Interactive Diet and Activity Tracking in AARP (iDATA) Consent Form

Full Study Title: Interactive Diet and Activity Tracking in AARP (iDATA): Biomarker based validation study of internet-based and conventional self-report instruments for assessing diet and physical activity within AARP

Conducted by: United States National Institutes of Health, National Cancer Institute, Division of Cancer Control and Population Sciences and Division of Cancer Epidemiology and Genetics

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Why is this study being done?

We are inviting you to take part in an important research study sponsored by the National Cancer Institute (NCI) and supported by AARP. Scientists still have much to learn about the relationship between diet, physical activity and disease. A limiting factor in current research is the lack of good tools to accurately measure self-reported food intake and physical activity levels during day-to-day living.

NCI has recently developed new web-based questionnaires to assess an individual's daily food consumption (the Automated Self-Administered 24-hour dietary recall, or "ASA24") and physical activity (the Activities Completed over Time in 24-hours, or "ACT24"). The ASA24 and ACT24 may be used in future studies involving large numbers of people. The aim of this study is to determine the accuracy of these new web-based questionnaires by comparing an individual's self reported diet and physical activity to measurements of nutrients in urine and blood, energy use in total and while resting and measures of physical activity collected with wearable motion-detection monitors. By comparing the web-based questionnaires to these measurements we will be able to determine whether or not the questionnaires accurately measure diet and physical activity.

Who is eligible for enrollment in this study?

To be eligible for participation in iDATA, you need to be between the ages of 50-74, be comfortable using a computer and the internet, have access to a high-speed internet connection (from home, office, internet café, etc.), be willing to participate in the study over a 12-month period, and be free of certain health conditions.

What do I have to do for the study?

Participants are being selected for this study on the basis of their age, health status, and availability to complete all study activities. The study will be conducted over a 12-month period. If you decide to

participate, you will be asked to visit our clinic in Pittsburgh three (3) times and complete questionnaires and will also complete activities at home. The activities that will be completed at the clinic and at home are listed below:

Automated Self-Administered 24-hour dietary recall (ASA24)

The ASA24 is an online computer program that asks questions about the foods you consumed during the previous day. The computer program will guide you through the recall process and will also prompt you with questions about possible forgotten foods, cooking methods, and other aspects of your diet that day. Every two (2) months, you will complete the ASA24 online. You will complete six (6) ASA24 in total.

Activities Completed over Time in 24-hours (ACT24)

The ACT24 is similar to the ASA24 but asks about all the things you did and how you spent your time during the previous day instead of your diet. Every two (2) months, you will complete the ACT24 recall online. Your will complete six (6) ACT24 recalls in total.

Other Diet Questionnaires

You will complete two (2) online diet history questionnaire, two (2) food checklists, and two (2) 4-day food records during the 12-month study. We hope that you will answer all of the questions; you can skip any questions that you do not want to answer. Online Diet history questionnaire will ask a list of foods with usual frequency of intake and portion size over the past 12 months. The food checklist will ask you to report foods you consumed over the previous 7 days from a list of food groups.

The 4-day food record is a detailed report of the types and mounts of foods you eat. You will be asked to keep two (2) 4-day dietary records during the study. You will record everything that you eat and drink for 4 days. There will be about a six month interval between the first record and the second.

You will return the completed 4-day food record to the research center in a pre-paid, pre-addressed envelope.

Other Physical Activity Questionnaires

You will complete three (3) physical activity questionnaires, one (1) sitting activities questionnaire, and one (1) brief physical activity screener two (2) times during the study. The physical activity questionnaires will ask about your activities during the past month and past 12 months including employment, volunteer, household, do-it yourself projects, and recreation and leisure activities. The sitting activities questionnaire will ask about the time you spent engaging in a list of 29 specific activities

during the past 7 days. The brief physical activity screener consists of two questions about how you would rate your usual level of physical activity at work or around the house and during leisure.

Saliva collection

You will provide two (2) saliva samples on three (3) separate days four (4) months apart. We will provide you with the supplies and instructions for collecting your saliva. We will send you a reminder and ask you to let us know when you will collect the saliva so we can arrange to pick them up at your home. Saliva samples will be used to study oral bacteria and individuals' metabolic profiles.

Physical Activity Monitors

You will wear two (2) physical activity monitors twice during the study, six months between wears. Physical activity monitors are small, portable, pager-sized devices that measure your physical activity. One will be worn at your hip on a fabric belt. The other will be won on the front of your thigh. The physical activity monitor worn at your hip measures your movement at different intensity levels. The monitor on your thigh measures when you are sitting or lying down. You will wear both physical activity monitors during waking hours for seven (7) consecutive days, except while swimming or showering, and record the time you put the monitors on and took them off each day on a log sheet. You will return the physical activity monitors after each use. There are no risks associated with wearing these monitors, but you may find it to be inconvenient at times.

