Consent to Participate in Research

Title of Research Study: EAT2

Principal Investigator: Nabil Alshurafa, Ph.D.

Supported By: This research is supported by The National Institute of Health (NIH).

Conflict of Interest Disclosure: The following disclosure is made to give you an opportunity to decide if this relationship will affect your willingness to participate in this research study: Dr. Nabil Alshurafa, the director of this study, is the inventor of the technology being tested in this study.

Key Information about this research study:

The following is a short summary of this study to help you decide whether to be a part of this study. Information that is more detailed is explained later on in this form.

- The purpose of this study is to test and refine our HabitSense activity detecting device system, allowing us to develop, determine, and compare the accuracy of the activity detection algorithm that incorporates different methods of censoring information that can be used to identify you, also known as 'obfuscation methods'.
- HabitSense is worn around the neck, points upwards toward the chin and captures color images without audio. You have been shown an example of what the device will record.
- You will be asked to wear HabitSense for four full weeks as you go about your normal schedule, keep a detailed daily food log and participate in brief regularly occurring calls with a dietitian.
- We will ask you wear the device during all waking hours, except in instances that could damage the device.
- You will make two short in-person visits to the Northwestern Chicago campus. During your first visit you will learn how to use the HabitSense device and food logging mobile app. Your second visit will involve returning the device and providing us with feedback on using the device.
- We expect that you will be in this research study for seven weeks. There will be a week in between each "active" week in which you will not wear the device, therefore your participation will conclude after seven weeks.
- The primary potential risk of participation is a breach of privacy, though the study team has taken measures to protect against threats to the confidentiality of the study. Information collected from surveys and from the HabitSense device will be stored securely and safely and encrypted.
- You can delete parts of your collected device data at the end of the study if you do not want something to be shared or stored.
- Participants are helping develop a state-of-the-art wearable behavioral observation system that allows researchers like us to collect crucial data on lifestyle habits without compromising the privacy of the wearer. However, we cannot promise any benefits to being in this study.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Why am I being asked to take part in this research study?

We are asking you to take part in this research study because you are 18 years or older; live in Chicago; are able to speak, read, and write in English; have a BMI of 18.5 and above, own a smartphone and have reliable access to a computer in the home.

How many people will be in this study?

We expect about 72 people will be in this second phase of the research study.

What should I know about participating in a research study?

- Someone will explain the research study to you formally when you arrive to the lab.
- You can contact the research team with any questions about the study.
- Whether or not you take part is up to you, participation is voluntary.
- 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.
- You do not have to answer any question you do not want to answer.

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

Before you began the study: You completed a survey collecting height, weight, age and relevant health information. If your answers to these questions aligned with our inclusion criteria, and you are 18 years or older, understand English, own a smartphone, have access to a computer and live in Chicago; you were eligible to participate in this study.

Main Study: After booking an appointment via phone or email, you were asked to visit the HABits Lab in downtown Chicago. Here, a member of the research team will explain the study to you, show you what the device captures, allow you to ask any questions and obtain your informed consent. The study member will then measure your height and weight and allow you to handle the device. HabitSense aims to capture the occurrence of certain lifestyle activities that have significant health consequences.

After consent, the first visit to the lab will involve learning how to use the HabitSense device and food logging smartphone application. You will learn how to 1) wear the HabitSense device and turn it on and off, 2) charge the device, and 3) log food items through the smartphone app. If the HabitSense device is on with its SD card inserted, it is always recording color images without audio. The study team will provide you with a device guide to refer to when using the technology. You will also be asked to eat a snack, use your phone, use the restroom and order an item from a restaurant while wearing the device in lab and will be shown what the device captured.

You will then take the HabitSense device home and wear it for four separate, one-week periods. We ask you to wear the device during all waking hours as part of your participation. After your first week of wear, you will not wear the device again until another week has passed. This schedule will repeat until you have worn the device for four full weeks. You will only need to log food items and complete

dietitian calls on the days that you are wearing the device. The wear schedule will remain rigid. If you forget to wear the device/choose not to wear the device on a scheduled active day, you should continue with the planned schedule. Do not intentionally add any extra days. The day before each active week, you will be shown your lab data with a different filter applied. This will be an example of what your data will look like after we apply our filters. You will also receive a zoom call to ensure that you have seen the video and are ready to start your active week.

Participants will keep a log of food items eaten on days when they are wearing the device. It is important to log all items consumed (meals, drinks, snacks, gum etc.). Three times per week, participants will complete a short phone call with a study team dietitian who will ask about the food items consumed during the day to determine portion sizes and recover any unlogged food items from memory.

The group of study participants you will be assigned to after your first week will be chosen by chance, like flipping a coin. Neither you nor the study team will choose which study group you are assigned to. You will have a one in six chance of being assigned to any given group.

At the end of the seven weeks, you will return to the lab to bring back the device and complete two final surveys about the device and its features. Your answers to all of our surveys will help us improve the device.

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. You will be making a positive contribution to a branch of science with the potential to help better the lives of anybody suffering the consequences of health-damaging lifestyle habits and potentially better managing your habits through the use of sensors and increased self and physiological monitoring.

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

A possible risk for any research is that confidentiality could be compromised – that is, that people outside the study might get hold of confidential study information. The study team has taken measures to protect against threats to the confidentiality of the study. Biometric information and information collected from surveys and the HabitSense device will be stored securely and encrypted.

