Protocol #: 22-2183
Project Title: Designing with dissemination in mind: Development of a theory-based physical activity intervention using the Multiphase Optimization Strategy; Aim 1, Phase 2
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Version Date: 3/29/23

I. Hypotheses and Specific Aims: A critical challenge in the prevention of cardiovascular disease (CVD) is increasing the proportion of adults who are able to lose weight and maintain their weight loss long-term.[1] Physical activity (PA) is a key predictor of sustained weight loss[2] and current guidelines recommend high levels of moderate-to-vigorous PA (MVPA, 300 min/wk) for weight management.[3] However, long-term adherence to PA remains low in adults with overweight or obesity enrolled in lifestyle weight management programs.[4-6] My previous work indicates that adults with overweight or obesity are more likely to adhere to PA when PA is consistent with their values and is perceived as enjoyable. This is consistent with Self-Determination Theory (SDT), which supports autonomous motivation as a critical factor in promoting sustained PA adherence.[7-10] Based on my work, and the work of others[11-14], I developed and piloted a *brief*, SDT-based, PA support program (called *Move*) in adults with BMI 25-45 kg/m^2 who were enrolled in a 12-month lifestyle weight management program. Currently, *Move* consists of two, group-based sessions that support autonomous motivation for PA by encouraging adults in choosing PA types that are personally meaningful and intrinsically motivated. Participants who attended both *Move* sessions demonstrated a greater increase in MVPA at 12 months compared to those who did not attend both *Move* sessions. Focus group feedback (n=39) indicated high enthusiasm for *Move,* but also a strong desire for individualized support and additional *Move* content. Thus, the next step to refine this intervention is to add novel intervention components that target barriers to PA that were identified in the focus group feedback. We propose to create *Move+* by developing 3 additional SDT-based components: 1) 1:1 support sessions (to provide individualized support), 2) guided positive exercise mental imagery sessions (to address negative feelings around PA), and 3) low-cost, livestream fitness membership (to improve PA access). We hypothesize that these *Move+* components will improve autonomous motivation for PA[15], which will lead to increased PA adherence, and thus long-term weight loss (**Fig 1**). Our specific aim is:

Aim 1 Phase 2: Pilot test the delivery of the *Move+* program. We will conduct a 12-week, single-arm field trial to pilot test the delivery of the *Move+* program.

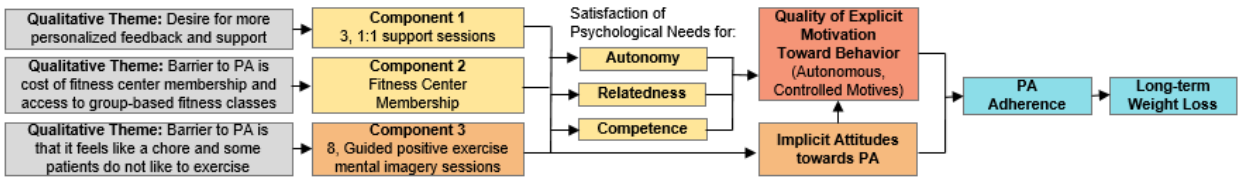

Fig 1: Conceptual model of how Move+ components impact long-term weight loss, through SDT-constructs

II. Background and Significance: The burden of obesity, associated with cardiovascular disease (**CVD**) and early mortality, will continue to be critical public health concern if the issues surrounding poor long-term weight loss maintenance are not addressed. Despite the short-term efficacy of lifestyle interventions for weight loss[16] many individuals regain over half of their lost weight within two years.[1] A high level of physical activity (PA; 250-300 min/wk moderate aerobic

PA) is a key predictor of weight loss maintenance[5, 17-19] and is universally recommended for prevention of weight regain.[20] In addition, increasing PA reduces risk for CVD, independent of weight loss.[21, 22]

Despite the benefits of PA, getting adults with overweight or obesity to adopt and maintain high levels of PA long-term remains a significant challenge.[4, 23] The vast majority (~90%) of adults with overweight or obesity enrolled in current lifestyle weight management programs do not meet PA guidelines for weight management long-term (≥12 months after start of intervention).[5, 23-25] Although many factors contribute to poor long-term PA adherence[4, 26-29], absence of accessible, effective, theory-based programs that account for each person's values[30], motivation, and preferences[31-34] remains a major barrier. Thus, there is a critical need for person-centered and scalable interventions that promote long-term adherence to PA in adults with overweight/obesity.

