



University at Buffalo Institutional Review Board (UBIRB)

Office of Research Compliance | Clinical and Translational Research Center Room 5018
875 Ellicott St. | Buffalo, NY 14203
UB Federal wide Assurance ID#: FWA00008824

Title of research study: *Study of Nutrition and Activity in Kids (SNAK)- Part 2* **Version Date:** July 2020
Investigator: *Jennifer L. Temple, PhD*

Key Information: The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.

Why am I being invited to take part in a research study?

You are being invited to take part in a research study because you have completed Part 1 of the UB SNAK study. You have expressed a willingness to have your body composition measured, to answer questionnaires on each visit, and to participate in a game to earn food rewards during appointments. You are also willing to attend up to three (90min) follow up appointments (every 9 months).

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?

The purpose of the study is to determine how repeated intake of snack foods affects adolescents' food preferences and if those food preferences lead to long term changes in weight. Adolescence is a time of major physical and mental developments, so it is important to understand how different factors contribute to weight. There is no direct benefit to the participant, but participants get the opportunity to learn about scientific research.

How long will the research last and what will I need to do?

We expect that you will be in this research study for three 90minute visits over 18 months (9 months apart). You are not being asked to re-consented as an adult, should they wish to continue in this study. You will be asked to have height and weight measurements taken and answer surveys at each appointment. More detailed information about the study procedures can be found under **"What happens if I say yes, I want to be in this research?"**

Is there any way being in this study could be bad for me?

There are no significant risks associated with these procedures, although you may feel uncomfortable or embarrassed while answering questionnaires for the pubertal assessment (on paper), or while having body composition measured in the BodPod room. More detailed information about the risks of this study can be found under **"Is there any way being in this study could be bad for me? (Detailed Risks)"**

Will being in this study help me in any way?

There are no benefits to you from your taking part in this research other than the possibility of gaining insight into the scientific process. We cannot promise any benefits to others from your taking part in this research. However, possible benefits to others include helping the scientific and health community know more about what is important to adolescent eating, nutrition, activity, and health.

What happens if I do not want to be in this research?

Your participation in this research study is voluntary. You may choose not to enroll in this study. Your alternative to participating in this research study is to not participate.

Detailed Information: The following is more detailed information about this study in addition to the information listed above.

Who can I talk to?

If you have **questions, concerns, or complaints, or think the research has hurt you**, talk to the research team at (716) 829-2022 or NHRLab@gmail.com. You may also contact the research participant advocate at (716) 888-4845 or researchadvocate@buffalo.edu.

This research has been reviewed and approved by an Institutional Review Board ("IRB"). An IRB is a committee that provides ethical and regulatory oversight of research that involves human subjects. You may talk to them at (716) 888-4888 or email ub-irb@buffalo.edu if:

- You have questions about your rights as a participant in this research
- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You want to get information or provide input about this research.

How many people will be studied?

We expect about 180 people in this research study.

What happens if I say yes, I want to be in this research?

- At each visit you will interact with a trained research assistant.
- All research will be conducted in the Nutrition and Exercise Science Department at UB South campus, in rooms Farber G62, and the BodPod Room (Kimball 119/120).
- Your data and survey responses will be kept confidential and not shared with one another.
- **Once you have turned 18 and are asked to re-consent as an adult, the parent components of each appointment become optional (see below).*

Appointment 10 (90min, ~33 months after initial appointment, ~ 9 months from visit 9)

The Parent will:*

1. Complete the consent process
2. Complete the pubertal assessment, eating questionnaires, child feeding questionnaires, a health change form, a contact form, and have their height and weight measured.
3. Be paid for their participation

The child will:

1. Complete the assent process
2. Complete the pubertal assessment, stress questionnaire, eating questionnaires, physical activity questionnaire, sleep questionnaires, and adolescent risk questionnaire
3. Have their body composition measured
4. Have their heart rate and blood pressure measured
5. Provide a recall of previous 24-hour diet and physical activity
6. Be paid for their participation

Appointment 11 (90min, ~42 months after initial appointment, ~ 9 months from visit 10)

The Parent will:*

1. Complete the pubertal assessment, eating questionnaires, child feeding questionnaires, a health change form, and have their height and weight measured.
2. Be paid for their participation

The child will:

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1. Be asked not to eat or drink anything other than water for 2 hours prior to the appointment
2. Complete the pubertal assessment, stress questionnaire, eating questionnaires, physical activity questionnaire, sleep questionnaires, and adolescent risk questionnaire
3. Have their body composition measured
4. Have their heart rate and blood pressure measured
5. Provide a recall of previous 24-hour diet and physical activity
6. Be asked to play a computer game for a snack food reward or activity time
7. Be paid for their participation

Appointment 12 (90min, ~51 months after initial appointment, ~ 9 months from visit 11)

The Parent will:*

1. Complete the pubertal assessment, eating questionnaires, child feeding questionnaires, a health change form, a contact form, and have their height and weight measured.
2. Be paid for their participation

The child will:

1. Complete the pubertal assessment, stress questionnaire, eating questionnaires, physical activity questionnaire, sleep questionnaires, and adolescent risk questionnaire
2. Have their body composition measured
3. Have their heart rate and blood pressure measured
4. Provide a recall of previous 24-hour diet and physical activity
5. Be paid for their participation

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible for: answering surveys about growth and development, eating, activity, sleep, and health. You will also have your height, weight, and body composition measured.

What happens if I say yes, but I change my mind later?

You can leave the research at any time it will not be held against you.

Is there any way being in this study could be bad for me? (Detailed Risks)

There are no significant risks to participating, although you may feel uncomfortable or embarrassed while answering questions, for the pubertal assessment (on paper), or while having your body measured.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical or education records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization. Your responses to surveys will not be disclosed to parents. You may be notified only under the rare circumstance in which responses suggest you may be in danger. Data from this study will be de-identified once your participation is complete. If identifiers are removed from your identifiable information, that information could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent. All data is stored, without identifiers in a password protected database at the University at Buffalo.

Can I be removed from the research without my OK?

The principal investigator of the study can remove your child from the research study without your approval, however this is not likely. One possible reason for removal includes frequently missed appointments.

What else do I need to know?

Who is paying for this research?

This research is being funded by the National Institute of Diabetes and Digestive and Kidney Diseases.

Will I get paid for my participation in this research?

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If you agree to take part in this research study, we will pay parents/guardians \$10 for each appointment, to help offset the cost of travel. You will earn up to \$90 over the course of the study. Should you need to end participation in the study, payment will be prorated based on what you have completed. The breakdown of earnings by visit is: V10 (\$30), V11 (\$30), V12 (\$30).

Payments that you receive for your participation in this research are considered taxable income. If the amount of payment that you receive reaches or exceeds \$600.00 in a calendar year, you will be issued a form 1099. Also, in order to support the involvement of families that may not have personal transportation available, we will reimburse the public travel cost of the parent, participant, and any siblings under 16 years of age that must travel with the parent to the appointment. The travel must be completed via NFTA bus or rail, on the date of appointment, and a receipt must be rendered in exchange for cash reimbursement for the fare. Those that have unlimited monthly NFTA passes will not be reimbursed.

Signature Block for Adult Consent

Your signature documents your permission for yourself to take part in this research. By signing this form you are not waiving any of your legal rights, including the right to seek compensation for injury related to negligence or misconduct of those involved in the research.

Printed name of participant

Signature of participant

Date

I certify that the nature and purpose, the potential benefits and possible risks associated with participation in this research study have been explained to the above individual and that any questions about this information have been answered. A copy of this document will be given to the subject.

Signature of person obtaining consent

Date

Printed name of person obtaining consent