First Morning Urine (FMU) and 24-Hour Urine Sample

Two (2) times during the 12-month study, you will provide a first morning urine and 24-hour urine samples. We will provide you with the supplies and instructions for collecting your urine, and we will pick up samples from your home or you can drop them off at our clinic. You will take para amino benzoic acid (PABA), tablets each day you collect urine. Because PABA is eliminated from your body at a constant rate, we can measure it in urine to verify that you have collected a complete 24-hour sample. This will help us know our laboratory measurements are correct. PABA is a safe ingredient found in many dietary and vitamin supplements and topical sunscreens and no serious side effects have been reported with PABA at low doses used in the study. Please note that you must refrain from taking acetaminophen or any dietary supplements other than PABA tables on the day before and the day of urine collection. Urine will be used to measure nutrients and characterize metabolic profiles.

Body Measurements

Three (3) times during the study, at each clinic visit, we will measure your height, weight, and circumferences of hip and waist.

Fasting Blood Draw

You will provide two (2) fasting blood samples at the clinic, six (6) months apart. You will fast overnight prior to the collection, meaning you will not consume any food or beverage (other than plain water) from midnight until you have taken your blood sample the following morning. We will collect about two-and-a-half tablespoons of blood with each draw (5 tablespoons total during the whole study). The blood you give will be frozen, stored, and used to measure levels of selected nutrients such as vitamin A, vitamin E, and folate.

Resting Metabolic Rate (RMR)

Your RMR is the number of calories you burn while you are resting and not exerting yourself in any way, and is calculated from the oxygen you breathe. Your RMR represents the calories the body uses to maintain vital body functions such as heart rate, brain function, and breathing. In simple terms, it's the number of calories a person would burn if awake, but at rest, all day. We will use a ventilated hood to measure your RMR. While you are resting quietly, a clear hood will be placed over your head to collect the oxygen you breathe in and the carbon dioxide you breathe out. The measurement should take about 5 – 10 minutes.

Step Test

To determine your level of cardiorespiratory fitness you will step up and down on a 12-inch step at a specific rate for three (3) minutes. At the end of the test your heart rate will be measured for one (1) minute.

Doubly Labeled Water (DLW)

DLW is a special type of water with heavy atoms that are nonradioactive and naturally found in your body. The 4-ounce (1/2 cup) dose of DLW water you will drink will slightly raise your body's level of these atoms. We will use urine samples to measure the heavy atoms as they are eliminated from your body. The rate of elimination depends on how many calories your body uses.

Altogether, the DLW procedure will involve the collection of eight (8) urine samples. You will be given a dose of DLW to drink at the clinic. Prior to drinking the DLW dose, you will be asked to provide two (2) urine samples. You will then drink a small amount of the DLW. Later that day, you will provide four (4) more urine samples. We will provide you with the supplies and instructions for collecting your last two urine samples at home 10 to 14 days later. We will call you to remind you about the collection days. We will pick up samples from your home or you can drop them off at our clinic.

One week before and about two weeks after you drink the DLW (3 weeks total), you will need to stay within 200 miles of your home. Remaining in the same area is important because water you drink in other areas may have different levels of the naturally-occurring heavy atoms. Those different levels could affect our test results.

Additional Procedure

A random sample of participants who successfully complete the DLW procedure will be asked to repeat the DLW and RMR procedures and wear a hear rate monitor for 7 consecutive days to measure physiologic responses to physical activity. If you are selected for this procedure you will be asked to provide consent for these repeated tests and a measure of hear rates.

How will this study be done?

This study will be conducted over a 12-month period. You will need to come to the clinic three (3) times during the year and will also complete activities at home on a monthly basis. Depending on when you enroll, the schedule of activities will vary. Following is a list of the study activities with the number of times they are completed:

Once:

- Resting Metabolic Rate
- Doubly Labeled Water
- Fitness test

Twice:

- Diet History Questionnaire – baseline and end of study
- Fasting blood collection – 6 months apart
- Food records – 6 month apart
- Food checklist – 12 months apart
- Physical Activity Monitors – 6 months apart
- Physical activity questionnaires– baseline and end of study
- 24-hour urine collections – 6 months apart

Three times:

- Height, weight, hip circumference and waist circumference
- Saliva collection

Six times:

- One 24-Hour Dietary Recall (ASA24) - *every other month*
- One 24-Hour Activity Recall (ACT24) - *every other month*

What are the benefits and risks of participating in this study?

Your participation in this research study is completely voluntary. There are no direct benefits to you for participating in this study. By participating in this study, you will help researchers develop new state-of-the-art tools for measuring diet and physical activity. The information you provide may benefit society by increasing understanding about how to best collect information for research on diet and daily activities.

There are no known risks associated with drinking 4 ounces (1/2 cup) of DLW. In a small number of people, this water can cause dizziness for up to 15 minutes after drinking. You will remain sitting in the clinic during this time. We will assist you in obtaining appropriate medical treatment if for any reason you experience a research-related injury related to dizziness (e.g., fall or accident), but we cannot provide financial assistance for medical or other costs.

