CONSENT TITLE: Pilot Trial of a Motivational Interviewing and Cognitive Behavioral Therapy (MI-CBT) Ketogenic Nutrition Adherence Program for Older Adults

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ion to Take Part in a Human Research Study

IRB Approval Date

Title of research study: Pilot Trial of a Motivational Interviewing and Cognitive Behavioral Therapy (MI-CBT) Ketogenic Nutrition Adherence Program for Older Adults

Primary Investigator: Julia L. Sheffler, Ph.D.

Key Information: The following is a short summary of this study to help you decide whether you would like to be a part of this study. More detailed information is listed later on in this form.

Why am I being invited to take part in a research study?

You were selected to participate in the current program because you indicated some concerns about your memory at the screening call, you are between the ages of 60 and 85, interested in completing a nutrition program (Alteration or treatment in an individual's diet with a planned goal), you do not currently have a diagnosed neurological condition, such as dementia, Alzheimer's, or Parkinson's disease, and you do not have an exclusionary health condition (e.g., type 1 diabetes, gallbladder disease). In addition to the above criteria, you may also have been selected based on your levels of self-reported pain at screening.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- 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.

Why is this research being done?

The purpose of the current study is two-fold. First, we are interested in understanding the effects of Mediterranean ketogenic nutrition (high-fat, adequate-protein, low-carbohydrate diet) on mental and physical health, as well as psychological and social outcomes (e.g., mood and daily activities). Secondly, we are interested in understanding whether the program we have developed can be helpful in maintaining the ketogenic nutrition plan, compared to providing nutrition information alone. With participant input, we hope to refine the program to be as useful and engaging as possible.

How long will the research last and what will I need to do?

The current study requires one initial in-person assessment, attending 7,1-hour online video group meetings weekly for 6 weeks, one in-person assessment at the end of the intervention (completed during week 6), and a follow-up in-person assessment completed 3 months after the final group meeting. These assessments will be completed in-person at the Center for Translational Behavioral Science. In addition to these individual tests, we are also requesting that if you are a patient at FSU SeniorHealth, you provide the study team access to your electronic health records, OR if you are NOT a patient at FSU SeniorHealth, that you provide a copy of your most recent medical records (including health conditions, medications, and recent lab work) or self-report health conditions and medications. These records will allow our team to examine whether this program affects health related outcomes relevant to your health.

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In your first meeting, we will complete a thinking and memory test, an emotion questionnaire, and a blood draw with a trained study team member. During this assessment appointment, you will be given information and materials for learning about ketogenic nutrition, as well as a bottle of ketone test strips (to test Ketones in your body) to track your adherence to the diet, and food logs (forms where you record the foods you eat). Throughout the intervention, you will also be e-mailed links to complete online surveys and a phone call for a detailed interview. Depending on the group you are assigned, you may also have other weekly practices each week related to motivation, nutrition, and learning strategies for problem solving – this will be included in your participant workbook. Further, the weekly meetings may vary slightly in structure between the groups, with one group receiving additional tools focused on goal-setting, motivation, and mental strategies, as well as encouraged group support (MI-CBT materials). The other group will receive all of the same nutritional information and access to a nurse practitioner with expertise in nutrition. For both groups, each week, we will look at your self-reported physical and mental health using an online questionnaire. In the final weeks of the program, you will complete the same thinking and memory tests emotion questionnaires, and blood draw you will complete in your first assessment appointment. Finally, you will be asked to provide feedback about the program through a semi-structured interview – both what you found helpful and what you found difficult. Lastly, we will complete a 3-month follow-up assessment after the intervention to assess memory and experiences since ending the program.

More detailed information about the study procedures can be found under ***"What happens if I say yes, I want to be in this research?"***

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

First, you will complete some challenging mental tasks (tasks that require a person to mentally process new information and allow them to recall, retrieve that information from memory and to use that information at a later time in the same or similar situation), which may cause mental fatigue. If this occurs, please let the researcher know, and breaks can be provided. You may choose to end your participation at any time during the assessment.

