain information or suggestions about the study. You can also call Susan Vogtner if you have questions or concerns about your rights in this study.

XI. Copy of Consent Form to Participant

We will give you a copy of this consent for to keep.

If you are at least 18 years old and you want your and your baby to be included in the study, sign below.

Print Participant's Name

Child's Name

Participant's Signature

Date

Principal Investigator or Researcher Obtaining Consent

Date

Mom & Baby Net: Assessment Summary & Risk Identification

Complete this document **before you leave the home** at the end of **every** in-home assessment or at any time during a participant's involvement in the study when risks, or issues needing clinical attention are reported or observed. If risks are identified, contact Dr. Baggett immediately to discuss a plan of action and submit this form for her review and signature within 24 hours of the visit.

ID #: _____

Completed by: _____

Visit1 Date: _____

Visit2 Date: _____

Contact Type: _____

(PRE, POST, Training, Coach Call, Other)

Information for Coach

Assigned Coach: _____

Best times to call: _____

Assessment Notes/Important Information about the family:

Elevated PHQ9 score? Yes No PHQ9 Total Score: _____

Depression resources provided Crisis Help Card provided

Referral to doctor or home visitor

Assessor/Coach Initials: _____

Risk Identification:

ATQ question #6 endorsed I don't think I can go on

PHQ9 question #9 endorsed Thoughts that I would be better off dead, or of hurting myself

Self-Harm

No plan, no intent to harm self, identifies reasons to not harm self

Lacks clear plan, states would not carry it out, identifies reasons to not harm self*

Has clear plan, means to harm self, cannot identify reasons to stop from harming self*

EMS Called* Participant called GA Crisis Line*

Contacted PI*

Child Abuse/Neglect

RPNI Completed* Safety information provided

Mandated Report Made*

Intimate Partner Violence

EMS called* Safety information provided

Referral to doctor or home visitor

Other Harm _____

Other: _____ **None**

**Must record in AE/SAE Log (on Google docs)*

Consult Needed: Yes No Date/time supervisor was consulted: _____
if you identified any risk above, a consult is needed

Is this a possible AE or SAE? Yes No AE/SAE #: _____

Report of clinical issue being addressed (List each issue one at a time and how it was addressed):

Report of consultation (what information was given to supervisor, what action needs to be taken, how did participant respond, what intervention was implemented, etc.):

Supervisor Comments (follow up steps needed, additional information, etc.):

Assessor/Coach Signature

Date

Supervisor Signature

Date

When complete, scan and email to Katy for filing and circulation to project team

Assessment Data Checklist

ID#: _____

PRE

POST

Date: _____

Before you leave the home:

Sprint signal: Successful Unsuccessful/Ineligible N/A

Questionnaire: Part 1 Part 2 Checked for missing data

Observation data

ASRI: Followed up for any endorsed safety questions

Safety Monitoring Forms (only used for participants with potential safety concerns)

iPhone Customization Questionnaire

Changes in Contact Information _____

Best times for calling to schedule/confirm training visit _____

Initial and date when items are complete: Initials: _____ Date: _____

At the office:

Enter Assessment Information into Access Database (S: drive)

Update Matriculation Table (Google docs)

Assessment Summary & Risk Identification completed and signed

- Email to supervisor if there is a safety concern
- Signed by supervisor if there is safety concern

Scan completed ASRI to Katy

On iPad, upload Observational Data to iCloud

Give all paperwork to project coordinator for final sign off

Initial and date when items are complete: Initials: _____ Date: _____

Project Coordinator:

Export PDF Questionnaires from Qualtrics and save in participant folder

Download observational data from iCloud and save in participant folder

Charge iPad fully

Initial and date when items are complete: Initials: _____ Date: _____

ID: _____

iPhone Customization Questionnaire

1. As part of the Mom & Baby Net program, we add emergency contacts to your phone. Please list your doctor's information below:

Well-Child Physician (Pediatrician)

Name:

Phone Number:

Specialty Doctor #1

Doctor Name:

Specialty:

Phone Number:

Specialty Doctor #2

Doctor Name:

Specialty:

Phone Number:

Specialty Doctor #3

Doctor Name:

Specialty:

Phone Number:

We will also add the following numbers to your phone:

- Poison Control: 1-800-222-1222
- MED National Suicide Prevention 1-800-273-8255
- MED Georgia Crisis & Access Line 1-800-715-4225
- MED Healthy Mothers, Healthy Babies healthcare referral 1-800-300-9003
- Babies Can't Wait 404-657-8224
- WIC of Georgia 1-800-228-9173
- United Way of Greater Atlanta 2-1-1

2. Please select up to 10 popular apps below that you would like added to your iPhone:

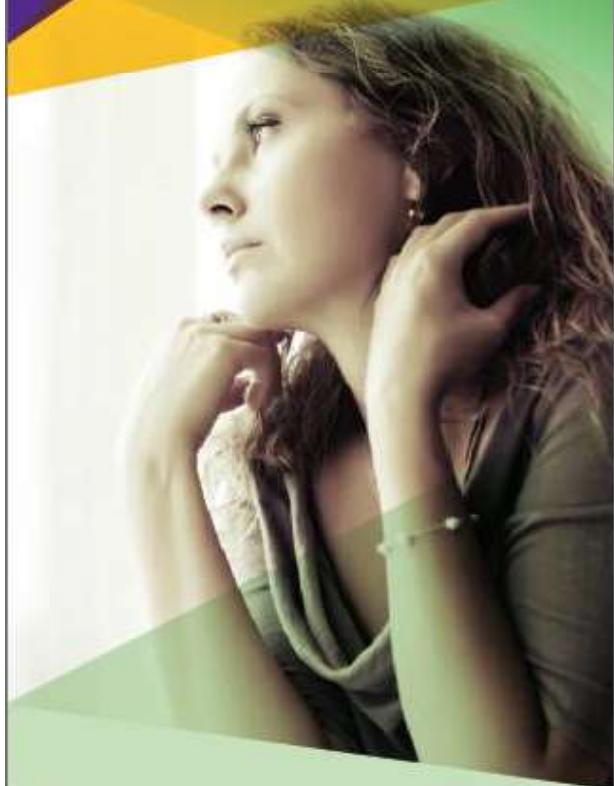
Facebook and Facebook Messenger
 Twitter
 Pinterest
 Instagram
 Snapchat
 What's App
 Map My Walk
 Big Oven (recipes)
 YouTube
 Google Maps
 Uber
 Lyft
 MARTA

Spotify
 Pandora
 Amazon
 Personal Email App: _____
 Other : _____

Postpartum Depression Facts



With postpartum depression, feelings of sadness and anxiety can be extreme and might interfere with a woman's ability to care for herself or her family.





What is postpartum depression?

Postpartum depression is a mood disorder that can affect women after childbirth. Mothers with postpartum depression experience feelings of extreme sadness, anxiety, and exhaustion that may make it difficult for them to complete daily care activities for themselves or for others.

What causes postpartum depression?

Postpartum depression does not have a single cause, but likely results from a combination of physical and emotional factors. Postpartum depression does not occur because of something a mother does or does not do.

After childbirth, the levels of hormones (estrogen and progesterone) in a woman's body quickly drop. This leads to chemical changes in her brain that may trigger mood swings. In addition, many mothers are unable to get the rest they need to fully recover from giving birth. Constant sleep deprivation can lead to physical discomfort and exhaustion, which can contribute to the symptoms of postpartum depression.

What are the symptoms of postpartum depression?

Some of the more common symptoms a woman may experience include:

- Feeling sad, hopeless, empty, or overwhelmed
- Crying more often than usual or for no apparent reason
- Worrying or feeling overly anxious
- Feeling moody, irritable, or restless
- Oversleeping, or being unable to sleep even when her baby is asleep
- Having trouble concentrating, remembering details, and making decisions
- Experiencing anger or rage
- Losing interest in activities that are usually enjoyable
- Suffering from physical aches and pains, including frequent headaches, stomach problems, and muscle pain
- Eating too little or too much
- Withdrawing from or avoiding friends and family
- Having trouble bonding or forming an emotional attachment with her baby
- Persistently doubting her ability to care for her baby
- Thinking about harming herself or her baby.

How can a woman tell if she has postpartum depression?

Only a health care provider can diagnose a woman with postpartum depression. Because symptoms of this condition are broad and may vary between women, a health care provider can help a woman figure out whether the symptoms she is feeling are due to postpartum depression or something else. A woman who experiences any of these symptoms should see a health care provider right away.

How is postpartum depression different from the “baby blues”?

The “baby blues” is a term used to describe the feelings of worry, unhappiness, and fatigue that many women experience after having a baby. Babies require a lot of care, so it’s normal for mothers to be worried about, or tired from, providing that care. Baby blues, which affects up to 80 percent of mothers, includes feelings that are somewhat mild, last a week or two, and go away on their own.

With postpartum depression, feelings of sadness and anxiety can be extreme and might interfere with a woman’s ability to care for herself or her family. Because of the severity of the symptoms, postpartum depression usually requires treatment. The condition, which occurs in nearly 15 percent of births, may begin shortly before or any time after childbirth, but commonly begins between a week and a month after delivery.

Are some women more likely to experience postpartum depression?

Some women are at greater risk for developing postpartum depression because they have one or more risk factors, such as:

- Symptoms of depression during or after a previous pregnancy
- Previous experience with depression or bipolar disorder at another time in her life
- A family member who has been diagnosed with depression or other mental illness
- A stressful life event during pregnancy or shortly after giving birth, such as job loss, death of a loved one, domestic violence, or personal illness
- Medical complications during childbirth, including premature delivery or having a baby with medical problems
- Mixed feelings about the pregnancy, whether it was planned or unplanned

- A lack of strong emotional support from her spouse, partner, family, or friends
- Alcohol or other drug abuse problems.

Postpartum depression can affect any woman regardless of age, race, ethnicity, or economic status.

How is postpartum depression treated?

There are effective treatments for postpartum depression. A woman's health care provider can help her choose the best treatment, which may include:

- **Counseling/Talk Therapy:** This treatment involves talking one-on-one with a mental health professional (a counselor, therapist, psychologist, psychiatrist, or social worker). Two types of counseling shown to be particularly effective in treating postpartum depression are:
 - Cognitive behavioral therapy (CBT), which helps people recognize and change their negative thoughts and behaviors; and
 - Interpersonal therapy (IPT), which helps people understand and work through problematic personal relationships.
- **Medication:** Antidepressant medications act on the brain chemicals that are involved in mood regulation. Many antidepressants take a few weeks to be most effective. While these medications are generally considered safe to use during breastfeeding, a woman should talk to her health care provider about the risks and benefits to both herself and her baby.

These treatment methods can be used alone or together.



What can happen if postpartum depression is left untreated?

Without treatment, postpartum depression can last for months or years. In addition to affecting the mother's health, it can interfere with her ability to connect with and care for her baby and may cause the baby to have problems with sleeping, eating, and behavior as he or she grows.

How can family and friends help?

Family members and friends may be the first to recognize symptoms of postpartum depression in a new mother. They can encourage her to talk with a health care provider, offer emotional support, and assist with daily tasks such as caring for the baby or the home.

If you or someone you know is in crisis or thinking of suicide, get help quickly.

- Call your doctor.
- Call 911 for emergency services or go to the nearest emergency room.
- Call the toll-free 24-hour hotline of the National Suicide Prevention Lifeline at 1-800-273-TALK (1-800-273-8255); TTY: 1-800-799-4TTY (4889).

The photos in this publication are of models and are used for illustrative purposes only.

Where can I find more information?

To learn more about postpartum depression, visit:

MedlinePlus (National Library of Medicine):

<http://medlineplus.gov>

(En Español: <http://medlineplus.gov/spanish>)

U.S. Department of Health and Human Services

Office of Women's Health: <http://www.womenshealth.gov>

For information on clinical trials, visit:

ClinicalTrials.gov: <http://www.clinicaltrials.gov>

For more information on conditions that affect mental

health, resources, and research, go to **MentalHealth.gov**

at <http://www.mentalhealth.gov>, the **NIMH website** at

<http://www.nimh.nih.gov>, or contact us at:

National Institute of Mental Health

Office of Science Policy, Planning, and Communications

Science Writing, Press, and Dissemination Branch

6001 Executive Boulevard

Room 6200, MSC 9663

Bethesda, MD 20892-9663

Phone: 301-443-4513 or

1-866-615-NIMH (6464) toll-free

TTY: 301-443-8431 or

1-866-415-8051 toll-free

Fax: 301-443-4279

Email: nimhinfo@nih.gov

Website: <http://www.nimh.nih.gov>



National Institute
of Mental Health

U.S. DEPARTMENT OF HEALTH

AND HUMAN SERVICES

National Institutes of Health

NIH Publication No. 13-8000



Stories of depression



Does this sound like you?

DEPARTMENT OF HEALTH AND HUMAN SERVICES • PUBLIC HEALTH SERVICE • NATIONAL INSTITUTES OF HEALTH

NIMH
National Institute
of Mental Health

Are you feeling really sad,
tired, and worried
most of the time?

Are these feelings lasting
more than a few days? If yes,
you may have **depression**.



Brenda's story:

"It was really hard to get out of bed in the morning. I just wanted to hide under the covers and not talk to anyone. I didn't feel much like eating and I lost a lot of weight. Nothing seemed fun anymore. I was tired all the time, yet I wasn't sleeping well at night. But I knew that I had to keep going because I've got kids and a job. It just felt so impossible, like nothing was going to change or get better.

"I started missing days from work, and a friend noticed that something wasn't right. She talked to me about the time that she had been really depressed and had gotten help from her doctor.

“I called my doctor and talked about how I was feeling. She had me come in for a checkup and gave me the name of a psychiatrist, who is an expert in treating depression.

“Now, I’m seeing the psychiatrist once a month and taking medicine for depression. I’m also seeing someone else for “talk” therapy, which helps me learn ways to deal with this illness in my everyday life.

“Everything didn’t get better overnight, but I find myself more able to enjoy life and my children.”



Rob's story:

“Things in my life were going all right. I had just gotten my GED and was starting a new job in a week. My family was really proud of me. But inside, I was feeling terrible.

