Title: Consent Form

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Consent for Research Participation

Research Study Title: Enhancing child digital dietary self-monitoring: Proof-of-concept trial

Researcher(s): Lauren Griffiths, MPH, Department of Nutrition, University of Tennessee, Knoxville
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Why am I being asked to be in this research study?

We are asking you to be in this research study because you have a child between 8-12 years.

What is this research study about?

The purpose of the research study is to test the usability, acceptability, and preliminary efficacy of a digital dietary self-monitoring (DSM) log that has been created for children. The log uses positive reinforcement strategies that may improve children's DSM.

How long will I be in the research study?

If you agree to be in the study, your participation will last for approximately 5 weeks and will involve two study visits (one in-person and one virtually) and up to one additional phone call.

What will happen if I say "Yes, I want to be in this research study"?

If you agree to be in this study, your family will be asked to attend two study visits, one in-person visit before you get started and one virtual visit after the 4 weeks of DSM is over. During your first visit, which will take place at the Healthy Eating and Activity Laboratory at the University of Tennessee (UT), you will be asked to complete some questionnaires about your family's demographics and your parenting style, and your child will be asked to complete some questionnaires about their motivation to engage in DSM, their motivation to eat healthfully, and their dietary intake. We will also measure your child's height and weight.

Once these measures are complete, you will be told to which study group you have been randomly assigned, and your family will receive brief training on how to use the features of a web-based DSM log. Your family will be randomly assigned to one of the following groups: Standard Group (standard DSM log), Praise Group (DSM log with caregiver praise), Game Group (DSM log with gamification), or Praise+Game Group (DSM log with caregiver praise and gamification).

If your family is assigned to Standard Group, your child will be asked to track their intake of fruits, vegetables, sweet and salty snack foods, and sugary drinks in the web-based DSM log for 4 weeks. Your child will be provided with a personal URL to access their log, which can be accessed from any internet-capable device (computer, phone, etc.). You will be asked to review your child's log each day and complete a caregiver check-in. You will receive a separate URL that allows you to view your child's log and complete check ins. To help get your child started, you will be instructed to sit with your child for the first 3 days of tracking to help with logging. If no

logging or caregiver check ins have been completed within the first 4 days of your family's DSM period, a research assistant will reach out to you to problem solve and provide support.

If your family is assigned to the Praise or Praise+Game Group, you will also be asked to provide praise to your child for engaging in DSM over the 4 weeks. During your first study visit, you will be provided with brief training on how to provide a type of praise called process praise. Additionally, when you complete caregiver check-ins in the DSM log, you will receive a prompt to also complete a praise check-in. If no praise check-ins are completed within the first 4 days of the DSM period, a research assistant will reach out to you to problem solve and provide support.

If your family is assigned to the Game or Praise+Game Group, your child's log will also include a virtual pet that evolves over time as your child uses the log. During your first visit, research staff will explain how points are accrued when using the log. As your child earns points, the pet will level up and grow over time.

During the week following your child's 4-week DSM period, you will be asked to attend a virtual visit to complete follow-up measures. During this visit, your child will again be asked to complete questionnaires about their motivation to engage in DSM, their motivation to eat healthfully, and their dietary intake. Additionally, you and your child will complete a short usability and acceptability survey to capture your experiences using the DSM log. During this visit, your family will also receive feedback on your child's dietary intake based on their DSM log. Days for which tracking was marked as completed will be used to calculate your child's daily servings of fruits and vegetables and daily intake of added sugars and saturated fats from sugar-sweetened beverages and sweet and salty snack foods. You will receive feedback that compares your child's intake to the recommendations in the Dietary Guidelines for Americans 2020-2025. Additionally, your family will be provided access to a short online behavioral nutrition education program that will consist of four short modules covering basic nutrition and behavioral change strategies.

What happens if I say "No, I do not want to be in this research study"?

Being in this study is up to you. You can say no now or leave the study later. Either way, your decision won't affect your relationship with the researchers or the University of Tennessee.

Instead of participating in the study, possible options available to you include talking to your child's primary care provider about ways to improve your child's diet.

What happens if I say "Yes" but change my mind later?

Even if you decide to be in the study now, you can change your mind and stop at any time.

