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NYU Langone Health

Research Subject Informed Consent Form

NYU RORY MEYERS COLLEGE OF NURSING

Title of Study: Feasibility of Using Wearable Sensors and Artificial Intelligence for Carbohydrate Counting in Chinese Americans with Type 2 Diabetes

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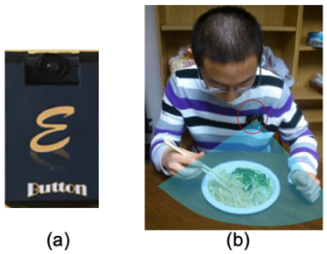
1. About volunteering for this research study

You are being invited to take part in a research study. Your participation is voluntary which means you can choose whether or not you want to take part in this study.

People who agree to take part in research studies are called “subjects” or “research subjects”. These words are used throughout this consent form. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. You may also decide to discuss this study and this form with your family, friends, or doctor. If you have any questions about the study or about this form, please ask us. If you decide to take part in this study, you must sign this form. We will give you a copy of this form signed by you for you to keep.

2. What is the purpose of this study?

The purpose of this research study is to evaluate the accuracy and acceptability of using eButton for carbohydrate counting. We are asking you to take part in this research study because you are an adult and have had Type 2 Diabetes for at least 1 year.



(a) (b)

Fig. 1 (a) The 2021 version of the eButton is about one-third of a credit card size; (b) eButton takes pictures automatically during an eating process.

The eButton (Fig.1) is a wearable camera (pinned near your upper chest) that is about the third of the size of a credit card and used to automatically record information about the food you consume during a meal. The recorded food picture data from eButton are processed by the artificial intelligence technology to automatically determine food names, volumes, and nutrient values (like grams of carbohydrates) of the food you eat. Usually, people with Type 2 Diabetes who count carbohydrates to maintain control of their blood sugar measure food portions, keep a food diary,

and calculate their carbohydrate intake, which can be inaccurate, challenging, and burdensome. We want to see if the eButton can provide a more accurate and convenient method for carbohydrate counting compared its results with: a) weighing food by registered dietitian nutritionist (“gold standard”) and b) your food diary.

3. How long will I be in the study? How many other people will be in the study?

This study will last about 4-5 weeks and will involve about 7 in person visits to our research lab. About 20 people will be in the study.

4. What will I be asked to do in the study?

If you are interested in the study and meet the other study inclusion criteria listed above, you will be eligible for the study. If you are interested in the study and sign the consent form.

This research study will consist of 7 study visits.

Visit 1: Your Screening and Enrollment
This visit will take about 1 hour. During this visit, you will be asked to complete questionnaires about your social-demographics(such as age, race, gender) and general health history. You will also be assessed for visual and hearing impairment and diabetes complications. We will also do a brief cognitive assessment at this visit, which evaluates your memory and thinking abilities, which might impact your usability of eButton and food diary.

We will show you how to use the eButton and the continuous glucose monitor (CGM). We will show you how to upload the data from the eButton to the study server. This involves connecting the eButton to the computer via USB cable, creating a zip file for the food pictures captured by eButton, and upload the zip file to the study server. We will also show you how to measure your food volumes using measuring utensils and food diaries.

You will provide link to the REDCap study site to view the IRB approved consent and electronically consent to participate in the study.

You will also need to wear the eButton 4 days a week, including 2 weekdays and 2 weekend days to detect any technical and logistic problems.

Visit 2: Your Baseline Visit
This visit will take about 2 hour . At this visit, we will see if you had any issues wearing or using the eButton, help you put on and use a CGM, provide you with detailed instructions on measuring food.

We will ask you to wear the eButton in front of your chest during meals for the next 2 weeks and to wear the CGM on the back side of your upper arm for the next 2 weeks.

You will complete questionnaires to assess your diet, physical activity, diabetes self-management, your intention to lose weight, and culturation.

In addition, we will review your medical record to get information about medical history: previous HbA1c results, height, weight, blood pressure, blood glucose, lipid, medical diagnosis and medicine history, and presence of diabetes complications and other illnesses (co-morbidities).

Visit 3-6: Your Intermediate visits

Each visit will take about 8 hours if you stay in the lab besides meal time, while it will take about 3 hours if you will not stay in the lab besides meal time. You will come to the lab 2 days per week. This is a total of 4 visits over 2 weeks. We will provide you with the free food to eat. You will choose the food from an available food list. In the lab, the registered dietitian or a trained student in nutrition will weigh your food to calculate carb grams as the gold standard.

