Study Title: Evaluation of Patient Coach Support for Older Adults with

Obesity Protocol ID: HUM00210504

NCT: NCT06624163

ICD Version IRB Approval Date: 1/3/2025

UNIVERSITY OF MICHIGAN

CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title: Evaluation of Patient Coach Support for Older Adults with Obesity

Study ID: HUM00210504

Company or agency sponsoring the study: National Institute on Aging: UM Pepper Center's Older Americans Independence Center Pilot and Exploratory Studies Core (PESC) Pilot Award.

Names, degrees, and affiliations of the principal investigator: Shenbagam Dewar, MBBS, Clinical Assistant Professor, Geriatric and Palliative Medicine, University of Michigan**.**

Study coordinator: Ryan Bade, Research Staff, Ann Arbor Veterans Health Administration

1.1 Key Study Information

You may be eligible to take part in a research study. This form contains important information that will help you decide whether to join the study. Take the time to carefully review this information. You should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others such as your family, friends, or other doctors about joining this study. If you decide to join the study, you will be asked to sign this form before you can start study-related activities. Before you do, be sure you understand what the research study is about.

A research study is different from the regular medical care you receive from your doctor. Research studies hope to make discoveries and learn new information about diseases and how to treat them. You should consider the reasons why you might want to join a research study or why it is not the best decision for you at this time. Research studies do not always offer the possibility of treating your disease or condition. Research studies also have different kinds of risks and risk levels, depending on the type of the study.

Behavioral intervention study

This research study is being done to learn whether the addition of a Patient Coach to support the Optimal Health Weight Lifestyle (OHWL) care, a patient-centered model of care developed by Dr. Dewar, can help promote weight loss, improve the function and quality of life of older adults with obesity, who face barriers to lifestyle change. This research will help provider pilot data for future research in the same area.

Study activities are summarized below.

During the 6-month period you are enrolled in the study, you should expect to attend:

- 4 Clinic visits (part of your regular obesity care under Dr. Dewar)
- 1 Social Work visit with follow up as needed. (part of your regular obesity care under Dr. Dewar)
- 2 or more Lab visits for blood draws (part of your clinical care). One each from baseline and 6 months and more if clinically needed.

Research related:

- 3 Telehealth/e-mail assessment visits with the Study Coordinator
- 12 Telehealth visits with the Patient Coach
- 6 weekly calls during the first 6 weeks
- 3 bi-weekly calls, every other week for the following 6 weeks
- 3 monthly calls for the final 3 months

There can be risks associated with joining any research study. The type of risk may impact whether you decide to join the study. Overall, this study is considered “low risk”, meaning you should not expect to encounter anything riskier than you might experience in your daily life or a routine visit to your doctor.(example: bruising from a blood draw).This study may offer some benefit to you now, or to others in the future by aiding you in your weight loss and health goals. There is also a risk that joining this research study may have no desired impact on your weight loss and health goals. We expect the amount of time you will participate in the study will be approximately 6 months.

You can decide not to be in this study. Alternatives to joining this study include Alternatives to joining this study include continuing forward with your obesity care with Dr. Dewar or join other clinical trials. Even if you decide to join the study now, you are free to leave at any time if you change your mind.

More information about this study continues in Section 2 of this document.

2. PURPOSE OF THIS STUDY

2.1 Study purpose:

Obesity is a growing health problem, and current models of obesity care are limited in older adults. Despite the unique health care needs of older adults with obesity, currently there is no evidence-based model for this age group to manage obesity and associated disability (such as in mobility), symptoms (such as pain), multiple health issues due to long term effects of obesity (such as heart failure, osteoarthritis and others), and care complexity related to social concerns. This research study is being done to learn whether the addition of a patient coach to Dr. Dewar’s OHWL patient-centered model of care can improve patient adherence to the program and in turn, improve the functioning and quality of life of older adults with obesity, especially those from vulnerable populations who face barriers to lifestyle change.

3. WHO MAY PARTICIPATE IN THE STUDY

Taking part in this study is completely **voluntary**. You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

3.1 Who can take part in this study?

Inclusion criteria:

- Age ≥60 and ≤ 85
- BMI≥35
- Ability to walk across a room with or without an assistive device
- Living in the community independently (with or without caregiver support)
- Ability to follow instructions to participate in the program
- Interest in weight management
- Have at least 2 of the following weight-related conditions (comorbidities):
    - o High blood pressure (Hypertension)
    - o Cardiovascular conditions (including heart failure)
    - o Type 1 or Type 2 Diabetes (Diabetes mellitus)
    - o High cholesterol (Hyperlipidemia)
    - o Non-alcoholic Fatty Liver Disease (Non-alcoholic steatohepatitis)
    - o Obstructive sleep apnea
    - o Osteoarthritis