I developed a brief, person-centered PA support program, called *Move*, designed to enhance explicit autonomous motivation for PA in adults with overweight or obesity. The *Move* program is based on the Self-Determination Theory (SDT) and targets enhanced PA adherence. *Move* supports autonomous motivation for PA by encouraging adults in choosing PA types that are personally meaningful and intrinsically motivated. SDT is compelling to focus on in the context of PA because it distinguishes the quantity from the quality of explicit motivation for PA. Autonomous motives, in contrast to controlled motives (e.g. rewards, guilt), are considered high-quality because PA is perceived to be consistent with individual values and inherent interests.[35] The quality of explicit motivation is determined by the extent to which a context (e.g. exercise) satisfies 3 basic psychological needs: autonomy (actions are authentic and freely chosen), competence (feeling capable of achieving goals), and relatedness (connection to others).[35] My work and the work of others has demonstrated that **explicit** motivation predicts PA adoption and maintenance.[36] I found that adults with autonomous PA motives sustained their initial increases in PA at 12 months whereas those with controlled PA motives did not.[37] These data, among others[11-13, 38], suggest the importance of autonomous motives for PA adherence and provided key insight for *Move*.

Move+ targets both explicit and implicit motivation, which may enhance PA adherence: PA motivation involves both explicit (conscious thoughts, autonomous motives) and implicit processes (automatic, may occur without awareness). Implicit attitudes towards PA represent an individual's 'gut' reaction towards a PA stimulus (e.g. seeing a person running)[39], can be positive or negative, and may occur without conscious awareness. There is increased evidence that these implicit processes are associated with PA behavior.[40-44] Dr. Conroy (collaborator) is an expert in studying this association. In his study of 201 participants, implicit attitudes towards PA prospectively predicted device-measured PA 1 week later.[41] Recently, the use of guided positive exercise imagery has been shown to impact implicit attitudes towards PA[45] and to improve autonomous PA motives[46], but it remains unclear whether changing implicit attitudes towards PA results in increased PA levels. This project will integrate guided positive exercise mental imagery as a novel *Move+* intervention component to support long-term PA adherence. Thus, the proposed study is novel because our SDT-based PA program targets improved long-term PA adherence by changing both explicit and implicit motivation through our focus on PA enjoyment and positive affect, an approach that has not yet been applied in a weight management program.

III. Preliminary Studies/Progress Report:

Two *Move* sessions improved explicit autonomous motivation for PA and PA adherence over 12 months: As part of my F32 award (DK122652), I piloted *Move* in adults with overweight or obesity enrolled in a 12-month lifestyle weight management program with two, 60-min group sessions. In a preliminary analysis, participants who attended both *Move* sessions demonstrated 1) a significant increase in autonomous motivation for PA at 12 months (**Fig 2A**), and 2) were more

likely to meet the PA guidelines of ≥300 min/week of device-measured moderate-to-vigorous intensity PA (MVPA) at 12 months (**Fig 2B**).

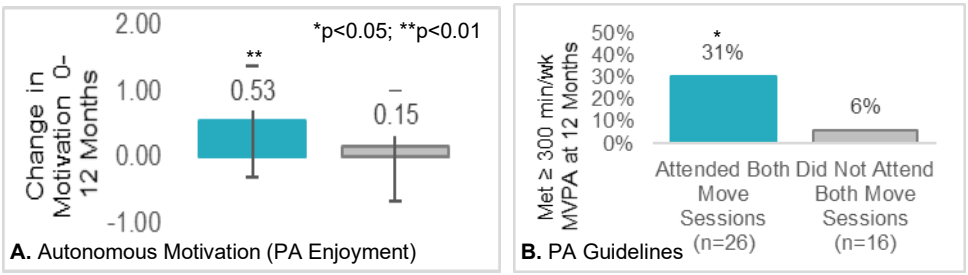

Fig 2A-B: Preliminary Data. Includes subjects who completed the 12-month study. **B** includes subjects who provided valid PA data (activPAL, ≥4 days; cadence ≥75)