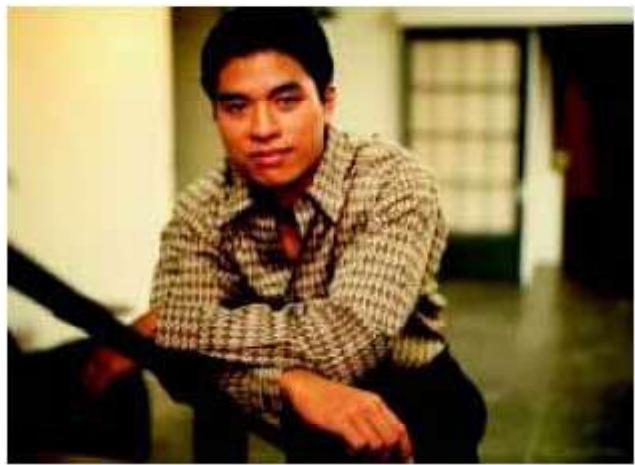
“At first I was feeling sad all the time, even though I had no reason to be. Then the sadness turned into anger, and I started having fights with my family and friends. I felt really bad about myself, like I wasn’t good enough for anyone. It got so bad that I wished I would go to bed and never wake up.

“My older brother, who I always looked up to, saw that I wasn’t acting like my usual self. He told me straight out that I seemed depressed and that I should talk to a doctor about it. I hate going to the doctor. I thought, “No way am I going in for this.”

“But after a few weeks, I started having problems at work too. Sometimes I wouldn't show up because I wasn't able to sleep the night before. When I got fired, I knew I had to listen to my brother and get help.

“I saw a doctor at the health clinic. He told me I had a common illness called depression and that treatment could help. So I started to see someone at the clinic each week for “talk” therapy. This treatment helps me learn to control depression in my everyday life. It has taken some time, but I'm finally feeling like myself again.”

Many people who have depression know something is wrong but don't know what to do about it. This booklet can help. It tells you about four steps you can take to understand and get help for depression.



Four steps to understand and get help for depression:

- 1 Look for signs of depression.
- 2 Understand that depression is a real illness.
- 3 See your doctor. Get a checkup and talk about how you are feeling.
- 4 Get treatment for your depression. You can feel better.

Step 1

Look for signs of depression.

Read the following list.

Put a check mark by each sign that sounds like you:

- I am really sad most of the time.
- I don't enjoy doing the things I've always enjoyed doing.
- I don't sleep well at night and am very restless.
- I am always tired. I find it hard to get out of bed.
- I don't feel like eating much.

- I feel like eating all the time.
- I have lots of aches and pains that don't go away.
- I have little to no sexual energy.
- I find it hard to focus and am very forgetful.
- I am mad at everybody and everything.
- I feel upset and fearful, but can't figure out why.
- I don't feel like talking to people.
- I feel like there isn't much point to living, nothing good is going to happen to me.
- I don't like myself very much. I feel bad most of the time.
- I think about death a lot. I even think about how I might kill myself.

If you checked several boxes, call your doctor. Take the list to show the doctor. You may need to get a checkup and find out if you have depression.

Suicide

Sometimes depression can cause people to feel like killing themselves. **If you are thinking about killing yourself or know someone who is talking about it, get help:**

- Call 911.
- Go to the emergency room of the nearest hospital.
- Call and talk to your doctor now.
- Ask a friend or family member to take you to the hospital or call your doctor.



Step 2

Understand that depression is a real illness.

Depression is a serious medical illness that involves the brain. Depression is not something that you have “made up in your head.” It’s more than just feeling “down in the dumps” or “blue” for a few days. It’s feeling “down” and “low” and “hopeless” for weeks at a time.

About 19 million Americans have depression. It can happen to anyone, no matter what age you are or where you come from.

Depression can make it very hard for you to care for yourself, your family, or even hold down a job. **But, there is hope.** Depression can be treated and you can feel better.

What causes depression?

You may want to know why you feel “depressed.” There may be several causes.

- Depression may happen because of changes in your brain.
- Depression runs in some families. This means that someone in your family such as a grandparent, parent, aunt, uncle, cousin, sister or brother may have depression.
- Sometimes painful events or losses such as deaths can lead to depression.
- Sometimes the cause of depression is not clear.

Step 3

See your doctor.

Don't wait. Talk to your doctor about how you are feeling. Get a medical checkup to rule out any other illnesses that might be causing signs of depression. Ask if you need to see someone who can evaluate and treat depression.

If you don't have a doctor, check your local phone book. Go to the government services pages (they may be blue in color) and look for "health clinics" or "community health centers." Call one near you and ask for help.



Step 4

Get treatment for your depression. You can feel better.

There are two common types of treatment for depression: (1) medicine and (2) “talk” therapy. Ask your doctor which type is best for you. Some people need both treatments to feel better.

Medicine

- Medicines for depression are called “antidepressants.” Your regular doctor or a **psychiatrist** (a medical doctor trained in helping people with depression) can prescribe them for you.
- Antidepressants may take a few weeks to work. Be sure to tell the doctor how you are feeling. If you are not feeling better, you may need to try different medicines to find out what works best for you.

- Medicines sometimes cause unwanted “side effects.” You may feel tired, have blurred vision, or feel sick to your stomach. Tell the doctor if you have these or any other side effects.

“Talk” therapy

- “Talk” therapy involves talking to someone such as a **psychologist**, **social worker**, or **counselor**. It helps you learn to change how depression makes you think, feel, and act. Ask your doctor or psychiatrist who you should go to for talk therapy.

You can feel better.



How to help someone who may have depression

If you know someone who seems depressed and may need help, here are some things you can do:

- Tell the person that you are concerned about him or her.
- Share this booklet with the person.
- Talk to the person about seeing a doctor.
- Take the person to see the doctor.
- If the doctor offers the name and phone number of a psychiatrist or someone for "talk" therapy, call the number and help the person make an appointment.
- Take the person to the appointment.
- "Be there" for the person after he or she starts treatment.
- Contact any of the places listed under "For more information" in this booklet.

For more information:

You can call or write any of these organizations for free information about depression. You can also find more information on their web sites. "Free call" phone numbers can be used free by anyone, anywhere in the United States.

National Institute of Mental Health
(NIMH)
Office of Communications and
Public Liaison
Information Resources and Inquiries Branch
6001 Executive Boulevard
Room 8184, MSC 9663
Bethesda, MD 20892-9663
Free call: 1-800-421-4211
Local call: 301-443-4513
Hearing impaired (TTY): 301-443-8431
Web site: <http://www.nimh.nih.gov>
E-mail: nimhinfo@nih.gov

**National Alliance for the Mentally Ill
(NAMI)**

2107 Wilson Boulevard, Suite 300

Arlington, VA 22201-3042

Free call: 1-800-950-6264

Local call: 703-524-7600

Web site: <http://www.nami.org>

**Depression & Bipolar Support
Alliance**

730 N. Franklin Street, Suite 501

Chicago, IL 60601-7204

Free call: 1-800-826-3632

Local call: 312-642-0049

Web site: <http://www.ndmda.org>

National Foundation for Depressive
Illness, Inc. (NAFDI)
P.O. Box 2257
New York, NY 10116
Free call: 1-800-239-1265
Local call: 212-268-4260
Web site: <http://www.depression.org>

National Mental Health Association
(NMHA)
2001 N. Beauregard Street, 12th Floor
Alexandria, VA 22311
Free call: 1-800-969-6642
Local call: 703-684-7722
Free call - hearing impaired (TTY):
1-800-433-5959
Web site: <http://www.nmha.org>

Things to remember:

- 1 Look for signs of depression.
- 2 Understand that depression is a real illness.
- 3 See your doctor. Get a check-up and talk about how you are feeling.
- 4 Get treatment for your depression. You can feel better.

Crisis Help Card

What's Going On?	What Should I Do?
<p>It's a life-threatening emergency:</p> <ul style="list-style-type: none">• Someone needs medical attention• You have hurt yourself• You are in danger of hurting yourself	<p>CALL 911</p>
<p>It could become an emergency day or night:</p> <ul style="list-style-type: none">• You are having thoughts about hurting yourself but will not act on them• You are safe right now but afraid that you might hurt yourself in the future	<p>Contact the National Suicide Prevention Line suicidepreventionlifeline.org or 1-800-273-TALK (8255)</p> <p>Or the Georgia Crisis and Access Line mygcal.org or 1-800-715-4225</p> <p>These are 24-hour, toll-free, suicide-prevention services available to anyone in suicidal crisis</p> 
<p>You need help; it's not an emergency</p> <ul style="list-style-type: none">• You feel sad, frustrated, or discouraged	<p>Talk to your coach on your next call</p> <p>Message your coach to let her know you want to talk with her about this on your next call</p>

III. Coach Manual

Mom & Baby Net Training Visit Procedures

- **BEFORE HOME VISIT**
- **RESCHEDULING**
- **DAY OF HOME VISIT**
 - **BEFORE ARRIVING**
 - **ARRIVE AT HOME**
 - **CONDUCT TRAINING**
 - **BEFORE LEAVING THE HOME**
- **AFTER HOME VISIT**

BEFORE HOME VISIT

1. Check Outlook calendar to confirm participant ID#, date, and time of assessment.
2. Look up participant in Access database to confirm names, address, field partner, and check for any notes specific to the assessment.
3. Contact the participant
 - a. Confirm the time and place; see RESCHEDULING below if needed.
 - b. Prepare mom for what to expect during the visit
 - 1-1.5 hour visit duration
 - Prepare mom for session. She will receive the iPhone and we will get familiar with the iPhone, program app, and begin the first session together.
 - Visit will go most quickly and smoothly if there is someone in the home who can care for baby and other children; we understand that this is not always possible and we will work with you if this can't happen, but it does make the process go faster during the visit
 - c. Ask if there are any questions
 - d. Let her know we are looking forward to meeting her and her baby
4. Print out map-quest map/directions or use navigator.
5. If applicable, contact field partner and confirm where/when you will be meeting for the assessment
6. Prepare for visit:
 - a. Create Mom & Baby Net user account on admin site and set up iPhone (see [Setting Up New Participant](#) document).
 - b. Schedule a Zoom call for the duration of your training visit and text the meeting ID number to mom's new iPhone.
 - c. Gather materials for visit:
 - i. iPhone, charger, headphones (leave box at the office)
 - ii. iPhone stand
 - iii. 2 copies of iPhone agreement
 - iv. Mom & Baby Net Handbook

RESCHEDULING: Tasks to complete for No-Shows, Cancelled or Rescheduled appointments

1. In Access, change appointment status to NO SHOW, CANCELLED or RESCHEDULED, and contact the participant to reschedule the appointment. Create a new line for any new appointment you book.

Appointment Details							Check the Completed Assessments			
Mom ID	Type	Date	Time	Assessor	Status	Q1	Q2	Interactions	IPhoneTrain	Notes
101	Pre	4/8/2015	9:00 AM	Sandra	<input type="button" value="Scheduled"/> <input type="button" value="Completed"/> <input type="button" value="Cancelled"/> <input type="button" value="Rescheduled"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
*	101				<input type="button" value="Scheduled"/> <input type="button" value="Completed"/> <input type="button" value="Cancelled"/> <input type="button" value="Rescheduled"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

2. Re-file participant materials in Assessor's designated file/storage area until the new appointment.

DAY OF HOME VISIT

BEFORE ARRIVING

1. Call or text (if approved by mom) 30 minutes – 1 hour ahead of time to let mom know your ETA.
2. Prepare yourself mentally: have a cool, calm, and matter-of-fact affect.
3. Arrive at the participant’s home at the scheduled time (call mom if an earlier assessment is running late and you will not be arriving on time).

ARRIVE AT HOME

1. **Greeting the participant: Politely introduce yourself and establish small talk to “break the ice”**
 - Avoid controversial or uncomfortable topics (politics, religion, moral issues, etc.)
 - The goal is to **begin building rapport**. Try to get mom talking about herself or her interests (How many kids in the home, how long have you lived in the area, etc.)
2. **Review order of events** with the mother so she knows what to expect during the home visit:
 - *Today you will be getting your iPhone and starting the Mom & Baby Net program.*
 - *We will go over an iPhone agreement and make sure you don't have any questions about using it for the program.*
 - *I will give you a handbook that will help you complete the program.*
 - *Lastly, we will get familiar with the Mom & Baby Net app and start Session 1 together.*
 - *Do you have any questions?*

CONDUCT TRAINING

1. Read iPhone agreement with mom and have her sign it. Leave her with her own copy.
2. Show mom the Mom & Baby Net Handbook. She will need to keep and use the book throughout the program;
 - a. Tell mom that everything that you cover in this meeting is also referenced in the book in greater detail.
 - b. The book has crucial information for using the program. Show her the major sections.
 - c. Store it in a place that is handy but kept away from opportunities for damage (children, animal, food spill, etc.). Talk with her about where this will be so that you can help problem solve if needed to ensure appropriate storage and easy access.
 - d. We want her to have it out for sessions and when she is in the call with you in case you need to look at it together- having it out and ready will reduce call time if it is needed.
 - e. Remind her to have it close by at the start of going through Session 1 and explain that her activity for the week will involve getting familiar with the book and the app.
3. Ask mom if she's ever used an iPhone before. If not, give her a brief tutorial (turning off and on; answering phone; sending texts; Safari browsing; opening and closing apps; taking pictures of screen). ***Reference handbook section that covers this.***
4. Show mom all of the apps and how to use them. ***Reference handbook section that covers this.***
5. Show mom all of the contacts that you added to her phone and explain the method for entering them (e.g., DR Smith Pediatrician; MED Poison Control). ***Reference handbook section that covers this.***
6. Show mom how to add numbers to Favorites (coach has already been added to favorites).
7. Have mom login to Mom & Baby Net using her login and password.
 - a. Explain how the program works (accessing one session each week and then having a coach call afterwards).
 - b. Show mom the menu (sessions, videos, ratings, resources, messages, and action plan) and explain how they work/how they will be used in the program. ***Reference handbook section that covers this.***
 - c. Have mom create a short 30-second practice video. Talk about tips for creating a good video (lighting, sound).
 - d. Talk about uploading the video and not using the phone during the upload.
 - e. Have mom play back video once it's been uploaded.
 - f. Finally, show her how to access Session 1 and remind her that Session 1 will cover most of this again to really help her get familiar with how to use the program.
8. Now that mom has a better idea of how the program works, show her Zoom and explain how it will be used for each call. Practice doing a Zoom call between your coach phone and mom's phone.
 - a. Sign into the scheduled Zoom meeting on your coach phone.

b. Then, have mom open Zoom, look at the text you sent her, and join the meeting.

