A Randomized Controlled Trial to Improve Mother-Infant Synchrony Among Women with Childhood Adversity

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Consent and Parental Permission to Participate in Research

Short Title: Mothers and Babies Project
Full Study Title: A Randomized Controlled Trial to Improve Mother-Infant Synchrony among Women with Childhood Adversity

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Summary of the research

If you are a parent of a child that is participating in this study, references to "you" and "your" throughout this document refer to both you and your child.

This is a consent form for participation in a research study. Your participation in this research study is voluntary. It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to ask questions before making your decision whether or not to participate.

You are being asked to participate in a study about a special kind of baby massage affecting mother-baby bonding and a bonding hormone. There are 4 study visits: once in pregnancy, and at 1, 2, and 3 months after birth. At study visits, you will have your blood drawn, we will collect a small amount of saliva from your baby, and you will answer some questionnaires. We would also visit with you in the College of Nursing within 7 days after birth, and you would have a 50/50 chance of being in 1 of 2 study groups: either learning how to give your baby a short massage (which you would do every day for 3 months) or learning more about how to take care of your baby. At the last study visit we video record each mother talking and playing with their baby for 4 minutes. We will reimburse you $50 cash for your time (and transportation) at 4

study visits, the after-birth teaching visit, and $100 cash at the final visit. The total amount is $300 if you attend all 4 study visits. The risks to participate are minimal, and typically mothers and babies enjoy participating.

Why is this study being done?

This is a research study to help mothers get to know their babies in the first 3 months after birth, and to better understand the hormones that help mothers bond with their babies.

What will happen if I take part in this study?

1. Allow us access to health information in your medical record related to your pregnancy, your delivery, and your baby's health. An authorization form will be provided for your signature.
2. At your 1st study visit, in the latter half of pregnancy, we will draw a small amount of blood (almost 2 tablespoons) to measure the bonding hormone oxytocin and ask questions about your health and how you are feeling. Besides measuring the bonding hormone oxytocin, we want to learn more about how oxytocin is regulated in the body. This study collects DNA to measure epigenetic marks and gene expression only in the oxytocin receptor gene. Epigenetic marks regulate gene expression, which is how much genes are turned on or off.
3. We will visit with you in the College of Nursing within 7 days after giving birth to teach you how to give the baby massage or teach you about safe infant care. There is a 50/50 chance of being assigned to either group.
4. If you are in the baby massage group, you will give your baby a 10-minute massage and 5 minutes of rocking once every day for 3 months. You will receive a daily text asking if you were able to give the massage that day.
5. In both groups, we will send a daily text and a weekly call to check-in and see how you and baby are doing.
6. In both groups, mothers and babies will come to 3 study visits at the University of Arizona College of Nursing when your baby is 1, 2, and 3 months old. You will answer questions about you and your baby's health. We will collect a small amount of blood from you (see description above for the 1st study visit), and collect a small amount of your baby's saliva (almost 1 teaspoon) (by him/her chewing on a cotton swab) to measure the hormone oxytocin.
7. If you are in the massage group, you will be video recorded at study visits as you show us how you give your baby the massage at each.
8. In both groups, at the 3rd (final) visit, we will video record you talking and playing with your baby for 4 minutes. From the video recordings we measure how you and your baby communicate.
9. At study visits, you will complete questionnaires about your mental health (past and current), stressful experiences (past and current), drug/alcohol/medication use, current health of you and your baby, your birth experience, parenting, and how you feed your baby. From you and your baby's medical record, we will collect information about the pregnancy and birth. We will include in our data analysis your scores from the Adverse Childhood Experiences questionnaire that was used in the screening process.

10. When your baby is 6 months old, we will call with a few questions about you and your baby. Then you will be finished with the study.

How long will I be in this study?