You will be asked to provide two blood samples for assessment of comprehensive metabolic profiles – in the first assessment and at the 6-week assessment. These will be completed by a certified medical assistant (CMA). There may be slight discomfort when inserting the needle. Please let the CMA know if you have fainted in the past from a blood draw or if you have a phobia of needles. The CMA will begin by gently pressing his or her fingers against your skin to locate the best vein. Then he or she will don gloves, clean the area with an alcohol pad, tie a tourniquet around your upper arm to increase blood flow, ask you to make a fist, and insert the needle. After the blood draw is completed, your phlebotomist will remove the needle, hold gauze against the puncture site, and ask you to apply pressure. Applying pressure directly following a blood draw mitigates the common side effect of bruising. Even with these precautions, minor bruising and swelling around the puncture site can occur. Because every person's veins are different, and veins move frequently, bruising can occur even with the most experienced CMAs. If you do bruise, it should go away within a few days. You will be required to fast for 8 to 12 hours in preparation for the blood draw, however we recommend fasting for 10 hours. This may cause some light-headedness; however, you will be given a snack once the blood draw is complete.

Primary risks associated with initially changing to a low-carb and high healthy fat diet includes: headache, fatigue (tiredness), bloating (a buildup of gas in the stomach and intestines), diarrhea, gas, and constipation. The risk for these side effects is reduced when you follow the recommended diet in the intervention plan. These side effects are usually temporary and will go away if you continue to

follow the diet plan; however, if any of these side-effects become severe, we ask that you report these experiences to the research team.

If you experience distress as a result of your participation and feel the need to talk with somebody, you will be provided with referral information for a local counseling center. You may cease participation in the experiment at any time.

Will being in this study help me in any way?

For the intervention portion of the study, you will be given free access to a ketogenic nutrition program. This program will involve providing you with information and materials for using ketogenic nutrition, as well as a supportive environment for doing so. Some research has already shown that diets low in carbohydrates and high in healthy fats may improve thinking and other aspects of health. Thus, if you are consistent with the application of the diet, you may experience some of these benefits. Depending on the group you are assigned, you may also learn skills for problem solving and making positive lifestyle changes .

What happens if I do not want to be in this research?

Participation in this study is voluntary. Your decision whether or not to participate in this study will not affect your current or future relations with the University or with your healthcare provider. If you decide to participate, you are free to withdraw at any time without affecting those relationships.

Detailed Information: The following provides more detailed information about this study in addition to the information listed above.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at:

- Julia Sheffler, Ph.D. (Julia.sheffler@med.fsu.edu) (850) 644-4199 (primary contact)
- Sylvie Naar, Ph.D. (Sylvie.naar@med.fsu.edu) (248) 207-2903
- Zhe He, Ph.D. (zhe.he@cci.fsu.edu)

This research has been reviewed and approved by an Institutional Review Board ("IRB"). You may talk to them at 850-644-7900 or humansubjects@fsu.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 subject.
- You want to get information or provide input about this research.

How many people will be studied?

We are currently recruiting up to 60 participants from the FSU SeniorHealth clinic, the Institute for Successful Longevity, and the Tallahassee community. There will be six groups with approximately 10 people in each group.

Permission to Take Part in a Human Research Study

What happens if I say "yes" to being in this research?

If you agree and are eligible to participate in this study, we will retain the data you provided during the screening call to include in the first assessment. We will then complete a final eligibility assessment based on your health records to fully ensure your safety. If eligible, you will be randomly assigned to one of two program groups. For both groups, we would ask you to do the following:

