Time Restricted Eating for Metabolic and Psychological Optimization

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University of North Carolina at Chapel Hill
Consent to Participate in a Research Study
Adult Participants

Consent Form Version Date: 5/29/2024
IRB Study # 22-2774
Title of Study: Time Restricted Fasting in Mild Cognitive Impairment
Principal Investigator: Patrick J. Smith, PhD, MPH
Principal Investigator Department: Psychiatry
Principal Investigator Phone number: 919-843-6884
Principal Investigator Email Address: Patrick_smith@med.unc.edu

Faculty Advisor: Patrick J. Smith
Faculty Advisor Contact Information: Patrick_smith@med.unc.edu

Funding Source and/or Sponsor: NIA

Study Contact Telephone Number: 919-966-6085
Study Contact Email: tempo@unc.edu

CONCISE SUMMARY

This research study is examining the feasibility and acceptability of a time restricted fasting intervention on cognitive and metabolic health. This study will assess whether a 12-week intervention changing the timing of eating behaviors may improve older adults memory and concentration abilities, and whether these improvements are related to changes in metabolic health, such as insulin sensitivity, glucose, and ketone metabolism. If you choose to participate, you will be asked to fast for 16-hours (e.g. from after dinner to the next day's lunch) several days per week, with the help of a behavioral psychologist. The treatment lasts for 12-weeks. The benefits of the study include improving your metabolic health and possibly your memory. You will also receive a modest monetary compensation for your time. Individuals with mild cognitive impairment and who are obese are eligible to participate. Although there are few risks of participation, all participants will be asked to complete tests of cognitive function, which they may find frustrating. There is also some risk of a breach of confidentiality.

What are some general things you should know about research studies?
You are being asked to take part in a research study. To join the study is voluntary.

You may choose not to participate, or you may withdraw your consent to be in the study, for any reason, without penalty.

Research studies are designed to obtain new knowledge. This new information may help people

in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies.

Deciding not to be in the study or leaving the study before it is done will not affect your relationship with the researcher, your health care provider, or the University of North Carolina-Chapel Hill. If you are a patient with an illness, you do not have to be in the research study to receive health care.

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study.

You will be given a copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study?

The purpose of this research study is to determine whether time restricted fasting is feasible among older individuals with mild cognitive problems, as well as determining whether fasting behaviors might improve cognitive functions. Time restricted fasting is the practice of limiting your eating behavior to particular hours of the day, such as between 12-8pm, on several days per week. By limiting your food intake to certain times, it may be possible to improve how efficiently your body uses energy and its ability to switch between different sources of energy such as from glucose and ketones. There is also some evidence that as your body and brain are better able to switch between using glucose and ketones, cognitive function may improve or stabilize among individuals experiencing cognitive decline. This study will test the feasibility and acceptability of a time restricted fasting intervention over the course of 12 weeks and look at changes in both cognitive and metabolic function as potential mechanisms by which treatment improved cognitive function (e.g. memory and concentration).

You are being asked to be in the study because you are an adult aged 65-85 with overweight or obesity and evidence of mild cognitive impairment, as determined by performance on a brief screening evaluation of cognitive function.

How many people will take part in this study?

Approximately 40 people at this institution will take part in this study.

How long will your part in this study last?

Participants will be in the study for 12-14 weeks.

What will happen if you take part in the study?

Potential participants will first undergo a screening to assess their potential eligibility. This will include a cognitive screening assessment and review of medical history. Once eligibility has been determined, participants will undergo an assessment of both cognitive and metabolic

functions. In order to assess your metabolic health (e.g. blood sugar levels), we will collect several blood samples from you both before and after the trial, with two blood draws at each time point and one at the halfway point of the intervention. These procedures will take approximately two hours, during which participants will complete tests of memory, concentration, and other cognitive functions under both normal and fasting conditions. For fasting assessments, participants will be asked to complete a briefer set of assessments (about an hour) after fasting for 12-16 hours. These assessments will be completed again at the end of the trial period. For all questionnaires and cognitive assessments, participants may choose not to answer items they feel make them uncomfortable or are unsure about.