- The 1st study visit in pregnancy will take about 1 hour.
- The teaching visit will occur within 7 days after giving birth. We will visit with you in the College of Nursing for about 1 hour to teach you how to care for your baby.
- During the 1st 3 months after birth, we will give you a brief phone call once per week to check-in and see how you and your baby are doing.
- The study visits at 1, 2, and 3 months after birth last between 1 – 2 hours each.
- If you are in the baby massage group, you will spend 15 minutes per day for 3 months talking, massaging, and rocking your baby.
- The phone call at 6 months after birth will take about 15 minutes.

How many people will take part in this study?

Approximately 300 mothers (and their babies) will take part in the study.

What benefits can I expect from being in this study?

We cannot promise any benefits to you or your baby from taking part in this research. We hope that your participation in the study may benefit other people in the future by helping us learn more about how baby massage affects how mothers and babies communicate with each other.

What risks, side effects or discomforts can I expect from being in the study?

This is minimal risk research.

Physical risks:

Risks associated with your blood draw may include discomfort (common), bleeding or bruising (occasional), fainting (rare), and infection (rare). **Solution:** We use professionals who are experienced with drawing blood.

Risk with questionnaires:

Some people are uncomfortable or anxious when completing questionnaires about mood, health, or stress. **Solution:** While completing our questionnaires, you can tell the researcher that you feel uncomfortable or do not want to answer a question. Additionally, you may choose to complete the questionnaire in the privacy of your own home.

If you let us know or the questionnaires show that you are having feelings of depression/anxiety, we will help you with obtaining a referral from a social worker, a community mental health service provider, or your primary care provider. If an emergency occurs, we will disclose information to the appropriate people to help you and others within

the emergency. Additionally, we have a responsibility to help children experiencing neglect or abuse by referring the information to the appropriate people.

Risk of loss of confidentiality:
A risk of participating in research is a loss of privacy (revealing to others that you are taking part in this study) or confidentiality (revealing information about you to others to whom you have not given permission to see this information). **Solution:** We take your privacy seriously and will do all we can to prevent a loss of confidentiality. All data we collect will be assigned a code without any information that can directly identify you. Electronic data will be securely stored on password-protected databases on a secure computer system at the University of Arizona. Paper data will be stored in a locked cabinet in a locked office in the College of Nursing.

Risks with giving blood and saliva samples:
While the risks to you and your family are very low, we are not able to know all of the risks from taking part in research with blood and saliva. **Solution:** Your privacy will be protected to the fullest extent possible. While this study uses your DNA to measure how the oxytocin receptor gene is regulated, this study does NOT use your DNA to generate any genetic information about your past, present or future health risks. A Federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. Be aware that this Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

What other choices do I have if I do not take part in this study?

Your participation is voluntary. The procedures in this research (baby massage, safe infant care education, and measuring oxytocin biomarkers) are experimental and separate from the standard of care that you receive from your health care provider; although your health care provider may provide some type of education on safe infant care. As there are no other alternative treatments, services, or procedures, the alternative is to decide not to participate in the study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with your health care providers or The University of Arizona. If you are a student or employee at the University of Arizona, your decision will not affect your grades or employment status.

When may participation in the study be stopped?

You have the right to withdraw your consent and leave the study at any time without penalty. If you choose to no longer be in the study and you do not want any of your future health information to be used, you must inform Dr. Bell in writing at the address below. Dr. Bell may still use your information that was collected prior to your written notice. The researchers and

sponsor also have the right to stop your participation in this study without your consent if:

- you no longer meet inclusion criteria (e.g. a preterm birth);
- you were to object to any future changes that may be made in the study plan.

What are the costs of taking part in this study?

There are no costs to you for participating in this research study, except for your time. The instruction and guidance on baby care or multisensory baby massage and laboratory analyses of the oxytocin system are performed for research only and are provided at no charge to you or your insurance company.

Routine medical care performed while participating in the study will be billed to you and/or your insurance company. This will include (but is not limited to) all physical exams, labs, and administration of medications, and the treatment of side effects.