3.2 How many people are expected to take part in this study?

40 research participants are expected to enroll in the study. Participants will be offered the opportunity to be recruited during their appointment with the physician, PI Dr. Dewar

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

1. Standard Clinical Care: **"[Not research]" and the only difference being, information will be shared with the study team.**

During the first clinic visit you will be evaluated by a specially trained physician in obesity and geriatrics with a focused review of medical problems specifically related to obesity, timed up and go test (for mobility and balance), hand grip mesurement

(for overall muscle strength) and you will be ordered blood tests to screen and manage as standard clinical care to manage obesity in older adults. The physician will help you set up three broad goals of care that are tailored to your needs. You will receive counseling to make lifestyle changes (diet and exercise) and plan for management with medications as part of usual obesity care in older adults.
You may be referred to other specialists, physical therapist or nutritionist as needed as a part of care
The physician will follow you up at 2-months, 4-months, and 6-months as well as for additional related clinical care as needed, including after the 6-month period as part of regular specialty obesity care.The 4 Clinic visits with Dr. Dewar will be no different than if you choose not to participate in the study. Use of metformin and older and newer weight loss medications are reviewed (if you are already on) or newly started and dose changed as part of clinical care. All above including labs are part of regular clinical care
Social worker referral: You may be referred to the clinic social Worker for social concerns including difficulty assessing any community resources. This support can continue beyond this initial evaluation if necessary.

2) *Patient Coach:* ***RESEARCH RELATED****:* As a main component of the project, you will be working closely with a trained health care worker (supported by research funds). The Patient Coach will follow up with you outside of your clinic appointments on the goals you had chosen to work, and will follow you throughout the study via 12 scheduled phone calls over a six month period to help you: 1) achieve your diet and physical activity goals, 3) help navigate challenges with your appointments , and 3) help guide access to community resources

3) *Assessments*: ***RESEARCH RELATED*** :You will be assessed by the Study coordinator, via email/Telehealth at baseline, 3-months, and 6-months. Each session will last up to 90 minutes, with the task of completing surveys that assess the following:

Quality of life

Disability status in relation to your daily activities

Pain level

How you use your living space daily

A review of the contents of your recent meals

If for any reason you do not wish to answer specific questions, you have the right to skip them without any penalty to you.

During your Patient Coach telehealth calls, there will be an initial goal assessment and plan finalized with you to address 3 meaningful goals that align with your care under the physician. Your first telehealth call will last up to one hour, with the following 5 scheduled calls to last up to an hour as well. The remaining 6 telehealth follow up calls will be expected to last up to 30 minutes. During the follow-up calls, the Patient coach will support, review, and adjust goals, and provide links to community resources if needed. You will remain responsible for any health care and travel-related costs that you would otherwise be responsible for if you were not participating in the study. This includes co-pays (if applicable) for appointments in the amounts outlined by your individual health insurance policy. If you are unsure of what costs are associated with visits to your doctor, social work, nutritionist, physical therapy, or any other specialty clinics, please contact your health insurance provider and speak with a representative. Participation in this study does not provide reimbursement for travel expenses for appointments with the physician, nor any specialists she may refer you to during your participation. Keeping with nutritionist, physical therapy and community resources if referred (based on needs) will be encouraged and tracked.

Your active participation would end at 6 months and we would use information from your medical record for a full year.

Subject (Participant) responsibilities: As a participant in this research study, you have certain responsibilities that may apply to this study, such as ensuring that you are available for all your scheduled coach telephone call appointments and report any adverse reactions you may develop during the study as part of clinical care recommendations.

We'll communicate with you about the study via the MyUofMHealth.com patient portal if you prefer. Please speak with our study team for help using the portal and accessing patient study-related information

4.2 How much of my time will be needed to take part in this study?

Each participant will expect to attend the following:

3 Virtual Video Telehealth Assessment visits with the Study Coordinator

- Each visit is approximately 45-90 minutes.
- Total time spent over 6 months = maximum of 4.5 hours

12 Patient Coach Telehealth visits

- 6 weekly visits, each up to approximately 1 hour
- 3 bi-weekly visits, each up to approximately 30 minutes
- 3 monthly visits, each up to approximately 30 minutes

4.3 When will my participation in the study be over?

Your participation in the study will end when you have completed the 6-month follow-up check-in, or sooner if you wish to leave the study before then.

After the 6-months follow-up, you may continue care for your medical conditions through the OHWL Clinic

Your active participation would end at 6 months and you are providing permission to use information from your medical record for a full year.

