Improving Detection and Evidence-based Care of NAFLD in Latinx and Black Patients With Type 2 Diabetes (NAFLD-DM): A Pilot Study

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Please complete the survey below.

Thank you!

CONCISE SUMMARY

NAFLD-DM is a program that is designed to promote detection and evidence-based management of nonalcoholic fatty liver disease (NAFLD) in people with type 2 diabetes. The purpose of this study is to determine whether NAFLD-DM is acceptable to participants, and whether it will be feasible to implement into our healthcare system. NAFLD-DM will be piloted in people who identify as either: Latino/Latina/Hispanic ethnicity and/or Black or African American race - the reason we are focusing on these groups is because we want to make sure that NAFLD-DM is designed to benefit individuals who are at highest risk of having bad outcomes related to NAFLD.
In this 3-month research study, all eligible participants will go through the NAFLD-DM program. This will include:

-Surveys to learn more about you and your medical history at the beginning and end of the study
-Blood tests to check hemoglobin HbA1c and liver tests at the beginning and end of the study
-Education about NAFLD and its risks
-Diet and lifestyle support to help with both diabetes and NAFLD
-Potential changes to diabetes medications to promote liver health
-If indicated, ordering of additional blood tests or imaging studies related to the liver

Risks of partaking in this study include: abnormal blood sugars, side effects to diabetes medications, blood sampling risks, loss of confidentiality.

You are being asked to take part in this research study because you have type 2 diabetes, and likely NAFLD based on abnormal liver tests. Research studies are voluntary and include only people who choose to take part. Please read this consent form carefully and take your time making your decision. As your study doctor or study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below. Please tell the study doctor or study staff if you are taking part in another research study.

Dr. Anastasia-Stefania Alexopoulos, MBBS will conduct the study and it is funded by Duke CTSA KL2 grant, which is in turn from the National Institutes of Health (NIH). This grant will pay Duke University to perform this research, and these funds may reimburse part of Dr. Alexopoulos's salary

WHO WILL BE MY DOCTOR ON THIS STUDY?

If you decide to participate, Dr. Alexopoulos will be your doctor for the study. She will be in contact with your regular health care provider throughout the time that you are in the study and afterwards, if needed.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to understand whether NAFLD-DM is acceptable to people with diabetes and NAFLD, and to determine if/how to refine NAFLD-DM so we can expand it and eventually integrate it into the healthcare system. In this study, we are focusing on individuals who identify themselves as Latino/Latina/Hispanic ethnicity and/or Black or African American race. These individuals are at highest risk of bad outcomes related to NAFLD, and we want to make sure that NAFLD-DM is designed in a way that will help these groups.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

Approximately 20-30 people will take part in this study at Duke.

WHAT IS INVOLVED IN THE STUDY?

Procedures related to the study:

1. If you agree to be in this study, you will be asked to sign and date this consent form.

2. We will ask you questions and review your medical records for information about you (age, race, etc.) and your health (medical history, lab values, etc.).

3. Although this study involves few risks beyond those that are part of routine diabetes care, the changes your body goes through during pregnancy may affect your diabetes treatment plan. Diabetes and liver disease in pregnancy are both associated with an increased risk of complications for mothers and babies, and women with these conditions are advised not to become pregnant without first talking to a specialist in high-risk pregnancy. If you are are currently pregnant or planning a pregnancy, you cannot participate in this study. If you do become pregnant during the study, we will continue with NAFLD-DM except for adding new medications. We will stop diabetes medications that are not indicated in pregnancy and reach out to your diabetes provider and a specialist in high-risk pregnancy to transition your medication management back to them.

4. The study will last approximately 3 months, and will include at least 6 virtual visits (including the enrollment visit to determine eligibility). Visits will occur at varying intervals over the course of the 3 months. See Table 1 for a summary of NAFLD-DM study visits.

a. Enrollment visit: This visit should take somewhere between 40 and 60 minutes. We will ask you to review and sign the online consent form for study participation. We will ask you to complete a series of questionnaires, which can be done remotely online or over the phone with study staff. We will work with you to plan when and where to complete your blood tests (for hemoglobin A1c, and liver tests) if needed. Approximately one tablespoon of blood will be collected, if you have not already done these within 3 months prior to enrollment. Participants will receive $50 for completing the enrollment visit including questionnaires and necessary blood tests.

b. NAFLD-DM. Once your enrollment visit is complete, you will start NAFLD-DM. This will include:
- NAFLD education: You will have a virtual/remote visit scheduled with Dr. Alexopoulos or another study member who will provide you with information about NAFLD, and to answer your questions.

