Automatic Assessment of Neuropsychiatric Symptoms at Home Predictive of Mental Health and Cognitive Disorders Using Non-Intrusive Ambient Intelligence Technologies

Informed Consent Form

NCT06704971

July 7, 2025

Are you participating in any other research studies? _____ Yes _____No

SUMMARY:

We are seeking your consent to participate in research investigating the development of neuropsychiatric symptoms (NPS) among people 65+ years of age who have or are at risk for cognitive decline and healthy controls. Neuropsychiatric symptoms (NPS) include a complex set of subsyndromes detectable by analyzing mobility, daily activities, and facial expressions. In this feasibility study, we aim to develop automated artificial intelligence methods to detect and track an individual's neuropsychiatric symptoms (NPS) using a non-intrusive video camera at home. Our software will document the sequence of occurrences of NPS, predict adverse events and provide interpretable data for accurate diagnosis during a clinic visit.

Currently, assessing NPS relies primarily on clinician observation and interviews with caregivers, usually within brief and infrequent clinical visits, resulting in highly subjective clinical decision-making and either undertreatment or overtreatment. Thus, precise assessment and monitoring methods for NPS are sorely needed. Such methods would incorporate objective, patient- and caregiver-friendly, real-time tools and provide reliable and frequently captured data. To date, however, minimal research has attempted to develop and test such tools.

Our goal is to collect data from participants via WYZE video/audio recording camera. The camera will be installed in the participant's primary room of use (likely the living room) for no less than 7 and up to 30 continuous days. This will be a small camera (2.05 in x 2.01 in x 2.3 in) that will be installed as near to the ceiling in the corner of the primary room in the home as possible. It would be at least 5 feet away from where people normally perform activities to allow for minimal occlusion, and the largest field of vision. The images/video & audio recordings made by these cameras in the room environment will be owned exclusively by participants.

Research study staff will install a microSD card in the WYZE camera to record your activities in the installed room during the observation period. Study staff will work with you, your family or caregiver to install a WYZE application on their phone or other compatible device. The WYZE application will allow the camera to be turned on/off at any time. Stanford research team has NO access to WYZE app, its functions or any data being recorded during the collection period.

When you download the app, you will need to agree to the app's Terms of Use and Privacy Policy. The Terms of Use and Privacy Policy are separate from this consent form and should be read carefully before you download the app onto your device.

At appropriate and necessary intervals during the agreed data collection period (most likely weekly), the Research Team will retrieve the microSD card in person or via pre-paid envelopes for analysis. Recordings will be transferred securely from the microSD card via a Stanford secure computer to Stanford HIPAA compliant central server for analysis.

Due to the nature of this study, which includes the analysis of patient's mobility, daily activities, and facial expressions and these cameras being located in the home, there is the possibility that they may record sensitive or private information. When appropriate and unnecessary to the study, we will take maximum measures to automatically remove such sensitive information by running face and person detection algorithms and blurring sensitive areas (for example, private body parts) before any data is analyzed by research staff members.

Other precautions to protect your privacy and data will include: Recorded data will only be linked to a participant's unique participant ID number. All data recorded on the microSD card will be destroyed to prevent an unauthorized use.

Your participation is voluntary, and you can choose to withdraw from the study at any time. Your involvement would be expected to be no less than 7 and up to 30 continuous days.

There will be no immediate benefit to you from participating in this study except for the satisfaction you might feel from contributing to research. In the future, this type of technology may lead to better diagnoses by clinicians, more personalized care, and ultimately, a better quality of life for seniors. When the algorithms are developed, we can provide you and your caregiver with a summary of your activities and neuropsychiatric symptoms during the data collection period.

PURPOSE OF RESEARCH

You are invited to participate in a research study of Automatic Assessment of Neuropsychiatric Symptoms at Home Predictive of Mental Health and Cognitive Disorders Using Non-Intrusive Ambient Intelligence Technologies. We hope to learn if changes in everyday activities and behavioral expressions can lead physicians to more easily make diagnoses. This information can help physicians devise better plans for clinical care.

You were selected as a possible participant in this study because you are a 65+ and have identified as experiencing or being at risk for cognitive decline or a healthy control.

This research study is looking for 20 to 25 eligible participants. We will also require the availability of an informant who has contact with the patient at least once a week. Your informant can also be the surrogate/Legally Authorized Representative (LAR) or a person of your choosing.