5. INFORMATION ABOUT STUDY RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?

As the role of the Patient Coach is to support me, I understand that there will be no additional risks physical/health risk due to involvement in the study.

There could be a risk due to the time involved in completing the surveys/interviews and questionaaires. However you have the option to refuse to answer any question and will be allowed to take breaks during the survey or to complete the survey once started at another time.

Additionally, there may be a risk of loss to confidentiality or privacy. For example, if individuals outside this study were to discover that you were a participant in this research, or if any collected identifiable health information were disclosed to unauthorized persons, there is a risk of discrimination by employers or insurance providers. The researchers have adopted privacy and confidentiality procedures to help prevent such disclosures. See Section 9 of this document for more information on how the study team will protect your confidentiality and privacy.

As with any research study, there may be additional risks that are unknown or unexpected.

Keep in mind, as well, that the committee (IRBMED) that reviews this study does not review risks associated with procedures that are conducted as part of your regular medical care and are not part of the research, including those marked “[Not research]” in section 4.1, above. Risks associated with your regular medical treatment should be discussed with your regular doctor.

We may publish what we learn from this study, but we won’t include any personal information such as names that would identify who said what. It is also possible that someone in your home could listen to your answers while you are participating in the interview. To protect your privacy, you may wish to do the interview when you are alone or in a private room.

5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?

The researchers have taken steps to minimize the risks of this study. Even so, you may still have problems or side effects, even when the researchers are careful to avoid them. Please tell the researchers listed in Section 10 about any injuries, side effects, or other problems that you have during this study. You should also tell your regular doctors or any other provider or hospital you visit**.**

Risks will be monitored by the Patient Coach who will be in touch with you throughout the duration of the study. Please report any changes in your health to the patient coach or the physician. The Patient coach will relay any reported adverse events to the study team and your physician team and they will work with you to address any health concerns and intervene, as necessary or refer you to your primary care provider based on the adverse event.

5.3 If I take part in this study, can I also participate in other studies?

Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers involved in each study.

5.4 How could I benefit if I take part in this study? How could others benefit?

You may not receive any personal benefits from being in this study. However, others may benefit from the knowledge gained from this study. Possible benefits to you may include weight reduction, reduction of A1c level, promotion of healthy eating and increased physical activity levels.

5.5 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?

Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information.

6. ALTERNATIVES TO PARTICIPATING IN THE STUDY

6.1 If I decide not to take part in this study, what other options do I have?

You will continue to receive standard of clinical care for obesity in the OHWL clinic without the patient coach support

7. ENDING THE STUDY

7.1 If I want to stop participating in the study, what should I do?

You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. You will not lose any benefits to which you may otherwise be entitled. If you choose to tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of the study record. If you decide to leave the study before it is finished, please tell one of the persons listed in Section 10 "Contact Information".

7.2 Could there be any harm to me if I decide to leave the study before it is finished?

You will not incur any penalty or harm from leaving the study before it is finished. The quality of care provided to you by Dr. Dewar will in no way be impacted if you choose to exit the study prematurely. You may continue seeing Dr. Dewar without being a part of this research study.

7.3 Could the researchers take me out of the study even if I want to continue to participate?

Yes, only if the study is suspended or canceled.

8. FINANCIAL INFORMATION

8.1 Who will pay for the costs of the study? Will I or my health plan be billed for any costs of the study?

The study will pay for research-related items or services that are provided only because you are in the study as outlined in section 4.1 as ***RESEARCH RELATED***. If you are not sure which procedures or services the study will pay for, ask the researchers for a list. If you get a bill, you think is wrong, call the researcher's telephone number listed in Section 10.1.

You or your health plan will pay for all the things you would have paid for even if you were not in the study, like:

- Health care given during the study as part of your regular care.
- Monitoring for side effects or other problems
- Deductibles or co-pays for these items or services.

If you do not have a health plan, or if you think your health plan may not cover these costs during the study, please talk to the researchers listed in Section 10 below or call your health plan's medical reviewer.

If you are injured or in the event of a medical emergency, dial 911 or visit your nearest Emergency Room. If you believe the study has made you sick or caused you injury, contact one of the people listed in section 10 of this document (Contact Information). If taking part in the study makes you sick or causes you injury, you or your insurance provider will be

billed for all costs of treatment as the study does not provide compensation for sickness or injury caused by the study. It is possible that your insurance will not cover these costs.

By signing this form, you do not give up your right to seek payment if you are harmed because of being in this study.

8.2 Will I be paid or given anything for taking part in this study?

No. You will not be paid for taking part in this study.

