Informed Consent

Randomized Explanatory Trial of a Mediterranean Dietary Pattern Weight Loss Intervention for Primary Care Practice—also known as the DELISH (Delicious Eating for Life in Southern Homes) Study

NCT number NCT04302727
Document Date 03/04/2022

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

Consent Form Version Date: March 4, 2022
IRB Study # 19-1712
Title of Study: Randomized Explanatory Trial of a Mediterranean Dietary Pattern Weight Loss Intervention for Primary Care Practice—also known as the DELISH (Delicious Eating for Life in Southern Homes) Study
Principal Investigator: Thomas Keyserling, MD, MPH
Principal Investigator Department: Medicine-Internal Medicine
Principal Investigator Phone number: (919) 966-6081
Principal Investigator Email Address: thomas_keyserling@med.unc.edu
Funding Source and/or Sponsor: NIH National Heart, Lung, and Blood Institute (NHLBI)

Study Contact Telephone Number: 919-843-9563
Study Contact Email: kiira_lyons@med.unc.edu or thomas_keyserling@med.unc.edu

---

SUMMARY
Intensive weight loss programs (14 or more counseling sessions over 6 months) are recommended for patients with a body mass index (BMI) greater than 30, yet long-term weight loss is often modest and many prior weight loss programs have not focused on what we now know to be a healthy eating pattern. This study will compare a new weight loss program that focuses on a healthy eating pattern (call Med-South) with WW™ (formally Weight Watchers™), an effective and widely available weight loss program. Those who take part will be randomly assigned (like flipping a coin) to either the new weight loss program or WW™. Both programs will last for 2 years with measurement visits at the start of the study and at 4-, 12-, and 24-month follow-up.

This is a low-risk study, as both weight loss programs follow current guidelines for such programs. There may be minor pain from the blood draws at each measurement visit. Intensive weight loss programs do involve many counseling visits so taking part does require a time commitment, as described below. We expect participants in both study groups will lose weight and consider this a benefit of taking part in the study.

(Please also see pages entitled "Information about Participating in a Research Study during COVID-19." Specific information related to COVID-19 and limitations on in-person counseling or group counseling are noted in italics below. This may change over time according to updates in guidelines about COVID-19.)

Introduction:
We invite you to take part in this research project. This form tells you about the project so you can decide if you want to join this study. If you do, you can change your mind and withdraw at any time. We think you will benefit from taking part in this study, but you may not, as the purpose of research studies is to gain new knowledge that may help others in the future. There also may be risks to being in a research project and these are noted on this form. If you do not take part in this study or you start the study and then decide to stop taking part before it is done, your decision will not be a problem for your doctors or other health care providers.

What is the purpose of this study?
The purpose is to develop and test a new weight loss program that includes a major focus on a healthy dietary pattern. A healthy dietary pattern includes eating more foods with high-quality fats (vegetable oils, nuts, seeds, fish) and high-quality carbohydrates (fruits, non-starchy vegetables, whole grains, and beans) and eating fewer foods with poor quality carbohydrates (sugar sweetened beverages, refined grains, and many processed foods). The eating pattern we are testing is similar to a Mediterranean dietary pattern. We call this new weight loss program the "Med-South Weight Loss Program" because it will be tested in the southern US. To learn if the Med-South Weight Loss Program is more effective than currently available weight loss programs, we will compare it to WW™ (formally Weight Watchers™). We have selected WW™ because it is an effective weight loss program that is widely available.

You are being asked to be in this study because your Body Mass Index (BMI) was greater than 30 (when last checked at the clinic) and your doctor approved for you to take part because he or she thinks you might benefit from losing weight.

How many people will take part in this study?
There will be about 360 people in this research study.

How long will your part in this study last?
About 2 years.

What will happen if you take part in the study?
First, we mailed you the study brochure and then study staff called to confirm that you are eligible and to see if you want to take part. If so, we mailed or emailed you this consent form. Next, we will call to answer any questions about this form. After doing so, if you want to take part, we will give you instructions on how to sign this form electronically or you may sign it at your first study visit (enrollment visit). Then, we will schedule the enrollment visit.