- Diet/lifestyle support: You will have three diet/lifestyle visits scheduled once per month for three months. Each of the three sessions will last approximately 30 minutes. During the sessions we will provide you with information about diet/lifestyle habits that will promote health of your liver. We will also review your diet/lifestyle patterns and promote goal setting together.

- Medication management: We will schedule a virtual visit with you and Dr. Alexopoulos to discuss and possibly adjust your diabetes medications. These sessions occur on an as needed basis each month and could last approximately 20 minutes each. You will be responsible for costs and copays of new medications that are started - if the cost is too high, you can let the study team know and it will be discontinued. The first medication management visit will be at baseline, soon after enrollment. During these visits, Dr. Alexopoulos will review your blood sugar values with you, and you will both decide on medication changes that may benefit NAFLD based on your medical history. If you need a new glucometer and/or supplies, Dr. Alexopoulos can prescribe this for you as part of the study, however you will be responsible for costs of these supplies.

Your primary care doctor or Endocrinologist will be alerted to changes through the Duke electronic health record, and once this 3-month study is over, you will continue to follow with your previous providers for your diabetes management.

- Clinically indicated liver tests/referrals: Dr. Alexopoulos will review your records to see whether any additional tests or referrals are needed for your liver - this will occur as part of medication management visits. As indicted in Table 1, frequency and timing of medication management and ordering of tests/referrals will vary by participant (and depending on medication adjustments made), but may occur monthly for the duration of the study (at 0,1,2,3 months).

c. At the end of the study (3 months), you will get repeat blood tests (hemoglobin A1c and liver tests) and we will work with you to arrange a time to complete final questionnaires and your interview. Virtual interviews will be audio recorded, and will be approximately 30 minutes in length. Participants will receive $50 after end-of-study questionnaires and interviews have been completed.

5. We will use your contact information to share study results with you.

6. Participating in this study is voluntary, and your refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled. If you do not sign this consent form, you will continue to receive care from your primary doctors, but not as part of this study.

7. You will continue to receive care for your diabetes, NAFLD and other conditions with your current providers throughout the study period. Your current Primary Care or Endocrinology will be updated about any changes made to your medications by the study team.

[Attachment: "Table 1 _consent.png"]

HOW LONG WILL I BE IN THIS STUDY?

The study will be approximately 3 months long. You can choose to stop participating at any time without penalty or loss of any benefits to which you are entitled. However, if you decide to stop participating in the study, we encourage you to talk with the study staff first.

Clinically relevant results of this research will be communicated with you after the study has been completed, and it will include aggregated data showing how acceptable NAFLD-DM was to participants (using a survey measure) and how feasible it was to conduct the study.

WHAT ARE THE RISKS OF THE STUDY?

- We expect that the physical risks and discomforts of this study will not be any different than usual care of diabetes and NAFLD. A risk of any diabetes medication is causing a low blood sugar.
o Symptoms of a low blood sugar can include sweating, confusion, and nausea, and rarely a loss of consciousness or seizure.

- You will receive blood test to check your HbA1c and liver tests up to two times during this study. Risks associated with blood draw include a momentary discomfort and/or bruising. Infection, excess bleeding, clotting or fainting are also possible, although unlikely.

- We will be collecting private health information from you during this study, which will be kept confidential. We will assign random study codes to participants to protect confidentiality, and this will allow information to be stored and analyzed on secure Duke servers without personal identifiers. There is still, however, the potential risk of loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed.

- Some patients may experience discomfort from being asked questions about their well-being as it relates to their diabetes and overall health. You may refuse to answer any of the questions and you may take a break at any time during the study. Study staff will be sensitive when asking questions and will allow you to recover before proceeding with further questions.

- Some questions we ask during the survey may be considered sensitive to some people; if you do not wish to answer any question, we can proceed to the next question upon your request.

- All surveys are completed using encrypted software and are kept confidential.

- If you experience discomfort that you think may be related to the research, you can call the study team.

There may be risks, discomforts, drug interactions or side effects with study participation that are not yet known.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this study, your diabetes and liver health may improve; however, this cannot be guaranteed. We hope that in the future the information learned from this study will also benefit other people with your conditions.

WILL MY INFORMATION BE KEPT CONFIDENTIAL?

Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total confidentiality. Your personal information may be viewed by individuals involved in this research and may be seen by people including those collaborating, funding, and regulating the study. We will share only the minimum necessary information in order to conduct the research. Your personal information may also be given out if required by law.

As part of this study, you will be asked to have certain lab and imaging tests performed. These tests would have been done as part of your regular care. The study doctor will use these test results both to treat you and to complete this research. These test results will be recorded in your medical record and will be reported to your primary care team, and the NAFLD-DM study team.