BEFORE LEAVING THE HOME

1. Schedule your Session 1 Zoom call with mom and show her how to use the calendar not only for reminding her of weekly Zoom calls, but for doctor's appointments or anything else she needs to schedule.
 - a. Have her enter your scheduled Zoom call and use a reminder.
 - b. It is suggested that when you add coach appointments to your calendar that you include a 'day before' reminder as well as a 15-minute reminder and send an Invite. It would be great if moms have a regular time that can be set up to 'Repeat Weekly', but if not, you could send week to week.
2. Update alternate contact info (at least 3); Confirm best means of contact for mom

AFTER HOME VISIT

1. Update Access Database:

- a. If applicable, update "Best times to call" under Notes in the "Tracking Information Form"

If this is a new Mom, you can click in the Date Received box and start entering data. If this is an existing Mom, use the drop down box to the right to look up Mom's

Mom ID (New) Date Received Referral Source

Is Mom eligible to participate in the study? Please choose a reason why Mom was ineligible.

Study Status If Not Active, Reason Please specify other:

Mom First Name Mom Last Name Marital Status Cell Phone

Street Address Other Address Home Phone

City State Postal Code Primary Language Other Phone

Mom Birthdate Email

Baby's Name Expected Due Date Baby's Birthdate Baby-Net for NICU App Tracking Information

Corrected Gestational Age at Birth Weeks Corrected Gestational Age at NICU Exit Days Month Days

Notes Baby-Net UserName Baby-Net Password

- b. Change the "Status" under Scheduled Appointment from "SCHEDULED" to "COMPLETE."

Scheduled Appointments						Check the Completed Assessments				
Mom ID	Type	Date	Appointment Details	Assessor	Status	Q1	Q2	Interactions	iPhoneTrain	Notes
101	Pre	4/8/2015	9:00 AM	Sandra	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
*					<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

c. **Check the ‘iPhone Train’ box**

d. Use “Notes” for things like missing data, etc., NOT crisis concerns.

Initial Visit					
Mom ID	Initial Visit Date	Assessor	Eligibility Status	Reason	Notes
101					

Scheduled Appointments						Check the Completed Assessments				
Mom ID	Type	Date	Appointment Details	Assessor	Status	Q1	Q2	Interactions	iPhoneTrain	Notes
101					<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
*					<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

2. **IF NECESSARY, complete safety monitoring forms:** Assessment Summary & Risk Identification (ASRI) and any remaining work on forms that are pertinent to the issue at hand.

a. If any concern may qualify as an Adverse Event (AE) or a Serious Adverse Event (SAE): **contact Kathleen immediately.** The PI needs to be notified immediately. In the event of an SAE, a letter needs to be sent out within 24 hours of the reported situation. If Kathleen is not in the office, send her a text to (816) 616-6568.

- You will need to provide the supervisor with a copy of all related Safety forms
- If any safety concerns are noted, you will need the supervisor’s signature on the ASRI and any and all safety forms prior to scanning**
 - If the supervisor is not in the office you will need to obtain an electronic signature by emailing the needed documents to the supervisor in Word format.

b. Scan the ASRI in **one PDF file** after needed signatures are obtained.

- ASRIs without potential safety concerns can be scanned without supervisor signature.
- The scan, with no identifying information, should be emailed to yourself.
- Save scanned ASRI and all other documentation in the participant’s ID folder in this location:
S:\ECSEHP\Projects\Baby-Net Depression NIH R01 2016-2021\Participant Data

Use this naming convention:

[ID] PRE/POST [document] mm-dd-yy

Example: 101 TRAIN ASRI 11-1-17

Mom & Baby Net
Participant iPhone Agreement

Georgia State University is working on a project that focuses on the use of an app-based parenting intervention to strengthen social-emotional development of infants. The study hopes to improve knowledge and practices for helping mothers in the future to best support their baby's development.

As a participant in the project, you agree with the following:

1. The iPhone, case, and power adapter is loaned to you by GSU for a limited period of time associated with the project, typically 8 months. Upon completion of the program and assessments, you will get to keep the iPhone.
2. There is no cost to your family for the loan of the iPhone or the free data, texting, and phone calls to use while you are participating in the study. After the study ends, you will be responsible for these costs.
3. As a condition of loaning the iPhone to you are required to engage in the study-related uses of the iPhone. This includes the following: (1) completing an app-based parenting program; (2) creating and sending session videos of you and your baby interacting; (3) participating in weekly calls with your coach to discuss what you are learning in the program.
4. Health-related apps, communicating with friends, family or health professionals, browsing the internet, and adding additional apps for other purposes are allowed on the phone. However, any apps that you add are at your expense.
5. The researchers follow standard privacy and security measures related to the iPhone using code numbers and no names. They also maintain the privacy and security of our health related communication and meetings; using electronic encryption of the visual meetings/data, all stored behind a secure computer firewall.
6. You agree to take steps in maintaining the iPhone including:
 - a. Ensuring the safety and security of the iPhone; this includes protecting the iPhone from harm and from theft;
 - b. Reporting issues with the iPhone immediately, for example loss, theft, or other disposal;
 - c. Reporting any repair issues with the iPhone immediately; and
 - d. Immediately returning the iPhone if you are no longer participating in the study or if requested to return it.
7. You agree to refrain from illegal use of the iPhone (i.e. computer hacking, communication harassment, accessing or creating illegal content, use while driving etc.). Any illegal use will result in immediate removal from the project. Such activity could result in possible legal action by authorities within the appropriate jurisdiction. The researchers are not responsible for your use or your family's use of the iPhone.
8. Any misuse, damage or loss of the iPhone may interfere with your ability to participate in this study; therefore, location tracking software is placed on the device to locate a lost or stolen phone.
9. If the phone is lost or stolen, the research team will take steps to protect your privacy and retrieve the phone. The phone will be locked, wiped clean, and a police report will be filed.

10. For initial instances of phones being stolen or damaged due to usual wear and tear, the phone may be replaced for continuance in the study. Subsequent losses or thefts are reviewed on a case by case basis to determine if the damage or theft was preventable and would likely reoccur in the future if the phone were replaced.

I have read and agree to the above statements and have received an Apple iPhone, Serial #_____
Electronic tracking of this iPhone identifies its location for use in retrieving lost or stolen phones.

Participant Name

Participant Signature

Date

Note: There may be pop-up advertisements that will appear on the iPhone. These are not controlled by GSU but rather by the vendor who connects the iPhone to the internet. These are routine with all phone and tablet connections to the internet and can be ignored. Beware of purchasing or providing any personal information online.

Mom & Baby Net Intervention Coach Call Guide

1. Establish rapport and welcome mom to the session. Remind mom that the call is being recorded for fidelity purposes and encourage mom to find a quiet place with no other people in the room to complete the call.

2. Discuss mom's session progress

- "How did it go for you completing the session this week?"
 - Praise mom's specific accomplishments; If there were barriers in the process- difficulty concentrating, praise mom's initiative in making it through with difficulties and brainstorm with mom about strategies she thinks she can use to get through the next session (best time of day, ways to remind her self, what works best for mom- finishing the session in one setting, breaking it up into 5 minutes a day? Celebrate small steps)
- What did you think about the session material?
- What did you learn about in the program this week?
- What questions do you have?
- Was there anything that surprised you in the session or that you found confusing- anything you would like me to explain?

3. Review and discuss video of mom-child interaction

"Let's spend a few minutes watching the video that you created with your baby"

- Ask mom what she noticed about her baby's signals – have her point them out.

-Celebrate mom's observations of baby's signals; If she struggles, stop video and point out baby's signals
- Ask mom what session skills she saw in the video with her baby?

-Celebrate mom's observations of successes; If she struggles, ask about ideas she has for trying out the PALS skills in response to baby signals.

4. Discuss mom's action plan

-Celebrate any accomplishments
-Discuss barriers and brainstorm together about ways mom can act on her plan in the next week

5. Conclude the session and plan for next call

- Highlight mom's accomplishments
- Talk with her about when she will complete the next session
- Encourage her to send a secure coach note if she has questions during the week
- Let her know you'll send her a secure coach note to remind her of her plan
- Confirm time for your next call

Mom & Baby Net DAS Session Call Guide

1. Establish rapport. Remind mom that the call is being recorded for fidelity purposes and encourage mom to find a quiet place with no other people in the room to complete the call.

2. Discuss mom's view of the session/program

- Discuss with mom what she thinks so far
- What questions does she have about the program?

3. Watch 2 pause points of mom-created video

- Ask mom about any new behaviors that she has seen in her behavior this week
- What is she celebrating - what milestones has she been watching for?

4. Create plan for next session

- Review mom's concise plan for the completing next session
- Review the time for your next call

5. Conclude Session with Reminder

- Help mom add the appointments to her calendar and set reminder for completing next session and having next call
- Set reminder in your calendar to send mom encouraging text the day before to complete next session & remind about next call

[date]

Dear [participant name],

I missed you at the time of our last scheduled appointment on [date]. I sent you coach notes on [dates] and have reached out to you on your project phone number as well as your preferred other contact numbers, but have not been able to reach you [as it seems that (if applicable, specify the issue- disconnected phone, full VM, etc)]. I hope that you receive this note with a reminder of my contact numbers and that all is well. I want you to know that I am here to support you however you would like to proceed, either in continuing in the intervention or discontinuing. Either way, please contact me (see contact information below) to let me know your preference for continuing in the intervention or whether you are ready to stop intervention and complete the post-assessment. If I don't hear back from you by [date], I will understand that you may not be interested in continuing the intervention at this time. I look forward to hearing from you.

[coach's name]

Mom & Baby Net Project
Georgia State University
Mark Chaffin Center for Healthy Development

(office) [coach's office number]

(cell) [coach's cell number]

(email) [coach's email address]

IV. Safety Monitoring Documents

Risk of Self Harm – Decision Tree

RESPONDING TO DEPRESSION AND POSSIBLE SUICIDE RISK

If person reports thoughts of death/suicide (ATQ #6 or PHQ9 #9 or spontaneously)

Check for a plan and protective factors:

"I noticed that you agreed with the statement..." "I'd like to talk with you a little more about that. Have you actually had any thoughts of harming yourself?"

If "Yes" ask:

- What kinds of thoughts have you been having?
- Have you thought about how you might do that? How?
- Do you have access to that (method mentioned -e.g., gun, pills, etc.)
- Have you thought about where you might do that/Where?
- Any things keeping you from carrying out plan? What? Anything Else?

If there is a **clear plan and no protections** (E above), proceed to **Box #1**.

If there is a **plan but person identifies protections from acting** (E above), proceed to **Box #2**.

If the person **has no plan, says they would not act** on the plan, and can **tell you why** they wouldn't act on the plan (e.g., I would never do that to my baby. I couldn't stand the thought of her not having a mom), let mom know "**I am glad to hear that!**" then proceed to **Box #3**.

1. Highest Risk:

Person states that:

- They are thinking about suicide
- They have a clear plan (how, when, where)
- Means are available (guns, pills, nobody home, etc.)
- They cannot identify things stopping them from carrying out their plan

2. Medium Risk:

Person acknowledges thoughts about suicide but

- Lacks a CLEAR plan
- States that they would not carry it out and identifies reasons why they wouldn't

3. Lowest Risk:

Person is showing signs of depression but denies any thoughts about self-harm/suicide OR

- Has had thoughts but **NO plan** and says they would **not do it** and identifies reasons why they wouldn't

- Do Not leave person alone unless your safety is threatened
--Text and Call your supervisor until you make contact (wait at least 30 minutes before intervening)

- If your safety is threatened, go to nearest safe place, call 911 & state exact concern
--Text and Call your supervisor for immediate support
--Do not leave until told by EMS that they do not need to speak to you at the scene.

3. If you cannot reach a supervisor and must intervene, do the following:

- Stay calm, be empathetic, and state your concern ("I'm concerned about your safety")
- State that the person needs to "see a doctor right away" /can share "Postpartum Depression Facts & Stories" and "Crisis Help Card"
- Give 3 choices and follow through
 - They can call 911 and ask for a ride to nearest hospital for emergency behavioral health services to find a way to feel better/not hurt self
 - You can place the call to 911
 - They can have another adult join the 2 of you and the other party can sign notification form to get help.
 - They can call the Georgia Crisis & Access Line 1-800-715-4225

- Use gentle, reflective & empathetic statements. Be clear that you are "not a therapist, but there are people out there who can help." Share "Postpartum Depression Facts & Stories" and encourage the person to share booklet with and talk to doctor.

- Share "Crisis Help Card" and offer to sit with mom while she contacts the Georgia Crisis & Access Line 1-800-715-4225

- Document on the **Assessment Summary and Risk Identification** exactly what the concerns were, what you did, and the mom's responses. Do not include identifiers. Email to Clinical Supervisor and **notify by text that you have done so.**

- "From the results of our assessment it looks like you might be experiencing Depression. I am not a therapist and I can't diagnose but there are people out there who can help. I wonder if anyone has ever talked with you about Depression." [Pause and give mom a chance to comment if she wishes] Share "Postpartum Depression Facts & Stories" and encourage the person to share booklet with and talk to their doctor or their baby's doctor at the next well child visit.
- Document on the **Assessment Summary and Risk Identification** exactly what the concerns were, what you did, and the mom's responses. Do not include identifiers. Email Supervisor. If you don't receive a signature reply within 24 hours, text and call. File signed copy + all other documentation in mom's folder within 72 hrs.

V. Adverse Event Guidelines

MOM & BABY NET GUIDELINES FOR ADVERSE EVENTS AND SERIOUS ADVERSE EVENTS:

General Notes:

AEs and SAEs are events that occur during the course of the participant's involvement in the project; that is, between signing the consent form and before completion of the final assessment.

Each AE and SAE will be recorded in the Adverse Events log, which will be reviewed weekly during supervision. The log must be updated on a regular basis to ensure accurate recording of events. Coaches and Assessors will fill out a clinical case note form and have them signed off by a supervisor within 48 hours (in some cases, additional forms will be required). The information contained in the Clinical Case Note Form will be entered into the AE log.

A unique tracking number will be assigned to each AE and SAE for reporting purposes. The tracking system will identify if the incident is an AE or an SAE and the next chronologically assigned number. For example, when the first AE is reported, it will be identified by "AE-01." If the next incident reported is an SAE, it will be identified by "SAE-01." The next AE would be identified by "AE-02" and so on.

Possible SAEs need to be reviewed immediately by the PI to determine if the event meets criteria for an SAE. If the event is determined to be an SAE a brief report needs to be written immediately and provided to the PI for review. This report needs to be provided to the NICHD project officer within 24 hours of our discovery of the event.

In cases where there appears to be overlap in criteria, such that an event could be classified as either an AE or an SAE, code and respond to it as an SAE.

Adverse Event Definition:

Adverse event (AE): Any unfavorable medical occurrence or change that may present itself during treatment or administration of an intervention and which may or may not have a causal relationship with the intervention.