If you decide to terminate your participation in this study, you please notify Dr. Ehsan Adeli via email eadeli@stanford.edu or phone 650-498-0616.

VOLUNTARY PARTICIPATION

Your participation in this study is entirely voluntary. Your decision not to participate will not have any negative effect on you or your medical care. You can decide to participate now but withdraw your consent later and stop being in the study without any loss of benefits or medical care to which you are entitled.

DURATION OF STUDY INVOLVEMENT

This research study is expected to take approximately 2 years. We estimate that it will take up to 12 months to collect data from 20-25 participants. The second 12 months of the project will be dedicated to developing the AI models, conducting analyses and interpreting the data, and finally summarizing results.

Your individual participation is expected to last for approximately 1 month.

PROCEDURES

If you choose to participate, Dr. Ehsan Adeli, Dr. Christine Gould, and their research study staff will ask your informant/study partner to complete an observational questionnaire (which will take ~15 to 30 min) at the beginning and at the end of the collection period. You also will be asked to complete a baseline questionnaire and a demographics survey, at the beginning and then a short survey at weekly intervals. Finally, an exit interview will be administered at the end of the collection period. You and your informant/study partner will also be asked to report any major health issues during the collection period. Therefore, your own involvement is expected to last for no less than 7 and up to 30 continuous days.

A member of the study team or their approved delegates will instruct you to place the WYZE camera in your primary room of use (most likely a kitchen or living room) for the data collection period. This will be a small camera (2.05 in x 2.01 in x 2.3) that will be placed as near to the ceiling in the corner of the primary room in the home as possible. The camera will be at least 5 feet away from where people normally perform activities to allow for minimal occlusion, and the largest field of vision. The images/video & audio recordings made by these cameras in the room environment will be owned exclusively by participants.

Research study staff will instruct you how to insert a microSD card in the WYZE camera to record activities in the installed room during the observation period. Study staff will work with you, your family or caregiver to install a WYZE application on their phone or other compatible device. The WYZE application will allow the camera to be turned on/off at any time. Stanford research team has NO access to WYZE app, it's functions or any data being recorded during the observation period.

When you download the app, you will need to agree to the app's Terms of Use and Privacy Policy. The Terms of Use and Privacy Policy are separate from this consent form and should be read carefully before you download the app onto your device.

At set intervals during observation period (most likely weekly) based on agreed to observation period, research team will pick up microSD card or participant will return via pre-paid envelopes for analysis.. Recordings will be transferred securely from the microSD card via a Stanford secure computer to Stanford HIPAA compliant central server for analysis.

Due to the nature of this study, which includes the analysis of your mobility, daily activities, and facial expressions and these cameras being located in the home, there is the possibility that they may record sensitive or private information. When appropriate and unnecessary to the study, we will take maximum measures to automatically remove such sensitive information by running face and person detection algorithms and blurring sensitive areas (for example, private body parts) before any data is analyzed by research staff members. (fig.1)

Other precautions to protect your privacy and data will include: Recorded data will only be linked to a participant's unique participant ID number. All data recorded on the microSD card will be destroyed to prevent an unauthorized use.

Once the images and audio of the everyday activities and behavioral expression are obtained, we will use artificial intelligence to learn to differentiate and identify various neuropsychiatric symptoms and syndromes so that they can be correctly identified and classified, and correlate these data with cognitive, behavioral, and

clinical test or questionnaire scores. An accurate and non-intrusive assessment of neuropsychiatric symptoms and behaviors can support clinicians to design better-informed, tailored clinical care plans for patients.

During the collection period, you will be asked to complete an assessment weekly while the camera is installed in the home.

After the data collection period has ended, you will be invited to complete an exit interview to discuss your experiences with the study's camera and whether you have any ongoing concerns with the study. This should not take more than 20 minutes of your time.

This study does not include any experimental treatment. The equipment installed is monitoring equipment only, and there will be no treatment differences between those participating in this study and those not participating.

Any of your data that are used in research may result in new products, tests, or discoveries. In some instances, these may have potential commercial value and may be developed and owned by the Investigators, Stanford University and/or others. However, participants that support the generation do not retain any property rights to the materials. Therefore, you would not share any financial benefits from these products, tests, or discoveries. However, we will keep all our study participants aware of the technological developments as an outcome of this research and will work with them to provide early access to any generated product.