However, participants were not randomized to receive *Move* and results are likely confounded by other factors, including overall attendance to group-based classes (78% vs. 60%, p<0.01). Importantly, qualitative data supports our intervention, as participants (n=39) reported high enthusiasm and acceptability for the *Move* program (abstract, *ObesityWeek* 2021). One participant stated: "You begin to enjoy [PA] because it becomes part of you. If you start moving in ways that you actually enjoy, it's no longer a chore. It's something that you just do." Participants also indicated a strong desire for additional *Move* program content.

IV. Research Methods

The study will take place at the University of Colorado Anschutz Medical Campus (CU-AMC). The overall objective is to engage research partners to refine *Move+* (Aim 1, Phase 2). Results will inform a future pilot feasibility trial of the refined Move+ intervention.

A. Outcome Measure(s): To achieve Aim 1 Phase 2, quantitative and qualitative data will be collected. Human-centered design testing[47, 48] will occur using a 12-week, single-arm field trial where a Registered Dietitian (RD) delivers ≥1 *Move+* session per week (group-class, 1:1, and/or guided imagery), remotely. Patients will receive a 12-week online fitness membership, using the option with the highest acceptability from cycle 1. Research partners recommendations will be used to refine intervention components. See **Table 1** for a description of the assessments by research partner type. The **primary study outcomes** are acceptability and feasibility of the *Move+* intervention. Other pre-specified study outcomes include exploring changes in SDT-constructs, explicit motivation for PA, implicit attitudes towards PA, weight, waist circumference, PA patterns, and cardiovascular markers.

Table 1. Assessments for Aim 1, Phase 2 by Research Partner Type

Outcome	Measure	Description	Participants (n=9)	RD (n=1)	Week 0	Week 12
Acceptability	90-min Semi-structured Focus Group via Zoom*	Explore acceptability; Identify any issues with the *Move+* components	x			x
	Semi-structured 60-min Interview[49] via Zoom*	Record reactions around acceptability using videoconferencing; identify any issues with the refined *Move+* components		x		x
	Net Promoter Score (NPS)®[50]	Scale -100 to 100; scores >0 indicate good acceptability	x	x		x
	Acceptability of Intervention Measures		x	x		x

	(AIM)[51]					
	Intervention Appropriateness Measure (IAM)[51]		x	x		x
	Likert scale (0-10)	Ratings of satisfaction for intervention component(s) by patients and staff every 3 weeks	x	x	x	x
Feasibility	Feasibility of Intervention Measure (FIM)[51]		x	x		x
	Perceived Characteristics of Intervention Scale (PCIS)[52]	PCIS measures trialability, relative advantage, compatibility, complexity, potential for intervention adaptation, etc.		x		x
	Organizational Readiness for Knowledge Translation (OR4KT)[53]	Setting-level factors that influence program adoption (organization climate, organization context, change content, leadership, organizational support, motivation)		x		x
	Reach/Recruitment	# of patients screened, proportion of eligible screens who enroll	x		x	
	Treatment Adherence	[# sessions attended/# provided], self-reported fitness membership usage	x			x
	Outcome Measure Rates	[# patients who complete measures at each time point/# patients randomized]	x		x	x
	Retention	[# patients who complete 12-wk intervention/# patients who start the intervention]	x			x
Fidelity and Adaptations	Direct Observation	*Move*+ sessions will be recorded, and the study PI will review recordings using an a-priori checklist			x	x
Physical Activity Patterns	Accelerometer	The activPALv4 (PAL) will be worn over 7 days to capture total stepping time, stepping time in MVPA, and sedentary behavior	x		x	x
	Global Physical Activity Questionnaire (GPAQ)	The GPAQ consists of 16 items which ask about the time spent doing different types of physical activity in a typical week	x		x	x
	Exercise and Sleep Log	Participants will be asked to record exercise and sleep over 15 days	x		x	x
SDT-constructs	Basic Psychological Need Satisfaction and Frustration Scale - Exercise (BPNSFS-E)[54]	SDT-based; Assesses satisfaction vs. frustration with basic psychological needs for autonomy, competence, and relatedness with regards to engaging in physical activity (for participants) or teaching the program (for providers)	x	x		x
Explicit PA Motivation	Behavioral Regulations for Exercise Questionnaire[55]	SDT-based; Provides separate scores for each behavioral regulation for exercise (amotivation, external, introjected, identified, integrated, and intrinsic)	x		x	x
Implicit Attitudes	Single	A computerized, time sorting	x		x	x

