

Title: Home Food Delivery for Diabetes Management in Patients of Rural Clinics  
PI: Pearl McElfish, PhD

**Home Food Delivery for Diabetes Management in Patients of Rural Clinics**

**NCT04876053**

**V.14; 07/24/2024**

## **Key Information for Home Food Delivery for Diabetes Management in Patients of Rural Clinics:**

This first part gives you key information to help you decide if you want to join the study. We will explain things in more detail later in this form.

We are asking if you want to volunteer for a research study to learn about persons who have type 2 diabetes within the state of Arkansas. By doing this study, we hope to learn if it will help persons with type 2 diabetes manage their disease better if they have healthy foods delivered to their home and have a someone help them know how to use those foods in a healthy way.

Please ask the research team if you have any questions about anything in this form. If you have questions later, contact the researcher in charge of the study. The contact information is on page 8 of this form.

### **What will happen if I join the study?**

If you join, your part in this research will last about 12months.

During the study, we will ask that you:

- answer some questions about you and your health before and after the study
- have a HbA1c test (the test for diabetes), a test for blood sugar and a test for fat substances in your blood (like cholesterol); before and after the study (this includes a finger stick to get a small amount of blood). Additionally, we may do a skin test that measures vegetable intake.
- have some additional health measures done such as measuring height, weight, Body Mass Index (BMI) calculated from your height and weight.
- talk with a dietitian for 60 minutes about healthy eating
- participate in your regular clinical visits for type 2 diabetes, typically scheduled every three months
- Half of the persons in the study will have a box of food and recipes for you and your family delivered to your home each week for 12 weeks and half of the persons in the study will not receive the food and recipes. The group you are in will be decided by chance – like flipping a coin – after you agree to be in the study. This means the research study person working with you will not know which group you will be in at the time you sign this form.

### **Do I have to join this study?**

No. It is okay to say no. You will not lose any services, benefits, or rights you would normally have if you decide not to join. If you decide to take part in the study, it should be because you really want to volunteer.

You will still be able to access the services of UAMS or your local healthcare provider if you are not in the study.

### **What do I need to know to decide if I should join this study?**

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People decide to join studies for many reasons. Here are some of the main things you should think about before choosing to join this study.

**Main reasons to join the study**

- ✓ You may benefit from the food and information provided to you
- ✓ You will help provide information that may benefit other persons with type 2 diabetes

**Main reasons not to join the study**

- ✓ It will take some of your time to participate in the survey and testing
- ✓ A finger stick is required to collect a small amount of blood for testing, this may cause some discomfort
- ✓ The questions may make you sad or uncomfortable
- ✓ Other clinic patients may see you talking with study staff and know you are part of the study

These are just some of the reasons to help you decide if you want to join the study. We will explain more about the risks, benefits, and other options to joining the study later in this form.

Tell the study team if you decide that you do not want to be in the study. Remember, it is okay to say no. Your medical care will not be impacted if you decide not to participate in the study.

## **University of Arkansas for Medical Sciences Informed Consent Form**

- We are asking you to be in a research study. You do not have to join the study.**
- You can still get your medical care from UAMS even if you are not in the study.**
- Take as much time as you need to read this form and decide what is right for you.**

### **Why am I being asked to be in this research study?**

- We want to learn more about persons with type 2 diabetes.
- By doing this study, we hope to find out if delivering healthy foods and recipes to a person with type 2 diabetes and giving them information about using those foods, will help them manage their diabetes better.
- We are asking people like you, with type 2 diabetes, to help us.
- Up to 440 people who are 18 years old and older will be part of this study.

### **What if I don't understand something?**

- This form may have words you do not understand. If you would like, research staff will explain them to you.
- You are free to ask questions at any time – before, during, or after you are in the study.
- Please ask as many questions as you would like before you decide if you want to be in this study. If you decide to take part in the study, it should be because you really want to volunteer.

### **What will happen if I say yes, I want to be in this study?**

First, we will see if you qualify to be in the study. We will confirm that you are not pregnant, speak English or Spanish, you are 18 years old or older, and that you have type 2 diabetes, with a qualifying HbA1c of 6.5 or higher.

