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

PURPOSE OF RESEARCH

You are invited to participate in a research study of how the brain supports our ability to learn and change our behavior. We hope to learn about whether engagement in different consumption behaviors (binge eating or smoking) is related to attention to cues and the speed of processing new information. Magnetic resonance imaging (MRI) will be used to measure brain activity while you perform cognitive tasks. You were selected as a possible participant in this study because as a healthy volunteer because our goal is to understand brain function and cognition.

If you decide to terminate your participation in this study, you should notify Dr. Russell Poldrack at 650-497-8488.

This research study is looking for 50 people who smoke and 50 people who binge eat. We will be enrolling participants in the United States. Stanford University expects to enroll 125-154 research study participants.

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 one and a half months. Your participation in this study will take approximately 6 hours of in-person engagement, and 28 days of remote engagement via our mobile interactive platform. Your involvement in this study will consist of one introductory session, two MRI sessions, and a 28-day mobile interaction period. The introductory session will last 30-60 minutes. The scan sessions will last 2.75 hours, consisting of 90 minutes (up to 120) in the scanner, plus up to one hour of setup and practice time. Thus, the entire study will last around 6 hours of in-lab participation and 28 days of mobile interaction. If you have any questions about your time involvement, please ask the investigator for clarification prior to signing this consent form.

PROCEDURES

If you choose to participate, Dr. Russell Poldrack and his research study staff will ask you to come in for the following: You will be asked to come in for one **30-60 minute introductory session**, followed by an **initial 2.75 hour MRI** session on a subsequent date, with 1.25 hours of pre-scan procedures and 1.5 hours of MRI scanning. At the introductory session, you will be asked to sign this research consent form, after which you will complete several questionnaires. These questionnaires will ask questions about smoking, drinking, marijuana and other drug habits. They will also ask for demographic information, such as age, financial habits, relationships, race, ethnicity, education, and engagement in risky behaviors. After completion of the first scan session, you will be asked to engage with an interactive mobile platform called Laddr® for 28 consecutive days, after which you will be asked to return for a **second 2.75 hour scan session,** with 1.25 hour of pre-scan procedures, and 1.5 hours of MRI scanning.

At the scan sessions, we will use a Magnetic Resonance Imaging (MRI) scanner to take images of your brain (called scans).

If you decide to be in this study, and are in the smoking group, you will be asked to abstain from smoking for **three hours** before both scan sessions, and for the duration of the scan session, totaling 5.75 hours of abstaining from smoking. If you decide to be in this study, and are in the Binge Eating group, you will be asked to fast for **three hours** prior to the scan sessions, and for the duration of the scan session, totaling 5.75 hours of fasting. You will be asked to weigh yourself on a body scale prior to entering the scanner, regardless of which group you are in.

During the scans, we may ask you to lie still or do some of the things listed here:

1. View pictures (including pictures of food or pictures of smoking), read about choices, answer questions, watch videos, or see shapes and pick between them by pressing buttons.

At the start of each session, we will let you know exactly what you will be asked to do. You can always stop participating at any time.

If you have been in a study in our lab before, we are also asking for your permission to use the data we collected that time in this study. That may include the answers to questionnaires, the results from all of the tasks we asked you to complete, and the brain images we collected.

At the discretion of the protocol director subjects may be taken out of this study due to unanticipated circumstances. Some possible reasons for withdrawal are:

- failure to follow instructions
- the investigator decides that continuation would be harmful to you
- the study is canceled
- not meeting inclusion criteria

Before the scanning session, you may perform some psychological tests and answer some questions about your medical history.

During the 28-day mobile interaction period, the study will involve four primary activities:

1. You will be asked to complete surveys in response to prompts four times per day using an application on your own smartphone. The surveys ask questions related to self-regulation as well as your eating or smoking behavior and context.
2. You will be asked to complete daily activities through Laddr, a science-based mobile application that may help people learn strategies and use tools to increase their self-regulation. These activities include tracking your goals.
3. You will be asked to either increase your physical activity throughout the study (if in the binge eating group) or make progress toward smoking abstinence (if in the smoking group).
4. You will be asked to either wear a wrist sensor for at least 12 hours per day to measure your physical activity levels (binge eating group) or use a carbon monoxide monitor daily and input your reading into Laddr (smoking group). You will be asked to remove and charge the wrist sensor while sleeping (binge eating group).