Test 1	The first appointment will consist of a thinking and memory test, emotion/social questionnaires, a brief health and wellness questionnaire, a fasting blood draw, ketone assessment, and assessment of basic vitals (i.e., blood pressure, weight, and height). We will provide you with a food log to record at least 3 days of your current, unchanged diet. This appointment will last approximately 2 hours, and you will be compensated $30.
Week 1 Virtual Meetings	Prior to the first group meeting, you will be contacted to make sure you have the ability to use video conferencing. In the first 7 days, there will be 2 group meetings scheduled. The first meeting will last approximately 1.5-hours. The first group meeting will introduce the nutrition plan, education about ketogenic nutrition and potential health benefits, as well as instruction on how to complete the at-home tests. Each meeting will be led by a licensed clinical psychologist and a nurse practitioner with expertise in nutrition. You will receive informational handouts, recipes, urine test strips for monitoring ketosis at home, and food logs. The second meeting, which will be scheduled later in the same 7-day period, will involve reviewing information from the first session and answering any questions that may have come up during the week. During the first week, we will ask you to begin tracking ketone levels and net carbohydrates. You will be asked to begin reducing your net carbohydrate intake to approximately 100-125g of net carbohydrates per day in the first week. Each week you will be sent an online survey link to enter your daily ketone levels and basic health information. Each week, you will be compensated $20 for completing the online assessments.
Weeks 2-4 Virtual Meetings	Each week, you will be asked to provide a food log describing up to 3 average days of meals and snacks by taking a picture of it, mailing or emailing it to us, or completing an online form. You will be asked to record your daily net carbohydrate, protein, and fat intake and a morning reading of your ketone level. You will complete a brief health screener at the beginning of each session online. Meetings are designed to provide information, a supportive environment, and to address difficulties you may have with the diet. Each week, you will be paid $20.00 as compensation for completion of research surveys and tracking. You will be asked to reduce your carbohydrate intake to approximately 50g of net carbohydrates per day by the 3rd week. Beyond this point, your

	recommended net carbohydrate level will be based on your level of ketones, with the goal of regularly maintaining ketosis in the final 3 weeks of the program. This will likely require restricting net carbohydrates to 20g or less. During the 4th meeting, we will schedule your follow-up assessment for week 6.
Weeks 5 & 6 Virtual Meetings	During the final week, you will be asked to complete tests in-person to examine the effect of ketosis on thinking and memory, as well as other aspects of functioning. The virtual meetings will continue to provide information and support. You will be asked to complete other brief questionnaires.
Follow-up Test 1 (6-weeks)	In week 6, you will be asked to complete tests of mood, physical health, and thinking and memory, with additional questions about your experience during the program. You will be asked to complete a second fasting blood draw, ketone assessment, and assessment of basic vitals (i.e., blood pressure, weight, and height) You will be compensated $30 for completing the follow-up measure.
3-Month Follow-up Test	Approximately 3 months after completing the final group meeting, you will be contacted by a member of the research team for an in-person meeting, where we will ask you to complete a semi-structed interview about your experiences since ending the program and follow-up measures of health and well-being. We will also complete a brief test of memory and thinking. This meeting will last approximately 1.5-hours. You will be compensated $30.

The blood draws will result in a comprehensive metabolic profile and HbA1c, which is intended for research, not diagnostics. Because of this, we will not generally provide feedback on your results. However, if a significant and concerning finding is identified by the team's Nurse practitioner, you may choose to sign a release of information for the results to be shared directly with your SeniorHealth physician. Exclusion from study participation may be determined at the nurse practitioner and team M.D.'s discretion. Blood samples will be stored until the analysis is complete and then discarded.

For in-person study activities, we are required to follow certain COVID-19-related precautions like social distancing and use of masks. However, we don't have to do this for persons who have completed a full COVID-19 vaccination. You may if you'd like share with us information about your COVID-19 vaccination, but this is your decision and is not required. You can still come to the study location, and we will follow our usual COVID-19 precautions. If you do share your COVID-19 vaccination information with us, then we will make a note of it in our study records.

In addition to the sessions and assessments listed above, the research team is also requesting that if you are a patient at FSU SeniorHealth, you provide the study team access to your electronic health records, OR if you are NOT a patient at FSU SeniorHealth, that you provide a copy of your most recent medical records (including health conditions, medications, and recent lab work) or self-report health conditions and medications. Electronic health records will only be extracted from the year prior to the

program and in the year following the program. Health records will be requested from all participants (electronic or self-report) at the beginning of the program and 6 months after the program. The requested disclosure of PHI is the minimum necessary for the research purpose as it will help us assess your cognitive and metabolic response to the nutrition program using information that is most relevant to your provider. This information will include: your problem/diagnosis list, medication list, vitals (e.g., blood pressure), height, weight, and bloodwork that includes a comprehensive metabolic panel and HbA1C, CRP, as well as relevant notes from your provider pertaining to memory and thinking and pain.

