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

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Abbreviations:
OHWL: Optimal health weight and lifestyle clinic
OCP: OHWL care provider
PC: Patient coach
SW: Social worker
OT: Occupational therapist
CAPABLE: Community aging in place-Advancing better life for elders
SDOH: Social determinants of health
BMI: Body mass index
MoCA: Montreal cognitive assessment score
SPPB: short physical performance battery
TUG: Timed-Up-Go

Summary

Evaluation of Patient Coach Support for Older Adults with Obesity	
Background and Rationale	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), and care complexity related to social determinants of health. As proof of concept, PI Dewar developed the **Optimal Health, Weight, and Lifestyle (OHWL) clinic** to optimize treatment of comorbid health conditions, physical function, and diet in older adults with obesity. Only 1/3 of the 44 initial participants were adherent to medical specialist and therapist referrals. The remaining patients faced challenges such as lack of support for adherence to lifestyle change, low self-efficacy, and poor linkage to community resources. The purpose of the present pilot is to evaluate the outcomes of adding a patient coach to support the OHWL Clinic plan developed by PI Dewar, specifically to address barriers and facilitators of adherence to

	the plan. This will be accomplished via a coach (described below) who is not embedded in clinic care and is supported by pilot research funds. Evaluation of the coach activities (described below), conducted by research personnel, will include compiling data from the electronic health record, a short set of patient report and performance measures, and qualitative interviews.
Aims and Hypotheses	*Primary Aim:* Conduct a mixed methods process evaluation of the coach activities, guided by the RE-AIM model. *Primary Hypothesis:* The coach support is feasible and acceptable, as indicated by participants who, by 6 months: 1) atleast attend 1 PT appointment and 1 nutrition appointment; 2) achieve treatment goals established by patient coach; and 3) access community resources if needs identified. *Exploratory hypothesis:* Qualitative data will help explain quantitative findings such as changes in weight, waist circumference, handgrip, TUG and lab data. Improvement in nutrition as evidenced by improvement in total kilocalories, fat, saturated fat, sodium, added sugar and alcohol Also identify barriers and facilitators to implementation and suggest needed modifications. *Secondary Aim:* 1. Evaluate extent of changes in key quantitative 6-month outcomes among participants (namely 1. pain, , 2. quality of life as measured by PROMIS-29 and 3. self-report of difficulty or dependency with performing activities of daily living measured by NHATS, and 4. lifespace assessment
Study Population	The study population will be drawn from those attending the OHWL Clinic, characterized by age ≥60 and ≤ 85 years, 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, and interest in weight management. Participants should have at least 2 of the following weight-related comorbidities: hypertension, cardiovascular conditions including heart failure, diabetes mellitus, hyperlipidemia, non-alcoholic steatohepatitis, obstructive sleep apnea, or osteoarthritis.
Investigational Plan	Patient coach A coach, a health professional who serves on the research team, follows patients outside of clinic (and supported by research funds) to ensure adherence with referral appointments such as PT, nutrition and use of recommended community resources. The coach assesses the participant at baseline, 3 months, and 6 months using the Patient-Specific Functional Scale and follows up with patients via a tapering phone call schedule over 6 months: weekly for first 6 weeks, biweekly for 6-12 weeks, and monthly at 4, 5 and 6 months. The coach utilizes S.M.A.R.T. (Specific, Measurable, Achievable, Relevant, Time-bound) goals to facilitate, for example, transportation, barriers to scheduling and clinical providers (difficulty connecting via phone/patient portal), and caregiver assist. Additionally, the coach follows up on specialist referral recommendations and physical therapy (especially home exercise programs) and nutrition program, as well as social work recommendations. Barriers and facilitators to plan adherence are identified and addressed. Research evaluation protocol *Data compilation*: The research **coordinator** will compile data from the activities to include MiChart data documenting the evaluation by the OHWL Care Provider (both initial and follow-up, to include demographic, biometric data, timed up and go test data, hand grip measurement value, medical problems and laboratory values), and from the SMART goal establishment and follow-up done by the coach. *Patient report measures:* The research **coordinator** will assess the following measures via telephone at

	baseline, three months and 6 months. These assessments (attached to the appendix) include: a) PROMIS-29 for pain and quality of life; b) an abbreviated NHATS measure for daily task difficulty and disability, c) the Life Space Assessment to determine extent of mobility both in and out of the home; and d) Nutrition, i.e. 24 hour formal food recall
Methods and Timeline	As per the investigational plan above. 1. Anticipated length of active enrollment is 6 months per participant 2. Medical chart review (only) at 12 months for data collection: biometric data, timed up an go test data, hand grip measurement value and laboratory values

