

Individualized Structured Eating Plans to Improve Glycemic Control in Adolescents with Type 1 Diabetes

NCT number NCT05147324
Document Date 09/20/2022

University of North Carolina at Chapel Hill
Assent to Participate in a Research Study
Participants age 12-14 years

Consent Form Version Date: 09-20-2022

IRB Study: 21-1337

Funder: National Institutes of Health

Title of Study: Individualized Structured Eating Plans to Improve Glycemic Control in Adolescents with Type 1 Diabetes

Principal Investigator: Dr. Elizabeth Mayer-Davis, PhD (919-966-7218, mayerdav@email.unc.edu); Sarah Couch, PhD (513-558-7504, couchsc@ucmail.unc.edu)

Principal Investigator Department: Nutrition

Co-Investigators: Nina Jain, MD (919-843-2915, nina_jain@med.unc.edu), Amy Shah, MD (513- 636- 4744, amy.shah@cchmc.org)

Summary of the study:

- The goal of this research study is to learn about whether following an eating plan designed for you would be something that you could do with help from a dietitian and your family. The researchers want to learn whether these eating plans help young people with type 1 diabetes take better care of their blood sugar.
- Via videoconference, you will attend weekly (first 2 months) and bi-weekly (last 4 months) virtual counseling sessions with a study dietitian.
- Your parent will attend at least the first 3 virtual sessions and the session half-way through the study.
- You will attend 2 measurement visits at the UNC Clinical & Translational Research Center or complete these visits over telemedicine
- You will complete questionnaires at the beginning of the study, 3 and 6 months.
- You will log food, exercise, and wake-up time in MyFitnessPal premium at least 3 days per week.
- Every week, you will work on goals to follow the personalized eating plan.
- This study will last about 6 months.
- You can earn up to 200 USD for completing the study.

Why are you being asked to be in this research study?

You are being asked to be in the study because you:

- are between 12 and 17 years old
- have been diagnosed with type 1 diabetes for longer than one year, and
- have an A1c test (average blood sugar level for the past 3 months) between 8 and 11%

How many people will take part in this study?

About 40-50 people will be in this study.

What will happen during this study?

- The study will last a little over 6 months (26 weeks)
- There will be two in-person study visits that will take place at the University of North Carolina Clinical and Translational Research Center in Chapel Hill. There is a possibility that we can use the measurements from your routine care visit. In this case, you will be mailed study materials and the study visits at the beginning and end of the study will take place over telemedicine instead of in-person and within 2 days of your routine care visit.
- At the first study visit, you will be asked to complete study questionnaires about yourself, and will be assisted in inserting a continuous glucose monitor.
- A study dietitian will show you how to use an app called “MyFitnessPal” to keep track of when you wake up, eat, and exercise. For the first 2 weeks, you will carry on with your regular eating and physical activity schedule. You will log in MyFitnessPal at least 3 days per week.
- On two of the days during this first two weeks, someone from University of North Carolina will call you to learn more details about what you eat and about your physical activity.
- The study dietitian will work with you and your parent or guardian on an eating plan that uses food you like to eat, and that is planned around your usual schedule during the week and on weekends. You will be asked to follow the eating plan for 6 months.
- Through telemedicine sessions, the study dietitian will help you learn how to follow your eating plan by meeting with you every week for the first 2 months, and then every 2 weeks for the last 4 months.
- We will ask you to track your food and physical activity on selected days during the study. During each session you will also set goals related to sticking to your eating plan until the next session.
- You will earn points for logging in MyFitnessPal and meeting your goals in between sessions. By completing logs, meeting goals, and completing questionnaires and measurements, you have the opportunity to earn up to 200 dollars.
- Two weeks before the study ends, you’ll put on a continuous glucose monitor that you will receive by mail.
- On two days during the last two weeks of the study, once again, someone from University of North Carolina will call you to learn more details about what you eat and about your physical activity.
- At your last study visit you will be asked about what you liked about the eating plan, and what you didn’t like. You will complete the same questionnaires you did at the beginning of the study. You will return your continuous glucose monitor either in-person or via pre-paid envelope.
- We will measure your height and weight at the beginning and end of the study. We will also ask you to weight yourself at home at the beginning, mid-point, and end of the study to make sure you stay healthy throughout the study.

Who will be told the things we learn about you in this study?