Participation in the trial is completely voluntary and participants may drop out at any time. Dr. Smith will be responsible for your welfare during the study and can be reached in his office (919-843-6884) or for emergencies after hours on his cell phone (919-619-2906).

Following baseline assessments, participants will begin participation in the time restricted fasting intervention over the next 12 weeks. Participants will be asked to meet for one hour each week, either in-person or potentially by telehealth, with a behavioral health psychologist to gradually alter their pattern of eating behaviors to achieve time restricted fasting. The goal will be for participants to have achieved two days of 16-hour fasting per week by the end of the 12-week intervention.

What are the possible benefits from being in this study?

Research is designed to benefit society by gaining new knowledge. The benefits to you from being in this study may be improved metabolic functioning (e.g. insulin sensitivity and/or inflammation) and possibly in cognitive performance.

What are the possible risks or discomforts involved from being in this study?

There is some risk of unexpected loss of confidentiality from participating in this study. Participants may also experience hunger, cravings, headaches, and lightheadedness during fasting periods, as well as discomfort during blood draws and frustration completing cognitive testing. There also may be uncommon or previously unknown risks.

Will I receive any other clinical results?

Other clinically relevant results of this research will be communicated with you by personal communication, if desired. Please inform the clinical trials coordinator or the principal investigator if you would like to receive results from the study so that they may send you a personal communication with any publications resulting from the trial.

How will information about you be protected?

Participants will be identified in any report or publication about this study. We may use de-identified data from this study in future research without additional consent. Every participant will be given a study identifier (e.g. 'TMP001') that will be used to link all study related data

collected. Participants names and other identifying information will be kept in a separate, encrypted file in order to mitigate the chances of unintended loss of confidentiality. Any physical records pertaining to your results will be kept in a locked filing cabinet in Dr. Smith's office.

Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, UNC-Chapel Hill will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research study could be reviewed by representatives of the University, research sponsors, or government agencies (for example, the FDA) for purposes such as quality control or safety.

What is a Certificate of Confidentiality?

This research is covered by a Certificate of Confidentiality. With this Certificate, the researchers 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 proceedings in the United States, for example, if there is a court subpoena, unless you have consented for this use.

The Certificate cannot be used to refuse a request for information from personnel of a federal or state agency that is sponsoring the study for auditing or evaluation purposes or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law, such as mandatory reporting requirements for child abuse or neglect, disabled adult abuse or neglect, communicable diseases, injuries caused by suspected criminal violence, cancer diagnosis or benign brain or central nervous system tumors or other mandatory reporting requirement under applicable law. The Certificate of Confidentiality will not be used if disclosure is for other scientific research, as allowed by federal regulations protecting research subjects or for any purpose you have consented to in this informed consent document.

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 an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

By signing this informed consent document, you agree that some of the information generated by participating in this study and/or a copy of the consent form may be included in your medical record and that this information may be viewed by other physicians or caregivers who provide healthcare services to you. This will allow the doctors caring for you to know what study medications or tests you may be receiving as a part of the study and know how to take care of you if you have other health problems or needs during the study. Additionally, the information may be shared with your medical insurance plan if the research services provided are billed to your insurance.

The National Institutes of Health, who is sponsoring this study, requires that a small blood sample from all participants be sent to a national repository for storage. These samples are

collected from most studies examining individuals at risk for dementia in order to conduct analyses of blood-based biomarkers for Alzheimer's Disease and Related Dementias, as well as other biological markers of dementia risk. Your identifying information will be removed prior to sending this information, in order to ensure your confidentiality.

Under North Carolina law, researchers are required to report information about the abuse or neglect of a child or disabled adult to local or state authorities.

Under North Carolina law, confidentiality does not extend to certain communicable diseases, such as TB, HIV, hepatitis, or other illnesses that put others at risk. If the researchers become aware that subjects have such an illness, they are required to report it to state authorities.

The study team would like to message you by e-mail, phone, or text, however you may say "no" to receiving these messages and still participate in this study. If you say "yes", messages may contain personal information about you and may be sent or received by the study team's personal electronic devices or in a method that is not able to be encrypted (protected) and there is the risk your information could be shared beyond you and the study team. This information may include information such as reminders and notifications to contact the study team.