Our definition of an AE will incorporate such non-medical occurrences as suicidal ideation, exacerbation of psychopathology, minor symptoms of withdrawal, harm to self or others, disclosure of HIV status, disclosure of a crime committed by juvenile, mandatory report of child abuse, change of home placement or guardianship, homelessness (e.g., runaway), incarceration, and other incidents similar in level of adversity.

The events listed in the above definition are not exhaustive. Other events resulting or having the potential to result in similar injury or distress should be recorded in consultation with the clinical supervisor or PI. Further elaboration of the definition is provided below.

1. **Events reflecting significant change in physical health** include illnesses or injury that either:
 - a. Interfere with usual functioning (e.g., absent from school or work); or
 - b. For which the subject receives medical treatment

These events do not include

- a. Pre-existing conditions unless they worsen during the study period
- b. Life-threatening illnesses (see SAE below)

Examples: Flu; Diagnosis of chronic disease; Broken limb; substance withdrawal; increase in frequency or intensity of asthma attacks

2. Events reflecting significant change in mental health include: onset or exacerbation of suicidal ideation/behavior or non-lethal self-harm; onset of disorder; significant worsening of disorder symptoms

These events do not include

- a. Pre-existing mental health conditions unless they worsen during the study period
- b. Behavior change that does not directly reflect on change in mental health
- c. Life-threatening suicide attempts or self-harm (see SAE below)

3. Events occurring within the family that could reflect or result in physical or psychological harm include: incidents of domestic violence that don't result in severe injury; child abuse reports to or investigations by DHS Child Welfare; testifying about prior abuse; parental separation or divorce; change in home placement or guardianship; youth running away; harm by family member to self or other.
4. Other Events that may cause psychological or minor physical distress include: criminal investigation, arrest, or short-term incarceration; automobile or other accident that does not result in serious harm; assault that doesn't require medical attention; economic stressors such as loss of job or eviction.

Serious Adverse Events:

Serious adverse event (SAE): Any medical occurrence that results in death; is life-threatening; requires in-patient hospitalization; creates persistent or significant disability/incapacity, or congenital anomaly/birth defects. These events do not include pre-existing conditions unless they worsen significantly during the study period.

Other events resulting or having the potential to result in similar injury or distress should be recorded in consultation with the clinical supervisor or PI. Further elaboration of the definition is provided below.

1. Medical event/injury that results in death or is life threatening would include those which: require or extend in-patient hospitalization; create persistent or significant disability/incapacity; or result in birth defects or congenital anomaly.
2. Serious events reflecting mental health/substance use problems would include: suicide attempts; drug overdose necessitating medical treatment; serious symptoms of withdrawal; admission to residential treatment center.
3. Violence within or outside the family that has the potential for serious bodily harm would include: incidents of domestic or nonfamilial violence that include actual or perceived threat of loss of life (e.g., use of weapons, choking, rape) whether or not the incident requires hospitalization.
4. Events that result in significant family disruption due to external intervention would include: DHS child welfare placement of child outside the home due to risk of or substantiated abuse, neglect, or endangerment; extended incarceration.

VI. COVID Remote Procedures

MOM & BABY NET RCT REMOTE RECRUITMENT CALL

After recording participant's responses to questions on the recruitment form, transfer the information to the Access Database & Matriculation Table

1. **Before the Call**
2. **Project Overview**
3. **Determine Eligibility**
4. **If Participant is Ineligible**
5. **Participant is Eligible - Schedule**
6. **Participant is Eligible - Waitlist**
7. **After the Call**

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1. **BEFORE THE CALL**

- Have mom's interest card available.
- Have recruitment form ready to record mom's responses.
- Have RCT consent form ready to go over.

2. **PROJECT OVERVIEW**

Introduction: *Hello.....my name is _____ and I am calling from Georgia State University about a new research project called Mom & Baby Net.*

You recently said you'd like to hear more about the program to see if you could be included.

Thank you for your interest! I would like to tell you a little more about the project and see if you would be interested in participating and ask you a few questions to see if you are eligible. It will take about 15 – 20 minutes. You can stop the call at any time or tell me if you do not want to answer any questions. Is now a good time?

- If they can't talk now, set up a date and time for you to call again

About the project: *I have a couple of points I'd like to quickly share with you about the Mom & Baby Net project....if you have any questions, feel free to stop me at any time*

- *The purpose of this research project is to test two iPhone-based program for moms who have been feeling down and their babies. We hope to use this information to improve our program in order to help more moms.*
- *Participants in our study will be given an iPhone to access the program during the course of the study. There is no cost to your family for the loan of the iPhone for free data, texting, and phone calls to use while you are participating in the study. Upon completion of the program and assessment visits, participants will be able to keep the iPhone.*
- *Participating in this project will not affect any other services you currently receive.*
- *We have two different programs that provide information to mothers.*

- Both of the programs include 14 sessions with one session to be covered each week. Most moms spend between 40-60 minutes each week using the iPhone to work on the program and you can start and stop as needed. It will save your place. Each mom will be assigned an individual coach who will provide support through a video call each week. The call will involve watching a video that was created during the session. Each call will last about 20-30 minutes.
- Participants will be asked to complete 4 remote assessment calls: 2 assessment calls at the beginning of the project and 2 assessment calls at the end. Each assessment call will last about 1 hour. On those calls, we will make a video of you and your baby playing together and looking at books. We will also complete some online questionnaires that asks questions about you and your baby.
- Once you complete the assessment calls, we will schedule one more call to show you how to use our app on the iPhone. This call will last about 1 hour. Then you will begin completing sessions on your own with the support of your coach.
- There may be some benefits to mothers who participate in the program.
 - You may find that answering questions about parenting your baby is helpful and interesting.
 - You will have the iPhone with free data, texting, and calls to use during the study.
 - You will be able to keep the iPhone upon completion of the study. Although we will not continue to pay for phone service, you can use the phone through wireless Internet if you have access to it.
 - You will have the videos on the iPhone that you created during on the program.
 - You will be helping researchers to learn whether the program you receive is helpful for mothers of infants.
- There are few risks to being in the program.
 - You may feel uncomfortable answering some of the questions asked today or during the project. You can stop this call at any time and skip any questions during the project that you do not want to answer.
 - All information we collect is stored in a secure, locked office or database that is only accessible by approved research staff. We will use a study number rather than your name on all study records. There is only one code sheet use to identify research participants and it is stored securely in a password-protected file on a locked computer in a locked office.
- If you have any concerns or complaints, you can find IRB contact information at gsu.edu/irb

Does this sound like something you might be interested in hearing more about?

- If no: select DECLINE for final status and Eligibility Status; in the reason box next to Eligibility Status, select TOO BUSY/TIME or NOT INTERESTED
 - Do you have any other questions I could answer for you?
 - Thank you for your time. If you change your mind, feel free to contact me in the future to see if we are still recruiting.
- If yes, continue

3. DETERMINE ELIGIBILITY

Now we need to make sure that you are eligible for the project. There are some requirements for participating. Before spending any more time explaining the program, I would like to ask you a few questions to find out if you can indeed participate in this study. Are you comfortable with that? Your answers will be kept strictly confidential.

Age:

- *Are you 18 years of age or older?*
 - If Yes, continue and record mom's birth date on the recruitment form.
 - If No, **ineligible**. Go to page 5.

Residency

- *Do you live in the metro Atlanta area and plan to stay here during the next year?*
 - If Yes, continue
 - If No, **ineligible**. Go to page 5.

Baby

- *How old is your baby?*
 - Ask mom baby's age and date of birth. Record on recruitment form.
 - If baby is younger than 12 months, continue.
 - If baby is older than 12 months, **ineligible**. Go to page 5.

Stressful Situations

Sometimes families are experiencing stressful situations in their lives that can make it hard for them to be a part of a study such as this, either because the situation makes it burdensome for the family to participate in the study and/or because the family may need help that cannot be provided within the study. I am going to read you a list of some situations that families experience that make it a good idea for them to NOT participate in this study for the reasons that I just mentioned. You don't have to tell me which of these situations apply to you if any do. When I finish reading the list, I'll ask if any of these situations describe you.

- 1) *You have been diagnosed with schizophrenia.*
- 2) *You have received treatment or medication to help with hallucinations or delusions such as seeing or hearing things other people can't see or hear or having ideas that others might think are odd or strange, like people are out to get you or trying to hurt you.*
- 3) *You are currently receiving inpatient substance abuse treatment.*
- 4) *You live in a homeless shelter or domestic violence shelter.*
- 5) *Your infant is currently in intensive treatment for a genetic or health condition.*
- 6) *You do not have permanent legal guardian custody of your infant.*

Again, you don't have to tell me which of those might apply to you. However, please think about the situations I just mentioned, and answer "yes" or "no." Do any of these situations apply to you?

- If YES, **ineligible**. Go to page 5.

- If NO, continue.

Depression Screening (only do if not already completed by referring provider; mark responses on PHQ2 form)

Lastly, since our program is for moms who have been bothered by feeling down, we want to see how you've been feeling over the past 2 weeks. I'm going to read 2 statements with some answer choices for each one.

Over the past 2 weeks, how often have you had little interest or pleasure in doing things? Not at all, several days, more than half the days, or nearly every day?

Over the past 2 weeks, how often have you felt down, depressed or hopeless? Not at all, several days, more than half the days, or nearly every day?

- If score is less than 3, **ineligible**. Go to page 5.
- If score is 3 or higher, continue.

- ❖ **If participant is Eligible and there is no waitlist, go to page 6**
- ❖ **If participant is Eligible and there IS a waitlist, go to page 8**

4. IF PARTICIPANT IS INELIGIBLE

Thank the Mom for her time and let her know that she is not eligible (choose the response below that best fits with why the participant is ineligible).

Thank you for taking the time to answer my questions. Unfortunately you are not eligible for the project at this time.

- **Age:** *The project requires that moms be at least 18 years of age*
- **Baby:** *The project requires that babies be younger than 12 months of age at the time we begin the first assessment.*
- **Residency:** *The project requires that moms must live in the metro Atlanta area and remain there for the next year.*
- **Stressful situations:** *We have found that participation in the study is very challenging for those that are dealing with other stressful situations in their life.*
- **Depression screening:** *Based on our brief screening, there are no signs that you are struggling with depression symptoms at this time. But we know these feelings can change. If anything changes we encourage you to follow up with your doctor and or local community program or reach back out to us in a few weeks.*

Update contact and eligibility information in Matriculation Table.

File recruitment form in ‘Not Enrolled’ folder (program coordinator’s office).

5. **PARTICIPANT IS ELIGIBLE – NO ACTIVE WAITLIST**

Based on the information you just gave me, you are eligible to participate in the program at this time.

What questions do you have right now? Answer any questions.

Schedule assessment call: *If you are interested in participating, the first step will be for us to complete the consent call. I will email you a copy of the project's consent form. This document will explain in detail the purpose of the Mom and Baby Net project, what you will be doing in the project, and how we will keep your information safe. We are taking necessary precautions to keep you, your family, and our staff healthy during the Coronavirus pandemic. The Pre-assessment and training calls will be conducted remotely using Zoom – an app that allows us to have a video call. I will later explain how Zoom works if you choose to participate. The iPhone agreement form will also be emailed to you. This document covers expectations of loaning you the iPhone to complete the Mom and Baby Net project. Your phone service will be covered while you are participating in the program. We will monitor your progress on a month to month basis. If you are making progress and staying in communication with your coach, we will renew your service for the next month. If we lose contact with you, or you are not making progress in the program, your phone service may be discontinued; If we cannot reach you and your phone is not returned, it will be reported as lost or stolen. I will also mail a copy of both of these forms to your home. Have you still been receiving mail and packages as usual during this time?*

I'd like to go ahead and set up a time for the first assessment call. It will take about 20 minutes.

- When scheduling the 1st call, it might be best to schedule this visit at a time of day when your baby is usually napping or can be watched by another adult in the home so you can focus on the information we will go over.*
- Let's schedule for 4-5 days from now to give time for the forms to arrive in the mail. When is good for you? Is there a day or time that works best for you? Do you prefer mornings or afternoon?*
 - Record the scheduled appointment time in the Access Database along with any notes*
 - Record appointment in the Mom & Baby Net Outlook calendar or other scheduling software*

Confirm all the contact and demographic information and edit if necessary in the database:

- NOTE:** Make sure to confirm if mailing address and physical address are different, confirm spelling of first and last name, and confirm date of birth and name of baby
- Is this the best number to call to follow-up with you?*
- Can we leave a message at this number? If it's a cell # - ask if you can text her appointment reminders.*
- If for some reason I can't get a hold of you, it would be helpful to have some contact names and numbers of people who would be able to reach you. Do you have one or two people who typically stay in touch with you and know how to locate you even if you move or change numbers? Can I get their names and phone numbers?*

- Record the contact names/numbers on the recruitment form

Recap:

- *I believe I have all the information I need. I'd like to quickly recap a couple of points*
 - I will email and mail you the consent form and iPhone agreement.
 - On our scheduled call, we will go over the forms and I will answer any questions you have. It will take about 20 minutes.
 - Then we will go over the next steps of sending the iPhone and setting up the next calls.
- *Do you have any questions about the project in general?*
 - If yes, try and answer any questions they have or let them know you will call back with the answer.
 - If no, continue.
- *Give us a call if you have any questions or concerns before your scheduled appointment. We will also give you a reminder call or text the day before your appointment.*
- *We really want to thank you for your interest in our study and being willing to let us come to your home during this busy time in your life. We look forward to meeting with you on _____ at _____ am/pm.*

❖ **CONTINUE TO 'AFTER THE INITIAL RECRUITMENT CALL' STEPS (page 9)**

6. **PARTICIPANT IS ELIGIBLE – WAITLIST**

Based on the information you just gave me, you are eligible to participate in the program at this time.

Explain Waitlist: *We currently have as many moms as we can take in the program right now but we will have openings soon. We estimate that you will be able to enroll in about [give approximate timeframe, i.e. 2 weeks, 1 month, etc.]. Since we already know you are eligible we will simply need to schedule the first **call** as soon as we have an opening. I will call back to schedule as soon as I know there's a spot. If I can't reach you within a week, I will have to move to the next person on the waitlist.*

What questions do you have right now? Answer any questions.

Let me confirm all of your contact information so we can be sure to reach you.

Confirm all the contact and demographic information. Unless they refuse, get at least 2 phone numbers:

- **NOTE:** Make sure to confirm if mailing address and physical address are different, confirm spelling of first and last name, and confirm date of birth and name of baby
- *Is this the best number to call to follow-up with you?*
- *Can we leave a message at this number? If it's a cell # - ask if you can text her appointment reminders.*
- *If for some reason I can't get a hold of you, it would be helpful to have some contact names and numbers of people who would be able to reach you. Do you have one or two people who typically stay in touch with you and know how to locate you even if you move or change numbers? Can I get their names and phone numbers?*
 - Record the contact names/numbers on the recruitment form

Recap:

- *I believe I have all the information I need.*
- *Give us a call if you have any questions or concerns before you hear from me again.*
- *We really want to thank you for your interest in our study and for your patience while we wait for a spot to open up.*

When you call mom back to schedule appointment, use scheduling script in section 5.