Towards PA	Category Implicit Association Test[56]	task, which asks participants to rapidly indicate, whether each presented PA stimulus belongs to one of two attributes (good/bad)			
Imagery Vividness	Vividness of Movement Imagery Questionnaire (VMIA-2)	A 12-item questionnaire where participants rate each mental image in 3 ways (internal visual imagery, external visual imagery, and kinesthetic imagery) from 1 (perfectly clear and vivid) to 5 (no image at all)	x	x	x
Imagery Ability	Movement Imagery Questionnaire (MIQ-3)	A 12-item questionnaire to assess an individual's ability to image four movements using internal visual imagery, external visual imagery, and kinesthetic imagery.	x	x	x
Weight Bias	Weight Bias Internalization Scale Modified (WBIS-M)[57]	An 11-item survey that measures the degree to which people apply weight-based stereotypes to themselves and base their self-evaluations on weight.	x	x	x
Body Dissatisfaction	Figure Rating Scale (FRS)	A 2-item survey that asks participants to rate their current body size and ideal body size.	x	x	x
Identity	Physical Activity Identity	A 4-item survey that asks about participant's physical activity identity	x	x	x
Physical Activity Habit Strength	Self-Report Index of Habit Strength (SRHI)	Involves 12-items that assesses habit strength of physical activity.	x	x	x
Diet	3-day Diet Record	Record food intake over 3 days (including 1 weekend day)	x	x	x
COVID-19 Tracking	Survey	A brief survey that asks about whether COVID-19 impacted participation in the study	x		x
Anthropometrics	Body Weight	Digital scale accurate to ± 0.1 kg	x	x	x
	Waist Circumference	Measured with a tape measure just over the iliac crest.	x	x	x
	Height	Measured with a stadiometer in cm	x	x	
Cardiovascular Markers	Blood Pressure	Automatic sphygmomanometer (average of 2 seated values taken after 5 min rest)	x	x	x
	Cardiorespiratory Fitness	Estimated using the YMCA 3-minute step test protocol[58]	x	x	x
Note: All proposed quantitative measures have demonstrated adequate reliability and validity *Focus groups and interviews will also be used to explore feasibility					

B. Description of Population to be Enrolled:

B.1 Patient and Provider Partners: Two types of partners (n=10 total) will be recruited, applying strategies learned from participatory and research partner-engaged research methods:

1. Adult participants with overweight or obesity seeking weight loss and/or improvements in health and well-being (n=9)

2. Providers, including Registered Dietitians (RDs) with experience delivering weight loss or lifestyle intervention curriculum (n=1)

We will enrich recruitment of minority participants above the Denver metro proportions[59] (target ≥15% Black, ≥30% Hispanic). A sample size of n=10 was chosen because ~10 research partners/cycle identify 95% of design issues.[60] Special classes of participants considered vulnerable populations will not be included in the study. Our primary recruitment strategy for this study will be university emails, recruitment from existing behavioral weight loss interventions (for participant partners), and through personal invitations (for RDs).

B.2 Eligibility Criteria: Eligibility criteria are designed to select a broad range of participant partners with overweight and obesity (women and men) for whom a physical activity program would be appropriate.