<u>MRI (Magnetic Resonance Imaging)</u>
MRI machines use a strong magnet and radiofrequency magnetic fields to make images of the body interior. The scanning procedure is very much like an X-ray or CT scan. You will be asked to lie on a long narrow couch for a certain amount of time (up to 120 minutes) while the machine gathers data. During this time, you will not be exposed to x-rays, but rather a strong magnetic field and radiofrequency magnetic fields, which you will not feel. You will, however, hear repetitive tapping noises that arise from the Magnetic Resonance scanner. We will provide earplugs or headphones that you will be required to wear. The space

within the large magnet in which you lie is somewhat confined, although we have taken many steps to relieve the "claustrophobic" feeling.

Risks:
Magnetic fields do not cause harmful effects at the levels used in the MRI machine. However, the MR scanner uses a very strong magnet that will attract some metals and affect some electronic devices. If you have a cardiac pacemaker or any other biomedical device in or on your body, it is very important that you tell the operator/investigator immediately. As metallic objects may experience a strong attraction to the magnet, it is also very important that you notify the operator of any metal objects (especially surgical clips), devices, or implants that are in or on your body before entering the magnet room. All such objects must be removed (if possible) before entering the magnet room. In some cases, having those devices means you should not have an MRI scan performed. In addition, watches and credit cards should also be removed as these could be damaged. You will be provided a way to secure these items. If you have any history of head or eye injury involving metal fragments, if you have ever worked in a metal shop, or if you could be pregnant, you should notify the operator/investigator.

Some of the radio frequency imaging coils, imaging software and devices being used in your scan are not approved by the FDA but are similar to counterparts that have been approved by the FDA. There is a small risk of heating from the cables associated with these devices. Please report any heating sensation immediately. You should also notify the operator/investigator if you have any tattoos on your body, including eyeliner and other permanent makeup. Tattoos could become warm and irritated during the scan and remain so for several days. If you would prefer not to participate in the MR scan due to the presence of tattoos on your body, please inform a research team member.

Two of the three MRI 3T scanners that may be used in this study are located at the Lucas Center. The third scanner is located at the CNI and will be the primary instrument used for this study. The two 3T scanners at the Lucas Center are FDA approved for diagnostic scanning, while the third scanner at CNI is an investigational system. The CNI scanner shares much of the same hardware and software of the FDA approved systems but has improved performance due to a better performing gradient coil. The CNI scanner has magnet strength, SAR limits, slew rates and noise characteristics consistent with the FDA approved scanners, so there is no additional risk.

There is a possibility that you will experience a localized twitching sensation due to the magnetic field changes during the scan. This is not unexpected and should not be painful. However, you may have the scan stopped at any time if this occurs.

Dizziness or nausea may occur if you move your head rapidly within the magnet.

IF YOU FEEL DISCOMFORT AT ANY TIME, NOTIFY THE OPERATOR AND YOU CAN DISCONTINUE THE EXAM AT ANY TIME.

If you have some type of implanted electrical device (such as a heart pacemaker), or if you could be pregnant, or if you wear braces on your teeth, you cannot participate in this study.

You will be told if any new information is learned which may affect your condition or influence your willingness to continue participation in this study.

The scans performed in this study are for specific research purposes and are not optimized to find medical abnormalities. The investigators for this project may not be trained to perform medical diagnosis. The investigators and Stanford are not responsible for failure to find existing abnormalities with these MRI scans. However, on occasion the investigator may notice a finding on an MRI scan that seems abnormal. When this occurs, a physician will be consulted as to whether the findings merit further investigation, in which case the investigator will contact you and your primary care physician and inform you of the finding. The decision as to whether to proceed with further examination or treatment lies solely with you and your physician. The investigators, the consulting physician, and Stanford are not responsible for any examination or treatment that you undertake based on these findings. Because the images collected in this study may not comprise a proper clinical MRI scan, these images will not be made available for diagnostic purposes.

