

**Libre 2 CGM plus Glycemic Excursion Minimization (GEM) in the Treatment of
PrEDiabetEs: The IMPEDE Study**

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Study Title: Libre 2 CGM plus Glycemic Excursion Minimization (GEM) in the Treatment of PreDiabetes: The IMPEDE Study

You are being asked to be in a research study. This form provides you with information about the study. A member of the research team will describe this study to you and answer all of your questions. Please read the information below and ask questions about anything you don't understand before deciding whether or not to take part.

Why is this study being done?

The GEM (Glycemic Excursion Minimization) guide is a new lifestyle treatment for prediabetes that aims to lower glucose levels after meals and snacks. This is different from the current lifestyle treatment, which is to lose weight. This study is trying to find out if people who are diagnosed with prediabetes can use a continuous glucose monitor together with the GEM lifestyle guide to improve management of their prediabetes. You are being asked to take part in this study because you have been diagnosed with prediabetes. Being in this study could require you to follow the GEM guide for up to 4.5 months instead of seeking the usual care of medications or weight loss programs to lower your blood glucose.

You might like to take part in this study because information from previous studies has shown that the GEM lifestyle treatment is better than weight loss for controlling diabetes and it doesn't restrict your diet as much as weight loss programs. You might not want to take part in this study because it involves using a continuous glucose monitor (CGM), which has a thin filament that you must insert under your skin once every 14 days.

You will probably be unfamiliar with the GEM lifestyle guide and CGM, but you will receive training for both if you are randomized to the intervention. If you take part in this study, you will meet with the study team at the beginning of the study for an assessment where the study team will ask questions about your prediabetes, give you a blinded FitBit activity monitor and a blinded Freestyle Libre 2 CGM. You will then be randomized to either intervention or usual care. If you are randomized to the intervention then you will wear an unblinded FitBit and CGM and follow the GEM lifestyle guide for 4.5 months (+/- 2 weeks). The study team will collect information about your prediabetes from you. They will also collect blood glucose data from your CGM and activity data from your FitBit. You will also be asked to have bloodwork completed several times. If you are randomized to usual care, you will still do blood work and do several assessments

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through surveys and scales, but will continue to treat your prediabetes as you have been prior, without intervention. Both groups will be see the study team at least four times and will complete the blood draws and behavioral and psychological questionnaires and wear a blinded CGM and FitBit for two weeks at the beginning and end of the study. If you are randomized to usual care, and you are willing and eligible at the end of the study period to continue, you will have the option to also complete the intervention portion of the study for an additional 4.5 months.

You do not have to take part in this study. You should only agree to take part in this study after reading this consent form and discussing it with the study team. You may also discuss this with your family, friends, health care providers or others before you decide.

Other people in this study

Up to 70 people from your area will participate in the study.

What happens if I join this study?

If you take part in this study, you will be randomized to either usual care or intervention. If you are randomized to intervention, you will follow the GEM lifestyle guide manual for 4.5 months (+/- 2 weeks) and wear a FitBit activity monitor and a Freestyle Libre 2 CGM. There will be assessments at the beginning and end of the study where the study team will ask questions about your prediabetes, give you the study equipment, and/or teach you how to use the equipment. There will be questionnaires about your prediabetes at the beginning and end of the study.

Major Study Procedures:

- Assessments to, start the study, receive equipment, and/or learn to use equipment. These visits will take about 1 to 1.5 hours.
- If randomized, follow the GEM Lifestyle Guide manual for 4.5 months (+/- 2 weeks)
- Wear a FitBit on your wrist for all 4.5 months (+/- 2 weeks)
- Wear a CGM for all 4.5 months (+/- 2 weeks)
- Complete questionnaires at the beginning and end of the study
- Complete bloodwork

What are the possible discomforts or risks?

There is a risk that people outside of the research team will see your research information. We will do all that we can to protect your information, but it can not be guaranteed.

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You will be assigned to a study treatment by chance, and the study treatment you receive may prove to be less effective or to have more side effects than the other study treatment(s) or other available treatments.

Risks of CGM use

Wearing a CGM will involve inserting a small thread-like sensor under your skin and securing a small transmitter (about the size of a half dollar) to the back of your upper arm with an adhesive patch.

- Some people find the sensor uncomfortable to wear or painful to insert
- A small number of CGM users get a rash, skin blistering, irritation, or infection at the location where the CGM is placed.
- Wearing the CGM may cause some people to feel embarrassed or different from others.
- The CGM sensor or transmitter could malfunction so that you receive an incorrect BG reading or no reading at all. Procedures to manage occasional CGM or sensor malfunction will be provided during the CGM training and in the CGM manual.

Risks from Completing Questionnaires

Some of the questions asked may be upsetting, or you may feel uncomfortable answering them. If you do not wish to answer a question, you may skip it and go to the next question.

What are the possible benefits of the study?

You may or may not benefit from being in this study. Possible benefits include better management of your prediabetes and delayed or no progression to type 2 diabetes . In addition, information researchers get from this study may help others in the future.

This study is not designed to treat any illness or to improve your health.

Are there alternative treatments?

You do not have to be in this study to be treated for your illness or condition. You can get the usual treatment even if you choose not to be in this study. The usual treatment would include:

- Weight-loss programs
- Medication for prediabetes

However, to do this study, we must withhold usual treatment at the start of this study. During this time, you may receive the GEM treatment. You will continue your regular visits with your doctor during the study, and you can return to usual care at any point in the study if your doctor feels it is medically necessary.