Study surveys are completed online before the enrollment visit. We will email you a link to access the surveys by smartphone, tablet, or computer. We expect it to take about 1.5 hours to fill out all surveys that ask about your lifestyle behaviors (like eating and physical activity habits) and other questions about your health. You do not need to complete them all at one time. You may re-access the surveys using the same link. *(We will call you within 24 hours before this and all study visits to review a symptom checklist related to COVID-19.)*

The enrollment visit, follow-up measurement visits, and in-person counseling visits will take place at the UNC Center for Health Promotion and Disease Prevention, 1700 Martin Luther King, Jr, Blvd., Chapel Hill, NC, which is located about 5 miles north of the UNC main campus. (We will send instructions on how to get to our office.) We will ask you to fast for 9 hours and avoid caffeine for 30 minutes before the enrollment visit and the other measurement visits, but if you are unable to fast you may still participate. We will schedule these visits in the morning. At the beginning of the visit, we will invite you to empty your bladder (recommended before measuring blood pressure). If you have not already signed the consent forms online, we will start the first visit by having you sign the consent forms. Then, we will check to see if all surveys have been filled out and complete any that may not have been done. Next, we will review your current medication listed in the UNC medical record and record medications you are taking for diabetes, high blood pressure, high cholesterol, and for heart burn or stomach ulcers.

Next, we will check your weight, height, and blood pressure. Then, we will ask you to put your finger in an instrument that checks skin carotenoid levels (which tell us about how much fruit and vegetables you eat or drink). This test does not hurt and takes less than 3 minutes. After that, we will collect a blood specimen (about 2 tablespoons). We will measure total cholesterol, HDL cholesterol, triglycerides, and A1c (a test of your blood glucose over the past 3 months). We will report the results of these tests to you and your primary care clinician. We will also do some special research blood tests to look at how what you eat impacts blood inflammatory markers. If you agree, we will also store blood for future research. (Please note: on occasion, a study phlebotomist [person who draws blood samples] may not be at our research office. If this occurs, we may ask you to stop by one of the nearby UNC phlebotomy sites, at either the ACC or Eastowne clinics, to get your blood drawn prior to your visit at our research office. If this occurs, a study staff member will meet you at the phlebotomy office to answer any questions about the study and to have you sign the consent forms, if you did not already do so online. We will provide additional compensation for this extra time, as noted below.)

There is a great deal of scientific interest in how dietary patterns may change the bacteria that live in your intestines (the microbiome) and if these changes impact weight change. So that we can learn if your microbiome changes in response to the weight loss programs, we invite participants to submit stool samples. This part of the study is voluntary. If you agree to do so, we ask you to collect and return (by mail) a stool sample within 2 weeks of the enrollment visit and the other study visits. Study staff will go over the instructions for collecting these samples at your first visit.

It will take about 30-45 minutes to complete the measures outlined above and to collect your blood sample.

After we collect the blood sample, study staff will randomly assign you (like flipping a coin) to receive either the Med-South Weight Loss Program or WW™. If you are assigned to the Med-South Weight Loss Program, you will receive your first counseling session, which should take 45-60 minutes. If assigned to WW™, we will give you instructions on how to get started with this program, which should take about 15-30 minutes. *(Note, these sessions will take place in a large conference room—you will be seated more than 10 feet away from study staff.)* If you bring your smartphone to the visit, we will help you download the WW™ App. Also, whichever

group you are in, you will be encouraged to do moderate physical activity, like brisk walking, which is recommended for all Americans.

Please note, WW™ is a safe and effective program that is considered a standard for community-based weight loss programs. If you are randomized to this program, we encourage you to engage with the program and take full advantage of what it has to offer. We do not know if the new program we have developed is better than WW™. That is what we hope to learn in this study. If it turns out the Med-South Program is better, then components of the Med-South Program may be added to other weight loss programs in the future.

