Informed Consent

Food is Medicine: A Randomized Clinical Trial of Medically Tailored Meals For Individuals with Type 2 Diabetes Mellitus and Food Insecurity

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

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IRB Study # 20-2847
Title of Study: Food is Medicine: A Randomized Clinical Trial of Medically Tailored Meals For Individuals with Type 2 Diabetes Mellitus and Food Insecurity
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CONCISE SUMMARY

Food insecurity, or not being able to afford healthy food, makes it harder to manage diabetes. The best way to treat food insecurity is unknown. This study will compare two programs to address food insecurity for people with diabetes; home delivery of medically tailored meals (MTM), or a subsidy that can be used to purchase healthy foods. MTM includes counseling sessions about how to eat more healthy foods (called lifestyle counseling). Those who choose to be a part of the study will be randomly assigned, like flipping a coin, to one of the two programs. Both programs will last for 6 months. There will be three study sessions where we measure things important for the study by having you answer surveys and you have blood drawn. One sessions will be at the start of the study, a second at 6 months after the start of the study, and a 3rd one 12 months after the start of the study, 6 months after the program ends, to see how you are doing after the intervention is over. There will also be one brief check-in at 3 months after the start of the study.

This is a low-risk study. The intervention simply provides healthy food, or money to buy healthy food. There may be minor pain from the blood draws at each measurement visit. Taking part does require a time commitment for study sessions calls and counseling calls. We expect participants in both study groups will have reduced food insecurity and consider this a benefit of taking part in the study.

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

You may choose not to participate. You may also leave the study at any time, for any reason. There will be no penalty.

Research studies are done to learn new information. 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 relationships with the researcher, Community Servings, or the University of North Carolina-Chapel Hill.

Details about this study are below. It is important that you understand this information so that you can make an informed choice about whether or not you would like to be in the study.

You have a copy of this consent form. As we go through the consent please ask any questions you may have at any time. Your understanding of the study is important.

What is the purpose of this study?

Having enough healthy food is a common problem for people with diabetes. This makes it hard to follow the diet needed to manage diabetes. In this study, we are comparing two programs to increase access to healthy food. We want to see if one helps improve blood sugar better than the other. The first program will send meals that are made for people with diabetes to their homes. People in this group will also get counseling to learn how to improve blood sugars with food and exercise. The second program will send people a subsidy for healthy foods in the form of a grocery store gift card. We will ask that this card be used to buy healthy foods. We will look at bloodwork to see if there is a difference in the blood sugar levels of the two groups. We will also use surveys to see if the programs affect people's lives in other ways. An example might be by reducing stress. Finally, we will use interviews to find out how the programs may have affected diabetes management.

You are being asked to be in the study because you have diabetes and have said you have trouble getting enough healthy food.

Reasons you should not be in this study:

You should not be in this study if:
- You are or have been in a diabetes, nutrition, or weight study in the last 12 months.
- Someone in your home is a part of this study. Only one member of each household may participate.
- You are considering bariatric surgery in the next year.
- You have had bariatric surgery in the past two years.
- You are homeless.
- You do not have a place to store food.
- You do not have a telephone.
- You are pregnant, breastfeeding, or intend to get pregnant in the next year.
- You have a history of cancer.
- You have stage 4 or 5 kidney disease.
- You have misused drugs or alcohol in the past 2 years.
- You have a psychiatric illness that will make you unable to participate in the study's activities.
- You intermittently use medications (like steroids) that are likely to raise your blood sugar

How many people will take part in this study?
Approximately 200 people will be in this study.

How long will your part in this study last?
You will be in the study for about 1 year.

What will happen if you take part in the study?
First, study staff called you to see if you were interested in the study. If you were, we mailed or emailed you this consent form. Now, we are calling to review the consent form with you and to answer any questions you have. After we have finished reviewing this form, you will decide if you would like to join the study. If yes, you will give verbal consent over the phone.

If you decide to participate, we will continue this phone call to start your first study session. You will answer questions about things like what you eat, what types of activities you do and other questions about your health. This call should last about 1 hour.

After the phone call, a nurse will come to your home to check your weight, height, and blood pressure. The nurse will also collect a blood sample to check your hemoglobin A1c. This is a test of your blood glucose over the past 3 months. We will report the results of these test to you and your primary care clinician. This nurse visit will take about thirty minutes.

When the nurse comes to your home, he or she will be wearing personal protective equipment, sometimes called "PPE". This is to protect both of you from the possible spread of infection. Their PPE will include a head cap, face shield, goggles, mask, suit, gloves and shoe covers. We ask that you also wear a mask while the nurse is in your home.

After this first study session, a computer program will randomly assign you, like flipping a coin, to receive either the Medically Tailored Meal Program or the Food Subsidy Program. You will then receive a call from a member of the study team to tell you which program you are in and go over next steps.

Medically Tailored Meal (MTM) Program
If you are assigned to this program, you will receive a Community Servings' meal delivery to your home each week for six months. The delivery will have five dinners, five lunches, milk, cereal, yogurt, fresh fruit and snacks. The meals are medically tailored. This means they are made to help improve your blood sugars. You will also receive counseling on ways to improve your blood sugar through lifestyle change. This will focus on healthy eating and staying active. You will have a coaching session over the phone that lasts about 45 minutes every month, for six months. You will also have a brief (about 15 minute) phone check-in one to two weeks after each coaching session. This will be a total of twelve phone sessions in six months.