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If you are an employee of University of Colorado your job will not be affected if you decide not to participate in this study. If you are a student at University of Colorado, your grades will not be affected if you decide not to participate in this study.

You should talk to your doctor about your choices. Make sure you understand all of your choices before you decide to take part in this study. You may leave this study and still have these other choices available to you.

Who is paying for this study?

This research is being sponsored by Abbott the manufacturer of the CGM.

Will I be paid for being in the study?

You will be paid \$100 for completing this study after eligibility is confirmed, and you will also receive a Fitbit activity monitor.

If you leave the study early, or if we have to take you out of the study, you will be paid only for the visits you have completed.

It is important to know that payments for participation in a study is taxable income.

Will I have to pay for anything?

You will not be charged for the CGMs or any of the study procedures or office visits for the study.

Is my participation voluntary?

Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you choose to take part, you have the right to stop at any time. If you refuse or decide to withdraw later, you will not lose any benefits or rights to which you are entitled.

Can I be removed from this study?

You can change your mind about being in the study any time. You can agree to be in the study now and change your mind later. If you decide to stop, please tell us right away. You do not have to be in this study to get services you can normally get at the University of Colorado.

Even if you do not change your mind, the study leader can take you out of the study. Some of the reasons for doing so may include

- a) Your study physician is concerned about your health
- b) Your disease gets worse
- c) The side effects of the treatment are too dangerous for you
- d) New information shows the treatment will not work or is not safe for you

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e) You do not follow your doctor's instructions

f) The study physician deems it inappropriate for you to continue for any reason

Who do I call if I have questions?

The researcher carrying out this study is Tamara K. Oser, MD. You may ask any questions you have now. If you have questions, concerns, or complaints later, you may call Tamara K. Oser, MD at **(303) 724-2060**. You will be given a copy of this form to keep.

You may have questions about your rights as someone in this study. You can call Tamara K. Oser, MD with questions. You can also call the responsible Institutional Review Board (COMIRB). You can call them at 303-724-1055.

Who will see my research information?

The University of Colorado Denver | Anschutz Medical Campus (the University) and its affiliated health systems have rules to protect information about you. Federal and state laws including the Health Insurance Portability and Accountability Act (HIPAA) also protect your privacy. This part of the consent form tells you what information about you may be collected in this study and who might see or use it.

The institutions involved in this study include:

- University of Colorado Denver | Anschutz Medical Campus

The institutions who will see your data, but it will be fully de-identified for analysis:

- University of Virginia

We cannot do this study without your permission to see, use and give out your information. You do not have to give us this permission. If you do not, then you may not join this study.

We will see, use, and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside the University and its affiliate hospitals may not be covered by this obligation.

We will do everything we can to maintain the confidentiality of your personal information, but confidentiality cannot be guaranteed.

The use and disclosure of your information has no time limit. You can cancel your permission to use and disclose your information at any time by writing to the study's Principal Investigator (PI), at the name and address listed below. If you do cancel your permission to use and disclose your information, your part in this study will end and no

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further information about you will be collected. Your cancellation would not affect information already collected in this study.

**Tamara K. Oser, MD
University of Colorado Anschutz Medical Campus
Academic Office One
12631 East 17th Avenue, Mail Stop F496
Aurora, CO 80045**

Both the research records that identify you and the consent form signed by you may be looked at by others who have a legal right to see that information, such as:

- Federal offices such as the Food and Drug Administration (FDA) and the Office of Human Research Protections (OHRP) that protect research subjects like you.
- The Institutional Review Board that is responsible for overseeing this research
- The study doctor and the rest of the study team.
- Officials at the institution where the research is conducted and officials at other institutions involved in this study who are in charge of making sure that we follow all of the rules for research

We might talk about this research study at meetings. We might also print the results of this research study in relevant journals. But we will always keep the names of the research subjects, like you, private.

The investigator (or staff acting on behalf of the investigator) will use your information for the research outlined in this consent form. They will also make *all or some* of the following health information about you collected in this study available to:

Information about you that will be seen, collected, used and disclosed in this study:

- Name and Demographic Information (age, sex, ethnicity, address, phone number, etc.)
- Your social security number (for payment)
- Portions of your previous and current Medical Records that are relevant to this study, including but not limited to Diagnosis(es), History and Physical, laboratory or tissue studies, radiology studies, procedure results
- Research Visit and Research Test records
- Tissue samples and the data with the samples.

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What happens to Data, Tissue, Blood and Specimens that are collected in this study?

Scientists at the University and the health systems involved in this study work to find the causes and cures of disease. The data, tissue, blood and specimens collected from

you during this study are important to this study and to future research. If you join this study:

- The data, tissue, blood, or other specimens given by you to the investigators for this research no longer belong to you.
- Both the investigators and any sponsor of this research may study your data, tissue, blood, or other specimens collected from you.
- If data, tissue, blood, or other specimens are in a form that identifies you, the University or the health systems involved in this study may use them for future research only with your consent or Institutional Review Board (IRB) approval.
- Any product or idea created by the researchers working on this study will not belong to you.
- There is no plan for you to receive any financial benefit from the creation, use or sale of such a product or idea.

Agreement to be in this study and use my data

I have read this paper about the study, or it was read to me. I understand the possible risks and benefits of this study. I understand and authorize the access, use and disclosure of my information as stated in this form. I know that being in this study is voluntary. I choose to be in this study: I will get a signed and dated copy of this consent form.

Signature:_____

Date:_____

Print Name:_____

Consent form explained by:_____ Date:_____

Print Name:_____