To be eligible to participate in this research, volunteers must meet the following criteria:

Inclusion Criteria:

- For all types of research partners:
    - Men and Women
    - Age 18-65 years
    - Have access to a computer and/or smart phone, and Wi-Fi
    - Speak English
- For the participant partners only:
    - Body Mass Index 25-45 kg/m^2
    - Insufficiently active (defined as <150 min/week of voluntary exercise at moderate intensity over the past 3 months)
    - Willing not to enroll in any other formal weight loss, physical activity program, or fitness center membership over the next 5 months.
    - Have a primary care physician (or has access to a healthcare professional and/or are willing to establish care with a primary care physician prior to study enrollment) to address medical issues which may arise during screening or study procedures/interventions.
    - Capable and willing to give informed consent, understand exclusion criteria, attend the *Move+* program sessions, and complete outcome measures.
- For the provider partners only:
    - >1 year experience with delivering lifestyle interventions involving changes in diet and/or exercise behaviors.

Exclusion Criteria

- For participant partners:
    - Considered high risk, based on the American College of Sports Medicine Guidelines for Exercise Testing and Prescription[61] (i.e. have CVD symptoms or known CVD, diabetes, or end–stage renal disease).
    - Females who are currently pregnant or lactating, were pregnant within the past 3 months, or planning to become pregnant in the next 5 months will also be excluded
    - Self-reported cardiovascular disease:
    - Cardiac, peripheral vascular, or cerebrovascular disease
    - Self-reported symptoms suggestive of cardiovascular disease:
        - pain, discomfort in the chest, neck, jaw, arms, or other areas that may result from cardiac ischemia; shortness of breath at rest or with mild exertion; dizziness or syncope; orthopnea or paroxysmal

nocturnal dyspnea; ankle edema; palpitations or tachycardia; intermittent claudication.
    - Self-reported end-stage renal disease
    - Self-reported diabetes (history of type 1 or type 2 diabetes)
    - Uncontrolled hypertension, defined as diastolic blood pressure >100 mmHG, systolic blood pressure >160 mmHG, or resting heart rate >100 bpm as measured in duplicate at the screening visit after 5 minutes of rest in a seated position.
    - Self-reported pulmonary disease requiring chronic oxygen supplementation; severe asthma or chronic obstructive pulmonary disease requiring hospitalization in past year.
    - Plans to relocate in the next 4 months
    - Currently participating in or planning to participate in any formal weight loss, dietary modification, or physical activity/exercise programs or clinical trials.
    - Current severe depression or history of severe depression within the previous year, based on DSM-IV-TR criteria for Major Depressive Episode. Score > 18 on BDI will require further assessment by the Study MD to determine if it is appropriate for the subject to participate in the study.
    - History of other significant psychiatric illness (e.g., psychosis, schizophrenia, mania, bipolar disorder) which in the opinion of the Study MD would interfere with ability to adhere to the exercise intervention.
    - History of clinically diagnosed eating disorders including anorexia nervosa, bulimia, binge eating disorder. Score >20 on the EATS-26 or pattern of response on the QEWP-5 suggestive of possible binge eating disorder or bulimia will require further assessment by the Study MD to determine if it is appropriate for the subject to participate in the study.
    - Current alcohol or substance abuse
    - Nicotine use (current or past 6 months)
    - Regular use of prescription or over-the-counter medications known to significantly impact appetite, weight, sleep, or energy metabolism (e.g., appetite suppressants, lithium, stimulants, anti-psychotics, tricyclic antidepressants)
    - Regular use of obesity pharmacotherapeutic agents within the last 6 months.
    - Previous obesity treatment with surgery or weight loss device, except: (1) liposuction and/or abdominoplasty if performed > 1 year before screening, (2) lap banding if the band has been removed > 1 year before screening, (3) intragastric balloon if the balloon has been removed > 1 year before screening (4) duodenal-jejunal bypass sleeve, if the sleeve has been removed > 1 year before screening or 5) AspireAssist or other endoscopically placed weight loss device if the device has been removed > 1 year before screening.
    - Has access to and currently uses (defined as having used membership at least once in past month) a fitness center membership.
- For RDs partners:
    - None