If you qualify, we will do these things:

- Ask about you, things like your age, gender, marital status, education, insurance coverage, and what you think about your health. We will also ask you about the food you ate in the last 24 hours, the fruits and vegetables you ate during the last 30 days, and

some questions about your ability to get the food you need. We will do a test for type 2 diabetes called an HbA1c, a test for blood sugar, and a test for fat in your blood (such as cholesterol); on a small amount of blood we collect from a finger stick. We may do a skin test that measures vegetable intake. We will take some measurements including height, weight, Body Mass Index (BMI) calculated from your height and weight. This will happen at the beginning of the study and at the end of the study, 6 months and 12 months after the study stops.

- Read the questions out loud and fill out the form with you.
- You do not have to answer any questions you do not want to answer.
- As part of the study, a person trained to help people make good choices about the food they eat will spend 60 minutes talking with you explaining the details of the study and answering your questions.
- Half of the persons in the study will get a box of food and recipes for you and your family delivered to your home each week for 12 weeks and half of the persons in the study will not receive the food and recipes. The group you are in will be decided by chance – like flipping a coin – after you agree to be in the study. This means the research study person working with you will not know which group you will be in at the time you sign this form. If you are chosen to be placed in the food box delivery group the food boxes may be delivered by research staff or by a third-party delivery service. We will do our best to maintain a contactless delivery to your home.
- The time to complete the questions, do the blood tests and take the measurements before you start the study, at the end of the study, and at six and 12 months after the study should be about 1 hour each time.
- As part of the data collection process, we will collect medical records information that includes healthcare visits and medication.

### **How long will I be in this study?**

You will be in the study for approximately 12 months from the first time you answer questions about yourself and have the tests done until the last time you answer the questions and have the tests done. It will include the four times we collect information about you, and if you are in the half of the study participants that receive food boxes, the talk about the food boxes, and the 12 weeks we deliver food boxes to your home.

### **What if I say no, I do not want to be in this study?**

- Nothing bad will happen because of what you decide.
- You can still get medical care at UAMS or your local healthcare provider.

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

- You can stop being in the study at any time.
- Nothing bad will happen because you change your mind and leave the study.
- You can still get medical care at UAMS or your local healthcare provider.
- If you decide to stop being in the study, the information that has already been collected will not be taken out of the study.
- If you decide to stop being in the study, contact Pearl McElfish at 479-713-8691, or send a letter to 2708 S 48th St, Springdale, AR 72762.

**Will it cost me anything to be in the study?**

The study will not cost you anything.

**Will I be paid for being in the study?**

Yes. We will give you a \$40 gift card for each time you complete answering the study questions and having the tests and measurements done. If you complete all four of these events, you will receive a total of \$160 in gift cards. This is to pay for your time. You will receive your gift card at the end of each event. If you change your mind and decide not to be in the study, you will only be paid for the parts you completed.

If you get more than \$600 in one year (January-December) from UAMS, we may send you a tax form if the law requires it.

**Will being in this study help me in any way?**

Being in the study may or may not help you, personally. But even if it does not help you, it may help people with type 2 diabetes in the future. What we learn may help in the following ways:

- Providing more nutritious foods for persons with type 2 diabetes.
- Finding ways to get food delivered to person's homes.
- Demonstrating that persons with healthier food are more successful at managing their type 2 diabetes.

**What are the risks of being in this study?**

A finger stick is required to collect a small amount of blood for testing, this may cause some discomfort.

The questions asked may make you sad or upset. Collection of medical records data could reveal information that you may not want revealed.

There is also the risk that someone could find out that you were in the study and learn something about you that you do not want others to know. We will do our best to protect your privacy, as explained in more detail later in this form.

**Reminder:** You do not give up any of your legal rights by agreeing to be in this study or by signing this form.

**What are the alternatives to being in this study?**

You do not have to be in this study.

There are no alternatives to being in this study because it does not involve any treatment or other procedures that may help you.

**Can I be taken out of the study even if I want to continue?**

Yes, the head researcher can take you out of the study if:

- You do not follow study instructions.
- It is not in your best interest to continue.
- The study is stopped for any reason.