Please note that all data review will take place after the data collection period and there will be no real-time monitoring of the collected data, which also ensures preserving your privacy. As such, the research team will not be able to activate emergency medical or law enforcement response should an adverse health or security event occur. If an event like this were to take place, there will be no real-time intervention from research staff or anyone else in response to data collected by the camera.

It is possible that, based on information gained from this study, the researchers may have serious concerns (relating to matters such as severe depression, physical abuse, etc.) about your health and/or safety; in such a case, the researchers may contact you (and/or your LAR) and provide a referral for your care. It is possible that, based on information gained from this study, the researchers may be required to report information (e.g., information relating to suicide, physical or sexual abuse) to the appropriate authorities.

<u>Future Use of Private Information</u>:

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Research using private information is an important way to try to understand human disease. You are being given this information because the investigators want to save private information for future research. Your data will be stored on a secure server per Stanford IT security recommendations. The data will be labeled with your unique participation code, which masks your personal or identifiable information.

Following the end of the research study, all collected data will be unlinked from your unique participation code. Because your private information will not be linked to your name after they are stored, you cannot withdraw your consent to the use of the data after they are collected.

Identifiers will be removed from identifiable private information and, after such removal, the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you. At that point, it would not be knowable that this information came from you.

The results of the study of your data from this project will be used for research purposes only, and you will not be told the results of the research.



Fig. 1 Sample data from RGB camera recording with privacy-protecting features

PARTICIPANT RESPONSIBILITIES

As a participant, your responsibilities include:

- Follow the instructions of the Protocol Director and study staff.
- Continue with usual behavior and do not tamper with installed secure video camera.
- Contact the Protocol Director or research study staff about any concerns about the installed equipment.
- Complete your questionnaires as instructed.
- Ask questions as you think of them.
- Tell the Protocol Director or research staff if you change your mind about staying in the study.

WITHDRAWAL FROM STUDY

If you first agree to participate and then you change your mind, you are free to withdraw your consent and discontinue your participation at any time. Your decision will not affect your ability to receive medical care, and you will not lose any benefits to which you would otherwise be entitled.

If you decide to withdraw your consent to participate in this study, you should notify Dr. Ehsan Adeli at 650-498-0616 (eadeli@stanford.edu). The camera will be uninstalled from your home immediately.

The research team members or their approved delegates will come to your house to uninstall the camera or send you pre-paid label to mail the camera back to study. All records linked to patient identification will be destroyed, i.e., entry interview, and any chart review. Following withdrawal from the study, recorded data may still be used in future research in a de-identified way with no way to link the data with your identity.

The Protocol Director may also withdraw you from the study without your consent for one or more of the following reasons:

- Failure to follow the instructions of the Protocol Director and study staff.
- The Protocol Director decides that continuing your participation could be harmful to you.
- The study is canceled.
- Other administrative reasons.

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- Unanticipated circumstances.

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POSSIBLE RISKS, DISCOMFORTS, AND INCONVENIENCES

There are risks, discomforts, and inconveniences associated with any research study. These deserve careful thought. You should talk with the Protocol Director if you have any questions.

Risks of participating in this study include the possibility of your images and audio recording data being linked with your identity. All reasonable precautions will be taken to protect all collected data from being identified. The research staff analyzing the data will not have access to any personally identifiable information. However, we cannot guarantee 100% that your recorded visual data cannot be re-identified.

There may be some emotional discomfort in answering questionnaires about how you are feeling or your wellbeing.

Lastly, there may be additional risks associated with this research which are currently unforeseeable.

POTENTIAL BENEFITS

There is no guaranteed benefit to participants from this study. In the future, it is possible that this type of technology may lead to the automatic detection of neuropsychiatric disturbances and hence minimize the need for unnecessary clinic/hospital visits, as well as a better quality of life for seniors. Some people derive satisfaction from contributing to medical research. We cannot and do not guarantee or promise that you will receive any benefits from this study.

ALTERNATIVES

The alternative to participating in this research is to not participate.

PARTICIPANT'S RIGHTS

You should not feel obligated to agree to participate. Your questions should be answered clearly and to your satisfaction. If you decide not to participate, tell the Protocol Director.

You have the right to refuse to answer particular questions. You will be told of any important new information that is learned during the course of this research study, which might affect your willingness to continue participation in this study.