You will follow the standard procedure to complete the food diary at home 3 days/week (including 2 week days and 1 weekend day) and 2 days /week at the lab. You will also take food weighing pictures before and after each meal 3 days/week at home. The food weighing pictures will be uploaded to our research server. When you weigh food and do food diaries at home, we will hold a meeting with you via Zoom to see if you have any questions to do food diaries. After Day 1, we will determine the frequency of the video conferences based on your performance. You will also upload the food pictures captured by eButton to our research server when you charge the devices (1-2 times/week).

Visit 7: Your Final Assessment Visit
This visit will take about 1 hour. You will complete the questionnaires to assess your acceptance of using eButton and CGM for carb counting. Also, we will conduct an audio-taped interview about your experience using eButton (approximately 30 minutes). This interview will take place at our research lab. You will be asked to sign a separate informed consent to allow us to audio-record you. We will ask you not to verbalize your name or any other identifying information to better ensure your confidentiality.

You will also be asked to return back the eButton and CGM. We will take off the CGM for you and take a picture. You will keep the measuring utensils for your use. We will also email or print a copy of the CGM report to you.

Any identifiable private information collected and/or used for the purposes of this research will not be used or distributed for future research studies.

5. What are the possible risks or discomforts?

Overheating Risk Associated with using eButton. The eButton is a wearable device containing a multicore microprocessor, a rechargeable battery capable of 10-15 hours of continuous operation (upon a flexible choice of battery capacity), a miniSD card for data storage. During the study period, you will attach the eButton to your clothing at your chest using a pin, a lanyard or a pair of magnets during meal times and re-charge the device at night. Once turned on, the eButton will take pictures of the food automatically while you eat. In very rare cases, an internal short circuit of the battery may occur, which could cause overheat and bodily injury. In case of wearable device overheating, during the baseline visit, we will instruct you that, if overheating is felt or observed, the device must be pulled forcibly from your clothing and discarded to a nearby fire-safe place (e.g., an open ground or a non-combustible surface).

Privacy Breach due to eButton. The eButton is used only while you eat. Before it takes images from the chest location, you will not appear in the images. However, it could be accidentally turned on by you to record other daily activities; the device could be lost with data stored within the device; there is a concern of privacy for human observation of these images; additionally, other people may appear in the view of the camera during the meal time. We will implement the following strategies for privacy protection: 1) you will be instructed how to turn off the device and remove it from clothing when you are not having a meal. However, if you have no privacy concerns in your living environment, you can save operating effort by omitting this step and let the device to record data continuously; 2) In order to protect data in case of loss of the devices, images will be encrypted so they are not readable except by our research software; and 3) The food image data will also be manually checked by our research team and the picture with human face

will be blurred using research-developed program. The food image data will be doubly checked by our research team member.

Risks of Wearing CGM. There is a low risk for developing a local skin infection at the site of the sensor is placed. Itchiness, redness, bleeding, and bruising at the sensor insertion site may occur. The most recent American Diabetes Association Standards of Medical Care stated that individuals with diabetes had issues such as contact dermatitis (both irritant and allergic). However, the risk for skin reactions from sensor use is minimal and rare. Also, the CGM might fell off after put on, although it is rare. The CGM sensor will be placed by the trained research assistant (RA) who has registered nursing license, or by yourself under the instruction by the trained RA. If you experience any irritant and allergic dermatitis, or the device falls off, please call us at 412-320-9103. We will instruct you to contact your primary care provider if the irritant and allergic dermatitis is abnormal. We will also mail you the 2nd CGM if the first one falls off.

Completing Study Questionnaires/Surveys and Tasks. The questionnaires and surveys you are being asked to complete may address some sensitive issues for you. You may feel uncomfortable about some of the questions and you may choose not to answer them. These questionnaires are for research purposes only and will not be used for medical/psychiatric screening or diagnosis. The tasks you are being asked to do may be challenging to complete. If you feel frustrated, you do not have to complete the tasks. You may feel inconvenienced by having to record information about your diabetes care during the study period.

Study Interview. When you participate in the individual interview, it may be upsetting because it focuses on your personal experience associated with your diabetes and using eButton. The audiotaping may cause some discomfort and distraction. If at any time you feel uncomfortable or upset during the interview you can ask that the interview be stopped.