**What information will be collected about me in the study?**

During the study, we will need to learn private things about you, including:

- General contact and background information about you, such as age, gender, marital status, education, and information about your healthcare.
- Information about the food you ate in the last 24 hours and the fruits and vegetables you ate over a 30-day period.
- We will ask questions about whether you have had enough food to eat.
- We will do a test for type 2 diabetes called an HbA1c, a test for blood sugar, and a test for fat in your blood (such as cholesterol); on a small amount of blood we collect from a finger stick. We will discard the blood collected immediately after the test is completed (at the time the other information is collected). We may do a skin test that measures vegetable intake. We will take some measurements including height and weight. We will not use the samples we collect from you for commercial profit.

- Current and past six months of other *healthcare visits* (including but not limited to: doctor's offices, clinics, urgent care, overnight hospitalizations, visits to hospital emergency rooms, home visits, or telephone calls) *for any reason*, current and past six months use of any type of *medication* (including the generic medication name, strength, number of units, day supply, and number of fills in the past six months).
- If you are placed in the food box delivery group We may share your address and phone number with the third-party delivery service in order for them to deliver your food box and contact you when they have completed the delivery. The delivery driver may take a photo of your food box delivery at your home for delivery records. They will not have access to your name or any other personal health information that you share with the research staff. They will only have your phone number and address during the time of delivery. They will not keep or store your information after they have delivered your food box.

**Who will see this information? How will you keep it private?**

- The local study team will know your name and have access to your information.
- We will do our best to make sure no one outside the study knows you are part of the study.
- We will take your name off information that we collect from you during the study. We will give your information and study samples a code, so that no one can identify you.
- When we share the results of the study in medical journals and presentations, we will not include your name or anything else that could identify you.
- There are people who make sure the study is run the right way. These people may see information that identifies you. They are
  - ✓ OHRP (Office for Human Research Protections), a federal agency
  - ✓ UAMS Institutional Review Board
  - ✓ Other institutional oversight offices
- State law requires that we tell the authorities if we learn about possible abuse or that you might hurt yourself or someone else.

**Where will my information be kept? For how long will it be kept?**

- A secure UAMS server and REDCap database.
- Once we give your information a code, we will keep the key to this code in a locked file.
- Only the lead researcher and the Study Coordinator will be able to link it to you.



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- Your information will be destroyed seven years after the end of the research.

**If I stop being in the study, what will happen to my information collected in the study?**

- We will be able to take your information out of the study after it has started.
- If you wish to have your information taken out of the study, call Pearl McElfish at 479-713-8691.

**Will my information from the study be used for anything else, including future research?**

Yes. If you agree, you will be provided some options to give permission for your de-identified data to be used and linked to other research. Below there are several options on the last page of this consent form to choose from.

- The Arkansas All-Payer Claims Database stores healthcare claims (billing) from public and private sources. If you agree, the researchers will request information from the Arkansas All-Payer Claims Database related to the cost of care you have received related to the information collected in this study.
- Other current UAMS studies related to this study
- You could give permission to use your de-identified information for future studies related to this study.
- You will retain the ability to withdraw your permission by contacting Pearl McElfish at 479-713-8691, or sending a letter to 2708 S 48th St, Springdale, AR 72762.

**Will you tell me the results of the study?**

Yes. We will provide you with your personal health information like HbA1c, blood pressure, BMI, glucose, and lipids results at the end of each visit. In addition, we will attempt to provide a summary of the results at your last visit or mail the summary to you if we have your address. If results are not within normal range according to the study biometric guidelines the research coordinator will inform you to seek further medical care. We plan to publish the results in an academic journal and present the findings at community and academic meetings. What we publish and present will not include anything that can identify you.

**Will you tell me anything you learn that may affect my health?**

Yes. If we learn something about you that might be important for your health, we will tell you.

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**What if new information comes up about the study?**

We will tell you if we learn anything that may change your mind about being in the study.

**Where can I find more information about this clinical trial?**

A description of this clinical trial will be available on <http://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 any time.

**What if I have questions?**

- Please call the head researcher of the study – Pearl McElfish at 479-713-8691 – if you
  - ✓ have any questions about this study
  - ✓ have questions about your rights
  - ✓ feel you have been injured in any way by being in this study
- You can also call the office at UAMS that supervises research if you cannot reach the study team or want to speak to someone not directly involved with this study. To do so, call the UAMS Institutional Review Board at 501-686-5667 during normal work hours.