These records will allow the team to examine whether the programs have an impact on clinically relevant outcomes. These records will be stored on secure FSU College of Medicine internal servers and will only be accessible by approved study team members. Any research findings from these records and the aforementioned tests will exclude all identifying information.

You may be contacted via phone or email for scheduling purposes. You will only be contacted by the listed study personnel or undergraduate research assistants working under the supervision of the listed personnel. Following completion of participation in the current study, you may be contacted by the primary investigator or other research personnel to participate in additional research projects if you indicate that you are interested in being contacted later on this form.

A description of the 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 the Web site at any time

What happens if I say "yes," but I change my mind later?

You can leave the research at any time and may choose to withdraw your data from the study or withdraw your consent for the team to access your healthcare data; it will not be held against you. You may choose to have your data withdrawn from the study at the time that you choose to end participation.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization.

Biological samples will be stored in a freezer in a locked room in the Center for Translational Behavioral Science phlebotomy lab until analyzed and then discarded.

If identifiers are removed from your identifiable private information or identifiable samples that are collected during this research, that de-identified information or those de-identified samples could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent.

It is also important to note that this study involves a group program and will be completed in collaboration with the FSU SeniorHealth clinic. Thus, you will have contact with other study participants, and we are not able to guarantee confidentiality of information that you share during these group meetings. However, we request that all identifying information be kept confidential to the group setting, and we ask that you not share or disclose other participant information outside of the group meetings. Additionally, clinic personnel may be made aware of your participation in the research study

and may communicate with the study team. Personal information you may choose to disclose during the group meetings will not be shared with your clinicians, unless it is deemed clinically relevant. In these situations, your verbal permission would be requested before such information is shared.

What else do I need to know?

There is no cost to you to participate in the current or related studies. You will be compensated $30 for completing the first visit, including the thinking, memory, and emotional test. For the intervention, you will be compensated $20 at each weekly meeting for your time completing weekly assessments, totaling $120 for completing all 6 weeks. Finally, you will be compensated $30 each for the follow-up assessment appointment and $30 for the 3-month follow-up appointment. Thus, in total, you may be compensated up to $210 in the form of mailed checks or cash for completing the program and pre- and post-intervention assessments.

Most tests done on samples in research studies are only for research and have no clear meaning for health care. Results of the neuropsychological tests (test to measure how well a person's brain is working) are not intended to be diagnostic for healthcare purposes; however, a goal of this study is a brief summary of these results can be provided by request for the purpose of follow-up with a licensed healthcare professional. Testing will be completed by either a trained research assistant or a licensed clinical psychologist, all tests will be reviewed by a licensed clinical psychologist. If neuropsychological results are provided by request, we will share these results with your clinician at the FSU SeniorHealth clinic for review to determine the need for additional testing, treatment, or care options. You may have to pay for those additional services yourself.

Statement of Consent

Do you agree to allow us to reach out to you about future research opportunities? Please check the box below next to your choice.

_____ Yes, you may contact me about future research opportunities.

_____ No, you may not contact me about future research opportunities.

By Checking "Yes" you are granting permission to be informed about future research opportunities in which you may be eligible. Your information provided below will be kept secure and confidential by FSU's Center for Translational Behavioral Science for you to be contacted about future research opportunities.

Contact Details

First Name*: _____

Last Name*: _____

Email Address*: _____

Primary Contact Number*: _____

Type*:

Cell

Home

Work

Cell Number: _____

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

_____ _____

Signature of subject Date

_____

Printed name of subject

_____

IRB Approval Date

Permission to Take Part in a Human Research Study

Florida State University

Research Authorization

For Use and Disclosure of Protected Health Information

Title of Study	Pilot Trial of a Motivational Interviewing and Cognitive Behavioral Therapy (MI-CBT) Ketogenic Nutrition Adherence Program for Older Adults
Protocol # (if applicable)	
Study Subject Name	_____

Please read this form before you sign it.