Minimal risks from sensors: As for the risks from the sensors: some participants also may experience slight initial discomfort while wearing the sensors. The HabitSense system has been approved by Northwestern's IRB, and no significant skin irritation has been reported. Thus, we assess the severity of the discomfort and irritation of wearing the devices to be low and entirely reversible once the participant removes the devices. As with any electrical device, the sensors can theoretically cause electrical shocks. Electrical shocks can be a health concern for participants with certain health conditions (e.g., heart conditions that require a pacemaker). However, the probability of a participant experiencing even minor electrical shocks is negligible. High impedance circuitry is used to limit current flow, even in the case of external events (e.g., through physical breaking of the sensor board or shorting of the battery leads).

Safety Monitoring / Adverse Event

Reporting in the case of any adverse events that may arise during the experiment, participants should contact or get the attention of study staff immediately (including the PI). Staff will immediately

consult with the PI and follow all necessary reporting procedures. Any participant that experiences an adverse medical event during the experiment, which makes it no longer medically safe for the individual to participate, will be withdrawn from the experiment. These cases will be promptly reported to the IRB.

What happens if I do not want to be in this research, or I change my mind later?

Participation in research is voluntary. You can decide to participate or not to participate. If you do not want to be in this study or withdraw from the study at any point, your decision will not affect your relationship with Northwestern University/Northwestern Memorial Healthcare.

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

If you decide to withdraw from this study, the researchers will ask you if information already collected from you (biometric information, food logs and personal HabitSense data) can be stored and used.

How will the researchers protect my information?

Confidentiality: All data collected from participants will be maintained using strict confidentiality procedures. Each participant is assigned an anonymous study ID, which is then used on all study forms and paper records that contain participant information (e.g., address lists, phone lists) are kept in secured, locked areas when not in use. In addition, such materials, when in use, are kept away from other participants and public scrutiny. Third, access to all participant data and information is restricted to authorized personnel. Sensor data have several identifying and socially revealing information such as travel patterns. The device collects raw data during all active weeks. However, the only data that will be stored in raw form for analysis will be from the first “unobfuscated active week”. The data collected during the following “obfuscated active weeks” will be filtered when the device is returned and stored for analysis in that form. The data stored on the hard drive will be encrypted and later assessed to determine the reliability of activity detection. Markers (of events such as eating, feeding gestures, swallows, chew rate, context, eating episode time and time of day) derived from them will be stored. All sensor data and information derived from them will be encrypted during storage and access will only be provided to researchers with human subject certification and authorization.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

Identifiable information that could still be disclosed beyond the research team: The Certificate does not stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate cannot be used to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate does not stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also does not prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

Who will have access to the information collected during this research study?

Efforts will be made to limit the use and disclosure of your personal information, including research study records, to people who have a need to review this information. We cannot promise complete secrecy.

There are reasons why information about you may be used or seen by other people beyond the research team during or after this study. Examples include:

- University officials, government officials, study funders, auditors, and the Institutional Review Board may need access to the study information to make sure the study is done in a safe and appropriate manner.
- The research team may give information to appropriate authorities for reasons of health and safety – for example, if you indicate that you plan to harm yourself or others, or for public health reasons.

If we learn about current or ongoing child abuse or neglect, we may be required or permitted by law or policy to report this information to authorities.

How might the information collected in this study be shared in the future?

We will keep the information we collect about you during this research study for study recordkeeping and for potential use in future research projects. Your name and other information that can directly identify you will be stored securely and separately from the rest of the research information we collect from you.

De-identified data from this study may be shared with the research community, with journals in which study results are published, and with databases and data repositories used for research without additional informed consent. We will remove or code any personal information that could directly identify you before the study data are shared. Despite these measures, we cannot guarantee anonymity of your personal data.

The results of this study could be shared in articles and presentations, but will not include any information that identifies you unless you give permission for use of information that identifies you in articles and presentations.

Will I be paid or given anything for taking part in this study?

The first active week of the study is uncompensated. If you leave or are removed from the study during the first week, you will not be compensated.

If you complete the full seven weeks, you can receive up to $370 for your participation. You will receive $17 per day for wearing the device, logging food items and completing dietitian calls and $13 for the final surveys. You must engage in all of the study tasks to receive any compensation for that day. If you forget to complete a food log or dietitian call, you will receive a reminder and will be given an opportunity to make up for the missing task to receive compensation for that day. If you continue

to only partially participate or are unresponsive to our requests, you will begin losing compensation for the entire day and may be dropped from the study. Should you choose to leave the study at any time, you will receive a prorated amount to match your participation broken down by the number of days you were actively and fully participating. You must return the device and charger at the conclusion of your participation.

Who can I talk to?

If you have questions, concerns, complaints or research-related injuries you can contact the Principal Investigator Nabil Alshurafa, Ph.D. at (312) 503-4517 or nabil@northwestern.edu; and Research Assistant Bonnie Nolan at bonnie.nolan@northwestern.edu.

This research has been reviewed and approved by an Institutional Review Board ("IRB") – an IRB is a committee that protects the rights of people who participate in research studies. You may contact the IRB by phone at (312) 503-9338 or by email at irb@northwestern.edu if:

- 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 have questions about your rights as a research participant.
- You want to get information or provide input about this research.

Optional Elements:

The following research activities are optional, meaning that you do not have to agree to them in order to participate in the research study. Please indicate your willingness to participate in these optional activities by placing your initials next to each activity.

I agree	I disagree	
_____	_____	The researcher may use video or photographs of me or collected by me in scholarly presentations or publications when showing my face or hearing my voice might serve to help others understand the research. I may be identifiable as part of this activity.
_____	_____	The researcher may keep my contact information in order to contact me in the future to see whether I am interested in participating in other research studies by the Principal Investigator.

Signature for Adult 18 or older

Your signature documents your permission to take part in this research.

_____ _____
Signature of participant Date

_____
Printed name of participant

_____ _____
Signature of person obtaining consent Date

_____
Printed name of person obtaining consent