C. Study Design and Research Methods

C.1 Screening

Interested participants will complete an initial REDCap screening questionnaire containing demographic information (age, sex at birth, gender, race, ethnicity, etc.). For participants with an age >89, their age will be recorded as 89 in the study database. Participant

partners will also be asked to self-report their exercise levels, body weight, height, weight loss history, and health history. Potential participants will receive a follow-up call from a member of the research team to validate their information from the screening questionnaire and interest in the interviews. Research partners who meet initial eligibility criteria will be contacted by the study PI or PRA to confirm eligibility. Research partners will receive an explanation of the purpose of the study and study expectations, including research partner responsibilities and potential risks related to study participation. Interested individuals will be scheduled for an in-person screening visit to determine eligibility for the 12-week field trial.

Participants will be asked to sign an eConsent via REDCap or Docusign if they agree to participate in the study. If a participant declines eConsent, they will be given the option to sign a paper consent in-person or remotely and email their signed consent to the study team. Following completion of informed consent procedures, potential participant partners will undergo a health history and physical examination. Health history and physical examinations will be performed by a qualified healthcare provider (Physician Assistant, Nurse Practitioner, or MD) to ensure that they meet study inclusion/exclusion criteria. Body weight and height will be measured to confirm the self-reported BMI. Resting blood pressure and heart rate will be measured. Participants will complete the Physical Activity Readiness Questionnaire (PAR-Q+)[114] to screen for any contraindications to exercise. Participants will also complete the Beck Depression Inventory (BDI)[62] to screen for depression, and the Eating Attitudes Test (EATS-26)[63] and the Questionnaire on Eating and Weight Patterns (QWEP-5)[64] to screen for eating disorders. Any screening results that preclude enrollment will be communicated to potential volunteers who will be recommended to consult with their primary care provider. Participants who meet eligibility criteria will be invited to participate in the study.

Study group assignment: Phase 2 is a single arm, 12-week field trial, thus all participant partners will receive the *Move+* program and there is no inactive control.

C.2 Study Procedures

C.2.1 Description of *Move+* Intervention: The *Move+* components are 1) group-based classes, 2) individual support sessions (for personalized support), 3) guided mental imagery sessions (to address negative feelings around PA), and 4) low-cost, virtual fitness membership (to improve PA access). I worked with Drs. Masters and Conroy to develop *Move+* curriculum (see **Table 2**) that targets SDT constructs.[65] The group-based sessions serve as the core curriculum for *Move+*, and three 1:1 support sessions help participants adopt the 3 PA messages from each group-based class into their daily lives. These 3 PA messages were inspired by a prior publication[14]. For the membership to livestream fitness classes, participants will receive 12-weeks, using the option with the highest acceptability from Aim 1 Phase 1 (COMIRB # 22-0147). The guided positive exercise imagery scripts were developed based on work from Williams et al.[66] and prompt several sensory and emotional experiences.[45]

Table 2. Description of *Move+* Intervention Activities, Targeted SDT Constructs, and Organizational-Level Personnel for Intervention Delivery

Component	*Move+* Activities	Targeted SDT Constructs	Organizational Delivery Mechanism
Core Curriculum of *Move+* Program			
Group-Based Classes	There will be 1 introduction group-based class, in addition to the 3 group-based sessions. Each of the 3, 60-min group-based sessions will focus on an autonomy-supportive PA message: 1) "All movement counts", 2) "Move in ways that make you feel good", and 3) "By moving more, you take better care of	Autonomy, Relatedness, Competence	Trained* Registered Dietitian (**RD**) teaches class via Zoom Videoconferencing

	yourself". All group-based classes will be digitally recorded for fidelity checks.		
Additional SDT-based *Move+* Components			
Individualized 1:1 Support Sessions	• 3, 45-min sessions to tailor PA messages & develop clear plan of action for PA • Encourage support of friends/family, demonstrate interest in person, use empathetic listening • All individualized support sessions will be digitally recorded for fidelity checks.	Relatedness, Competence	Trained* RD provides via Zoom Videoconferencing
Online Fitness Membership	• Choice in PA type: cardio, strength and conditioning, yoga, meditation • Opportunities for social support from other fitness members	Autonomy, Relatedness	Participants access online
Guided Imagery	• Weekly 3-5 min recorded sessions • Mental images of a positive, fun PA experience[46] and moving with confidence	Autonomy, Competence	Trained* RD provides online access to recordings to participants
*Training will ensure RDs provide an autonomy-supportive environment and are confident in teaching PA content			