❖ CONTINUE TO ‘AFTER THE INITIAL RECRUITMENT CALL’ STEPS (page 9)

7. AFTER THE INITIAL RECRUITMENT CALL

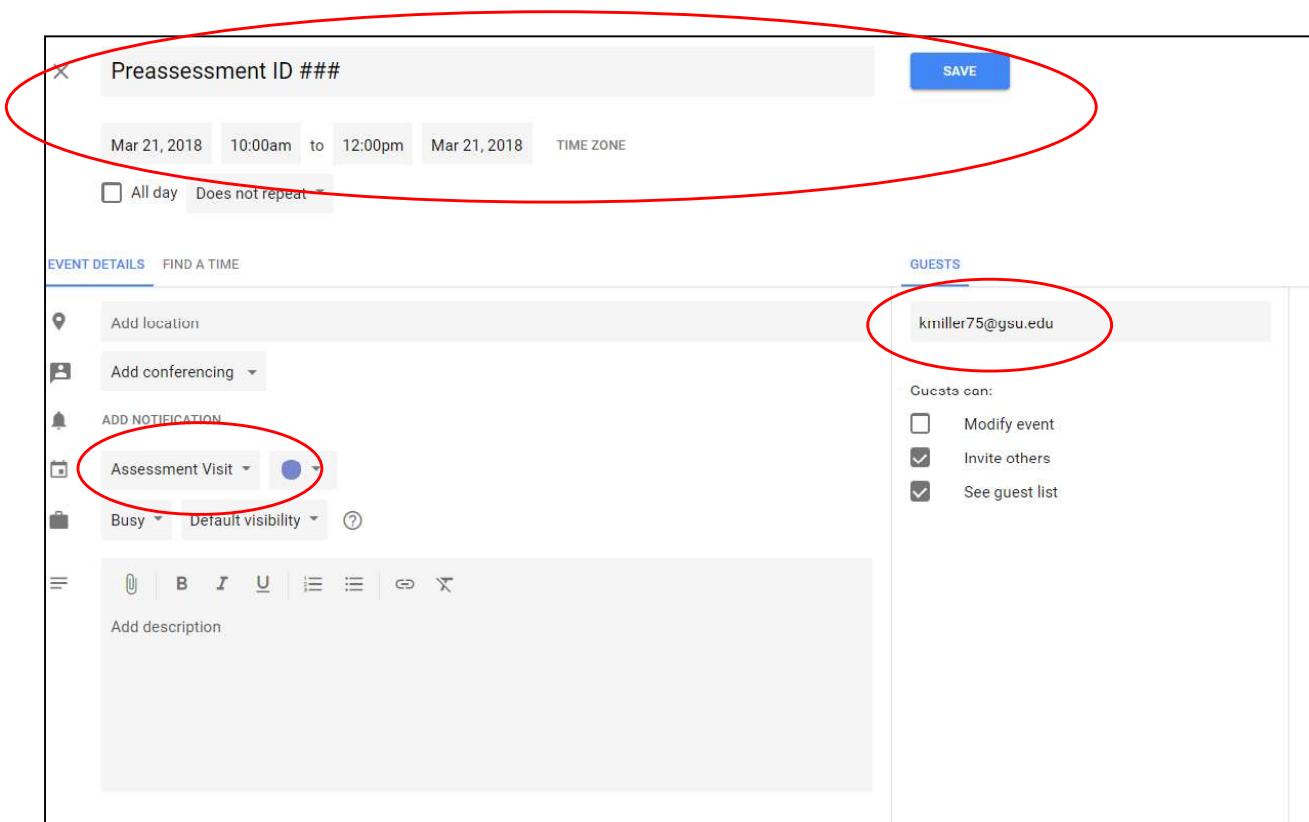
- Update Access Database - Tracking Information Form
 - Update/confirm contact, alternate contact, and demographic information
 - Enter phone screen information
 - Enter eligibility information
 - Enter Call Attempt information and enter Call Back Date if needed to call back to schedule preassessment

- If applicable, enter Scheduled Appointments information

Scheduled Appointments						
Mom ID	Type	Date	Appointment Details			Check the Completed Assessments Q1 Q2 Interactions iPhoneTrain Notes
			Time	Assessor	Status	

- Update Matriculation Table
 - Entire 'Screening' section
 - 'PreAssessment Scheduled' column of 'PreAssessment' section (if scheduled)

- Update Google calendar
 - Add scheduled preassessment on Assessment Visit calendar
 - Add assessor as 'guest' when known



Preassessment ID ###

Mar 21, 2018 10:00am to 12:00pm Mar 21, 2018 TIME ZONE

All day Does not repeat

EVENT DETAILS FIND A TIME

Add location

Add conferencing

ADD NOTIFICATION

Assessment Visit

Busy Default visibility

Add description

kmiller75@gsu.edu

GUESTS

Gucata can:

Modify event

Invite others

See guest list

Mom & Baby Net Remote Assessment & Training Procedures

Schedule Consent Call (10 minutes) [PROJECT COORDINATOR]

1. Explain changes in procedures (moms on wait list)
 - a. *Hi! This is [name] with the Mom & Baby Net project. Do you have about 10 minutes to talk? I was calling to let you know that we have a spot open for you in the project but our procedures will be a little different since we cannot do home visits right now. Are you still interested in participating and hearing what the next steps will be?*
 - i. If no: *I'm sorry to hear that. Can I ask why you are no longer interested?* If mom is too overwhelmed right now, offer to leave her on the waitlist and check back again when the next spots are open.
 - ii. If yes: continue with script
 - b. *Great! If you remember, the usual next step would have been to do the first home visit, but due to coronavirus, we are not doing home visits. Instead, we will do everything via phone or video call. We will walk you through each step along the way. After this call, you will be in touch with your coach, who you will be working with you for the rest of the program.*
2. Explain sending consent and iPhone agreement
 - a. *I will email you a copy of the project's consent form. This document will explain in detail the purpose of the Mom and Baby Net project, what you will be doing in the project, and how we will keep your information safe. We are taking necessary precautions to keep you, your family, and our staff healthy during the Coronavirus pandemic. The Pre-assessment and training visits will be conducted remotely using Zoom – an app that allows us to have a video call. I will later explain how Zoom works if you choose to participate.*
 - b. *The iPhone agreement form will also be emailed to you. This document covers expectations of loaning you the iPhone to complete the Mom and Baby Net project. Your phone service will be covered while you are participating in the program. We will monitor your progress on a month to month basis. If you are making progress and staying in communication with your coach, we will renew your service for the next month. If we lose contact with you, or you are not making progress in the program, your phone service may be discontinued; If we cannot reach you and your phone is not returned, it will be reported as lost or stolen.*
 - c. *I will also mail a copy of both of these forms to your home. Have you still been receiving mail and packages as usual during this time?*
 - d. *What questions do you have? [answer any questions]*
 - e. *The next step is to schedule a call to talk about the Consent and iPhone agreement forms after you receive them in the mail. You will do this call with your Coach, who will be with you for the rest of the program. She will go over both of these forms, answer any questions you have, and explain the next step which will be sending the iPhone and materials to you. Please think about a time where you will be able to talk for about 15 minutes and she will reach out tomorrow to schedule that call.*

3. Confirm email and mailing address

After Consent Scheduling Call

1. Assign participant ID and enter into Access
2. Notify coach ASAP to reach out to participant to schedule consent call.
3. Mail & email Consent and iPhone agreement
 - a. Note to add in email/envelope: We will review these documents on our next call. After all your questions are answered, you will sign them, take a picture of each signature page, and will text them to the project staff member who you speak with on that call.

Day Before Consent Call

1. Call or text mom to confirm she received the consent & iPhone agreement in the mail
2. Confirm time of call for next day
 - a. Reschedule if necessary (update Access and Matriculation table)

Consent Call (20 minutes) [ASSIGNED COACH]

1. Review consent the same as you would at a home pre-assessment (mom looking along on own copy)
2. Review iPhone agreement the same as you would at a home training visit (mom looking along on own copy)
3. *What other questions do you have about either of these documents or the program?* [answer questions]
4. *Are you still interested in participating?*
 1. If yes: *Great! Please go ahead and sign both pages. As soon as we get off the phone, take a picture of every page (even those that don't have a signature) and text them to the number I am calling from ####-####-####.*
 2. If no: *I am sorry to hear that. Can I ask why you changed your mind?*
5. Explain drop off or mailing of phone/accessories/manual
 1. *The next step is to drop off or mail your iPhone, accessories, and materials. We will sanitize all materials before getting them to you. In the bag you will find two baby books, your Mom and Baby Net handbook, iPhone, charger, headphones, and a tripod stand. Inside your Mom and Baby Net handbook in the front pocket of the binder, you will find a card with information about how to connect on Zoom.*
 2. If dropping off (if they have experienced issues getting UPS packages, this will be the best option): *To minimize contact and keep with social distancing, I will call once I have arrived outside and parked. I will remain on the phone with you, place your bag at the door, and let you know when to retrieve it. While you are on the phone, we will select a time for us to have our next call.*
 3. If mailing: *I will track the package and call or text to confirm it has arrived.*
6. Explain Zoom Training & Preassessment calls

1. *After you receive everything, we will have another call. We will connect via Zoom video chat and you will get an instruction card for that in your materials. Once you are familiar using Zoom, that's how we will communicate for the rest of the program. Also, on that call, we will record 2 5-minute videos of you and [baby's name] playing together and looking at some books that we will send. We will also begin the surveys, which are split into 2 parts. We will likely not finish everything on one call, so we will go ahead and schedule 2 separate calls for the same week.*
7. Ask mom some questions to determine the best time and way to complete the pre assessment remotely

 1. *Do you have laptop or tablet that is on data and/or wifi?*

 - i. If yes: *Great – if you would like, you can use your laptop/tablet to do the surveys. You can connect to Zoom on the project iPhone.*
 - ii. If no: *That is fine – you will be able to use the project iPhone to complete everything.*
 2. *The videos need to be created away from other people so that the interaction will not be interrupted by other people in the home; The video will need to be created away from sources of noises that could be picked up on the camera's microphone (like a noisy kitchen, television, or street). Where do you think the best place will be in your home to make the video?*
 3. Ask questions to help mom determine when would be the best time to do the call to record videos and complete the surveys. Some moms may know exactly when a good time is while others may need to think through some of these questions to figure it out. The purpose of these is to prime mothers for a successful video capture call.

 - i. *We want to make sure that we schedule the call at a time when your baby has been recently fed, is not sleepy and is feeling well AND when your other children are busy doing something fun that they like to do.*
 - ii. If there are other children in the home: *Was there a time yesterday when your older children were busy doing something that they were having fun with? What was it?* If it was appropriate, find out the details so you can encourage it for the call. If it is not appropriate or feasible, then help her think of something that is (i.e. watching an appropriate movie/show, playing a game). *When did they do that? Where? How long?* If the mother identifies something realistic and doable, encourage her to do that and have her set the specific reminder on her phone to get the other kids set up doing that activity 15 minutes BEFORE your scheduled call.
8. After working through these questions, schedule 2 1-hour sessions on different days, as close together as schedules allow (e.g., Wednesday & Thursday or Wednesday & Friday) with the mom to complete the pre assessment procedures. They should be 4-5 days after you drop off box of materials at UPS.

 1. Ask the mother to schedule the appointment times in her phone and show you:

 - i. 15 min before Call 1: Activity for other children
 - ii. Time of Part I Call (videos & Part 2 Qs)
 - iii. 15 min before Call 2: Activity for other children
 - iv. Time of Part II Call (Part 1 Qs)

9. Confirm shipping address (for UPS packages) or physical address (if dropping off materials)
10. iPhone Customization Form
 1. *The last information we need from you is to set up your iPhone before we send it. We will create an Apple ID for the phone and you will get the password for that once you finish the program. That means you will not be able to add apps once you get the phone. We have to control the space on the phone to make sure there is enough space for our app to run smoothly while you are in the program. I am texting you a link to an online form where you can choose up to 10 apps to have on the phone. We will add those when we set it up.*
 2. Text mom link to iPhone customization form: [link & add to preassessment links page]
11. Wrap up & signature reminder
 1. *Do you have any final questions? [answer questions]. We are excited to have you in the program and thank you for your patience. Remember to sign the consent form and iPhone agreement and send me a photo of every page as soon as we get off the phone and complete the iPhone customization form using the link. Once we have that, we will get the phone and materials ready to send to you.*

After Consent Call

1. In Access, add appointment(s) as 'scheduled' for pre assessment (enter both dates and times on separate lines)
2. In Matriculation Table, list scheduled pre assessment date
3. Let Assessment Coordinator know as soon as participant texts Consent and iPhone Agreement (all pages, not just signature page). Assessment Coordinator will set up iPhone.
4. Prior to iPhone set up, the Intervention Project Coordinator implements randomization procedures. Using a random number generator, mother-infant dyads were randomized, in a 1:1 allocation, to one of the two parallel interventions: Mom and Baby Net or Depression and Developmental Awareness. The Intervention Project Coordinator notifies the PI to review condition assignment and assigns case to intervention coach.
5. Drop off/mail materials (Assessment Coordinator)
 2. Prior to dropping off bag to participant or box to UPS, confirm that mom texted signature pages.
 3. Drop off sanitized iPhone w/ case + headphones + charger + tripod + program handbook (make sure Zoom instruction card is in inside pocket) + books + welcome letter
 4. When you receive email confirmation that box has been delivered, call or text mom to confirm that she received everything.

Day Before Pre-Assessment Call

1. Send mom a reminder via text or call
 - a. Remind her of time for scheduled call
 - b. Remind her that the videos need to be created:
 - i. At time when your baby has been recently fed, is not sleepy and is feeling well
 - ii. Away from other people so that the interaction will not be interrupted by other people in the home;
 - iii. Away from sources of noises that could be picked up on the camera's microphone (like a noisy kitchen, television, or street)

- c. Remind her, if applicable, of the fun activity for her older children, which they are going to get set up before the call with you
- d. Confirm that she has all the project materials that were sent to her & that her phone will be charged to at least 50% for the call. She will want to have headphones to use for the surveys unless it is just her and the baby in the home.