If you don't know what something means, you can ask us.

Before you sign this, you can talk it over with someone you trust.

In our research, we use and share information about people and their health. We know that this information is private. Federal law protects health information.

The law lets FSU staff use and share information as a part of doing business. This means FSU may use and share information about you:

- To treat you.
- To do billing and get payment.
- To make sure our work is of high quality.

The law lets us use and share health information for research if you agree to let us do this. If you let us use and share information about you, we will protect it as required by law.

If you sign this form, it means you are letting us use and share this information for research.

This form explains how we will use and share your health information. It lists who can see and use your information. It explains what we will do to keep your information private.

Who will disclose (share), receive, and/or use your information?

To do this research, FSU and the people and organizations listed below may use or share your information. They may only use and share your information:

- With the people and organizations on this list.
- With you or your personal representative.
- As allowed by law.

FSU and the people and organizations listed below may use or share information about you to do this research:

1. The research team, including the Principal Investigator, study coordinator, research assistants, and all other research staff.

2. All health care and other FSU staff who treat and serve you at the FSU SeniorHealth clinic as related to this research.

3. Every research site for this study. This includes the research and medical staff at each site and FSU.

4. Any agency of the federal, state, or local government that regulates this research. This includes the Food and Drug Administration (FDA) and the Department of Health and Human Services (DHHS).

5. The members of the FSU IRB/Privacy Board.

6. Staff in the FSU Office of Research, and other FSU offices who oversee this research.

7. Data Safety Monitoring Board and staff: **None**

Who else can use and share this information?
Only the above mentioned study team can use this information and share it within the team. It will not be shared with anyone outside the study team or FSU.

Others not listed here may be able to get information about you from those listed above. That is only allowed when the law does not require them to keep your information private.

What information will be used or shared?

By signing this form, you are letting FSU collect, use, and share the following information collected from FSU SeniorHealth medical records:

- Portions of your medical record pertaining to the study described above. This information will include: your problem/diagnosis list, medication list, vitals (e.g., blood pressure), height, weight, and bloodwork that includes a comprehensive metabolic panel and HbA1C, CRP, as well as relevant notes from your provider pertaining to memory and thinking and pain.

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You may not want FSU to use or share some kinds of information. List any kinds that you do not want us to use or share in the space below. If you list nothing here, we can use and share all of the information listed above.

_____

_____

_____

_____

Your Rights

You can refuse to sign this form.

If you do not sign this form:

- You will not be able to take part in this research and you will not get the study treatment.
- This will not change your health care outside of this study.
- This will not change your health care benefits.
- This will not change the costs of your health care.

You can revoke this form at any time. This means you can tell FSU to stop using and sharing your information. If you revoke this form:

- We will stop collecting information about you.
- You cannot withdraw information that we had before you told us to stop. We may already have used or shared it. Or we may need it to complete the research.
- Staff may follow-up with you if there is a medical reason to do so.

To revoke this form, you must tell us in writing. Please write to:

Principal Investigator: Julia.sheffler@med.fsu.edu

For IRB Study #00001833: humansubjects@fsu.edu

Date This Form Expires
This form will not expire, unless you revoke it in writing.

By signing below,

- I agree that I have read this form or someone has read it to me.
- I agree that I have gotten answers to all of my questions.
- I agree to let FSU collect, use, and share information about me as explained on this form.

I will be given a copy of this form after I have signed it.

Permission to Take Part in a Human Research Study

_____

Signature of Subject or Personal Representative

_____

Printed Name of Subject or Personal Representative

_____

Date

Explain authority of Personal Representative: _____

Subject's Contact Information

Subject's Address:

_____

_____

_____

_____

Subject's Phone:

_____ (Day)

_____ (Evening)

E-mail Address (optional):

_____