

Official Title: eFIcacious-Diabetes Care: a Pilot Study of a Pharmacist-Led Optimization Intervention to Achieve Guideline-based Care for Frail Older Adults

NCT05047237

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Section on Gerontology and Geriatric Medicine and the Center for Healthcare Innovation

EFI-CACIOUS DIABETES MANAGEMENT
Study Summary for Research Participants
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SUMMARY

You are invited to participate in a research study. The purpose of this research is to explore whether a pharmacist-led diabetes management program can help optimize diabetes care for older adults. You are invited to be in this study because you have been diagnosed with type 2 diabetes, your recent blood tests and medical records show that you may benefit from taking fewer medications, and your primary care doctor agreed that you would be appropriate for this study. Your participation in this research will involve 2-6 visits (in person or through telehealth) and last about 3-6 months.

Participation in this study will involve meeting with a pharmacist who works with your doctor, getting some routine bloodwork typical for people with diabetes, and potentially adjusting your diabetes medications to reach American Diabetes Association guidelines. All research studies involve some risks. A risk to this study that you should be aware of is that with adjusting your medications, your blood sugars may increase; our team will work with you to monitor your blood sugars. You may benefit from participation in this study: research from other centers has shown that many older adults are taking more medication for their diabetes than is likely to help them, and may be taking higher-risk medications as well. This study aims to bring older adults with diabetes whose measurements and medications are different from the guidelines of the American Diabetes Association, into guidelines-based ranges.

Your participation in this study is voluntary. You do not have to participate in this study if you do not want to. There may be other choices available to you. Some other choices may include asking your doctor if changing medicines is right for you. You will not lose any services, benefits, or rights you would normally have if you choose not to participate.

The remainder of this form contains a more complete description of this study. Please read this description carefully. You can ask any questions if you need help deciding whether to join the study. The person in charge of this study is Dr. Kathryn E. Callahan. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study her contact information is: [REDACTED].

If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact the Institutional Review Board at [REDACTED] or the Research Subject Advocate at Wake Forest at [REDACTED].

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

About one hundred people will take part in this study.

Page 1 of 6
Study Summary for Research Participants

WHAT ARE THE RISKS OF THE STUDY?

The risk of harm or discomfort that may happen as a result of taking part in this research study is not expected to be more than in daily life or from routine physical or psychological examinations, tests, or adjustments to your medications in routine care. You may have a change (increase) in your usual blood sugars; the pharmacist will work with you and your doctor to monitor your blood sugar levels. If, while participating in the study, your sugars go up beyond a level that is decided by you and the pharmacist, you will be instructed to call the pharmacist and/or your doctor's office. You should discuss the risk of being in this study with the study staff.

There is a slight risk of a breach of confidentiality. We will do our best to protect your confidential information. Efforts, such as coding research records, keeping research records secure and allowing only authorized people to have access to research records, will be made to keep your information safe.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

You are not expected to receive any definite direct benefit from taking part in this research study. However, research at other centers and guidelines from the American Diabetes Association suggest that changing diabetes targets for older adults can promote good function and avoid side effects of too-low blood sugars. (see **Table**, from “Older adults: Standards of medical care in diabetes-2021. *Diabetes Care*. 2021; 44 (Supplement 1): S168-S168.) The primary goal is that we hope the information learned from this study will benefit other people in the future.

WHAT ARE THE COSTS?

All study costs, related directly to the study, will be paid for by the study. Costs for your regular medical care, which are not related to this study, will be your own responsibility. There may be medical co-pays for pharmacist visits or for lab tests, just as with usual visits to your doctor.

WILL YOUR RESEARCH RECORDS BE CONFIDENTIAL?

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed unless it is authorized by you, required by law, or necessary to protect the safety of yourself or others. There is always some risk that even de-identified information might be re-identified.

Participant information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate 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 action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not

connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by National Institute on Aging which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). 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 you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of harm to self or others, such as elder abuse.

WILL YOU BE PAID FOR PARTICIPATING?

You will be paid \$25 if you complete all the scheduled study visits.

WHAT ABOUT MY HEALTH INFORMATION?

In this research study, any new information we collect from you about your health or behaviors is considered Protected Health Information. The information we will collect for this research study includes: medical diagnoses, medications you take, blood test results such as glucose, kidney function, and hemoglobin A1c, and information about emergency department and hospital visits.

If this research study involves the diagnosis or treatment of a medical condition, then Protected Health Information collected from you during this study will be placed in your medical record, and may be used to help treat you, arrange payment for your care, or assist with Medical Center operations.

We will make every effort to keep your Protected Health Information private. We will store records of your Protected Health Information in a cabinet in a locked office or on a password protected computer.

Your personal health information and information that identifies you ("your health information") may be given to others during and after the study. This is for reasons such as to carry out the study, to determine the results of the study, to make sure the study is being done correctly, to provide required reports and to get approval for new products.