Pre-Assessment Call: Videos & Questionnaires [Assigned Coach]

(Split into 2 calls, 1 hour each; schedule 2 days as close together as possible)

1. Prior to getting on call
 - a. Gather needed paperwork (or go to electronic versions on Dropbox -> MomAndBabyNetNIHR01 -> Assessment -> Assessment Protocols & Forms -> Remote Assessments
 - i. ASRI
 - ii. Data checklist
 - iii. PDFs of surveys
 - iv. If mom is using a laptop/tablet to complete the surveys, have an email prepped with the link to send her. Do not send the day before.
2. Start Zoom call and greet mom as you normally would.
3. Zoom & iPhone orientation
 - a. Make sure mom is familiar with Zoom and troubleshoot if she has any issues with audio, video, etc.
 - b. Ask mom if she's ever used an iPhone before.
 - i. If not, give her a brief tutorial (turning off and on; answering phone; sending texts; Safari browsing; opening and closing apps; taking screenshots). Reference handbook section that covers this.
 - ii. Show mom all of the contacts that you added to her phone and explain the method for entering them (e.g., DR Smith Pediatrician; MED Poison Control). Reference handbook section that covers this.
 - iii. Show mom how to add numbers to Favorites (coach has already been added to favorites).
4. Review what you will be doing for the assessment part of the project
 - a. *For the pre assessment, we will record 2 5-minute videos of you and your baby – one of you playing together and one of you looking at the two books we included in your box of program materials. You will answer some questions on a survey I will send the link to. It is split up into 2 parts so we will probably not complete everything today, which is why we scheduled 2 times to meet. Also, it's important for you to understand that this will be very different from the actual program – it will be a little more tedious and less interactive, but then we will get to the app program, which will be more interactive and informative!*
5. Assessment Videos
 - a. *First, we will record the two videos.*

b. Setting up for videos

- i. Before beginning video protocol, ask the mother if she began the activity for other children as planned. Praise her successful action if she has done this already. If she has not done this, let her know that you want her to do this now. Help her with suggestions if needed.
- ii. Prepare for Video Recordings
 1. Remind the mom that it's important that baby is feeling well, is not hungry, and is not sleepy. If hungry, mom needs to feed baby first. If baby is sleepy or not feeling well, the videos can be captured during the next call. Proceed to complete questionnaires (get both done if possible).
 2. Let mom know that we need a relatively quiet place with plenty of light. Remind her of the location she identified and that
 - a. The space should be away from others so that the interactions will not be interrupted by other people in the home
 - b. If possible, pick a room away from sources of noises that could be picked up on the camera's microphone (like a noisy kitchen, television, or street)
 3. Guide mom on how to set up the phone for the videos
 - a. Landscape view (horizontal)
 - b. Can view enough area to have mom & baby in screen
 - c. Confirm there is enough light (not in front of a window)
 - d. Make sure the television/music is off (no background noise)
 4. Tips and Troubleshooting
 - a. Coach should not talk during video recording.
 - b. If mom asks you to stop recording video or if mom needs to leave the room, pause the recording until mom is ready to resume.

c. Free Play Video

- i. Record Free Play Instructions
 1. Select record on Zoom
 2. *Let's get started with the first part of the video by spending five minutes with you and your baby doing something that you enjoy doing together.*
 3. *What I'm interested in seeing are things that you and your baby are both comfortable with and used to, and things that your baby loves to do.*
 4. *Please feel free to move around as is comfortable for you and your baby but make sure that both you and your baby are visible on the screen at all times.*
 5. *Attend to any needs your baby might have during this time just as you normally would.*
 6. *After these 5 minutes, I will stop recording then I will give you the instructions for the second part of the recording which lasts 5 minutes. What questions do you have?*

7. Answer any questions mom has.
8. Stop recording on Zoom.

- ii. Record Free Play Video
 1. Give mom time to finish setting up for the video and confirm that she is ready.
 2. Coach should record using Speaker View and have the running time visible (or use a timer on your phone) set to make sure you get a minimum of 5:30 minutes of recording.
 3. *I am going to start recording, say an intro sentence for the video, then ask you to begin.*
 4. Select 'record' on Zoom
 5. *This is an interaction video with participant [say ID #], the mother's initials are [say mom's initials]*
 6. To mom: *You can begin now.* Coach – mute your microphone to mute your own background noise.
 7. After 5:30 minutes, stop recording on Zoom, unmute yourself, and say *Ok, the first video is finished.* Allow the mom to transition. *Now we will do the second video.*

- d. Books video (use Color and Animal baby books given to all moms)
 - i. Record Book video instructions
 1. Select record on Zoom
 2. *During the next five minutes, you and your baby can spend a little time with these books.*
 3. *However you want to use the books with your baby is fine.*
 4. *Feel free to attend to whatever needs your baby might have.*
 5. *What questions do you have?*
 6. Answer any questions mom has.
 7. Stop recording on Zoom.
 - ii. Record Books Video
 1. Give mom time to finish setting up for the video and confirm that she is ready.
 2. Coach should record using Speaker View and have the running time visible (or use a timer on your phone) set to make sure you get a minimum of 5:30 minutes of recording.
 3. *I am going to start recording, say an intro sentence for the video, then tell you to begin.*
 4. Select 'record' on Zoom
 5. *This is an interaction video with participant [say ID #], the mother's initials are [say mom's initials]*
 6. To mom: *You can begin now.* Coach – mute your microphone to mute your own background noise.
 7. After 5:30 minutes, stop recording on Zoom, unmute yourself, and say *Ok, the second video is finished.*

- e. Reset Zoom

- i. *Great job on the videos! Now we can continue to the surveys. So we don't run out of time, I am going to end this call and we are going to get right back on this same Zoom to continue.*
- ii. End Zoom call then start again immediately.
- iii. Ask mom if she needs to take care of any needs for the baby or if she is able to put the baby down or give to another adult so she can focus on the surveys.

6. Questionnaires

- a. Pre Assessment Questionnaire Part 1 (labeled as part 2 in Qualtrics: T1_part2)
 - i. *Now we will begin the questionnaires. They are split into two parts, so we don't have to complete both today. Each part will take 30-40 minutes to complete. We can start Part 1 and see how far we get. If we need to, we can complete the rest of the survey on our next scheduled call.*
 - ii. *I am now sending you a link to the first survey we will complete. Please let me know when you have received it and you can go ahead and click on it.*
 - iii. Send link to T1_Part 2 survey to mom
 - 1. Link: (see links document)
 - 2. If mom is doing surveys on their phone, text survey link to mom's project phone
 - 3. If mom is using laptop, email survey link
 - 4. If mom is restarting a partially finished survey, see steps below to get link to that survey and start where she left off
 - iv. Coach will have PDF of survey open to look at (printed or on computer). If mom needs to stop before reaching the end of this survey, make a note on the PDF of where she ended.
 - v. Set up surveys
 - 1. If mom is using their project phone: *When you click on the link, we will stay on Zoom. Even though we won't be looking right at each other through video, I will walk you through everything.*
 - 2. If mom is using own laptop/table: *If you want to set your phone up somewhere during these surveys, we will not necessarily need to see each other, but I will be walking you through each section of the survey.*
 - vi. Coach will instruct mom how to fill out the first page of info: ID #, mom initials, assessor name, date (mm/dd/yyyy)
 - vii. Read instructions for each section
 - 1. Coach will read through introductory instructions and instructions for first section.
 - 2. *Please stop and let me know each time you get to a picture, which indicates a new section. I will go over the instructions for the new section and answer any questions you have. If you have questions while you are completing the survey, please stop and ask. I will be on Zoom the entire time.*
 - 3. *Finally, you'll let me know when you reach the stop sign at the end of the survey. After the stop sign, you'll continue to the final questions.*

- viii. When mom reaches stop sign, tell her to continue to next page (shows embedded safety data – will have to check once survey is submitted)
- ix. Tell mom to continue to next page to the Services questions.
 - 1. *I will go through these last questions with you.*
 - 2. Go through the services questions with mom and give her time to answer each question.
- x. Have mom click final 'submit' button to record answers. She will see a full copy of the entire survey.
 - 1. *Great job - you have finished the first survey! Please give me a few minutes to make sure everything submitted ok.*
- xi. Check survey in Qualtrics
 - 1. Coach will log into Qualtrics bit.ly/qualtricsGSU
 - 2. Look for T1_Part2 survey
 - 3. Click on 3 dots to the right of that survey and click 'Data & Analysis'
 - 4. Look for mom's ID # and info for that survey to confirm submission; if not there yet, wait a minute and refresh
- xii. Record embedded data on ASRI
 - 1. Record total PHQ score ('score' column in Qualtrics) on page 1 of ASRI and check 'yes' or 'no' for elevated score
 - a. If yes – ask mom if she has recently discussed her mood with a doctor; did the doctor have any recommendations?; were there any recommendations discussed between coach and mom during the program you can revisit?
 - 2. Check PHQ self harm item (phq #9 column in Qualtrics)
 - a. If response of 1, 2, or 3 – check box
 - b. Tell mom: *The only responses I can see are items related to your safety and I wanted to follow up on this item.*
 - c. Follow decision tree, as usual, to address potential safety concern with mom
 - d. Check appropriate box under 'Self Harm' after completing decision tree discussion
- xiii. Continue or prepare to finish the next day
 - 1. If mom seems focused with no distractions, give her the option to continue to the second part of the survey
 - 2. If mom is distracted, does not want to continue, or you have any concerns about others interrupting the call (such as other young children who cannot realistically be sustained in another activity), confirm the time you are meeting tomorrow to finish
- b. Pre assessment Questionnaire Part 2 (labeled as Part 1 in Qualtrics: T1_Part1)
 - i. *We will do the last part of the survey just like we did the first one. I am sending the link now. Please let me know when you get it and go ahead and click on it.*
 - ii. Send link to T1_Part1 survey to mom (link is specific to each mom)
 - 1. Link: (see links document)

2. If mom is doing surveys on their phone, text survey link to mom's project phone
3. If mom is using laptop, email survey link
4. If mom is restarting a partially finished survey, see steps below to get link to that survey and start where she left off
- iii. Coach will have PDF of survey open to look at (printed or on computer). If mom needs to stop before reaching the end of this survey, make a note on the PDF of where she ended.
- iv. Set up surveys (if need to do again)
 1. If mom is using their project phone: *When you click on the link, we will stay on Zoom. Even though we won't be looking right at each other through video, I will walk you through everything.*
 2. If mom is using own laptop/table: *If you want to set your phone up somewhere during this piece, we will not necessarily need to see each other, but I will be walking you through each section of the survey.*
- v. Coach will instruct mom how to fill out the first page of info: ID #, mom initials, assessor name, date (mm/dd/yyyy)
- vi. Read instructions for each section
 1. Coach will read through introductory instructions and instructions for first section.
 2. *Please stop and let me know each time you get to a picture, which indicates a new section). I will go over the instructions for the new section and answer any questions you have. If you have questions while you are completing the survey, please stop and ask. I will be on Zoom the entire time.*
 3. *Finally, you'll let me know when you reach the stop sign at the end of the survey. After the stop sign, you'll continue to submit your final responses.*
- vii. When mom reaches stop sign, tell her to continue to next page (shows embedded safety data – will have to check once survey is submitted)
- viii. Tell mom to continue to next page to submit the survey.
- ix. Make sure mom clicks final 'submit' button to record answers. She will see a full copy of the entire survey.
 1. *Great job - you have finished the surveys! Please give me a few minutes to make sure everything submitted ok.*
- x. Check survey in Qualtrics
 1. Coach will log into Qualtrics (sign in page link)
 2. Look for T1_Part1 survey
 3. Click on 3 dots to the right of that survey and click 'Data & Analysis'
 4. Look for mom's ID # and info for that survey to confirm submission; if not there yet, wait a minute and refresh
- xi. Record embedded data on ASRI
 1. Check ATQ self harm item ('ATQ6' column in Qualtrics)
 - a. If response of 3, 4, or 5 – check box

- b. Tell mom: *The only responses I can see are items related to your safety and I wanted to follow up on this item.*
- c. Follow decision tree to address potential safety concern with mom
- d. Check appropriate box under 'Self Harm' after completing decision tree discussion
- c. *Great job – you finished the surveys! Now we just have some final information to go over together.*
- d. Unfinished surveys
 - i. If a mom needs to stop either Part 1 or Part 2 of the survey before she gets to the end, that is ok.
 - ii. Tell mom: *We can definitely stop and pick back up tomorrow. Make sure you finish the page you are on and click to the next page so it saves. Then you can close the browser/window.*
 - iii. Wrap up the call with mom and confirm the time you will be meeting tomorrow via Zoom.
 - iv. Make a note of where mom ended (ideally mark the page if you have the PDF printed)
 - v. About 4 hours after you end the call, check Qualtrics to make sure the incomplete survey submitted.
 - 1. Log into Qualtrics
 - 2. Find survey that was partially completed
 - 3. Click on 3 dots to the right of that survey and click 'Data & Analysis'
 - 4. Look for mom's ID # and info for that survey to confirm submission; if not there yet, wait a little while and refresh to check again
 - vi. Restart survey the next day
 - 1. Before starting call again with the mom, log into Qualtrics
 - 2. Find survey that was partially completed
 - 3. Click on 3 dots to the right of that survey and click 'Data & Analysis'
 - 4. Find mom's partially completed survey (by ID and date)
 - 5. On that line, to the very right, click the arrow under the 'Actions' column
 - 6. Click 'Retake Response' (do NOT click 'Retake as New Response')
 - 7. A box will pop up with a link – this is the link you will send to the mom
 - 8. When she clicks on the link, the survey will open to the first page (ID, mom initials, etc.) but should be completed already. Instruct her to click through until she reaches the page where she left off.
 - 9. Review the instructions again for the section she is on.
 - 10. Continue as usual through the rest of the survey.

Schedule App Training Visit

1. Explain app training visit
 - a. *On our next call, we will get familiar with the Mom & Baby Net app and start the first session together.*

2. Ask mom some questions to determine the best time and way to complete the call remotely
 - a. Discuss devices to use for this call
 - i. If mom used a personal phone or laptop for the pre assessment calls, tell her she might want to do the same for the next call. She can connect to Zoom through her personal device then use the project phone to learn the app.
 - ii. If mom does not have another device to use, ensure her that is perfectly fine, and they will be able to do everything through the project iPhone
 - b. Ask questions to help mom determine when would be the best time to do the call. Some moms may know exactly when a good time is while others may need to think through some of these questions to figure it out. The purpose of these is to prime mothers for a successful video capture call.
 - i. *If possible, we want to schedule the call at a time when your baby is napping or resting or can be with another adult so you can focus on the call and follow along in the app.*
 - ii. If you know there are other children in the home: *How did the activity for your older children work during these pre assessment calls? What was it?* If it was appropriate, find out the details so you can encourage it again for the next call. If it is not appropriate or feasible, then help her think of something that is (i.e. watching an appropriate movie/show, playing a game). *When did they do that? Where? How long?* If the mother identifies something realistic and doable, encourage her to do that and have her set the specific reminder on her phone to get the other kids set up doing that activity 15 minutes BEFORE your scheduled call.
3. After working through these questions, schedule a 1.5 hour call to complete the App Training (may not take that long but have it scheduled in case it does)
4. Enter scheduled day/time into Access database.