When you begin the study, you will be given a study identification number. This number identifies you rather than using your name. Your information will remain private and only the people working on the study will be able to see this. We will not tell anyone what you tell us without your permission unless there is something that could be dangerous to you or someone else.

These are some things we want you to know about research studies:

Your parent needs to give permission for you to be in this study. You do not have to be in this study if you don't want to, even if your parent has already given permission.

You may stop being in the study at any time. If you decide to stop, no one will be angry or upset with you. Your doctors will still continue to take good care of you.

Sometimes good things happen to people who take part in studies, and sometimes things happen that they may not like. We will tell you more about these things below.

What are the good things that might happen?

Research is designed to benefit young people with type 1 diabetes by producing new knowledge. You may not benefit personally from being in this research study, but it is possible you may like the eating plan and find that it benefits your glycemic levels.

What are the bad things that might happen?

Sometimes things happen to people in research studies that may make them feel bad. These are called "risks." Although it is possible, we do *not* think that any of the study activities would be harmful. Discussions with the dietitian will focus on your eating and physical activity, and how you manage your blood sugar. We do not think that these discussions will be upsetting. We expect that any physical discomfort you have in our study will be the same as when you visit the doctor for your diabetes. The height, weight, HbA1c, and continuous glucose monitoring measurements that you will complete during the study are similar to what you experience in routine diabetes care.

If anything happens to you that we do not expect, you should report problems to any member of the research staff.

How will we keep in touch with you throughout the study?

With your permission, we will send you and your parent text and e-mail reminders to help you remember to complete study activities, like logging in MyFitnessPal, completing questionnaires, or sticking to your goals throughout the study. We'll also e-mail or text you and your parent the links to the questionnaires to fill out about yourself so that you can fill them out ahead of in-person visits and don't have to spend as much time at the clinic. If you agree, you'll provide your cell phone number and e-mail address below so that we can send you these messages. Text and e-mail messages are not protected ("encrypted"), so there's always a chance that your privacy will not be protected. However, very limited personal information will be in the text and e-mail messages we send you because the messages will never refer to anything besides activities related to the study.

The staff will send you these reminders and questionnaire links using phone numbers and e-mail addresses that are different from the ones you'll use to contact study staff in order to re-schedule appointments or if you have questions or concerns related to the study. Do not use these phone numbers or e-mail addresses to contact the study staff. If you want to contact study staff because you have a question/concern related to the study, or because you want to reschedule a study visit or session, you or your parent can call the study phone number at the number that we provide you with at the beginning of the study. Using your personal phone number and e-mail address, you can e-mail or text the study staff through group text message or e-mail message. This means you would send the message to the study staff and your parent's e-mail address. You can also contact the study staff by having your parent send an e-mail or text message the study staff on your behalf.

With your permission, the dietician will also e-mail you and your parent a copy of what you go over together and the goals you set at each online study session. This information may help you stick to your goals and put into practice the things you go over with the dietician every week. You or your parent can respond to that e-mail to talk with the dietician about what she/he sends you.

If you lose access to your cell phone, 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 you request to stop receiving communication, you will no longer receive messages specific to this study.

Study staff will not use your e-mail or phone number to contact you for any other reason than those discussed in this form.

 Yes, I agree to receive un-protected group messages about the study (i.e., texts, e-mails that include both me and my parent)

phone number

e-mail

 No, I do not agree to receive un-protected group messages about the study (i.e., texts, e-mails that include both me and my parent)

Will you get any money or gifts for being in this research study?

You will receive up to a \$200 gift card for taking part in this study. You will earn money for completing questionnaires and measurements throughout the study, logging your food and physical activity, and meeting your eating goals. You will receive the total amount you earned in the form of a gift card when you complete the study. You will also be reimbursed for a year long subscription to MyFitnessPal Premium.

Who should you ask if you have any questions?

If you have questions you should ask the people listed on the first page of this form. If you have other questions, complaints or concerns about your rights while you are in this research study you may contact the Institutional Review Board by phone 919-966-3113 or by email to

IRB_subjects@unc.edu

☐ **I voluntarily agree to take part in this research study.**

Sign your name here if you want to be in the study

Date

Print your name here if you want to be in the study

☐ **I do not agree to take part in this research study.**

Signature of Research Team Member Obtaining Assent

Date

Printed Name of Research Team Member Obtaining Assent