The risks associated with blood collection are expected to be small given the detailed instructions we will provide for overnight fasting and care. You may develop a bruise or pain where the blood sample is taken. There is also a small risk of infection, lightheadedness, and/or fainting.

Some people are allergic to PABA. You should not take the PABA tablets if you have a known sensitivity to PABA and have developed skin rashes or itching following the application of sunscreens containing PABA. You should not take the PABA tablets if you have diabetes, kidney or liver disease, or are currently taking Dapsone (an antibacterial for susceptible cases of leprosy or for dermatitis herpetiformis), sulfonamide antibiotics (such as Azulfidine, Bactrim, Gantrol, Gantrisin, Septra, and Thiosulfil), or Pronestyl or Procan (a cardiac antiarrythmic drug).

Will the information I give be kept private?

In becoming a study volunteer, the information you provide comes under the National Institutes of Health (NIH) privacy policy for research participants, and not the AARP's privacy policy. This means that if you give us your consent to participate in the study by signing below, NIH will not share with AARP any identifiable information, and AARP will not share with NIH any identifiable information other than your contact information and current AARP membership status. This NIH privacy policy is summarized in the following two paragraphs:

The personal information you provide in this study will be kept private and secure. All personal identifying information will be securely encrypted and stored separately from the responses you give on the study questionnaires. Personal identifying information will be stored in a secure, password protected, and locked data file and only identified by a study number. In order to protect the privacy of

the information you give us, only a study number will be used to identify you and the information you provide.

The results of the tests administered in this study will be kept private under the Privacy Act. Your name will not appear on the label of the urine and saliva samples or blood tube or any of the study questionnaires. Results will be grouped and reported as summaries and will not contain any individual names. The study staff is required to keep your identity private and your name will never be used in any publications or presentations about this study. All staff working on the study will be required to sign a statement pledging to maintain the privacy of all data. Access to study data will be limited to the staff working on the study.

When the study is complete or until the data is no longer required for research, the data will be archived and/or destroyed.

What else do I need to know about the study?

Your participation in this study is completely voluntary. If you decide to participate, you may decide not to answer specific questions or leave the study at any time. When you agree to participate in the study, even if you later leave the study, all information collected from you will be securely stored and used in study analyses unless you indicate otherwise. There will be no penalty or loss of benefits to you if you decline to participate in the study or if you decide to leave the study at any time. However, if you decide to participate, we hope that you will complete all study parts because we will need all of the information to draw correct conclusions.

What if I have questions, comments, or concerns?

This consent form explains the research study. If you have any questions, comments, or concerns about the study or the informed consent process, you may telephone or email the Principal Investigators, Dr. Heather Bowles (301-435-2845; heather.bowles@nih.gov) or Dr. Yikyung Park (301-594-6394; yikyung.park@nih.gov).

If you have any questions about being a research participant, you may contact the study by email at iDATAStudy@westat.com or call us toll-free at XXX-XXX-XXXX.

If you have any questions about any aspect of the study or your rights as a volunteer, a staff person will be on hand to answer them before you sign this consent form. Before you sign this form, please ask any questions on any aspects of this study that are unclear to you.

Approvals

This study protocol and this informed consent form have been reviewed by the Special Studies Institutional Review Boards of the United States National Cancer Institute and Westat in monitoring the

research data. These review committees monitor the safety and the rights of individuals participating in this research study.

Legal Rights

You are not waiving any of your legal rights by reading this consent form and agreeing to participate in the study.

Remuneration

In appreciation of your contribution of time and effort to this study you will receive $175 at the end of the first clinic visit; $150 after the second clinic visit; and $125 at the end of the third clinic visit.

Use of Specimens for Future Research Projects

If future research or testing arises where your blood, urine or saliva samples could be useful, we ask you to designate as to whether or not your samples can be used. Any future research use will require approval by the institutional review committees.

Please initial by the line if you agree to allow use of your samples for other tests or research in the future.

____ I give permission to use my blood, urine and saliva samples in future studies.

Authorization:

The above study has been explained to me, and I have read the information given. I voluntarily consent to be a part of this research. I have had a chance to ask questions and understand that future questions I may have about the research or about my rights will be answered by one of the investigators or staff listed below.

I understand the purpose of this study. I agree to participate with the understanding that I may withdraw at any time without any penalty.

_____	_____	_____
DATE	PARTICIPANT'S NAME	SIGNATURE

_____	_____	_____
DATE	WITNESS NAME	SIGNATURE

Project Coordinator's Statement:

I have provided an explanation of the above research project. The participant was given an opportunity to discuss the procedures and to ask any additional questions. A signed copy of the consent form has been given to the participant.

_____	_____	_____
DATE	PROJECT COORDINATOR	SIGNATURE