Immediately After Pre-Assessment Call(s)

1. Save videos to Dropbox as follows (Dropbox -> MomAndBabyNetNIHR01 -> Participant Data -> [participant's folder])
 - a. Rename files the drag and drop into participant folder
 - i. [ID] PRE free play instructions [date]
 - ii. [ID] PRE free play [date]
 - iii. [ID] PRE book instructions [date]
 - iv. [ID] PRE book [date]
2. Complete documents and save documents to Dropbox (Dropbox -> MomAndBabyNetNIHR01 -> Participant Data -> [participant's folder]) & save paper copies to file later
 - a. ASRI
 - i. Mark appropriate boxes, add report if necessary, and add signature (printed or digital)
 - ii. Email to Kathleen if consultation needed (if self-harm endorsed)
 - iii. Save or scan/save as “[ID] PRE ASRI [date]” (if consult needed, only save final version with all signatures)

- b. Data Checklist
 - i. Check off all appropriate boxes, initial, and date
 - ii. Save or scan/save as “[ID] PRE Data Checklist [date]”
- 3. Update Access
 - a. Update scheduled appointments form
 - i. Change ‘scheduled’ to ‘complete’
 - ii. If mom completed everything in one call, mark second day as ‘canceled’ and in notes write ‘call not needed – mom completed on first call’
 - iii. Add training visit day and time as new appointment – ‘scheduled’
- 4. Update Matriculation table
 - a. Assessment tab: Mark pre assessment completed (Y)
 - b. Training tab: enter scheduled training visit date

Day Before App Training Visit

- 1. Send mom a reminder via text
 - a. Remind her of time of call via Zoom
 - b. Remind her of the fun activity for their older children, which they are going to get set up before the call with you
 - c. Confirm that she has ear buds as these will be required unless she is alone or only with her baby throughout the assessment;
 - d. Confirm that she has all of her materials together and that her phone will be charged
- 2. Make sure you have or have access to all necessary materials
 - a. iPhone with the Mom and Baby Net app downloaded, so you are able to show moms app features while using Zoom on your computer
 - b. Tripod to help moms with set up during call

App Training Call (1.5 hours)

- 1. Log onto Zoom and greet the participant as you normally would
- 2. Review order of events with the mother so she knows what to expect during the call:
 - a. *Today you will be starting the weekly Mom & Baby Net program.*
 - b. *We will go over all the materials you received, including the handbook that will help you complete the program.*
 - c. *Last, we will get familiar with the Mom & Baby Net app and start Session 1 together.*
- 3. *Do you have any questions?*
- 4. During training visit, Coaches will use Zoom to screen share and watch videos together
- 5. Show mom the Mom & Baby Net Handbook. She will need to keep and use the book throughout the program;
 - a. Tell mom that everything that you cover in this meeting is also referenced in the book in greater detail.
 - b. The book has crucial information for using the program. Show her the major sections.

- c. Store it in a place that is handy but kept away from opportunities for damage (children, animal, food spill, etc.). Talk with her about where this will be so that you can help problem solve if needed to ensure appropriate storage and easy access.
- d. We want her to have it out for sessions and when she is in the call with you in case you need to look at it together- having it out and ready will reduce call time if it is needed.
- e. Remind her to have it close by at the start of going through Session 1 and explain that her activity for the week will involve getting familiar with the book and the app.

6. Have mom login to Mom & Baby Net using her login and password.

- a. Explain how the program works (accessing one session each week and then having a coach call afterwards).
- b. Talk to mom about the logistics for uploading weekly videos (completed after session, mom and baby both in video, and uploaded 24 hours before scheduled coach call)
- c. Show mom the menu (sessions, videos, ratings, resources, messages, and action plan) and tell her we will watch a video explaining what is in each of the sections.
- d. Show her how to access Session 1 which will help her get familiar with how to use the program
- e. After the create-see video tour, pause session 1 and have mom create a short 30-second practice video. Talk about tips for creating a good video (lighting, sound).
- f. Talk about uploading the video and not using the phone during the upload.
- g. Have mom play back video on her Create/See Video page once it's been uploaded. Troubleshoot with mom if needed with tips for recording, uploading, etc.

7. For moms using Zoom on the project iPhone

- a. Review pages as you normally do during training visit by holding your phone to the camera to allow moms to follow along and answering any questions she has.
- b. For moms in PALS condition only: When you get to setting mood anchor page, have mom pause zoom by returning to home screen, and advancing until she reaches page shown on screen. You will talk to mom about setting mood anchors as she does it on her device; She will then follow along with audio for the next couple of pages as she practices rating her mood.

8. For moms in the PALS condition who using Zoom on a device other than project iPhone

- a. Have moms set phone she is using on Zoom on tripod, and have her go through the pages on her project phone, as coach screen shares. Mom will be able to see both coach and video as she follows along
- b. For mom in PALS condition only: ask mom to show you her page when setting mood anchors and rating mood
- c. Review pages via screen sharing as you normally do during training visit and answer questions mom has about different pages in section menu of app.

Before ending the call

1. Schedule your Session 1 Zoom call with mom and show her how to use the calendar not only for reminding her of weekly Zoom calls, but for doctor's appointments or anything else she needs to schedule.
 - a. Have her enter your scheduled Zoom call and use a reminder.

- b. It is suggested that when you add coach appointments to your calendar that you include a 'day before' reminder as well as a 15-minute reminder and send an Invite. It would be great if moms have a regular time that can be set up to 'Repeat Weekly', but if not, you could send week to week.
- 2. Ask if there are any updates to her alternate contact info (at least 3); Confirm best means of contact for mom

After App Training Call

- 1. Update Access
 - a. Update scheduled appointments form
 - i. Change 'scheduled' to 'complete'
 - b. If needed, update contact information
- 2. Update Matriculation table
 - a. Training tab: Mark training visit completed (Y)

<>REMOTE POST ASSESSMENT PROCEDURES<>

Schedule Post Assessment

- 1. Coach will schedule post-assessment with mom during session 14 (or last) Coach Call as usual
 - a. *Typically, we would do the last visit in the home, but due to the coronavirus we will complete post assessments using Zoom as we did for our coach calls. Just as we did at the pre-assessment, you'll complete some questionnaires and we will make 2 videos of you and your baby. To get ready for our Post-Assessment Zoom Call, I'd like to get a little information from you.*
- 2. Ask mom some questions to determine the best time and way to complete the post assessment remotely
 - a. *Do you have laptop or tablet that is on data and/or wifi?*
 - b. *Do you have headphones to use with your phone?* (if no, mail new ones)
 - c. *Do you have the books we gave you at pre-assessment* (pink and yellow Colors & Animals books)?
 - i. If yes, have them show them to you.
 - ii. If no: *Can you show me some books you use at home with your child?* (if they have board books or soft books they can use those; if they don't have appropriate books, we can mail some if mom is still able to receive UPS packages). Confirm mailing address and send to Katy to mail books.
 - d. *The videos need to be created away from other people so that the interaction will not be interrupted by other people in the home; The video will need to be created away from sources of noises that could be picked up on the camera's microphone (like a noisy kitchen, television, or street). Where do you think the best place will be in your home to make the video?*

- e. Ask questions to help mom determine when would be the best time to do the call to record videos and complete the surveys. Some moms may know exactly when a good time is while others may need to think through some of these questions to figure it out. The purpose of these is to prime mothers for a successful video capture call.
 - i. *We want to make sure that we schedule the call at a time when your baby has been recently fed, is not sleepy and is feeling well AND when your other children are busy doing something fun that they like to do.*
 - ii. If you know there are other children in the home: *Was there a time yesterday when your older children were busy doing something that they were having fun with? What was it?* If it was appropriate, find out the details so you can encourage it for the call. If it is not appropriate or feasible, then help her think of something that is (i.e. watching an appropriate movie/show, playing a game). *When did they do that? Where? How long?* If the mother identifies something realistic and doable, encourage her to do that and have her set the specific reminder on her phone to get the other kids set up doing that activity 15 minutes BEFORE your scheduled call.
- 3. After working through these questions, schedule 2 1-hour sessions on back to back days (e.g., Wednesday & Thursday) with the mom to complete the post assessment procedures.
 - a. Ask the mother to schedule the appointment times in her phone and show you:
 - i. 15 min before Call 1: Activity for other children
 - ii. Time of Part I Call (video & Part 2 Qs)
 - iii. 15 min before Call 2: Activity for other children
 - iv. Time of Part II Call (Part 1 Qs)

Immediately After Scheduling Call

- 5. In Access, add appointment(s) as 'scheduled' for post assessment (enter both dates and times on separate lines)
- 6. In Matriculation Table, list today's date as 'mom ready for post' and list scheduled post date
- 7. Email Katy the following information
 - a. Mom's ID
 - b. Scheduled post date
 - c. If mom needs books, send address (or confirm address listed in Access)
- 8. Katy will send back phone info (locked or unlocked) and Sprint PIN # (this changes periodically)

Day Before Post Assessment

- 2. Send mom a reminder via text or Coach Talk
 - a. Remind her of time of call tomorrow
 - b. Remind her that the videos need to be created:
 - i. At time when your baby has been recently fed, is not sleepy and is feeling well
 - ii. Away from other people so that the interaction will not be interrupted by other people in the home;
 - iii. Away from sources of noises that could be picked up on the camera's microphone (like a noisy kitchen, television, or street)

- c. Remind her of the fun activity for their older children, which they are going to get set up before the call with you
- d. Confirm that she has ear buds as these will be required unless she is alone with her baby throughout the assessment;
- e. Confirm that she has received the books that were sent and/or has books available for post call

3. Make sure you have or have access to all necessary information

Post Assessment Call: Videos & Questionnaire (1.5 hours) [COACH]

(Breaks during the call will be provided and most will be split into 2 separate calls)

- 1. Prior to getting on call
 - a. Gather needed paperwork (or go to electronic versions on Dropbox -> MomAndBabyNetNIHR01 -> Assessment -> Assessment Protocols & Forms -> Remote Assessments)
 - i. ASRI
 - ii. Data checklist
 - iii. PDFs of surveys
 - iv. PDF of follow up form
 - v. Phone info
 - vi. Participant account info (in individual participant folder on Dropbox)
- 2. Start Zoom call and greet mom as you normally would.
- 3. Review what you will be doing
 - a. *For the post assessment, we will record 2 5-minute videos of you and your baby – one of you playing together and one of you looking at books together. You will answer some questions on a survey I will send the link to you. It is split up into 2 parts so we may not complete everything today, which is why we scheduled 2 times to meet. Last, we will go over the information about the phone and follow ups.*
- 4. Assessment Videos
 - a. *First, we will record the two videos.*
 - b. Setting up for videos
 - i. Before beginning video protocol, ask the mother if she began the activity for other children as planned. Praise her successful action if she has done this already. If she has not done this, let her know that you want her to do this now. Help her with suggestions if needed.
 - ii. Prepare for Video Recordings
 - 1. Remind the mom that it's important that baby is feeling well, is not hungry, is feeling well, and is not sleepy. If hungry, mom needs to feed baby first. If baby is sleepy or not feeling well, the videos can be captured during the next call. Proceed to complete questionnaires (get both done if possible).
 - 2. Let mom know that we need a relatively quiet place with plenty of light. Remind her of the location she identified and that

- a. The space should be away from others so that the interactions will not be interrupted by other people in the home
 - b. If possible, pick a room away from sources of noises that could be picked up on the camera's microphone (like a noisy kitchen, television, or street)
3. Guide mom on how to set up the phone for the videos
 - a. Landscape view (horizontal)
 - b. Can view enough area to have mom & baby in screen
 - c. Confirm there is enough light (not in front of a window)
 - d. Make sure the television/music is off (no background noise)
4. Tips and Troubleshooting
 - a. Coach should not talk during video recording.
 - b. If mom asks you to stop recording video or if mom needs to leave the room, pause the recording until mom is ready to resume.

c. Free Play Video

- i. Record Free Play Instructions
 1. Select record on Zoom
 2. *Let's get started with the first part of the video by spending five minutes with you and your baby doing something that you enjoy doing together.*
 3. *What I'm interested in seeing are things that you and your baby are both comfortable with and used to, and things that your baby loves to do.*
 4. *Please feel free to move around as is comfortable for you and your baby but make sure that both you and your baby are visible on the screen at all times.*
 5. *Attend to any needs your baby might have during this time just as you normally would.*
 6. *After these 5 minutes, I will stop recording then I will give you the instructions for the second part of the recording which lasts 5 minutes. What questions do you have?*
 7. Answer any questions mom has.
 8. Stop recording on Zoom.
- ii. Record Free Play Video
 1. Give mom time to finish setting up for the video and confirm that she is ready.
 11. Coach should record using Speaker View and have the running time visible (or use a timer on your phone) set to make sure you get a minimum of 5:30 minutes of recording.
 2. *I am going to start recording, say an intro sentence for the video, then tell you to begin.*
 3. Select 'record' on Zoom
 4. *This is an interaction video with participant [say ID #], the mother's initials are [say mom's initials]*

5. To mom: *You can begin now.* Coach – mute your microphone to mute your own background noise.
6. After 5:30 minutes, stop recording on Zoom, unmute yourself, and say *Ok, the first video is finished.* Allow the mom to transition. *Now we will do the second video.*
- d. Books videos (use Color and Animal baby books given to all moms at pre-assessment or appropriate board/soft books mom has at home)
 - i. Record Book video instructions
 1. Select record on Zoom
 2. *During the next five minutes, you and your baby can spend a little time with these books.*
 3. *However you want to use the books with your baby is fine.*
 4. *Feel free to attend to whatever needs your baby might have.*
 5. *What questions do you have?*
 6. Answer any questions mom has.
 7. Stop recording on Zoom.
 - ii. Record Books Video
 1. Give mom time to finish setting up for the video and confirm that she is ready.
 12. Coach should record using Speaker View and have the running time visible (or use a timer on your phone) set to make sure you get a minimum of 5:30 minutes of recording.
 13. *I am going to hit record, say an intro sentence for the video, then tell you to begin.*
 14. Select 'record' on Zoom
 15. *This is an interaction video with participant [say ID #], the mother's initials are [say mom's initials]*
 16. To mom: *You can begin now.* Coach – mute your microphone to mute your own background noise.
 17. After 5:30 minutes, stop recording on Zoom, unmute yourself, and say *Ok, the second video is finished.*
- e. Reset Zoom
 - i. *Great job on the videos! Now we can continue to the surveys. So we don't run out of time, I am going to end this call and we are going to get right back on this same Zoom to continue.*
 - ii. End Zoom call then start again immediately.
 - iii. Ask mom if she needs to take care of any needs for the baby or if she is able to put the baby down or give to another adult so she can focus on the surveys.