Study Design:

Study Type: Interventional

Primary Purpose: Supportive Care

Interventional Study Model: Single Group Assignment

Number of Arms: 1

Enrollment: 40 [Anticipated]

Inclusion Criteria:
The study population will be drawn from those attending the PI Dewar's OHWL Clinic (n=40), characterized by age ≥60 and ≤ 85 years, 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, and interest in weight management. Participants should have at least 2 of the following weight-related comorbidities: hypertension, cardiovascular conditions including heart failure, diabetes mellitus, hyperlipidemia, non-alcoholic steatohepatitis, obstructive sleep apnea, or osteoarthritis. Patients will be enrolled at a goal of approximately 1-2 new patients/week for the first 6 months (to allow for 6-month follow-up of the last enrollees).

Exclusion Criteria:
• Active mental health disorder, such as major depression

• Moderate to severe cognitive impairment
• Mobility limited to bed-bound status

Background Information

Obesity among older adults is common. Obesity rates in older adults have increased nationally (41%)[1] and worldwide with rates tripling over the past 40 years[2]. With increased life expectancy there is a demographic shift towards a larger population of older adults, predicted to reach 83.7 million by 2030[3]. Severe obesity (BMI≥ 35) is increasing nationally, and the prevalence is predicted to reach 27.2% in Michigan by 2030[4].This confluence of aging with obesity leads to significant multimorbidity[5,6] resulting in an older population with impaired physical function[7], decreased quality of life[8], institutionalization[9], and increased mortality[10,11]. In the Michigan Medicine Geriatrics Clinic, more than half (57%) of patients aged 65-80 have a BMI>30[12].

To care for the older adult with obesity, a team approach is needed: Currently there is a misconception, including by health care providers, that obesity stems from a lack of willpower [13], despite its multifactorial causes, making obesity one of the most undertreated chronic conditions[14]. The issues above suggest a need for a specialized interdisciplinary team approach, which is patient-and obesity centered. Recent approaches to obesity care have suggested utilization of home and community based services[15], particularly in those older adults with obesity who have increased psychosocial and functional needs and high-risk medical conditions, and are at risk for caregiver dependency and institutionalization. Community services are currently being focused to address a variety of conditions and diseases in older adults (such as dementia and heart failure) but there is less of a focus on older adults with obesity.

Development of the OHWL Clinic

As proof of concept, PI Dewar developed the **Optimal Health, Weight, and Lifestyle (OHWL) clinic** to optimize treatment of comorbid health conditions, physical function (via a physical therapist), and diet (via a nutritionist) in older adults with obesity (n=44, mean age 74, mean BMI 42). **Table 1** shows the advanced age, high BMI (including in those aged 75 and older), high number of obesity-related medical problems (particularly cardiovascular-related), pain, and mobility disability (based on the utilization of an assistive device). Only 1/3 of these participants were adherent to medical specialist and therapist referrals and subsequently demonstrated at least 5% weight loss. For the remaining patients, there was likely an unmet need for additional adherence support for lifestyle change, issues of low self-efficacy, and poor linkage to community resources.

Table 1. OHWL Pilot Cohort (n=44) Characteristics

Mean Age (range)	74(61-84)
Mean BMI (range)	42(31-60)
# Class I (BMI 30-34.9)/#>age75/%	8/88%
# Class II (BMI 35-39.9)/#> age 75/%	13/69%
# Class III (BMI > 40)/# > age 75/%	23/78%
Mean # Obesity-related medical problems	16
% With Osteoarthritis	98%
% With Hypertension	100%
% With Heart Failure (HF)	18%
% With Intermediate-high CV[a] risk (if no current HF)	100%
% With Diabetes/Prediabetes	84%
% With established atherosclerotic vascular disease	32%
% With Pain	96%
% With Assistive device	55%

Standard of Care-(NON-RESEARCH) The patients seen for clinical care for new patient obesity visit by the physician (PI) at University of Michigan East Ann Arbor geriatrics center is handed a paper copy of consent at the end of the visit, based on confirmation of eligibility of study.

