Official Title: Using Digital Health Technologies to Prevent Obesity Among Infants of Parents Receiving Nutrition Assistance Benefits

NCT06319807

IRB Approval Date: 04/02/2025

ADVOCATE HEALTH

Wake Forest University School of Medicine

GrowWell: Using digital health technologies to support parents of infants receiving nutrition assistance benefits.

Informed Consent Form to Participate in Research
ADULT
Melissa Kay, PhD. Principal Investigator

SUMMARY

You are invited to participate in this study. The purpose of this study is to develop and test a digital intervention. We want to see if it can support parents and caregivers in their decisions to care for their infants. You are invited to be in this study because you have a newborn and are using a bottle to feed your baby. Your participation in this research study will involve:

1. Participating in a text messaging intervention for up to 12 weeks.
2. Participating in one interview online or on the phone, at the end of the intervention.
3. Optional participation in a video observation of infant feeding.

The study will take about three (3) months to complete.

All research studies involve some risks. However, the risks for participating in this study are minimal and there are no physical risks.

Your participation in this study is voluntary. You do not have to participate in this study if you do not want to. You will not lose any services, benefits, or rights you would normally have if you choose not to participate.

The remainder of this form contains a more complete description of this study. Please read this description carefully. You can ask any questions if you need help deciding whether to join the study. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study please contact the Principal Investigator, Dr. Melissa Kay, at [redacted]

If you have any questions, suggestions, or concerns about your rights as a volunteer in this research, contact the Institutional Review Board at [redacted] or the Wake Forest University Health Sciences Research Subject Advocate at [redacted].

INTRODUCTION

You are invited to be in a research study. Studies help principal investigators learn new information that may help other people in the future. You are being asked to be in this study because you have a newborn and you are using a bottle. Your participation is voluntary. You do not have to be a part of this study if you do not want to. Please take your time in making your decision if you would like to join. Ask the principal investigators and research assistants to explain any words or information in this informed consent document that you do not understand. You may also discuss the study with your friends and family.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to learn more about a program designed to help address the needs of parents and caregivers using a bottle to feed their baby. We want to test a new digital health tool to see if it helps caregivers when feeding their infants as a way to support healthy growth. With this knowledge, we can develop better ways to support families when feeding their babies.

WHO IS SPONSORING THIS STUDY?

This study is being sponsored by the Department of Pediatrics at Atrium Health Wake Forest Baptist.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

Up to 60 mothers will take part in this study.

HOW LONG WILL I BE IN THE STUDY?

You will be in the study for approximately 3 months. With your permission, we may also contact you about additional study interviews as your child gets older. You are free to participate or to decline this interview and any future interviews at any time. You can choose to stop participating at any time without penalty or loss of any benefits to which you are entitled.

WHAT IS INVOLVED IN THE STUDY?

If you take part in this study, you will participate in the following activities:

Activity	During this activity, you will	How long is this activity?
Complete surveys	• The surveys are about yourself and your thoughts on how you feed your baby. • We will send a link to these surveys in email and text message. • If you would like, the research team can schedule a call with you via phone based on your preference to complete these surveys.	Once at the beginning and once end of the intervention for about 30 minutes.
Interact with text messages	• You will participate in an interactive text messaging program focused on supporting you in feeding your child.	Every day for about 1 minute.
Video a feeding	• Participate in two scheduled feedings where either Microsoft Teams or Webex will be used to record your feeding session with your baby	Once at the beginning and end of the intervention for about 30 minutes.
Complete an interview	• Participate in one interview online or on the phone upon completion of the program.	30 minutes

You will be randomized into one of the study groups. One group will receive messages about feeding and soothing and the other will receive messages about feeding and safety. Randomization means that you are put into a group by chance. It is like flipping a coin.

WILL I RECEIVE THE RESULTS OF THE STUDY?

Clinically relevant results of this research will be communicated with you via email at the end of the study upon analysis and write up.

What are the risks of the study?