5. Questionnaires
 - a. Post Assessment Questionnaire Part 1 (labeled as part 2 in Qualtrics: T2_part2)
 - i. *Now we will begin the questionnaires. They are split into two parts, so we don't have to complete both today. They are very similar to the questionnaires you completed at your very first home visit. Each part will take 30-40 minutes to*

complete. We can start Part 1 and see how far we get. If we need to, we can complete the rest of the survey on our next scheduled call.

- ii. I am now sending you a link to the first survey we will complete. Please let me know when you have received it and you can go ahead and click on it.*
- iii. Send link to T2_Part 2 survey to mom
 1. Link: (see links document)
 2. If mom is doing surveys on their phone, text survey link to mom's project phone
 3. If mom is using laptop, email survey link
 4. If mom is restarting a partially finished survey, see steps below to get link to that survey and start where she left off
- iv. Coach will have PDF of survey open to look at (printed or on computer). If mom needs to stop before reaching the end of this survey, make a note on the PDF of where she ended.
- v. Set up surveys
 1. If mom is using their project phone: *When you click on the link, we will stay on Zoom. Even though we won't be looking right at each other through video, I will walk you through everything.*
 2. If mom is using own laptop/table: *If you want to set your phone up somewhere during these surveys, we will not necessarily need to see each other, but I will be walking you through each section of the survey.*
- vi. Coach will instruct mom how to fill out the first page of info: ID #, mom initials, assessor name, date (mm/dd/yyyy)
- vii. Read instructions for each section
 1. Coach will read through introductory instructions and instructions for first section.
 2. *Please stop and let me know each time you get to a picture, which indicates a new section. I will go over the instructions for the new section and answer any questions you have. If you have questions while you are completing the survey, please stop and ask. I will be on Zoom the entire time.*
 3. *Finally, you'll let me know when you reach the stop sign at the end of the survey. After the stop sign, you'll continue to the final questions.*
- viii. When mom reaches stop sign, tell her to continue to next page (shows embedded safety data – will have to check once survey is submitted)
- ix. Tell mom to continue to next page to the Services questions.
 1. *I will go through these last questions with you.*
 2. Go through the services questions with mom and give her time to answer each question.
- x. Have mom hit final 'submit' button to record answers. She will see a full copy of the entire survey.
 1. *Great job - you have finished the first survey! Please give me a few minutes to make sure everything submitted ok.*
- xi. Check survey in Qualtrics

1. Coach will log into Qualtrics bit.ly/qualtricsGSU
2. Look for T2_Part 2 survey
3. Click on 3 dots to the right of that survey and click 'Data & Analysis'
4. Look for mom's ID # and info for that survey to confirm submission; if not there yet, wait a minute and refresh

xii. Record embedded data on ASRI

1. Record total PHQ score ('score' column in Qualtrics) on page 1 of ASRI and check 'yes' or 'no' for elevated score
 - a. If yes – ask mom if she has recently discussed her mood with a doctor; did the doctor have any recommendations?; were there any recommendations discussed between coach and mom during the program you can revisit?
2. Check PHQ self harm item (phq #9 column in Qualtrics)
 - a. If response of 1, 2, or 3 – check box
 - b. Tell mom: *The only responses I can see are items related to your safety and I wanted to follow up on this item.*
 - c. Follow decision tree, as usual, to address potential safety concern with mom
 - d. Check appropriate box under 'Self Harm' after completing decision tree discussion

xiii. Continue or prepare to finish the next day

1. If mom seems focused with no distractions, give her the option to continue to the second part of the survey
2. If mom is distracted, does not want to continue, or you have any concerns about others interrupting the call (such as other young children who cannot realistically be sustained in another activity), confirm the time you are meeting tomorrow to finish

b. Post assessment Questionnaire Part 2 (labeled as Part 1 in Qualtrics: T2_Part1_DAS or T2_Part1_PALS)

- i. *We will do the last part of the survey just like we did the first one. I am sending the link now. Please let me know when you get it and go ahead and click on it.*
- ii. Send link to T2_Part 1 survey to mom (link is specific to each mom)
 1. Link: (see links document)
 2. If mom is doing surveys on their phone, text survey link to mom's project phone
 3. If mom is using laptop, email survey link
 4. If mom is restarting a partially finished survey, see steps below to get link to that survey and start where she left off
- iii. Coach will have PDF of survey open to look at (printed or on computer). If mom needs to stop before reaching the end of this survey, make a note on the PDF of where she ended.
- iv. Set up surveys (if need to do again)

1. If mom is using their project phone: *When you click on the link, we will stay on Zoom. Even though we won't be looking right at each other through video, I will walk you through everything.*
2. If mom is using own laptop/table: *If you want to set your phone up somewhere during this piece, we will not necessarily need to see each other, but I will be walking you through each section of the survey.*
- v. Coach will instruct mom how to fill out the first page of info: ID #, mom initials, assessor name, date (mm/dd/yyyy)
- vi. Read instructions for each section
 1. Coach will read through introductory instructions and instructions for first section.
 2. *Please stop and let me know each time you get to a picture, which indicates a new section). I will go over the instructions for the new section and answer any questions you have. If you have questions while you are completing the survey, please stop and ask. I will be on Zoom the entire time.*
 3. *Finally, you'll let me know when you reach the stop sign at the end of the survey. After the stop sign, you'll continue to the final questions.*
- vii. While mom is completing survey, coach can be prepping AppleID account info and phone service info to send to mom through Coach Talk at end of call
 1. Find mom's account info: Dropbox -> MomAndBabyNetNIHR01 -> Participant Data -> [open folder with mom's ID #] -> '[ID] account info' PDF
 - a. Mom will need all account info for AppleID and Gmail + security questions and answers
 2. Phone service info: Dropbox -> MomAndBabyNetNIHR01 -> Assessment -> Assessment Protocols & Forms -> Remote Post Assessments
 - a. Document 'Your iPhone Form for User at End of Project – [locked or unlocked]' – can copy and paste to mom in Coach Talk
- viii. When mom reaches stop sign, tell her to continue to next page (shows embedded safety data – will have to check once survey is submitted)
- ix. Tell mom to continue to next page to the Satisfaction questions.
 1. *This last section asks you questions about the program. Again, let me know if you have any questions and let me know when you hit the final submit button.*
 2. Give her time to answer final questions
- x. Make sure mom hit final 'submit' button to record answers. She will see a full copy of the entire survey.
 1. *Great job - you have finished the surveys! Please give me a few minutes to make sure everything submitted ok.*
- xi. Check survey in Qualtrics
 1. Coach will log into Qualtrics (sign in page link)

2. Look for T2_Part1_DAS or T2_part1_PALS survey (whichever condition mom is in)
3. Click on 3 dots to the right of that survey and click 'Data & Analysis'
4. Look for mom's ID # and info for that survey to confirm submission; if not there yet, wait a minute and refresh

xii. Record embedded data on ASRI

1. Check ATQ self harm item ('ATQ6' column in Qualtrics)
 - a. If response of 3, 4, or 5 – check box
 - b. Tell mom: *The only responses I can see are items related to your safety and I wanted to follow up on this item.*
 - c. Follow decision tree to address potential safety concern with mom
 - d. Check appropriate box under 'Self Harm' after completing decision tree discussion
- c. *Great job – you finished the surveys! Now we just have some final information to go over together.*
- d. Unfinished surveys
 - i. If a mom needs to stop either Part 1 or Part 2 of the survey before she gets to the end, that is ok.
 - ii. Tell mom: *We can definitely stop and pick back up tomorrow. Make sure you finish the page you are on and click to the next page so it saves. Then you can close the browser/window.*
 - iii. Wrap up the call with mom and confirm the time you will be meeting tomorrow via Zoom.
 - iv. Make a note of where mom ended (ideally mark the page if you have the PDF printed)
 - v. About 4 hours after you end the call, check Qualtrics to make sure the incomplete survey submitted.
 1. Log into Qualtrics
 2. Find survey that was partially completed
 3. Click on 3 dots to the right of that survey and click 'Data & Analysis'
 4. Look for mom's ID # and info for that survey to confirm submission; if not there yet, wait a little while and refresh to check again
 - vi. Restart survey the next day
 1. Before starting call again with the mom, log into Qualtrics
 2. Find survey that was partially completed
 3. Click on 3 dots to the right of that survey and click 'Data & Analysis'
 4. Find mom's partially completed survey (by ID and date)
 5. On that line, to the very right, click the arrow under the 'Actions' column
 6. Click 'Retake Response' (do NOT click 'Retake as New Response')
 7. A box will pop up with a link – this is the link you will send to the mom

8. When she clicks on the link, the survey will open to the first page (ID, mom initials, etc.) but should be completed already. Instruct her to click through until she reaches the page where she left off.
9. Review the instructions again for the section she is on.
10. Continue as usual through the rest of the survey.

6. End of program information

- a. Follow-ups and video release
 - i. *The last thing we ask moms to complete is one follow-up. We will not have to see you for these. 6 months after today, you will get an email that has a link to a 5-10 minute survey. If you do not complete the survey on your own, we will follow up via phone to remind you and you can do it over the phone if you want. Do you have any questions about the follow up? I will also send you the date for your follow up through Coach Talk.*
 - ii. *I am sending you a link now to a form. Please let me know when you get it and I will go through it with you.*
 1. Send mom link the same way survey links were sent
 2. bit.ly/MBNpostInfo
 - iii. *Once mom has form open: First, we need the best email address to reach you. This is where the follow-up email will come 1 month from today.*
 - iv. *Next, please put the best phone number, other than the project phone number, to reach you. Then you can click to the next page.*
 - v. *Explain Video Release: Last is the video release. If you agree, we may use your videos from assessments and app sessions for training purposes in the future to continue helping other moms in the program. This may include other professionals to help them understand how the program works and how mothers use the program. Please check the box whether you agree or do not agree to this and type in your name. Again, this is optional and completely up to you.*
 1. If mom agrees, the next page will ask for her address. Tell her to complete that info then submit the form. Confirm receipt.
 2. If mom does not agree, the form will submit and she is done.
- b. Phone service & apple ID
 - i. *Last, I will be sending you 2 pieces of information through Coach Talk on the app. One has the Gmail account and Apple ID information and passwords. We created the Gmail in order to create the Apple ID, so it is yours now. You can keep it and use it or you can go in and delete it. I will send the passwords for both account as well as the answers to the security questions for you to access your Apple account.*
 - ii. *The second information is about the phone and service. The phone will be paid for until [month] 16th (ex. if you are doing a post on March 26, the phone will be paid for until April 16).*
 1. If phone is unlocked (check with Katy prior to call): *The phone is unlocked and can be switched to any service. If you want to keep it on a Sprint personal account or move to Boost, please let us know as soon as*

possible – we can initiate that transfer through our account. If you move it to another service, they will change the sim card to that service. You will need the account pin number listed on the sheet, so have that handy when you take it to the provider you want to switch to. If you do not move it to a personal service, you can continue to use it on WiFi. I will send you all of this info immediately after this call and you will get a reminder about a week before the service shuts off.

2. If the phone is NOT unlocked (check with Katy prior to call):
Unfortunately, the phone is not unlocked and cannot be transferred to a different company at this time. If you want to transfer it to a personal Sprint account, we can initiate that. I will send the phone number for Sprint if you want to see how much their plans are. You can also continue using the phone on WiFi – all the apps will work and you can use a wifi calling app like Google Voice, Skype, or Text Now for calls and texts. I will send you all of this info immediately after this call and you will get a reminder about a week before the service shuts off.
- c. *What final questions do you have?*
- d. *We really appreciate you participating and hope you have enjoyed the program!* End call as you normally would end the program on a mom's final call.

Immediately After Post Assessment Call(s)

5. Send mom Account Information and Phone Information through Coach Talk
 - i. Account info
 1. Dropbox -> MomAndBabyNetNIHR01 -> Participant Data -> [open folder with mom's ID #] -> '[ID] account info' PDF
 2. Mom will need all account info for AppleID and Gmail + security questions and answers
 - ii. Phone service info
 1. Dropbox -> MomAndBabyNetNIHR01 -> Assessment -> Assessment Protocols & Forms -> Remote Post Assessments
 2. Document 'Your iPhone Form for User at End of Project – [locked or unlocked]' – can copy and paste to mom in Coach Talk
6. Save videos to Dropbox as follows (Dropbox -> MomAndBabyNetNIHR01 -> Participant Data -> [participant's folder])
 - a. Rename files the drag and drop into participant folder
 - i. [ID] POST free play instructions [date]
 - ii. [ID] POST free play [date]
 - iii. [ID] POST book instructions [date]
 - iv. [ID] POST book [date]
7. Complete documents and save documents to Dropbox (Dropbox -> MomAndBabyNetNIHR01 -> Participant Data -> [participant's folder])
 - a. ASRI

- i. Mark appropriate boxes, add report if necessary, and add signature (printed or digital)
 - ii. Email to Kathleen if consultation needed (if self harm endorsed)
 - iii. Save or scan/save as “[ID] POST ASRI [date]” (if consult needed, only save final version with all signatures)
- b. Data Checklist
 - i. Check off all appropriate boxes, initial, and date
 - ii. Save or scan/save as “[ID] POST Data Checklist [date]”

8. Update Access

- a. Update scheduled appointments form
 - i. Change ‘scheduled’ to ‘complete’
 - ii. If mom completed everything in one call, mark second day as ‘canceled’ and in notes write ‘call not needed – mom completed on first call’

9. Update Matriculation table

- a. Assessment tab: Mark post assessment completed (Y)
- b. Training tab: enter date of post assessment and length of time in program

10. Project coordinator will complete

- a. Matriculation table
 - i. Mark model release signed (Y or N)
 - ii. Enter follow up assessment dates
- b. Project calendar
 - i. Enter follow up dates
- c. Download survey PDFs and save to participant folder
- d. Update follow up contact info (email & phone)
 - i. Access
 - ii. Qualtrics