RESEARCH: The participants(patients) receive a phone call from the study research coordinator few days following the initial visit to confirm participation (if participant is willing to take part in the study) and if confirmed followed by email to obtain the eConsent "Sign Now" and confirmed enrollment once signed,

RESEARCH: Study research coordinator interaction: The research coordinator completes 4 assessments, 3 of them using REDCap generated survey questionnaire a) PROMIS-29 for pain and quality of life; b) an abbreviated NHATS measure for daily task difficulty and disability, c) the Life Space Assessment to determine extent of mobility both in and out of the home; and d) Nutrition, i.e. 24 hour formal food recall by referring to ASA24 website. If the participants have difficulty completing by these modes, it is completed by the research coordinator by phone.

Coach telephone calls: Supportive intervention: After this initial step, a patient coach, a health professional (occupational therapist) who serves on the research team, follows patients outside of clinic by a telephone call for coaching calls:

I. to ensure adherence with referral appointments (physical therapy and nutrition)
II. use of recommended community services if needed.
III. The coach utilizes S.M.A.R.T. (Specific, Measurable, Achievable, Relevant, Time-bound) goals to facilitate adherence with diet and physical activity goals, The coach assesses the participant using the Patient-Specific Functional Scale and follows up with patients via a tapering phone call schedule over 6 months: weekly for first 6 weeks, biweekly for 6-12 weeks, and monthly at 4, 5 and 6 months
IV. Offer support to navigate transportation, barriers to scheduling and clinical providers (difficulty connecting via phone/patient portal), and caregiver assist. Barriers and facilitators to program adherence are identified and addressed

RESEARCH: At the end of 6 months the participants are approached by a phone call by the research coordinator for a satisfaction survey and they have the option to decline to participate

RESEARCH : Clinical Records Data Collection:

- Clinical data from patient's medical record is collected by the study team. Details include, if participants have diagnosis of pre-selected list of obesity related medical problems (at baseline only) AND variables on weight in pounds, Waist circumference (cm), BMI, Hand-grip strength, Timed-Up and Go at baseline, 6 mo and 12 mo data from study entry
- Lab results data from clinical records at baseline and repeat labs at clinically relevant intervals with last data collection at 12 mo from study entry

Research Study Procedures:
Research Coordinator Assessment: (Assessor)

- PROMIS-29

- PROMIS Global Pain
- NHATS
- Lifespace Assessment
- 24 Automated Survey Assessment (Food quality)

Coach calls and assessments:

- Successful goals achieved (diet/physical acitvity)
- Attended atleast 1 physical therapy appointment
- Attended atleast 1 nutrition appointment
- Patients who reported using a community resource (such as a gym, community park, or other similar resource) at least once during the course of the study if newly discussed by coach

Clinical Records Data Collection:

During visit: Standard of care (Data abstracted from EMR)
Obesity related medical problems: Assessed as part of Standard of care

1. Sleep disordered breathing: (yes/No): if Yes
    - Obstructive Sleep Apnea
    - Insomnia
    - Primary snoring
    - Restless Legs Syndrome
    - None
2. Asthma or COPD
3. Osteoarthritis
4. Metabolic syndrome
5. Dyslipidemia
6. Hypertension
7. Heart Failure
8. Lower extremity swelling/other concerns: (yes/No): if Yes
    - Leg edema
    - Venous stasis
    - Lymphedema
9. Any Cancer: (yes/No): if Yes
    - Obesity-related
    - Non-obesity related
10. Glycemic status
    - Diabetes
    - Pre-diabetes

- Normal

11. Hyperuricemia
12. Liver dysfunction:
    - Normal LFT
    - Elevated LFT
    - NAFLD by US
13. Chronic Kidney Disease: Glomerular Filtration Rate (GFR categories)
    - G1: Normal or High >90
    - G2: Mildly decreased 60-89
    - G3a: Mildly to moderately decreased 45-59
    - G3b: Moderately to severely decreased: 30-44
    - G4: Severely decreased 15-29
14. Pain
15. Mental Health Disorders:
    - Major depression
    - Bipolar disorder
    - Panic disorder
    - Generalized anxiety and other anxiety disorder
    - Posttraumatic stress disorder
    - Eating disorders
    - Alcohol use disorder
    - No mental health disorder

Lab data monitored as part of clinical care Longitudinal (baseline and varying intervals per clinical needs until 12 months (approx Q3-6 mo): (Data abstracted from EMR)- last Lab data: 12 months