PARTICIPANT RESPONSIBILITIES

As a participant, your responsibilities include:

- Follow the instructions of the Protocol Director and study staff.
- Keep your study appointments. If it is necessary to miss an appointment, please contact the Protocol Director or research study staff to reschedule as soon as you know you will miss the appointment.
- Tell the Protocol Director or research study staff about any side effects, doctor visits, or hospitalizations that you may have.
- Tell the Protocol Director or research staff if you believe you might be pregnant or gotten your partner pregnant.
- 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.

If you decide to withdraw your consent to participate in this study, you should notify Dr. Russell Poldrack at 650-497-8488.

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.
- Pregnancy
- You need treatment not allowed in the study.
- The study is cancelled.
- Other administrative reasons.
- Unanticipated circumstances.

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.

This may include the inconvenience of travel to and from the study location. Other risks may include possible fatigue, frustration, or the discussion of sensitive or personal information. To address possible fatigue and frustration, the research team has limited the number of surveys and tasks and the length of each survey and task. You may choose to not answer particular mobile surveys and may continue in the remainder of the study without penalty. (You must complete all baseline and follow-up surveys and tasks to participate in the study.) You are free to discontinue participation at any time.

If in the binge eating group, you may also experience slight discomfort from wearing the wrist sensor, such as minor skin irritations. However, the wrist sensors have been used in hundreds of studies, and most participants adjust to wearing the bands with no skin irritation. The severity is minimal, and any irritation is entirely reversible once you remove the wrist sensor. You may remove the wrist sensor at any time for any reason.

You may also experience discomfort from increases in physical activity. We will encourage you to align your physical activity goals with your current health and fitness status. If you have concerns about increasing your physical activity, please contact a medical professional.

POTENTIAL BENEFITS

We cannot and do not guarantee or promise that you will receive any benefits from this study. This study may benefit you indirectly in that it will further our knowledge about the brain-basis of normal and abnormal cognition. We can also provide you a picture of your brain on request.

You may learn self-regulation techniques through a mobile application called Laddr® that may help you reduce health risk behavior.

ALTERNATIVES

The alternative is not to 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 will be told of any important new information that is learned during the course of this research study, which might affect your condition or your willingness to continue participation in this study.

If you have read this form and have decided to participate in this project, please understand your participation is voluntary and you have the right to withdraw your consent or discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled. The results of this research study may be presented at scientific or professional meetings or published in scientific journals. However, your identity will not be disclosed**.** You have the right to refuse to answer particular questions.

DATA SHARING

The data from this study will be shared openly with other researchers across the world, for research on any topic that might be unrelated to the goals of this study. To the best of our knowledge, the data we release to the general public will not contain information that can directly identify you. The data will not have your name on it, only a code number, so people will not know your name or which data yours are. In addition, the data will not include data that we think might help people who know you guess which data yours are, such as your facial features or the date that you participated. While it is impossible to guarantee that someone could not identify you as the source of the data, the risk is very low.

Letting us use and share your data is voluntary. However, you must be willing to share your data in this way in order to participate in this study. If you are not willing, you cannot participate in this study.

ClinicalTrials.gov

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.

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.

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.

The purpose of this research study is to obtain data or information on the safety and effectiveness of Laddr; the results will be provided to the sponsor, the Food and Drug Administration and other federal and regulatory agencies as required.

CERTIFICATE OF CONFIDENTIALITY

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by NIH which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

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?
You are invited to participate in a research study of how the brain supports our ability to regulate our behavior. Magnetic resonance imaging (MRI) will be used to measure brain activity while you perform cognitive tasks. As a healthy volunteer, you are invited to participate because our goal is to understand brain function and cognition. Your health information may be used to evaluate your suitability for our study, and for research purposes of better understanding the relationship between brain function and behaviors like binge eating and smoking.

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 Dr. Russell Poldrack, at 450 Jane Stanford Way Building 420, Stanford California, 94305.

What Personal Information Will Be Obtained, Used or Disclosed?