There are no physical risks to you for being in this research. Taking part in this research study may involve providing information that you consider confidential or private. Efforts, such as coding research records, keeping research records secure and allowing only authorized people to have access to research records, will be made to keep your information safe. You may discuss the risk of being in this study with the study staff.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this study, there may or may not be direct benefit to you. We hope the information learned from this study will benefit other people in the future. The benefits of participating in this study may be learning new information about how parents feed their baby.

WHAT OTHER CHOICES ARE THERE?

You may choose not to participate in this study.

WHAT ARE THE COSTS?

There are no costs to you for being in this study. However, there may be costs involved in text messages sent or received, depending on your mobile carrier and plan.

WILL YOU BE PAID FOR PARTICIPATING?

You will receive reimbursements in the form of Walmart gift cards, we will offer $25 at the first data collection visit and $35 at the 2nd data collection visit at the end of the pilot study. You will receive $20 for each completed recorded video feedings (up to two) if you choose to participate. You may also participate in an interview at the end of the study to understand what it was like participating in the study and ways to improve the intervention. If you participate in this interview, you will receive an additional $30 in the form of a Walmart gift card.

WILL YOUR RESEARCH RECORDS BE CONFIDENTIAL?

Your participation in this research and any study records created about your participation will be kept as confidential as possible. The overall results of this study may be presented at scientific or medical meetings or published in scientific journals. Your identity will not be shared unless is required by law to protect you or others.

Your information may be provided to Federal and other regulatory agencies as required.

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 Web site at any time.

I give permission to Advocate Health - Wake Forest University School of Medicine, and their respective affiliated entities and representatives (including third-party agents if applicable) to contact me by text message at the number I provided to send information, reminders, and to communicate with me about the research study. I understand that I am responsible for the standard text message rate of my carrier. I also understand that text messaging is not a secure form of communication and I accept the risk that individuals not involved in the research study may be able to access the text messages. I also understand that texting is not to be used for emergency situations.

By providing my email address, I give permission for Advocate Health, Wake Forest University School of Medicine, and their respective affiliated entities and representatives (including third-party agents if applicable) to send me information, reminders, and messages about the research study by email. I understand that these email messages may not be encrypted, and I understand and accept the risks that individuals not involved in the research study may be able to access unencrypted email messages. I also understand that email is not to be used for emergency situations.

WHO WILL SEE MY PROTECTED PERSONAL INFORMATION?

Who may have access to my information:	*Purpose:*
Principal investigator and approved study staff.	To oversee the study and make sure the information is correct.
Consultants and employees of Advocate Health – Wake Forest University School of Medicine, including IRB members.	To protect the rights and safety of subjects and make sure the study information is correct.
Organizations that regulate research (such as the FDA, Office for Human Research Protections (OHRP), or similar government agencies in the US and other countries).	To make sure applicable laws are being followed.
Monitors, auditors, IRB or other regulatory agencies may be granted direct access to your medical record.	To verify clinical trial procedures or data.

By signing this form, you are giving the principal investigators permission to use and share your personally identifiable information.

Please note that the principal investigator or study staff may also share personal information about you if required by law (for example, if the principal investigator or study staff suspects that you are going to harm someone or yourself). If you have questions about this, please ask the principal investigator.

How will my information be used for this study?
You must authorize the use and sharing of your information by signing this form or you cannot be in the study.

WFU School of Medicine
Institutional Review Board
IRB Number:IRB00110194
Meeting Date Approved 4/2/2025
Version Valid Until: 4/1/2026

The study principal investigator and study staff will collect, use, and share identifiable health information about you for the following reasons:

- to conduct this research study.
- to review the study, and to check the safety and results of the study.

Information used and shared may include:

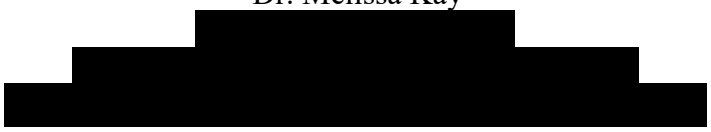
- your name, telephone number, email address
- information collected from text messages, surveys and interviews as part of the study.