Med-South Weight Loss Program
Most weight loss programs offer weekly one-on-one or group counseling sessions for 16-20 weeks. The Med-South Weight Loss Program is different and is given in 3 phases. The program begins with **Phase I**, a 4-month lifestyle phase that focuses on the "basics" of healthy eating rather than weight loss. Over the next 8 months in **Phase II**, we focus on weight loss, followed by a year-long (**Phase III**) phase to help you maintain weight loss. In Phases I, the main counseling sessions are given monthly, followed by check-in phone calls 1-2 weeks later. In Phase II, the main counseling sessions will occur weekly for the first 8 weeks, then monthly for the remaining 6 months, depending on your progress. There are also check-in phone calls--the number will vary based on your progress. During Phase III, there are 2 main visits and follow-up phone calls. More details about these visits are in the table below.

Some of your counseling visits will be face-to-face with your counselor and some by phone. Only one member of a family may join this study, but other family members are invited to take part in face-to-face and phone counseling sessions. *(As of September 2020, due to COVID-19 only one other family member or friend may come with you to in-person visits.)* The face-to-face format will be required for a total of 5 visits – the *first visit* in each of the 3 phases (right after study measurements at enrollment, and 4 and 12 months), 2 months after starting the weight loss program in Phase II, and mid-way during Phase III (about 18 months after starting the Program). *(As of September 2020, we will allow other visits to be done in person if that is the preference of the study participant. Otherwise, the other visits will be done by phone or videoconferencing.)* The other sessions may be done by phone/videoconference or in-person. During Phases II and III, when you come to our office for a face-to-face counseling session, we will also check your weight.

During face-to-face sessions, you and the counselor will use a web-based program or the paper format to review educational materials, select dietary goals, and list first steps to reach these goals. If the phone format is used for major counseling sessions, you may view the educational content online or use your paper version. The program also includes brief telephone calls to check on progress towards goals selected at previous sessions and provide support for lifestyle change. The number of phone calls you get will depend on if you are meeting your personal weight loss goals in Phase II or keeping the weight off in Phase III. The table below has more information.

Phases	# Contacts	Contact Length	Estimated Total Contact Time

Phase I	• 8 total ○ 4 core sessions: the first must be in-person; choice of in-person or phone for all others ○ 4 follow-up phone calls	• Core session = 45-60 min. • Follow-up call = 15 min.	4 - 5 hours
Phase II	• 14 core sessions: the first and a visit about 2 months later must be in-person; choice of in-person or phone for all others. • 6-12 follow-up phone calls	• Core session (in-person) = 45-60 min. • Core session (phone) = 30-45 min. • Follow-up call = 20-30 min.	8.7 – 14 hours (core) 4.7 – 9.5 hours (Follow-up)
Phase III	• 2 core sessions (both in-person) • 12-24 follow-up phone calls (1-2 per month)	• Core session (in-person) = 45-60 min. • Follow-up call = 15-20 min.	1.25 – 2 hours (Core) 3 – 8 hours (Follow-up)
2-Year Program TOTAL	**44 – 60 Contacts**	**--**	**21.7 – 38.5 hours**

If you agree, we may audio-record a few counseling sessions for quality improvement purposes (to check on how our counselors are doing and provide feedback on areas needing improvement). These recorded sessions will be kept as electronic files but without information that could be used to identify you (other than your voice).

WW™ Weight Loss Program

If you are randomized to WW™, you will have access to both the workshop and digital components of the WW™ Program for 2 years. WW offers in-person coaching and community-based learning through weekly Workshops at WW™ Studios. The Workshop component allows for attending weekly group meeting at a WW™ studio (local WW™ office). [*As of September 2020, due to COVID-19, the workshop component will be available in a virtual videoconferencing [Zoom™] format in most locations, but may be available for in-person group sessions at some locations (where sessions are given in a large room with limited attendance and following North Carolina guidelines for wearing masks and social distancing.)]*

The Digital component can be accessed using the WW™ website or a smartphone App. The digital tools available in the WW™ Digital program include food tracking (either manually or with bar code scanning), progress charts, lifestyle coaching with 24/7 chat with a WW Coach, ability to track activity (manually or by syncing a fitness tracking device), incentives for behavior change (WellnessWins), recipes, and even local restaurant recommendations using GPS. You will also have access to Connect, a digital community for WW™ members. Study staff will provide basic instructions on how to use the WW™ digital resources.