Your health information related to this study will be used for our research purposes only, and will not be disclosed to others. We will collect your name, email address, phone number, health information including structural and functional MRI brain data, physiological data including respiration, galvanic skin response, and heart rate, questions about age, sex, ethnicity, demographics, substance abuse, context such as mood, companionship, location and temptation to binge eat, mobile sensing data used to infer physical activity, survey and usage data from the Laddr mobile application, carbon monoxide readings used to infer smoking, previous illnesses, as well as habits regarding smoking and/or eating. Additional information collected includes all items on Center for Cognitive and Neurobiological Imaging (CNI) or Richard M. Lucas Center for Imaging screening form, as well information collected via online screening including IP address numbers, vision, health and medical history. You do not need to include any identifying information in your Fitbit account, which will be created for you. Any identifying information, such as your name, that you include by updating your Fitbit account will be available to Fitbit, Inc. and Small Steps Labs LLC.

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: Dr. Russell Poldrack

- The Stanford University Administrative Panel on Human Subjects in Medical Research and any other unit of Stanford University as necessary
- Research staff from Dr. Poldrack's lab including Dr. Patrick Bissett, and other research staff, Dr. Judith Prochaska and her research staff, and Dr. Cara Bohon and her research staff.

Who May Receive or Use the Information?

The parties listed in the preceding paragraph may disclose your health information to any members of the Science of Behavior Change research team for their use in connection with this research study. These include, but are not necessarily limited to, the following persons and organizations:

- The Food and Drug Administration
- National Institutes of Health
- Fitbit, Inc.
- Small Steps Labs, LLC (Fitabase)

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.

When will my authorization expire?

Your authorization for the use and/or disclosure of your health information will end on December 31, 2250 or when the research project ends, whichever is earlier.

_____ _____

Signature of Adult Participant Date

_____

Print Name of Adult Participant

FINANCIAL CONSIDERATIONS

Payment/Reimbursement

You will receive up to $350 over the study period. You will receive $20 for completion of Session 1, $61 for completion of the first scan session, up to $208 in the 28-day mobile interaction period, and $61 for completion of the second scan session. The potential payment for the intervention stage breaks down as follows:

You can earn $.50 for completing each survey during the four-week period. There will be four survey prompts per day over 28 days for a total of up to $56. If you complete 90% of the EMAs for a given week, you will also receive a $10 bonus, for up to $40 over the duration of the study period.

You can earn $2 per day for completing Laddr activities. Over 28 days you can earn up to $56.

If in the smoking group, you can earn $2 per day for using the carbon monoxide monitor daily and inputting your carbon monoxide reading into Laddr. Over 28 days you can earn up to $56.

If in the binge eating group, you can earn $2 per day for wearing the wrist sensor for a minimum of 12 hours per day and inputting your activity data into Laddr. Over 28 days you can earn up to $56.

Payments may only be made to U.S. citizens, legal resident aliens, and those who have a work eligible visa. You may need to provide your social security number to receive payment.

Costs

There is no cost to you for this study. The National Institutes of Health are providing financial support and/or material for this study. You will be paid in one lump sum at the end of the study after returning the wrist sensor or headphone jack adapter. You will be paid in cash if you are an American citizen. If you are a Visa/Green Card holder, you will be compensated via an Amazon gift card.

The research team may deduct up to $55 from your compensation for failure to return, or for damage to, the wrist sensor, band, charging cable ($50) or USB wall charger ($5). The research team may withhold all payment until the wrist sensor, band, charging cable and USB wall charger have been returned.

You may keep the carbon monoxide monitor, which is intended for use by a single person. The research team may deduct up to $10 from your compensation for failure to return, or for damage to, the lightning or micro-USB-to-headphone jack adapter if you borrowed one. The research team may withhold all payment until the adapter has been returned.

Sponsor

NIH is providing financial support and/or material for this study.

Consultative or Financial Relationships:

None

COMPENSATION for Research-Related Injury

All forms of medical diagnosis and treatment – whether routine or experimental – involve some risk of injury. In spite of 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, Dr. Russell Poldrack. You may contact him now or later at 650-497-8488.

Injury Notification: If you feel you have been hurt by being a part of this study, please contact the Protocol Director, Dr. Russell Poldrack at 650-497-8488.

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.

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 Person Obtaining Consent Date

_____
Print Name of Person Obtaining Consent