If you wish to stop receiving unprotected communication from the study team or have lost access to your device, please notify the study team using the study contact information on the first page of this consent form. After the study is complete and all research activities finished, or you withdraw from the study or request to stop receiving unprotected communication, you will no longer receive un-encrypted (un-protected) messages specific to this study.

_____ Yes, I consent to the study team utilizing the following (e-mail, phone call, text message) to send communication: _(List e-mail, cell-phone #)_____

_____ No, I do not consent to receive un-protected communication from the study team.

Will you receive results from research involving your specimens?

Most research with your specimens is not expected to yield new information that would be meaningful to share with you personally. There are no plans to re-contact you or other subjects with information about research results.

The use of your samples may result in commercial profit. You will not be compensated for the use of your samples other than what is described in this consent form.

What will happen if you are injured by this research?

All research involves a chance that something bad might happen to you. If you are hurt, become sick, or develop a reaction from something that was done as part of this study, the researcher will help you get medical care, but the University of North Carolina at Chapel Hill has not set aside funds to pay you for any such injuries, illnesses or reactions, or for the related medical care. Any costs for medical expenses will be billed to you or your insurance company. You may be

responsible for any co-payments and your insurance may not cover the costs of study related injuries.

If you think you have been injured from taking part in this study, call the Principal Investigator at the phone number provided on this consent form. They will let you know what you should do.

By signing this form, you do not give up your right to seek payment or other rights if you are harmed as a result of being in this study.

What if you want to stop before your part in the study is complete?

You can withdraw from this study at any time, without penalty. The investigators also have the right to stop your participation at any time. This could be because you have had an unexpected reaction, or have failed to follow instructions, or because the entire study has been stopped.

If you withdraw or are withdrawn from this study all data collected up until the point of withdrawal will be retained, however no additional information will be collected unless you provide additional written permission for further data collection at the time of your withdrawal

Will you receive anything for being in this study?

You will be receiving $200 for taking part in this study. Any payment provided for participation in this study may be subject to applicable tax withholding obligations

Your name, address, and U.S. tax payer identification number (SSN or ITIN) are required to process payments and/or to report taxable income to the IRS. You must complete a W-9 (for U.S. persons) or W-8BEN and the Foreign Vendor Withholding Assessment with supporting documents (for non-resident aliens) in order to receive payment for participation.

U.S. person participants must complete Form W-9 in order to receive payment for participation. If payment by UNC equals or exceeds $600 per calendar year for U.S. persons, UNC will report the amount to the Internal Revenue Service on Form 1099. Nonresident alien participants must complete Form W-8BEN and the Foreign Vendor Withholding Assessment with supporting documents in order to receive payment for participation. Payments to nonresident alien participants may be subject to tax withholding and are generally reported to the Internal Revenue Service on Form 1042-S. This information will not be linked to any of the study data and will only be used for payment purposes.

If you do not provide your SSN or ITIN, or complete the appropriate documentation noted above, we cannot issue you a payment for participation. However, you may still choose to participate in this study.

Will it cost you anything to be in this study?
It will not cost you anything to be in this study.

What if you are a UNC student?

You may choose not to be in the study or to stop being in the study before it is over at any time. This will not affect your class standing or grades at UNC-Chapel Hill. You will not be offered or receive any special consideration if you take part in this research.

What if you are a UNC employee?
Taking part in this research is not a part of your University duties, and refusing will not affect your job. You will not be offered or receive any special job-related consideration if you take part in this research.

Who is sponsoring this study?
This research is funded by the National Institute of Aging, a division of the National Institutes of Health. This means that the research team is being paid by the sponsor for doing the study. The researchers do not, however, have a direct financial interest with the sponsor or in the final results of the study.

What if you have questions about this study?
You have the right to ask, and have answered, any questions you may have about this research. If you have questions about the study (including payments), complaints, concerns, or if a research-related injury occurs, you should contact the researchers listed on the first page of this form.

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

What if you have questions about your rights as a research participant?
All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject, or if you would like to obtain information or offer input, you may contact the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

Participant's Agreement:

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study.

_____
Signature of Research Participant

_____
Date

_____
Printed Name of Research Participant

_____
Signature of Research Team Member Obtaining Consent

_____
Date