CONFIDENTIALITY

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed except as authorized by you or as required by law**.** However, there is always some risk that even de-identified information might be re-identified or decoded.

Patient information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction during the time that your identity is linked to the data.

CERTIFICATE OF CONFIDENTIALITY

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.

There are some important things that you need to know. 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.

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Authorization To Use Your Health Information For Research Purposes

Because information about you and your health is personal and private, it generally cannot be used in this research study without your written authorization. If you sign this form, it will provide that authorization. The form is intended to inform you about how your health information will be used or disclosed in the study. Your information will only be used in accordance with this authorization form and the informed consent form and as required or allowed by law. Please read it carefully before signing it.

What is the purpose of this research study and how will my health information be utilized in the study?

The purpose of this study is to use continuous secure monitoring and recording with depth and color video image, and altered audio, to describe behavioral expressions and everyday activities of patients age 65+ years old and use machine learning to help patients receive more accurate diagnoses. We hope that, in the future, this type of technology can be used to better assess patients' symptoms, provide more personal care plans, and lead to more timely intervention. Participants' health information will be used to understand measures related to quality of life, baseline health status, and the occurrence of neuropsychiatric disturbances. Following the conclusion of the study, participants' collected video data may be used for publication, but all identifiers linking participants to the video data will be removed prior to publication.

Do I have to sign this authorization form?

You do not have to sign this authorization form. But if you do not, you will not be able to participate in this research study. Signing the form is not a condition for receiving any medical care outside the study.

If I sign, can I revoke it or withdraw from the research later?

If you decide to participate, you are free to withdraw your authorization regarding the use and disclosure of your health information (and to discontinue any other participation in the study) at any time. After any revocation, your health information will no longer be used or disclosed in the study, except to the

extent that the law allows us to continue using your information (e.g., necessary to maintain integrity of research). If you wish to revoke your authorization for the research use or disclosure of your health information in this study, you must write to: Ehsan Adeli, Ph.D. at eadeli@stanford.edu or 401 Quarry Rd, Stanford, CA 94305-5717.

What Personal Information Will Be Obtained, Used or Disclosed?
Your health information related to this study, may be used or disclosed in connection with this research study, including: your name, demographics, home address, date of hospital admission, telephone number, email address, medical record number, unique research participation number, clinical narratives or non-imaging procedure reports, medication or prescription information, diagnosis codes included in your medical records, questionnaires related to quality of life, and computer video recordings of activities in the home. None of this information will be disclosed to anyone outside of the approved Stanford research team.

Who May Use or Disclose the Information?
The following parties are authorized to use and/or disclose your health information in connection with this research study:

- The Protocol Director: Ehsan Adeli, Ph.D.
- The Stanford University Administrative Panel on Human Subjects in Medical Research and any other unit of Stanford University as necessary
- Research Staff

Who May Receive or Use the Information?
The parties listed in the preceding paragraph may disclose your health information to the following persons and organizations for their use in connection with this research study:

- The Office for Human Research Protections in the U.S. Department of Health and Human Services
- Stanford research team delegates for the purposes of installation/deinstallation of camera equipment
- NIH

Your information may be re-disclosed by the recipients described above, if they are not required by law to protect the privacy of the information.

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When will my authorization expire?

Your authorization for the use and/or disclosure of your health information will end on December 31, 2050 or when the research project ends, whichever is earlier.

_____ _____
Signature of Adult Participant Date

_____
Print Name of Adult Participant

_____ _____
Signature of Legally Authorized Representative (LAR) Date
(e.g., guardian or conservator)

_____
Print Name of LAR

_____
LAR's Authority to Act for Participant
(e.g., guardian or conservator)

FINANCIAL CONSIDERATIONS

Payment/Reimbursement

You will receive payments of $150 for every week/7days, up to a maximum of 4 weeks/30 days. Payments will be in the form of Amazon gift cards for under $200 or check payment for $200 or more upon completion of the collection period and the microSD card has been uninstalled from your WYZE camera and returned to the research study. If participants will be paid $200 or more, payments may only be made to U.S. citizens, resident non-citizens, and those who are in a status that allows them to receive a taxable payment from a U.S. payer. You may need to provide your social security number to receive payment. The WYZE camera can be kept by any participant regardless of withdrawal from study. The researchers retain the rights to the uninstalled microSD card, to wipe clean of data and re-use with another participant.