Unforeseeable Risks. In addition to the risks, possible risks and/or discomforts listed above, there may be risks/discomforts involved in this study that are not known at this time.

6. Can I be in the study if I am pregnant or breastfeeding?

You cannot be in the study if you are pregnant. You should not become pregnant, breastfeed a baby while in the study. Participants who can bear children will be confirmed no pregnancy by self-report.

7. What if new information becomes available?

During the course of this study, we may find more information that could be important to you. This includes information that might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

8. What are the possible benefits of the study?

There are no known direct benefits to participation in this study. The data collected in this study will inform the development of intervention using eButton for dietary management for adults with type 2 diabetes, which may benefit future patients.

9. Will I be paid for being in this study?

You will receive the following payment for participation:

1. The survey completion $25 gift card
2. Wearing the eButton and CGM for 2 weeks $25 gift card
3. Measuring food volumes $25 gift card
4. The audio-interview $25 gift card

5. MetroCards paid by study

If you complete all the study visits, you will receive $100 for being in this study.

As is required by the laws that apply to NYU Langone, in order for you to receive a payment, you need to give the study staff either your Social Security number or your Alien Registration number and will be asked to complete an IRS W9. If you do not have either of these numbers or are not willing to complete the IRS W9, you may be in the study but will not receive any payment.

You must let us know immediately if/when the total research payments presently equal or are likely to exceed $600.00 total (not including travel reimbursements) for this calendar year. If your total payments (for one or more studies) reach $600.00, please tell the PI on page 1. However, you are required to report to the IRS all payments made to you by NYU Langone for your participation in any research for this calendar year, even payments under $600.00.

In order to receive payments for your participation in research, you may need to provide your Social Security number. This is because NYU Langone is required to report to the Internal Revenue Service (IRS) any amounts that are paid to research participants that are equal to or greater than $600.00. If you will receive payments in any amount by a check, you will need to provide your Social Security number or Alien Registration number and will be asked to complete an IRS W9. If you do not have either of these numbers or are not willing to complete the IRS W9, you may be in the study but will not receive any payment.

We will pay you back for travel costs to and from the study site and any hotel costs related to the study. In order to be paid, you must give the receipts to the study staff.

10. Will I have to pay for anything?

You don't need to pay anything including the CGM, measuring utensils, or lab food.

You and/or your health insurance may be billed for the costs of medical care during this study if these expenses would have happened even if you were not in the study, or if your insurance agrees in advance to pay. If you have health insurance, the cost of these services will be billed to your insurance company. If your insurance does not cover these costs or you do not have insurance, these costs will be your responsibility.

11. What happens if I am injured from being in the study?

For medical emergencies contact 911. If you think you have been injured as a result of taking part in this research study, tell the principal investigator as soon as possible. The principal investigator's name and phone number are listed at the top of page 1 of this consent form.

We will offer you the care needed to treat injuries directly resulting from taking part in this research. We may bill your insurance company or other third parties, if appropriate, for the costs of the care you get for the injury, but you may also be responsible for some of them.

There are no plans for the NYU School of Nursing or NYU Langone Health to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form.

12. When is the study over? Can I leave the Study before it ends?

This study is expected to end after all participants have completed all visits, and all information has been collected. This study may also be stopped or your participation ended at any time by your physician without your consent because:

- The principal investigator feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.
- You have not followed study instructions.
- The principal investigator or other body responsible for monitoring the safety of the study has decided to stop the study.

If you decide to participate, you are free to leave the study at any time. Leaving the study will not interfere with your future care, payment for your health care or your eligibility for health care benefits.

13. How will you protect my confidentiality?

Your medical information is protected health information, or "PHI", and is protected by federal and state laws, such as the Health Insurance Portability and Accountability Act, or HIPAA. This includes information in your research record as well as information in your medical record at NYU Langone Health. In compliance with NYU Langone Health policies and procedures and with HIPAA, only those individuals with a job purpose can access this information.

Medical information created by this research study may become part of your medical record. We may include your research information in your medical record for several reasons, including for the billing of services provided in connection with the study, to securely document any medical services you receive, and so that other members of the NYU Langone Health community who may treat you have access to important information about your health.

You have a right to access information in your medical record. In some cases, when necessary to protect the integrity of the research, you will not be allowed to see or copy certain information relating to the study while the study is in progress, but you will have the right to see and copy the information once the study is over in accordance with NYU Langone Health policies and applicable law.