8.3 Who could profit or financially benefit from the study results?

No person or organization has a financial interest in the outcome of the study.

Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.

9. CONFIDENTIALITY OF PARTICIPANT RECORDS AND AUTHORIZATION TO RELEASE YOUR PROTECTED HEALTH INFORMATION

The information below describes how the confidentiality of your research records will be protected in this study, and any sub-studies described in this document.

9.1 How will the researchers protect my information?

Your participation will occur at Michigan Medicine. Your data will be kept confidential, to the extent permitted by applicable laws, in the following manner:

- Your name will not be used in any reports about the study.
- You will be identified only by a study code.
- Your identifying information will be kept secure.

Despite these protections, some study data may contain information that could be used (perhaps in combination with other information) to identify you (e.g., initials, date of birth).

Your research information will be stored in a locked cabinet and will not be made a part of your regular medical record. Research records will be kept in a separate research file that does not include names, registration numbers, or other information that is likely to allow someone other than the researchers to link the information to you. All electronically stored information will be maintained on University of Michigan server space as well as on a secure, HIPAA-compliant, online database (REDCap). All will be password protected, accessible only to approved study team members, and your information will be identified using a unique study identification number assigned to you upon enrollment. It will also be stored on the cloud; the term “cloud” refers to large computers located in different parts of

the world where individuals may keep and remotely access their personal and professional files. Each cloud service has its own policies and methods for preventing unauthorized individuals from accessing files stored on their cloud servers. The cloud service used to store files associated with this study meets University of Michigan protection standards. Only members of the study team will have access to your study information.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that we cannot release or use information, documents, or samples that may identify you in any action or suit except as described below. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other legal proceedings. An example of a situation in which the Certificate would apply would be a court subpoena for research records.

There are some important things that you need to know:

- The Certificate does not stop reporting or information-sharing that you agreed to in this consent document. For example, we may share information with appropriate authorities if we think you may harm yourself or others. We may also share your information with other researchers.
- The Certificate does not stop reporting that federal, state, or local laws require. Some examples are laws that require reporting of elder abuse and of some communicable diseases.
- The Certificate cannot be used to stop a sponsoring United States federal or state government agency from checking records or evaluating programs.
- The Certificate does not stop disclosures required by the federal Food and Drug Administration (FDA).
- We may also release information about you to others when you say it is okay. For example, you may give us permission to release information to insurers, medical providers, or anyone else.
- The Certificate of Confidentiality does not stop you from personally releasing information about your involvement in this research if you wish.

More information about Certificates of Confidentiality and the protections they provide is available at https://www.era.nih.gov/erahelp/CoC_Ext/Content/A-Introduction/Introduction.htm

ClinicalTrials.Gov

Required Registration and Reporting for ACTs for NIH and others.

Applicable Clinical Trials (ACTs) including this study is required **by federal law** to be registered.

This trial is registered at ClinicalTrials.gov with Identifier: NCT06624163 (approved on Oct 1, 2024)

and may report results on www.ClinicalTrials.gov, a publicly available registry of clinical trials."

Questions? Contact the Medical School's Office of Regulatory Affairs by emailing UMMS-RegAffairs@med.umich.edu or calling 734-647-1576.

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 at any time.

9.2 What protected health information (PHI) about me could be seen by the researchers or by other people? Why? Who might see it?

Signing this form gives the researchers your permission to obtain, use, and share information about you for this study, and is required for you to take part in the study.

Medical information and billing records are protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA). This type of information is called protected health information (PHI). PHI about you may be obtained from any hospital, doctor, and other health care provider involved in your care, including:

- Hospital/doctor's office records, including test results (X-rays, blood tests, urine tests, etc.)
- All records relating to your condition, the treatment you have received, and your response to the treatment.
- Demographic information
- Personal identifiers

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- The researchers may need the information to make sure you can take part in the study.
- University, Food and Drug Administration (FDA) and/or other government officials, auditors, and/or the IRB may need the information to make sure that the study is done in a safe and proper manner and for quality improvement purposes.

- Study sponsors or funders, or safety monitors or committees, may need the information to:
  - Make sure the study is done safely and properly.
  - Learn more about side effects.
  - Analyze the results of the study.
- Information about your study participation may be included in your regular Michigan Medicine medical record.
- Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.

The results of this study could be published in an article but would not include any information that would let others know who you are.

9.3 What happens to information about me after the study is over or if I cancel my permission to use my PHI?

As a rule, the researchers will not continue to use or disclose information about you but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you to continue to be used or disclosed, even after you have canceled your permission, or the study is over.