I acknowledge that I will need to provide my social security number to Stanford Finance receive a payment of $200 or more.	_____ *Initials*

You will also be offered an optional summarization report of individual findings once observation and data analysis have been completed. If requested, we expect to be able to provide the summarization report 3 to 6 months from completion of the participant observation period.

Costs

There is no cost to you for participating in this study.

Sponsor

Stanford University is providing financial support and material for this study. Additional funding has been provided by the National Institute of Health Sciences via John Hopkins University & the University of Rochester and the Stanford Institute for Human Centered Artificial Intelligence.

COMPENSATION for Research-Related Injury

All forms of medical diagnosis and treatment – whether routine or experimental – involve some risk of injury. Despite all precautions, you might develop medical complications from participating in this study. If such complications arise, the Protocol Director and the research study staff will assist you in obtaining appropriate medical treatment. In the event that you have an injury or illness that is directly caused by your participation in this study, reimbursement for all related costs of care first will be sought from your insurer, managed care plan, or other benefits program.

You will be responsible for any associated co-payments or deductibles as required by your insurance.

If costs of care related to such an injury are not covered by your insurer, managed care plan or other benefits program, you may be responsible for these costs. If you are unable to pay for such costs, the Protocol Director will assist you in applying for supplemental benefits and explain how to apply for patient financial assistance from the hospital.

You do not waive any liability rights for personal injury by signing this form.

CONTACT INFORMATION

Questions, Concerns, or Complaints: If you have any questions, concerns or complaints about this research study, its procedures, risks and benefits, or alternative courses of treatment, you should ask the Protocol Director, Ehsan Adeli at 650-498-0616. You should also contact him at any time if you feel you have been hurt by being a part of this study.

Independent Contact: If you are not satisfied with how this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a participant, please contact the Stanford Institutional Review Board (IRB) to speak to someone independent of the research team at (650)-723-5244 or toll free at 1-866-680-2906. You can also write to the Stanford IRB, Stanford University, 1705 El Camino Real, Palo Alto, CA 94306.

Alternate Contact: If you cannot reach the Protocol Director, please contact Christine Gould, Ph.D. at cegould@stanford.edu.

EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

As a research participant you have the following rights. These rights include but are not limited to the participant's right to:

- be informed of the nature and purpose of the experiment;
- be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized;
- be given a description of any attendant discomforts and risks reasonably to be expected;
- be given an explanation of any benefits to the subject reasonably to be expected, if applicable;

- be given a disclosure of any appropriate alternatives, drugs or devices that might be advantageous to the subject, their relative risks and benefits;
- be informed of the avenues of medical treatment, if any available to the subject after the experiment if complications should arise;
- be given an opportunity to ask questions concerning the experiment or the procedures involved;
- be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation without prejudice;
- be given a copy of the signed and dated consent form; and
- be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion or undue influence on the subject's decision.

May we contact you about future studies that may be of interest to you? ☐ Yes ☐ No

Signing your name means you agree to be in this study and that you will receive a copy of this signed and dated consent form.

_____ _____
Signature of Adult Participant Date

_____
Print Name of Adult Participant

_____ _____
Signature of Legally Authorized Representative (LAR) Date
(e.g., guardian or conservator)

_____
Print Name of LAR

_____
LAR's Authority to Act for Participant (e.g., guardian or conservator)

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_____ _____
Signature of Person Obtaining Consent Date

_____
Print Name of Person Obtaining Consent

The following witness line is to be signed only if the consent is provided as a summary form and accompanied by a short form foreign language consent.

_____ _____
Signature of Witness Date

_____
Print Name of Witness

(e.g., staff, translator/interpreter, family member)

- Translated short form must be signed and dated by both the participant (or their LAR) AND the witness.
- The English consent form ("summary form"):
  - Must be signed by the witness AND the Person Obtaining Consent (POC).
  - The non-English speaking participant/LAR does not sign the English consent.
  - The non-English speaking participant/LAR should not sign the HIPAA participant line if the participant or the LAR is non-English speaking, the Person Obtaining Consent (POC) must ensure that 1) the LAR's Description of Authority is completed and 2) that any questions or options presented by the consent form are documented and initialed by the POC on the Summary Form, per the participant's wishes, as they are understood during the consent process.