How will my information be kept confidential?
We will keep your personal health information as confidential as possible. Your identity will be protected as required by law and according to any policies described in the study consent form. Principal investigators may share your information with representatives and agents of the sponsor(s) for the purposes of managing and overseeing the study. Usually, the health information sent to sponsors does not directly identify participants (for example, by name or address). Instead initials and a code number are used. Some personal information, such as date of birth, will usually be included but will not be used to identify you.

Once your information leaves the organization we cannot control how it is used, and the law may not require other groups to protect the privacy of your information.

How do I cancel my authorization?
You can cancel your authorization to use and share your information at any time by writing a letter to the principal investigator. If you cancel your authorization, you will not be able to continue in the study. If some aspects of the study were optional, you may cancel your authorization for the optional part(s) of the study and still remain in the main study.

Dr. Melissa Kay



If you cancel your authorization, no new information will be collected without your permission. The principal investigator and study staff will still be able to use and share your information that has already been collected to maintain the integrity of the study.

When will my authorization expire?
This authorization to use and share your information expires one year after the end of the research study when data analysis is complete, and study records have been destroyed.

If study information is used for scientific publications or educational purposes, all identifying information will be removed.

WHAT ARE MY RIGHTS AS A RESEARCH STUDY PARTICIPANT?

Taking part in this study is voluntary. You may choose not to take part, or you may leave the

study at any time. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences. The investigators also have the right to stop your participation in the study at any time. This could be because it is in your best interest, new information becomes available, you failed to follow instructions, or because the entire study has been stopped. Information that identifies you may be removed from the data or specimens that are collected as part of this study and could be used for future research or shared with others without additional consent.

You will be given any new information we become aware of that would affect your willingness to continue to participate in the study.

You may be asked to complete a survey about your experiences participating in a research study.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or in the event of a research-related injury, contact the principal investigator, contact Dr. Kay at [redacted] during regular business hours.

The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, or you would like to discuss problems or concerns, have questions or want to offer input, or you want to obtain additional information, you should contact the Chairman of the IRB at [redacted] or the Research Subject Advocate at [redacted].

You will have the opportunity to download a copy of this consent form after completion of the first survey.

SIGNATURES

- I have read this form and the research study has been explained to me.
- I have had ample time to consider participation in the study and have been given the chance to ask questions, and my questions have been answered. I have been told who to call if I have more questions.
- I understand the research study and voluntarily agree to be in the research study described above.
- I will receive a copy of this consent form after I sign it. A copy will be put in my study record.
- I am not giving up any of my legal rights by signing this form.
- I agree to follow the investigator's instructions.
- I understand and agree that representatives from the sponsor, regulatory authorities and the institutional review board will be granted direct access to my private information records.
- I understand that I may decide to refuse participation or stop participating at any time without penalty and without affecting the quality of my health care or the relationship with the principal investigator.
- I understand that there may be consequences to my withdrawal from the study as noted within this document.

WFU School of Medicine
Institutional Review Board
IRB Number:IRB00110194
Meeting Date Approved 4/2/2025
Version Valid Until: 4/1/2026

- I understand and agree that personal information about me will be collected in this study and used and processed (manually and by computer) for the purposes of the study by the manufacturer of a medical device used in my treatment or any other designated party that is involved in the study (e.g. hospital, principal investigator, regulatory authorities, ethics committees).
- If I so choose, I have provided the name of a person to be contacted by the principal investigator in case I cannot be reached for follow-up.

_____
Participant Name

_____
Participant Signature Date Time am/pm

For Site Use only:
By agreeing to participate I certify the following:

- The subject has been given enough time and an adequate place to read and review this form.
- All elements of the study, as contained in this document, were explained, and discussed with the subject or his/her legally authorized representative **before** research-related procedures began.
- The subject has had a chance to ask questions and receive answers about this study.
- The subject expressed understanding of the study.
- The subject/LAR will receive a copy of the signed and dated consent form/authorization.

_____
Name of person obtaining informed consent

_____
Signature of person obtaining informed consent Date Time am/pm