Nutrition and Cognitive Function in Preadolescents

NCT02636998

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CONSENT AND HIPAA FORM

STUDY TITLE:	Nutrition and Cognitive Function in Preadolescents
PRINCIPAL INVESTIGATOR:	R. Terry Pivik, Ph.D. 15 Children's Way Little Rock, AR 72202 Phone: 501-364-3346 After Hours: 501-217-8505
CO-INVESTIGATORS:	Aline Andres, Ph.D. Kelly P. Jarratt, Ph.D. Mario A. Cleves, Ph.D.
STUDY SPONSOR:	Arkansas Children's Nutrition Center (ACNC) United States Department of Agriculture (USDA)
STUDY LOCATION:	Arkansas Children's Nutrition Center 15 Children's Way Little Rock, AR 72202

The following information is provided to tell you about the research study and your participation in the study. Please read this form carefully. Feel free to ask any questions you may have about the study and the information below. You will be given a chance to ask questions and your questions will be answered. You will be given a signed copy of this consent/HIPAA (Health Insurance Portability & Accountability Act) form.

Purpose of the Research: This is a research study conducted by the Principal Investigator Dr. Terry Pivik and his Co-Investigators at the Arkansas Children's Nutrition Center. We plan to enroll 140 children, between 9 and 10 years of age and their mothers.

You and your child are being invited to take part in this research study which is designed to evaluate cognitive function in preadolescents who have different body types as determined by height and weight measurements.

Study Visits: We plan to conduct all study procedures at ACNC. You will be asked to attend two study visits at ACNC.

1. **Visit 1 – Phase A:** The first part of the visit will be conducted at the ACNC and last about 2½ hours. During this visit we will obtain consent/assent and then confirm eligibility with a few questions and with the assessments listed below. If your child does not meet the required criteria, he/she will be released from the study and you will be provided with the compensation for this visit. If your child continues to qualify, we will proceed with Phase B.
    a. We will assess the following with your child:

i. Height/weight/head circumference measurements
ii. Vision
iii. Hearing
iv. Handedness
v. Arithmetic Performance
vi. Intelligence Quotient (IQ) test

b. We will ask you to provide the following information
i. Background information
ii. Eating questionnaire – report how your child is eating
iii. Sleep questionnaire – report how your child is sleeping
iv. With your permission, we will request a release of medical information from your OB/GYN's office in order to obtain additional information on your pregnancy with the participant including weight gain during pregnancy and gestational age. There will be a separate release that you may sign. We will also ask you what your weight gain and gestational age were for your pregnancy in the event we are unable to receive the records from your OB/GYN office.

2. **Visit 1 – Phase B:** This part of the visit will last about 2 hours. The following body composition and standardized tests will be administered:
a. For your child:
i. A BodPod measure will be obtained to determine how much muscle and fat your child has. The BodPod is a large, egg-shaped device with a seat and a sealed window. This assessment takes 2-5 minutes to complete.
ii. We will also have your child take developmental, cognitive, and behavioral tests (such as, mental health and personality evaluations), appropriate for his/her age.
iii. Hand scan
b. For you:
i. Intelligence Quotient (IQ) test
ii. Questionnaires about your child's mental health and emotional well-being

3. **Visit 2:** You and your child will stay overnight at the ACNC and a prepackaged dinner will be provided for your child to consume that evening. We will also ask your child to complete a physical activity questionnaire. An actigraph watch will also be provided to be worn on your child's wrist on the night before the visit to ensure adequate sleep is obtained. Upon awakening, a mouth swab will be obtained from your child and again within 30 minutes to measure cortisol awakening response. A third sample will be taken following the brain function recordings. We will attempt to collect a blood sample. We may collect up to 15ml total (~1/2oz). These samples may be used to evaluate hormonal status, molecular and metabolic markers (e.g. insulin, leptin, glucose, triglycerides, HDL, LDL, C-reactive protein). A standard breakfast will be provided for your child. Once the sleep data are reviewed, the brain function testing will occur. This

is where information from sensors placed on the skin and head will detect changes in brain waves, heart rate, breathing, skin resistance, eye movements, and muscle activity of your child. Recordings from these sensors will be made as your child is presented with and responds to tones and on-screen stimuli (math problems and letters). Your child can earn up to $12 depending on their answers as an incentive to stay on task. Developmental, cognitive and behavioral tests will also be performed. The morning portion of the visit will take about 4 hours.

If data collection for a study visit has been unsuccessful, some or all parts of a visit may be rescheduled.

Potential Risks Associated with Participation in This Study: There are few expected risks to you and your child for being in this study.