**University of Arkansas for Medical Sciences HIPAA Research Authorization (Permission)  
Form**

**What is HIPAA?**

HIPAA is the Health Insurance Portability and Accountability Act of 1996. It helps to keep your health information private and secure. When we say “you” or “your”, we are talking about the person who takes part in the research and the person who gives the permission to be in the research study.

**What is the purpose of this HIPAA form?**

The word “you” means both the person who takes part in the research, and the person who gives permission to be in the research. This form and the research consent form need to be kept together.

We are asking you to take part in the research described in the consent form. To do this research, we need to collect health information that tells who you are. We will create the following health information about you:

- HbA1c
- Blood glucose (sugar)

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- Lipid test results (Low Density Lipoprotein [LDL], High Density Lipoprotein [HDL], total cholesterol, triglycerides)
- We may do a skin test on your finger that measures vegetable intake.
- Height, weight, and Body Mass Index
- Questions about the food you eat and drink
- Questions about how you access healthcare
- Healthcare visits (current and past six months current and past six months of other *healthcare visits* (including but not limited to: doctor's offices, clinics, urgent care, overnight hospitalizations, visits to hospital emergency rooms, home visits, or telephone calls) for any reason.
- Medication (current and past six months use of any type of *medication* (including the generic medication name, strength, number of units, day supply, and number of fills in the past six months) for any reason.

Being part of this study will create new health information to improve our understanding of managing type 2 diabetes. This information will be used to learn more about using diabetes self-management education. We will only ask for information we need for the research. For you to be included in this research, we need your permission to collect, create and share this information.

We will, or may, share your health information with people at the University of Arkansas for Medical Sciences (UAMS) who help with the research or things related to the research process, such as the study staff, the UAMS Institutional Review Board and the research compliance office at the University of Arkansas for Medical Sciences. We may share your health information with people at the University of Arkansas for Medical Sciences (UAMS). These are people who help with the research or things related to research, such as the research staff. Additionally, we may need to share your health information with people outside of UAMS who make sure we do the research properly, such as the Office for Human Research Protections. We believe that those involved with research understand the importance of preserving the confidentiality of your health information. However, some of the people outside of UAMS may share your health information with someone else. If they do, the same laws that UAMS must obey may not apply to others to protect your health information.

The authorization to collect, use and share your health information expires at the end of the research study. You do not have to sign this form. However, if you decide not to sign this form, you cannot be in the research study.

If you sign this form but decide later that you no longer want us to collect or share your health information, you must send a letter to Pearl McElfish at the address listed on the first page of this form. The letter needs to be signed by you, should list the Study Title listed on this form, and should state that you have changed your mind and that you are revoking your "HIPAA Research Authorization". You will need to leave the research study if we cannot collect and share any more health information. However, in order to maintain the reliability of the research, we may still use

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and share your information that was collected before the Principal Investigator received your letter withdrawing the permissions granted under this authorization.

If you decide not to sign this form or change your mind later, this will not affect your current or future medical care or benefits at the University of Arkansas for Medical Sciences.

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**By signing the document, I am saying:**

- ✓ I agree to be in the study.
- ✓ I know that joining this study is voluntary.
- ✓ Someone has talked with me about the information in this form and answered all of my questions.

**I know that:**

- ✓ I can stop being in any and all parts of the study at any time and nothing bad will happen to me.
- ✓ I can still get medical care at UAMS or your local healthcare provider no matter what I decide.
- ✓ I can call the office that supervises research (UAMS Institutional Review Board) at 501-686-5667 if I have any questions about the study or about my rights.
- ✓ I do not give up any of my legal rights by signing this form.

☐ YES ☐ NO I consent to have my data from this study linked to information about me in the Arkansas All-Payer Claims Database which stores healthcare claims (billing) data from public and private sources.

☐ YES ☐ NO I consent to my medical record data abstraction of other healthcare visits and medication.

☐ YES ☐ NO I give permission for UAMS Principal Investigator to link information from this study to other UAMS research related data.

☐ YES ☐ NO I agree to my de-identified information being used for future research related to this study.

☐ YES ☐ NO I agree to being contacted for future research related to this study.

\_\_\_\_\_  
Your name (please print)

\_\_\_\_\_  
Your signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed name (person obtaining consent)

\_\_\_\_\_  
Signature (person obtaining consent)

\_\_\_\_\_  
Date