Some of the people, agencies and businesses that may receive and use your health information are the research sponsor; representatives of the sponsor assisting with the research; investigators at other sites who are assisting with the research; central laboratories, reading centers or analysis centers; the Institutional Review Board; representatives of Wake Forest

University Health Sciences and North Carolina Baptist Hospital; representatives from government agencies such as the Food and Drug Administration (FDA) or the Office of Human Research Protections (OHRP), the Department of Health and Human Services (DHHS) and similar agencies in other countries.

Some of these people, agencies and businesses may further disclose your health information. If disclosed by them, your health information may no longer be covered by federal or state privacy regulations. Your health information may be disclosed if required by law. Your health information may be used to create information that does not directly identify you. This information may be used by other researchers. You will not be directly identified in any publication or presentation that may result from this study unless there are photographs or recorded media which are identifiable.

If required by law or court order, we might also have to share your Protected Health Information with a judge, law enforcement officer, government agencies, or others. If your Protected Health Information is shared with any of these groups it may no longer be protected by federal or state privacy rules.

Any Protected Health Information collected from you in this study that is maintained in the research records will be kept for at least six years after the study is finished. At that time any research information not already in your medical record will either be destroyed or it will be de-identified. You will not be able to obtain a copy of your Protected Health Information in the research records until all activities in the study are completely finished.

You can tell Dr. Callahan that you want to take away your permission to use and share your Protected Health Information at any time by sending a letter to this address:

Kathryn E. Callahan MD, MS
[REDACTED]

However, if you take away permission to use your Protected Health Information you will not be able to be in the study any longer. We will stop collecting any more information about you, but any information we have already collected can still be used for the purposes of the research study.

WHAT ARE MY RIGHTS AS A RESEARCH STUDY PARTICIPANT?

You may choose not to take part or you may leave the study at any time. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff. The investigators also have the right to stop your participation in the study at any time. This could be because it is in your best medical interest, you failed to follow instructions, or because the whole study is stopped. Information about you may be removed from the study data and could be used for future research or shared with other researchers without additional consent from you.

By continuing, I agree to take part in this study. I authorize the use and disclosure of my health information as described in this consent and authorization form. I have had a chance to ask questions about being in this study and have those questions answered. By taking part in the

Page 4 of 6
Study Summary for Research Participants

study, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Page 5 of 6
Study Summary for Research Participants

Table 12.1—Framework for considering treatment goals for glycemia, blood pressure, and dyslipidemia in older adults with diabetes

Patient characteristics/ health status	Rationale	Reasonable A1C goal [‡]	Fasting or preprandial glucose	Bedtime glucose	Blood pressure	Lipids
Healthy (few coexisting chronic illnesses, intact cognitive and functional status)	Longer remaining life expectancy	<7.0–7.5% (53–58 mmol/mol)	80–130 mg/dL (4.4–7.2 mmol/L)	80–180 mg/dL (4.4–10.0 mmol/L)	<140/90 mmHg	Statin unless contraindicated or not tolerated
Complex/ intermediate (multiple coexisting chronic illnesses* or 2+ instrumental ADL impairments or mild-to-moderate cognitive impairment)	Intermediate remaining life expectancy, high treatment burden, hypoglycemia vulnerability, fall risk	<8.0% (64 mmol/mol)	90–150 mg/dL (5.0–8.3 mmol/L)	100–180 mg/dL (5.6–10.0 mmol/L)	<140/90 mmHg	Statin unless contraindicated or not tolerated
Very complex/poor health (LTC or end- stage chronic illnesses** or moderate-to- severe cognitive impairment or 2+ ADL impairments)	Limited remaining life expectancy makes benefit uncertain	Avoid reliance on A1C; glucose control decisions should be based on avoiding hypoglycemia and symptomatic hyperglycemia	100–180 mg/dL (5.6–10.0 mmol/L)	110–200 mg/dL (6.1–11.1 mmol/L)	<150/90 mmHg	Consider likelihood of benefit with statin

This table represents a consensus framework for considering treatment goals for glycemia, blood pressure, and dyslipidemia in older adults with diabetes. The patient characteristic categories are general concepts. Not every patient will clearly fall into a particular category. Consideration of patient and caregiver preferences is an important aspect of treatment individualization. Additionally, a patient's health status and preferences may change over time. ADL, activities of daily living; LTC, long-term care. [‡]A lower A1C goal may be set for an individual if achievable without recurrent or severe hypoglycemia or undue treatment burden. *Coexisting chronic illnesses are conditions serious enough to require medications or lifestyle management and may include arthritis, cancer, congestive heart failure, depression, emphysema, falls, hypertension, incontinence, stage 3 or worse chronic kidney disease, myocardial infarction, and stroke. "Multiple" means at least three, but many patients may have five or more (50). **The presence of a single end-stage chronic illness, such as stage 3–4 congestive heart failure or oxygen-dependent lung disease, chronic kidney disease requiring dialysis, or uncontrolled metastatic cancer, may cause significant symptoms or impairment of functional status and significantly reduce life expectancy. Adapted from Kirkman et al. (3).