- During the collection of blood, there is a slight amount of pain, the possibility of a bruise (hematoma) and a remote chance of infection. There is also the possibility for your child to feel sick or dizzy.
- The mouth swab may cause minimal but possible discomfort to the participant.
- The cognitive/neuropsychological measures and mental health or personality tests are all standardized tests used routinely in clinical evaluations. These assessments might be associated with mild feelings of boredom or frustration.
- The study rooms in which brain function and other physiological recordings are conducted are small and participants have an array of sensors attached. The brain function recording will be conducted in an unfamiliar room, which may cause mild stress or anxiety. The brain function recordings have been used for several decades with no risks. However, placing the sensors on his or her skin may cause minor irritation or discomfort. These are standard procedures that we and others have used for years.
- The overnight visit will involve staying for an extended time in an unfamiliar room; any stress associated with this may be offset by the presence of the caregiver in the same room, and there will be trained staff on duty throughout the night to address any issues that might come up. The rooms have a design and furnishings similar to a home setting or hotel suite.

- In past studies, a small number of participants have felt anxious or claustrophobic inside the BodPod. This device has a large opening to minimize these feelings. If you or your child become(s) uncomfortable during the test, the test will be stopped.
- A possible risk is the loss of confidentiality about your information. Your health information will be coded with a special number just for you. This information is kept in locked confidential files and a secure database with standard security precautions. There is a risk that someone could get access to the data we have stored about you. There could be other privacy risks we don't know about. We believe the chances these things will happen are very small, but we can't make promises. Your privacy and the confidentiality of your information are very important to us and we will try our best to protect them. More about the protection is described in the section of this consent form labeled "Privacy Disclosure of Participating in this study".

We do not foresee any other risks associated with this study. The procedures are minimally-invasive. If you or your child becomes uncomfortable at any time during the visits, the procedures can be stopped immediately to address any concerns.

Potential Benefits Associated with Participation in this Study: Your child will receive no direct health benefits from participating in the study. However, in the future, other children may benefit from this research. If your child attends a nutrition education session, they could directly benefit from the study.

Alternative to Participating in This Study
You may choose not to participate in the study.

Privacy Disclosure of Participating in This Study
Any personal facts collected during this study will be kept private. The results of this study may be published in a medical journal and/or presented at medical/scientific meetings, but you or your child will not be identified by name. In the incidence of an official audit, representatives of the Institutional Review Board (IRB) at the University of Arkansas for Medical Sciences (UAMS), the Office for Human Research Protections (OHRP), the Arkansas Children's Hospital Research Institute (ACHRI), the Food and Drug Administration (FDA), the United States Department of Agriculture (USDA) or other institutional oversight offices may be given access to research study records and pertinent health records that may contain your or your child's name or other identifying facts. By law, some of our study personnel must release certain information to the appropriate authorities if at any time during the study there is concern that adult or child abuse and/or neglect has possibly occurred or you disclose a desire to harm yourself or others.

Compensation for Participation in This Study: Compensation will be given to the participant's parent/guardian for completion of this study. You will receive a $25 gift card for completing visit 1, Phase A and a $25 gift card for completing visit 1, Phase B, and a $250 gift card/check for completing visit 2. Your child will receive up to $12 depending on their performance in the Brain Lab. Participants who return to the ACNC to complete assessments at a repeat visit may be given an additional $50 gift card. The gift cards will be to Wal-mart or a similar retailer. Meals and snacks will be provided to you and your child. Partially completed visits will be partially compensated. You will not be billed for any part of this study. After visit 2, you will be offered a nutrition education session with an ACNC staff member if you desire to meet with them to discuss your child's diet and physical activity.
Right to Refuse or Withdraw from the Study: Your child's participation in this study is voluntary. You may choose to withdraw permission to continue with this study at any time. If you do, all study related procedures will stop immediately. A decision to refuse to participate in this study or to withdraw from the study will not affect your right to present and/or future medical care.

Reasons You May Not Be Able to Stay in the Study: The investigators conducting this study may remove your child from this study without your consent. Usual reasons for the investigator to remove you/your child from the study are:

- Your child's condition changes in a way that would expose your child to undue risk or make study procedures difficult or impossible to complete.
- You or your child do/does not comply with study-related procedures.
- The study is halted for any reason.

New Information: You will be notified, verbally or in writing if any new information becomes available during this study that, in the opinion of the investigator, might affect your willingness to continue participation in the study.