- HbA1C
- Total cholesterol
- Triglycerides
- LDL
- HDL

weight loss promoting medications:

a. Metformin
b. Older generation weight loss medications

Phentermine/Topiramate

Naltrexone/Bupropion

c. Newer generation weight loss medications

Semaglutide

Tizepatide

	Baseline Clinic Visit	Consent	Pre-Assessment	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 8	Week 10	Week 12
Informed Consent	**X**	**X**										
Study Enrollment		**Xe**										
Demographics		**Xe**										
Assessment Surveys:												
PROMIS 29			**Xd**									**Xd**
PROMIS pain			**Xd**									**Xd**
NHATS			**Xd**									**Xd**
Lifespace			**Xd**									**Xd**
24ASA Food Recall			**Xd**									**Xd**
Coach Phone Calls				**Xa**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**
Provider:												
Provider Visit	**Xb**									**Xb**		
Labs	**Xc**									**Xc**		
Standard of Care Measurements	**Xc**									**Xc**		
Obesity related Medical Issues and obesity Medications	**Xc**									**Xc**		

a. Will only occur after baseline assessments completed

b. Occurs with or without assessments

c. Occurs every 2 months after meeting provider

d. Completed via phone or online survey

e. Collected once Provider has decided the participant meets study criteria

RESEARCH EVALUATION PROTOCOL

Patient Recruitment

The study population will be drawn from those attending the OHWL Clinic, characterized by age ≥60 years, 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, and interest in weight management. Participants should have at least 2 of the following weight-related comorbidities: hypertension, cardiovascular conditions including heart failure, diabetes mellitus, hyperlipidemia, non-alcoholic steatohepatitis, obstructive sleep apnea, or osteoarthritis.

We will seek approval from the IRB for the following recruitment plan. The OCP will introduce the study to patients for recruitment purposes, making it clear that participation is voluntary, and that the decision will not affect their clinical care. If patients agree, then a research **coordinator** member of Dr. Alexander's research team staff will approach the patient, by phone/email, for consent.

Safety Considerations

The coach activities and research assessments are no more than minimal risk to the participants. Coach activities involve telephone gathering of self-report information. The patient report measures utilize well-validated standardized questionnaires that are also thought to be of low risk.

In case of any issues or safety concerns, participants and caregivers will be given the direct phone extensions to key study team members and will be reminded to dial 911/visit a local Emergency Room (ER) should any emergent needs arise.

Data Management

Data Source/Data elements:

Data for the study to be abstracted from MiChart will include height, weight, body mass index, waist circumference, blood pressure, grip strength, timed up and go test, medical problems from the problem list, medications specifically weight loss promoting medications ie metformin and older and newer generation of weight loss medications, and laboratory tests including HbA1C,and lipid panel.

Data from the formal research assessments include patient report measures, PROMIS -29, PROMIS Global pain, the abbreviated NHATS, ASA24 (24-Hour food Recall), and the Life Space Assessment

Data Security

Data will be recorded in within a coded database on REDCap. This HIPAA-compliant online database will include assessment data that will be filed under a randomly assigned ID number for each participant, generated by the REDCap system. That ID number will be used in the password protected Excel crosswalk as a key to link the personally identifiable information of each participant to their unique ID. Only IRB approved study team members will have access to both the REDCap database and the Excel crosswalk. This method will prevent any of the stored data from being directly associated with the participant's identity. Upon study completion, the crosswalk file will be deidentified and put into a server file. Six years after the fiscal year when the study is terminated, the crosswalk file and all research data may be destroyed.

Data analysis/interpretation

Participant data will be collected from research coordinator assessments and coach (goal setting, monitoring and tracking, attending physical therapy and nutrition appts and assessing community resources) and entered in REDCap . The exploratory outcomes such as changes in weight, waist circumference, handgrip, TUG and lab data gathered from clinic visits and entered in REDCap; These outcomes will be compared at study entry (baseline), end of month 3 and end of month 6. Outcome analyses will focus on **PROMIS-29 scores, PROMIS pain scores, NHATS, lifespace mobility and** change in weight, waist circumference, timed-up and go test, hand grip measure, food quality **weight, HbA1c level, and lipids.** Improvement in nutrition as evidenced by improvement in total kilocalories, fat, saturated fat, sodium, added sugar and alcohol (baseline, 3 months and 6 months)

Analyses of outcomes will include descriptive and standard statistical tests to determine the relationships between predictors and any changes occurring over time.