Not all insurance companies are willing to pay for services performed in a clinical trial. You will be responsible for any charges that your insurance does not cover including regular co-payments and deductibles. Please speak with your insurance company to find out what you may be financially liable for. However, there are no charges associated with this study.

Will I be paid for taking part in this study?

You will receive $50 cash before you leave each study visit, and you will receive $100 cash at the final study visit (at 3 months after birth). If you complete the study from start to finish, you will have received a total of $300 cash. If you do not finish the study, you will only be compensated for the visits you have completed. Compensation for participation in a research study is considered taxable income for you. We are required to obtain your name, address, and Social Security number for federal tax reporting purposes. If your compensation for this research study or a combination of research studies is $600 or more in a calendar year (January to December), you will receive an IRS Form 1099 to report on your taxes. Please note, if you are an employee of UArizona, any compensation from a research study is considered taxable income. If you want to participate in this study but choose to not provide your SSN, you may participate but will not be provided compensation.

Will my data or specimens be stored for future research?

All identifiers will be removed from data with private information. After removal, the de-identified information may be used for unspecified future research studies without additional informed consent.

After the study is over, video recordings will be destroyed 6 years later, and any left-over blood/saliva samples (stored frozen in locked laboratories at University of Arizona) will also be destroyed 6 years later. Blood/saliva samples and video recordings are the property of the University of Arizona and they are not labeled with any identifying information other than a

special code. Samples will not be labeled with your name, your baby's name, or any other identifying information. These stored blood/saliva samples may be used to allow for additional analyses of the oxytocin system (and childbirth-related or stress-related biomarkers) in future research conducted by our research team.

Permission for future contact:

After this study ends (with a phone call at 6 months after birth) we might like to contact you with additional questions (for example about parenting) as your baby gets older or about research projects related to this study. Your decision does not affect participating in this current study.

Researchers from this project can contact me about future research.

☐ I agree - Initials _____.

☐ I DO NOT agree - Initials _____.

Will my specimens be sold for commercial profits?

No, the specimens used in this research will not be shared with outside organizations and will not be sold for any kind of commercial profit.

Will I hear back on any results that directly impact me?

Results will not be shared since there are no diseases/medical problems that our tests identify.

Will Whole Genome Sequencing be done with my specimen?

No, there will be no whole genome sequencing.

Will my study-related information be shared, disclosed, and kept confidential?

Efforts will be made to keep your personal information confidential; however, we cannot guarantee absolute confidentiality. In general, information about you, or provided by you, during the research study, will not be disclosed to others without your written permission. However, laws and university rules might require us to tell certain people about you. For example, study information which identifies you and the consent form signed by you may be looked at and/or copied for quality assurance and data analysis include:

- Research consultants specializing in infant massage and in measuring synchrony
- Office for Human Research Protections, Food and Drug Administration, or other federal, state, or international regulatory agencies
- The University of Arizona (UA) and the UA Institutional Review Board
- The sponsor and/or funder supporting the study, their agents or study monitors

Who can answer my questions about this study?

If at any time you feel you have had a research-related injury, or for questions, concerns, or complaints about the study you may contact the Principal Investigator Dr. Aleeca Bell at 520-621-8348 or Mothers-Babies@arizona.edu.

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact the Human Subjects Protection Program at 520-626-8630 or online at http://research.arizona.edu/compliance/human-subjects-protection-program.

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

Signing the consent and parental permission form

I have read (or someone has read to me) this form, and I am aware that I am being asked to participate in a research study, and give permission for my infant to participate after birth. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study, and give parental permission for my infant after birth to participate**.** I am not giving up any legal rights by signing this form. I will be given a signed copy of this form**.**

Printed name of subject	Signature of subject	Date

Investigator/Research Staff

I have explained the research to the participant or the participant's representative before requesting the signature(s) above. There are no blanks in this document. A signed copy of this form has been given to the participant or to the participant's representative.

Printed name of person obtaining consent	Signature of person obtaining consent	Date

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