The counseling sessions will be recorded for quality improvement. This will let us check to see how our counselors are doing. We can then work with them to make sure they are doing their best. These recorded sessions will be kept as electronic files but without information that could be used to identify you (other than your voice).

Food Subsidy Program
If you are randomized to the food subsidy program, you will be sent one $40 grocery store gift card each month, for six months. These cards are to be used to purchase healthy foods. We will send you a booklet with information on foods to purchase. We will also call you once a month to find out what types of foods you have bought with the card and to see how you are doing.

Follow-up Study Sessions
You will have two follow-up study sessions. The first will be about 6 months after you start the study. The second will be about 12 months after you start the study. They will be the same as your first study session. You will be called and asked to answer questions over the phone. This call will take about 1 hour. Then you will have a nurse visit to your home. The nurse will check your weight, blood pressure, and take blood to check your hemoglobin A1c. Hemoglobin A1c is a measure of your blood sugar.

When the nurse comes to your home, he or she will be wearing personal protective equipment, sometimes called "PPE". This is to protect both of you from the possible spread of infection. Their PPE will include a head cap, face shield, goggles, mask, suit, gloves and shoe covers. We ask that you also wear a mask while the nurse is in your home.

You may also be asked to be interviewed about your experiences with the study. These interviews are optional. They would be completed after the 6 and 12 month nurse visits.

Check in Call
You will have one brief check-in call at 3 months.

What are the possible benefits from being in this study?
Research is done to gain new knowledge. By being in this study you may have more access to healthier foods and better blood sugar control. These are not guaranteed benefits.

What are the possible risks or discomforts involved from being in this study?
There are not many possible risks and discomforts from being in this study. Those that are possible are listed below.

- We do not think there is risk to you from the food, money to buy food, or dietary advice given as part of the program.
- You may choose to lose weight as part of this program. If you do not eat enough, you could lose weight too fast. We will ask you to check your weight often. This way we will know if you are losing too much weight too quickly.
- Doing more physical activity is not the main focus of this study. However, the medically tailored meal program 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. Minor muscle pain will go away. This type of activity rarely, less than 1 in a 100, causes serious health problems such as chest pain.

- Changing how you eat could lead to lower blood sugar. Sometimes this could include hypoglycemia. This has occurred in less than 1 in a 100 people in our past studies. We will provide information on how to reduce the risk of low blood sugar.
- For those with high blood pressure, changing how you eat could lead to lower blood pressure. Blood pressure that is too low can cause dizziness and even falls. It is very rare that this could be a serious risk, (less than 1 in a 100 people). Typically, the blood pressure is lowered slowly. This will allow your doctor time to observe the lower blood pressure and reduce any blood pressure medicine you may be taking.
- A blood sample will be collected by trained staff three times during the study. The risk of minor pain is very common. It has been seen 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. This means the risk that others may see your study information. As we describe in more detail 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, including uncommon or previously unknown risks. Because gestational diabetes is a different medical condition than type 2 diabetes, if you become pregnant during the study you will be removed from the study. 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 your willingness to continue participating.

Will I receive any other clinical results?

You will receive all clinical results. We will send you the results of your blood work, for example, your hemoglobin A1c. We will also send you any other measurements such as blood pressure and weight we obtain.

How will information about you be protected?

Your study bloodwork, your hemoglobin A1c, will be sent to a commercial lab for analysis (LabCorp). The bloodwork will have your name on it when it is sent. These samples are typically thrown away 3 days after collection. The results of your bloodwork along with your study surveys and interviews will be stored with your study ID number and your first and last initial. They will NOT be recorded 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/permission 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.

When writing reports or publishing articles participants will not be identified by name. 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 providing informed consent, you agree that some of the information generated by participating in this study and/or a copy of this consent form may be included in your medical record. You also agree 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. They will then know how to take care of you if you have other health problems or needs during the study.

If you are put in the medically tailored meals program you will participate in phone coaching sessions. These sessions will be recorded for review. These recordings will be identified by your study ID number, not by your name.

Part of the study involves optional interviews that will be recorded for review. You do not have to participate in these interviews to participate in the rest of the study, and we will ask you before each interview whether you want to participate in it.

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.

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. 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 kept. No new 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?

Participants will receive $20 for completing the 3 month check-in call, $20 for completing the 6 month study session, and $50 for completing the 12 month study session. Select participants will receive $20 for completing the 6 and 12 month interviews ($20 at 6 month and $20 at 12 months). If you complete all study sessions and the check-in call, you will receive $90 in total. If you complete both a 6 month and 12 month interview, you will receive $40 in total. If you complete all research visits and 2 interviews, you will receive $130 in total.

Any payment provided for participation in this study may be subject to applicable tax withholding obligations

Will it cost you anything to be in this study?

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

Who is sponsoring this study?
This research is funded by 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 results of the study.

Outside of the specific funding for this study, Jean Terranova, one of the study investigators, is an employee of Community Servings. John Buse, another study investigator, has a role in The National Center for Advancing Translational Science (NCATS) Clinical & Transitional Science of Awards Program Steering Committee(CTSA).

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 called the Institutional Review Board or IRB. This committee works to protect your rights and welfare. If you have questions or concerns about your rights, would like more information or have suggestions please contact them. You can call the Institutional Review Board at 919-966-3113 or you can email IRB_subjects@unc.edu.

Are there any other questions I can answer for you?

{If No, proceed below}

Do you voluntarily agree to participate in this research study?

Yes {Proceed}

No {Say: “That is OK. Thank you for your time.”, and end call}