Quantitative data analysis: We will obtain descriptive statistics (frequencies and means) at baseline and examine change over time (from baseline to 6 months) in the outcome measures. Parametric and non-parametric comparison tests will be used to examine change in continuous variables over time and chi-square tests will be used for categorical variables. Sample size (n=40, with the understanding that some participants may not fully complete the 6-month follow-up) is dictated by the resources provided by pilot funding but given the previous clinic data, should provide meaningful insight into patterns meriting further study.

Qualitative data analysis: We will record and transcribe participant and staff in-depth interviews, with permission from interviewees. We will use standard qualitative analysis procedures to analyze data. All meaningful text in interviews will be assigned a code or codes capturing key content. These will later be organized into themes and subthemes by two evaluators (Dr. Janevic and a student assistant), to ensure a robust and reliable scheme. We will then review the thematic structure of the data to develop an overall understanding of the participant (and staff) experience, as well as the specific dimensions. These data can help explain patterns found in the quantitative outcomes (e.g., why certain types of participants were successful with adherence and positive outcomes). Data will also inform modifications and will allow us to identify core elements to include in an implementation package to be developed.

Quality Assurance
All study team members are trained in Good Clinical Practice (GCP) and the investigator is responsible for ensuring the accuracy, completeness, legibility, and timeliness of the data. All source documents should be attributable, legible, contemporaneous, original, accurate, and complete to ensure accurate interpretation of data. The investigator will ensure that the conduct of the trial is compliant with the currently approved protocol, GCP, and any applicable regulatory requirements.

Dissemination of Results
Results will be disseminated via planned presentation of data at national meetings and preparation of manuscripts for publication.

Anticipated Problems
The patients participating in this study may be chronically ill with multiple comorbidities. Therefore, medical instability may interfere with participation.

Ethics

Institutional Review Board (IRB)
The protocol and informed consent forms will be submitted to the University of Michigan IRB for review and approval. Approval of both the protocol and the informed consent form must be obtained before any subject is enrolled. Any amendment to the protocol or change to the consent forms will require review and approval by the IRB before the changes are implemented to the study.

Ethical Conduct of the Study
The study will be conducted in accordance with the protocol, following standards of Good Clinical Practice (GCP) and in compliance with applicable regulatory requirements.

The Principal Investigator will maintain appropriate oversight of this research protocol and research staff, and appropriately delegate research responsibilities to authorized study team members.

Informed Consent Process
The study team will assess the subject's capacity to consent to a research protocol. The study team will provide the prospective subject sufficient opportunity to consider whether or not to participate. The study team will ensure that information is provided to the subject, and, if applicable, their legally authorized representative, in a language that is understandable to the subject or representative. The following considerations will be clearly communicated to minimize the possibility of coercion or undue influence:

- Patients will receive the same outpatient care by the PI Dewar regardless of whether they enroll in this study.
- Participants will always have the option to opt out of the assessment.

The investigators will advise research subjects to review the risks of "usual care" procedures that are not part of the research with their health care providers. An authorized study team

member will obtain a legally effective informed consent form and HIPAA Authorization form that is signed and dated by the subject and then signed and dated by the study team member obtaining consent. The study team will appropriately document the informed consent process, save the original copy in investigator files, and give a copy to each subject. The original paper copy will not be destroyed. For all the patients who are already enrolled and signed the consent form we will make a telephone call to inform them that "the funding agency is requiring you to provide them with information about their participation in the study: **The National Institutes of Health (NIH) and its authorized representatives** may look at or receive copies of information in participants' study records. This is a requirement and that we would like you to be aware that NIH will receive your study records but no information that would identify you would be provided to the National Institutes of Health". We would then follow up with a document mailed to them with this same information with the date of the phone call, who they spoke with, and a phone number to contact if they have any questions

Respect of Privacy and Confidentiality

The study team will respond to participants' complaints or requests for information.
The identifiable information collected during this research study will not be reused or disclosed to any person or entity outside the University of Michigan other than those identified in the consent/ authorization form, except as required by law, for authorized oversight of this research study. The participants' identifying information will be stored separately from study data in password-protected Excel files, HIPAA compliant online database REDCap, MiChart, and all files will be saved on a secure University of Michigan network drive protected by firewall and accessible only by study team members.

Policies for Payments and Reimbursement

Participants are receiving services to benefit their health and as such will not be receiving any compensation.

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