Examples of reasons for this include:

- To avoid losing study results that have already included your information.
- To provide limited information for research, education, or other activities. (This information would not include your name, social security number, or anything else that could let others know who you are.)
- To help University and government officials make sure that the study was conducted properly.

As long as your information is kept within the University of Michigan Health System, it is protected by the Health System's privacy policies. For more information about these policies, ask for a copy of the University of Michigan "Notice of Privacy Practices". This information is also available on the web at http://www.uofmhealth.org/patient+and+visitor+guide/hipaa. Note that once your information has been shared with others as described under Question 9.2, it may no longer be protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

9.4 When does my permission to use my PHI expire?

Your permission does not expire unless you cancel it. You may cancel your permission at any time by writing to the researchers listed in Section 10 "Contact Information" (below). If you withdraw your permission, you may no longer be eligible to participate in this study.

10. CONTACT INFORMATION

10.1 Who can I contact about this study?

Please contact the researchers listed below to:

- Obtain more information about the study.
- Ask a question about the study procedures or treatments.
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished.
- Express a concern about the study.

Principal Investigator: Shenbagam Dewar, MBBS
Mailing Address: University of Michigan, 300 North Ingalls Bldg. Rm 910, Ann Arbor, MI 48109
Telephone: (743) 764-5101

Study Coordinator: Ryan Bade
Mailing Address:2215, Fuller Road, VA Ann Arbor Health System, Ann Arbor, MI 48105
Telephone: 810-299-1749

You may also express a question or concern about a study by contacting the Institutional Review Board listed below:

University of Michigan Medical School Institutional Review Board (IRBMED)
2800 Plymouth Road
Building 520, Room 3214
Ann Arbor, MI 48109-2800
Telephone: 734-763-4768 (For International Studies, include the appropriate calling codes.)
Fax: 734-763-1234
e-mail: irbmed@umich.edu

If you are concerned about a possible violation of your privacy or concerned about a study, you may contact the University of Michigan Health System Compliance Help Line at 1-866-990-0111.

When you call or write about a concern, please provide as much information as possible, including the name of the researcher, the IRBMED number (at the top of this form), and details about the problem. This will help University officials to look into your concern. When reporting a concern, you do not have to give your name unless you want to.

RE-CONTACT

We would like to keep your contact information on file so that we might contact you to discuss another OHWL related study opportunity if it occurs. Please check or initial next to one of the following:

Sig-A

I voluntarily AGREE to be re-contacted in the future to see if I am willing to participate in some form of continued OHWL related study activities and/or provide follow-up information about my health or medical care.

Printed Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

_____*I DO NOT agree to be re-contacted in the future to discuss future OHWL related study activities and/or provide follow-up information about my health or medical care.*

11. RECORD OF INFORMATION PROVIDED

11.1 What documents will be given to me?

Your signature in the next section means that you have received a copy of the following document(s):

- This "Consent to be Part of a Research Study" document.

- "You will receive a copy of the signed and dated informed consent document.
- (*Note: In addition to the copy you receive, copies of this document will be stored in a separate confidential research file and may be entered into your regular University of Michigan medical record.)*

12. STORAGE, USE, AND SHARING OF SPECIMENS AND INFORMATION COLLECTED OR GENERATED IN THE STUDY DESCRIBED ABOVE

- **12.1 What is meant by the storage, future research use, and sharing of study participants' medical information and leftover samples (sometimes referred to as biospecimens) taken from me?**
- Individual researchers, the University of Michigan, and companies that design and sponsor studies often want to keep subjects' medical information to use in future research. These future research uses take different basic forms, which are described below. The medical information may also be shared with other researchers so that they can use it in their studies.
- The purpose of storing, using, and sharing participants' medical information is to promote more research that might lead to useful medical discoveries.
- In some cases, researchers need your consent to store, use, and share your medical information in other cases, they can store, use and/or share it without your consent. Whether or not researchers need your consent depends on if the stored information would still be identifiable as yours or whether the researchers would first remove all information connecting them back to you.

13. SIGNATURES

Sig-B

Consent/Assent to Participate in the Research Study

I understand the information printed on this form. I have discussed this study, its risks and potential benefits, and my other choices _____. My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in Section 10 (above). I understand that I will receive a copy of this form at the time I sign it and later upon request. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Sig-G

Principal Investigator or Designee

I have provided this participant and/or his/her legally authorized representative(s) with information about this study that I believe to be accurate and complete. The participant and/or his/her legally authorized representative(s) indicated that he or she understands the nature of the study, including risks and benefits of participating.

Printed Legal Name: _____

Title: _____

Signature: _____

Date of Signature (mm/dd/yy): _____