The WW™ Program uses "SmartPoints" assigned to foods based on energy content and nutritional value, allocating a certain number of points to users daily based on their starting

weight, weight loss goals, age, and sex. You'll receive a personalized SmartPoints budget made up of Daily SmartPoints, plus some extra Weekly SmartPoints for those days when you need a "cushion."

If you are assigned to the WW™ Program, you get to decide how many workshops to attend and how often to use the digital program. You can decide to not attend the workshops and only use the phone App and/or website. *(As noted above, as of June 2020, due to COVID-19, the workshop component will be in a virtual videoconferencing [Zoom™] format, until further notice.)* At the 4 month follow-up visit, we will check to see if you have been using the WW Program. If not, we will ask if you would like study staff to check in with you about using this Program.

Follow-up measurement visits
About 4, 12, and 24 months after starting the study, we will ask you to return for follow-up measures, which will be like those collected at study enrollment. We will ask you to fill out surveys online before this visit. It will take about 1 to 1.5 hours to fill out the surveys and 30 minutes for the measurement visits. Please note that for us to understand if the Med-South Weight Loss Program is effective, we must carefully measure many study outcomes. Most of these outcomes are measured by questionnaire. The amount of blood work drawn for measurement is like that taken at routine office visits when several tests are ordered (about 2 tablespoons at baseline and 12 months; and 1.5 tablespoons at 4 and 24 months). The stool test is optional. As outlined below, we will compensate for your time spent on measurement at a rate of $20 to $30 dollars per hour. And we thank you in advance for your willingness to complete this very important part of the study. (Please note: on occasion, a study phlebotomist [person who draws blood samples] may not be at our research office. If this occurs, we may ask you to stop by one of the nearby UNC phlebotomy sites, at either the ACC or Eastowne clinics, to get your blood drawn prior to your visit at our research office. If this occurs, either study staff will meet you at the phlebotomy office or we will drop off the collection tubes in advance and ask you to bring them to the office. We will provide additional compensation for this extra time, as noted below.)

Contacting you for follow-up visits
We will call you up to 3 times over a 4-week period during regular work hours and after hours. We may also send up to 2 texts and/or emails if you agreed to receive texts or emails while taking part in this study. If we cannot reach you, we will send a letter and invite you to contact us if want to continue in the study or if you want to stop, to let us know why. Again, it is fine to stop taking part in this study at any time.

Will I be informed about the study's findings?
We will inform all who take part about the study's findings. If the Med-South Weight Loss Program results in greater weight loss, we will make the Med-South Program materials available to those who received the WW™ Program.

Should I take part in this study?
Prior research indicates that for weight loss studies to be effective, they must offer an intensive

intervention, defined as at least 14 sessions over a 6-month period. That is why the Med-South Program includes many contacts and why WW™ suggests frequent contact with their program. So, you need to ask yourself if you are willing to make this type of commitment to a weight loss program. If you are, we welcome you to this study! We will do all we can to accommodate your schedule or any special needs you may have as you take part in the weight loss programs and return for measurement visits.

What are the possible benefits from being in this study?

We think you may benefit from being in this study by improving your lifestyle and losing weight. However, you may not benefit from being in this study.

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

The possible risks and discomforts from being in this study are few and are listed below.