14. HIPAA Authorization

As noted in the Confidentiality section above, federal law requires us, and our affiliated researchers, health care providers, and physician network to protect the privacy of information that identifies you and relates to your past, present, and future physical and mental health conditions. We are asking for your permission (authorization) to use and share your health information with others in connection with this study- in other words, for purposes of this research, including conducting and overseeing the study.

Your treatment outside of this study, payment for your health care, and your health care benefits will not be affected even if you do not authorize the use and disclosure of your information for this study.

What information may be used or shared with others in connection with this study?

All information in your research record for this study may be used and shared with those individuals listed in this section. Additionally, information in your medical record that the research team believes may be important to the study may be accessed by those listed here. This includes, for example, results from your physical examinations, laboratory tests, procedures, questionnaires, and diaries.

Who may use and share information in connection with this study?

The following individuals may use, share, or receive your information for this research study:

- The research team, including the Principal Investigator, study collaborators, study coordinators, and personnel responsible for the support or oversight of the study
- Governmental agencies responsible for research oversight (e.g., the Food and Drug Administration or FDA).
- Health care providers, including your doctors and others who provide services to you in connection with this study, and laboratories or other individuals who analyze your health information in connection with this study.

Your information may be re-disclosed or used for other purposes if the person who receives your information is not required by law to protect the privacy of the information.

What if I do not want to give permission to use and share my information for this study?
Signing this form is voluntary. You do not have to give us permission to use and share your information, but if you do not, you will not be able to participate in this study.

Can I change my mind and withdraw permission to use or share my information?
Yes, you may withdraw or take back your permission to use and share your health information at any time for this research study. If you withdraw your permission, we will not be able to take back information that has already been used or shared with others. To withdraw your permission, send a written notice to the principal investigator for the study noted at the top of page 1 of this form. If you withdraw your permission, you will not be able to stay in this study.

How long may my information be used or shared?
Your permission to use or share your personal health information for this study will never expire unless you withdraw it.

15. Electronic Medical Record and Release of Study Related Information

What is an Electronic Medical Record?
An Electronic Medical Record (EMR) is an electronic version of your medical chart within NYU Langone Health. An EMR is simply a computer version of a paper medical record.

If you are or have been a patient at NYU Langone Health in the past, you have an EMR at NYU Langone Health. Information from your research participation will be added to this EMR.

If you have never been a patient at NYU Langone Health, you may not have an EMR at NYU Langone Health. In connection with your participation in this study, an EMR will be created for you. The purpose of your EMR at NYU Langone Health will be to facilitate this research study and allow the researchers to maintain information arising from your participation in this research study. The creation of this EMR is a requirement of your participation in this study. In order to create your EMR, the study team will need to obtain basic information about you that would be similar to the information you would provide the first time you visit a hospital or medical facility, for example, your name, the name of your primary doctor, the type of insurance you have, your date of birth and other health-related information.

What may be placed in the EMR?
Information related to your participation in the research will not be placed in your EMR maintained by NYU Langone Health.

Will I have access to research-related information within the Electronic Medical Record?

The 21st Century Cures Act allows patients increased access to their EMR. If you agree to participate in this study, this means that any research-related information placed in your EMR will be available to you immediately.

As a research participant, this means that you have immediate access to any research-related information that is placed in your EMR before the researchers have had an opportunity to review the information.

Access to research-related information within your EMR can be found through NYU Langone Health's patient portal, MyChart; however, the research-related information in this study will not be included in the EMR.

16. The Institutional Review Board (IRB) and how it protects you

The IRB reviews all human research studies – including this study. The IRB follows Federal Government rules and guidelines designed to protect the rights and welfare of the people taking part in the research studies. The IRB also reviews research to make sure the risks for all studies are as small as possible. The NYU IRB Office number is (212) 263-4110. The NYU School of Medicine's IRB is made up of doctors, nurses, scientists, and people from the community.

17. Who can I call with questions, or if I'm concerned about my rights as a research subject?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on top of the page 1 of this consent form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Institutional Review Board (IRB) at (212) 263-4110.

When you sign this form, you are agreeing to take part in this research study as described to you. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer.

Name of Subject (Print)	Signature of Subject	Date

Name of Person Obtaining Consent (Print)	Signature of Person Obtaining Consent	Date