Questions About This Study: If you have any questions during this study, you should contact Dr. Terry Pivik at 501-364-3346 (office) or 501-217-8505 (after hours). If you have any questions about your rights as a research subject or concerning a research-related injury, you can call an IRB representative at 501-686-5667. Also, you may call this number if you are unable to reach the investigator or wish to speak to someone not directly related to this study. You have not waived any legal right to which you are legally entitled by signing this form.

HIPAA Research Authorization:
To do this research, we need to collect health information about you and your child. We will only collect information that is needed for the research. This may include name, address, date of birth, height and weight, mother's cognitive testing results and information concerning pregnancy, your child's cognitive function, sleep, body composition, emotional well-being, and physiological responses. Being in this research study will create new health information about metabolism. For your child to be in this research study, we need your permission to collect, create, and share this information.

We may share your child's health information with people at the University of Arkansas for Medical Sciences (UAMS), Arkansas Children's Hospital (ACH), and Arkansas Children's Nutrition Center (ACNC) who help with the research or things related to the research process, such as the study staff (including the investigators and research coordinators/assistants), the UAMS Institutional Review Board, and the research compliance offices at UAMS and ACH. Additionally, we may need to share your health information with people outside of UAMS and ACH who make sure we do the research properly, such as the Office for Human Research Protections or the Food and Drug Administration. We believe that those involved with research understand the importance of preserving the confidentiality of your health information. However, some of the people outside of UAMS and ACH may share your health information with someone else. If they do, the same laws that UAMS and ACH must obey may not apply to others to protect your child's health information.

This authorization to collect, use, and share your child's health information expires at the end of the research.

If you sign this form, you are giving us permission to create, collect, use and share your child's health information as described in this form. You do not have to sign this form. However, if you decide not to sign this form, your child cannot be in the research study.

If you sign this form but decide later that you no longer want us to collect or share your child's health information, you must send a letter to Dr. Terry Pivik, whose address is on the first page of this form. The letter needs to be signed by you, should list the "Study Title" listed on this form, and should state that you have changed your mind and that you are revoking your "HIPAA Research Authorization". You will need to leave the research study if we cannot collect and share any more health information from your child. However, in order to maintain the reliability of the research, we may still use and share your information that was collected before Dr. Pivik received your letter withdrawing the permissions granted under this authorization.

If you decide not to sign this form or you change your mind later, this will not affect your child's current or future medical care at UAMS or ACH.

CONSENT TO PARTICIPATE:

Please read the additional, optional choices below and **initial** if you wish to participate. You can still participate in the study we have discussed if you choose not to participate in these additional uses of your information.

Information collected during the study:

_____Yes - By initialing this section, I agree to make accessible my and my child's personal information as well as any data collected in this study for use in other current and future studies related to cognitive function. The data collected will be identified by your study number only and stored in locked areas at the Nutrition Center for a period of 20 years. If you wish to no longer have your data stored, simply send a letter to Dr. Pivik with your name, your child's name, and date of birth.

_____No, I do not agree to allow to make accessible my and my child's personal information as well as any data collected in this study for use in other current and future studies related to cognitive function.

Storage of Samples –You can participate in the study even if you do not choose to provide samples for future research. If you decide later to withdraw permission for use of biological samples collected for future research, this will not affect your participation in the research. The samples will be identified by your study number only and stored in freezers in locked ACNC laboratories. The samples will be stored until needed for analyses related to similar research questions as this study. If you wish to no longer have your samples stored, simply send a letter to Dr. Pivik with your child's name and date of birth. Please initial next to one of the two options below:

_____Yes, I will allow samples collected from my child, including blood and saliva to be stored by the Arkansas Children's Nutrition Center for use in future research studies.

_____No, I do not allow any samples collected from my child, including blood and saliva to be stored by the Arkansas Children's Nutrition Center for use in future research studies.

Future Contact:

_____Yes - By initialing this section, I agree to be contacted about other research studies I may be interested in.

_____No, I do not agree to be contacted about other research studies.

The purpose and voluntary nature of this study, as well as the potential benefits and risks that are involved have been explained to me. I have been able to ask questions and express

concerns, which have been satisfactorily responded to by the study team. I have been told that I will be given a copy of this consent form.

By signing this form, I verify that I have legal authority (legal custody) to give permission for this person to participate.

Print Name of Participant (Mother) Participant ID

Print Name of Participant (Child)

Signature of Participant (or Parent/Guardian if applicable) Date

Relationship to Participant

Signature of Person Obtaining Consent. *I have fully explained to all involved parties the nature and purpose of the above described procedures and risks involved. Any study-related questions expressed by the people whose signature is above have been answered. I have given a copy of the consent to the participant.*

Signature of Person Obtaining Consent Date