As part of the study, results of your study-related laboratory tests, and procedures may be reported to Duke and its affiliates. In addition, your records may be reviewed in order to meet federal or state regulations. Reviewers may include representatives and affiliates of the Duke University Health System Institutional Review Board, and others as appropriate. If any of these groups review your research record, they may also need to review your entire medical record. At the end of the study, you will be asked to conduct a 30-minute (virtual) interview that will be audio recorded. The recordings will be saved in a secure Duke folder behind the Duke Firewall. Audio recordings will not be transcribed, and they will be deleted from the Duke folder 3 years after the study concludes.

The study results will be retained in your research record for at least six years after the study is completed. At that time either the research information not already in your medical record may be destroyed or information identifying you will be removed from such study results at DUHS. Any research information in your medical record will be kept indefinitely. While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your name or other personal information will not be revealed. While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your name or other personal information will not be revealed.

Some people or groups who receive your health information might not have to follow the same privacy rules. Once your information is shared outside of DUHS, we cannot guarantee that it will remain private. If you decide to share private information with anyone not involved in the study, the federal law designed to protect your health information privacy may no longer apply to the information you have shared. Other laws may or may not protect sharing of private health information.

WHAT ARE THE COSTS TO YOU?

You or your insurance provider will be responsible and billed for all costs related to your routine medical care, including copayments and deductibles. Routine medical care services are those that you would have received for your condition if you were not participating in this research study. Not all services are covered by insurance. Some procedures or scans may require pre-authorization by your insurance plan. We will notify you if we learn that a service is not covered by your insurance plan as part of the pre-authorization process. If it is not covered, you will be responsible for paying for it. The amount of your out-of-pocket expense will depend on your insurance plan. For beneficiaries with Medicare Advantage Plans, traditional Medicare is billed for the routine cost of a research study. You may have more or higher co-pays than with a Medicare Advantage plan. Please discuss the costs of the study with Dr. Anastasia-Stefania Alexopoulos. At your request, a Financial Counselor in the clinic may provide you with an estimate of costs for routine services.

WHAT ABOUT COMPENSATION?

You will be compensated up to $100 for completing all visits as part of this study. After completing the baseline assessment, you will receive $50.You will also be compensated $50 for completing the end-of study assessment (which includes surveys and the interview).

WHAT ABOUT RESEARCH RELATED INJURIES?

Immediate necessary medical care is available at Duke University Medical Center in the event that you are injured as a result of your participation in this research study. However, there is no commitment by Duke University, Duke University Health System, Inc., or your Duke physicians to provide monetary compensation or free medical care to you in the event of a study-related injury.

For questions about the study or research-related injury, contact Dr. Anastasia-Stefania Alexopoulos at 919-684-8111, or request page to 970-1154 during regular business hours, after hours, or on weekends and holidays.

WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?

You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes unless the data concern an adverse event (a bad effect) related to the study. If such an adverse event occurs, we may need to review your entire medical record.

Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care at Duke, and will not affect your job status if you are a Duke employee. If you do decide to withdraw, we ask that you email Dr. Alexopoulos at asa61@duke.edu.

We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

Your doctor may decide to take you off this study if your condition gets worse, if you have serious side effects, or if your study doctor determines that it is no longer in your best interest to continue. The sponsor or regulatory agencies may stop this study at anytime without your consent. If this occurs, you will be notified and your study doctor will discuss other options with you.

Your data may be stored and shared for future research without additional informed consent if identifiable private information, such as your name and medical record number, are removed. If your identifying information is removed from your data, we will no longer be able to identify and destroy them. The use of your data may result in commercial profit. You will not be compensated for the use of your data other than what is described in this consent form.

A description of this clinical trial will be available on https://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.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or a research-related injury, or if you have problems, concerns, questions or suggestions about the research, contact:

- Dr. Anastasia-Stefania Alexopoulos at 919-684-8111 (request page to 970-1154) during regular business hours, after hours, or on weekends and holidays.

- Susanne Danus, Clinical Research Coordinator, at 919-681-4453 during regular business hours.

For questions about your rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111.

STATEMENT OF CONSENT

"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

Please select one:

◯ I have read the consent document and I wish to participate in the study.
◯ I have read the consent document and I DO NOT wish to participate in the study.

Participant First Name

Participant Last Name

Participant's E-mail Address

Participant Signature

Date

Protocol Number

Pro00113239

Consent Version Date

05/18/2023

Consent Expiration Date

05/18/2025

Please feel free to download a copy of the consent form for further review.

[Attachment: "NAFLD_DM_ICF_Approved 2023.04.18.pdf"]