If you decide to stop before the study is completed, please contact Lauren Griffiths (email: lgriff31@vols.utk.edu, phone: 865-974-0752) and let her know that you would no longer like to participate. Any information already collected for the research will be returned to you, if you request it. If you do not request for your data to be returned to you, any data already collected will be kept and used for analysis.

Are there any possible risks to me?

It is possible that someone could find out you were in this study or see your study information, but we believe this risk is small because of the procedures we use to protect your information. These procedures are described later in this form.

Dietary self-monitoring may increase your awareness of eating behaviors in your child that do not match current recommendations. Additionally, feedback received at the end of the study may not accurately reflect your child's nutrition status if self-monitoring is very inaccurate and/or insufficient.

Are there any benefits to being in this research study?

We do not expect you to directly benefit from being in this study. Your participation may help us to learn more about helping children engage in DSM. We hope the knowledge gained from this study will benefit others in the future.

Who can see or use the information collected for this research study?

We will protect the confidentiality of your information by removing any identifying information that would connect you to your data and responses. Your paper data will be stored in locked filing cabinets in private laboratory spaces, and any documents with identifying information (like this consent form) will be stored separately from your research data so that it cannot be connected to you. Data collected electronically will be collected using REDCap, a secure web platform. DSM data entered into your child's log will be stored in a UT-affiliated Google Drive, for which data is encrypted at rest, on the server, and in transit. Any other digital data that is created will be stored on UTK's secure servers.

If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

We will make every effort to prevent anyone who is not on the research team from knowing that you gave us information or what information came from you. Although it is unlikely, there are times when others may need to see the information we collect about you. These include:

- People at the University of Tennessee, Knoxville (UTK) who oversee research to make sure it is conducted properly.
- Government agencies (such as the Office for Human Research Protections in the U.S. Department of Health and Human Services), and others responsible for watching over the safety, effectiveness, and conduct of the research.
- If a law or court requires us to share the information, we would have to follow that law or final court ruling.
- Business offices at the University of Tennessee, Knoxville may be given name and address to issue your payment and report tax information.
- A description of this study will be posted on a public website, http://ClinicalTrials.gov, and summary results of this study will be posted on this website at the conclusion of the research. No information that can identify you will be posted.

What will happen to my information after this study is over?

We may keep your information to use for future research. Your name and other information that can directly identify you will be kept secure and stored separately from your research data collected as part of the study.

We may share your research data with other researchers without asking for your consent again, but it will not contain information that could directly identify you.

Will I be paid for being in this research study?

You will receive two $25 gift cards to Walmart, one for you and one for your child, after completing measures at your final study visit. These will be mailed to you upon completion of your visit.

Will it cost me anything to be in this research study?

If you agree to be in this study, the only potential costs to you will be any charges you may incur related to data usage on mobile devices.

What else do I need to know?

We may need to stop your participation in the study without your consent. If your child's DSM log is not used (self-monitoring or check-ins) within the first 4 days of the DSM period, a research assistant will reach out to you to problem solve and provide support. We will attempt to contact you 3 times. If we are unable to reach you after 3 contact attempts, you will be removed from the study.

If we learn about any new information that may change your mind about being in the study, we will tell you. If that happens, you may be asked to sign a new consent form.

Who can answer my questions about this research study?

If you have questions or concerns about this study, or have experienced a research related problem or injury, contact the researchers, Lauren Griffiths, lgriff31@vols.utk.edu, 865-974-0752 or her advisor Dr. Hollie Raynor, hraynor@utk.edu, 865-974-9126, ext. 1.

For questions or concerns about your rights or to speak with someone other than the research team about the study, please contact:

Institutional Review Board
The University of Tennessee, Knoxville
2240 Sutherland Ave., Suite 2
Knoxville, TN 37919
Email: utkirb@utk.edu
Phone: 865-974-7697

STATEMENT OF CONSENT

I have read this form and the research study has been explained to me. I have been given the chance to ask questions and my questions have been answered. If I have more questions, I have

been told who to contact. By signing this document, I am agreeing to be in this study. I will receive a copy of this document after I sign it.

Name of Adult Participant	Signature of Adult Participant	Date

Researcher Signature (to be completed at time of informed consent)

I have explained the study to the participant and answered all of his/her questions. I believe that he/she understands the information described in this consent form and freely consents to be in the study.

Name of Research Team Member	Signature of Research Team Member	Date