- We do not think there is risk to you from the dietary advice given as part of the Med-South Program or WW™.
- Eating less is a part of standard weight loss programs. If you do not eat enough, you could lose weight too fast. By asking you to check your weight often, the weight loss programs in this study will let you know if and when you are losing weight too fast.
- Although doing more physical activity is not the main focus, both weight loss programs will recommend you do moderate physical activity. Those who increase their level of physical activity may experience minor muscle pain (this is common, affecting more than 50 in a 100 people), but this type of activity rarely (fewer than 1 in a 100) causes serious health problems such as chest pain or asthma.
- For those with diabetes, losing weight and reducing carbohydrate in the diet can lead to lower blood sugar, including hypoglycemia. This has occurred in less than 1 in a 100 people in our past studies. We will provide those with diabetes information on how to reduce the risk of low blood sugar.
- For those with high blood pressure, losing weight can lead to lower blood pressure, which can cause dizziness and even falls. Adverse outcomes related to low blood pressure are very rare in weight loss studies, occurring in less than 1 in a 100 people. Typically, the blood pressure is lowered slowly with weight loss, allowing your doctor time to observe the lower blood pressure and reduce your blood pressure medicine.
- A blood sample will be collected by trained staff. The risk of minor pain is very common (in more than half of people). Bruising does not happen often (about 1-10 of every 100 persons) and the risk of infection or fainting is rare (fewer than 1 in 100).
- In all studies, there is a very slight chance of loss of privacy (that is, others may see your study information). As stated below, we will do all we can to make sure this does not happen.

Also, there may be other risks we did not list here. You should report to the research team any problems that may be due to this study.

What if we learn about new findings or information during the study?

You will be given any new information gained during the study that might affect the risk of taking part in this study.

How will information about you be protected?

Your study bloodwork for routine tests (cholesterol levels and A1c) will be stored with your name as this will be sent to a commercial lab for analysis (LabCorp). These samples are typically thrown away 5-7 days after collection. Your study surveys and bloodwork for the inflammatory markers will be stored with your study ID number and your first and last initial, but NOT with your name (we call this de-identified data). No one other than study staff will be able to connect your name and study ID as we will follow standard procedures to protect the privacy of research data.

We may use your de-identified data, as described above, in future research without additional consent. However, in some cases, the Institutional Review Board (called IRB and described below) may require that you be re-contacted and asked for your consent to use your data in a specific research study. You have the right, at that future time, not to participate in any research study for which your consent is sought.

Participants will not be identified in any report or publication about this study. 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 agents of the University or research sponsors for purposes such as quality control or safety.

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 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.

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.

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.

What will happen if you are injured by this research?
It is not likely that you will be injured by this research, but all research involves a chance of injury. If a medical problem occurs, the researchers will help you get medical care, but costs for this care will be billed to you and/or your insurance company. The University of North Carolina at Chapel Hill has not set aside funds to pay you for injuries or medical care. However, by signing this form, you do not give up any of your legal rights.

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 research team also has the right to stop your participation at any time. This could be because you have had an unexpected reaction, or did not follow instructions, or because the entire study has been stopped.

Will you receive anything for being in this study and will it cost you anything to take part?
You will receive the weight loss program and lab work free of charge. You will receive $60 payment for your time devoted to study measures at the start of the study and at 4-, 12-, and 24-month follow-up. The payment rate is $20-30/hour. If you complete all measurement visits, you will receive a total of $240. In addition, you will receive $30 reimbursement for each stool specimen you submit and $20 reimbursement if we you have your blood work done at one of the UNC phlebotomy offices.

We will calculate the one-way distance from your home address to our research office and will reimburse mileage for measurement visits as below. Note, there is *no reimbursement for mileage* if you attend a WW™ workshop or if you come in for a Med-South Weight Loss Program counseling visit that does not include a measurement visit (measurement visits are: enrollment visit and 4-, 12-, and 24-month follow-up visits). Parking is free. All reimbursement will be by gift card.

Mileage reimbursement rate:

- Less than 10: $0
- 10-19 miles: $10
- 20-29 miles: $20
- 30-39 miles $30
- 40-49 miles $40
- 50-59 miles $50
- 60 or more $60

Who is sponsoring this study?
This study is funded by the National Heart, Lung, and Blood Institute (NHLBI). This means the research team is being paid by NHLBI for doing the study. The researchers do not have a financial interest in the final results of the study.

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.

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.

I also agree to submit stool samples as part of my participation in this study.
____ yes
_____no

_____ _____
Signature of Research Participant Date

_____
Printed Name of Research Participant

_____ _____
Signature of Research Team Member Obtaining Consent Date

_____
Printed Name of Research Team Member Obtaining Consent