C.2.2 Delivery of *Move+* Program: 10 research partners (9 patients, 1 RDN) will complete a single-arm 12-week field trial, where an RDN delivers ≥1 *Move+* session per week (group-class, 1:1, and/or guided imagery), remotely. Patients will receive a 12-week online fitness membership, using the option with the highest acceptability from Aim 1 Phase 1 (COMIRB # 22-0147). Research partner recommendations will be used to refine intervention components. Research partners will be compensated for their time in completing the 12-week single-arm field trial and the quantitative and qualitative measures. See Table 3 below for the schedule of delivery of components.

Table 3. Schedule of Delivery of *Move+* Program Components

	Intervention Week												
Program Component	0	1	2	3	4	5	6	7	8	9	10	11	12
Introduction to the Study	x												
Group-Based Class		x			x				x				
Individualized Support Session				x			x				x		
Guided Imagery Sessions		x	x	x	x	x	x	x	x	x	x	x	x
Access to Online Fitness Center Membership		x	x	x	x	x	x	x	x	x	x	x	x

C.2.3 Physical Activity Prescription:
Participants will receive a recommendation to gradually increase moderate intensity PA to 150 min/week over the initial 12 weeks. This target is consistent with current PA guidelines for overall health[67, 68]. Participants will be instructed in how to use a relative intensity scale [67] to achieve the target moderate intensity.

D. Description, Risks and Justification of Procedures and Data Collection Tools:

Screening:
Description: See detailed description in Section C.1 above.

Justification and Risks: The primary risk from screening measures is diagnosis of a previously unknown disease. If a previously undiagnosed disease is found during screening or during any of the procedures, the PI will contact the participant and discuss the diagnosis and its ramifications, and when appropriate, the volunteer will be referred to their Primary Care Provider.

Move+ Program and Exercise Prescription:

Description: See detailed description in Section C.2 above.

Justification and Risks: The exercise prescription is part of current guidelines for overall health. Subjects in will receive a recommendation to gradually increase moderate intensity PA to 150 min/week over the 12 weeks. This target is consistent with current PA guidelines for overall health[67, 68]. Subjects will be provided an outline of weekly PA goals (min/week) to gradually progress to the target of 150 min/week by week 12. Subjects will be instructed in the use of a relative intensity scale to achieve the target intensity as outlined in current PA guidelines[67] (moderate-intensity activity defined as a level of effort of 5 or 6 on a scale of 0 to 10, where 0 is the level of effort of sitting, and 10 is maximal effort). The primary risks associated with beginning an exercise program are likely to be fatigue, shortness of breath, or muscle soreness during or after the training sessions. It is expected that when these symptoms occur, they will be minor and brief. During exercise there is a small risk subjects may experience musculoskeletal injuries. During exercise there is a small risk subjects may trip or fall. During exercise there is a very small risk subjects will experience cardiovascular symptoms such as chest pain, shortness of breath, dizziness, syncope, or lower extremity claudication.

- Risks of the exercise program will be minimized by ensuring all subjects meet the specific inclusion/exclusion criteria. Subjects will have previously undergone a medical screening including medical history interview and physical exam, and assessment of blood pressure. According to the most recent American College of Sports Medicine (ACSM) Guidelines for Exercise Testing and Prescription[61], exercise stress testing prior to initiation of moderate or vigorous exercise is only indicated for high-risk individuals (i.e. individuals with symptoms of CVD or individuals with known CVD, diabetes, pulmonary disease, or end–stage renal disease). Subjects with these conditions are excluded from our study, thus all subjects in our study will be classified as low- or moderate-risk by ACSM guidelines and thus routine screening exercise stress testing prior to exercise initiation is not recommended.
- If subjects experience muscle soreness, we will prescribe light stretching, and hot/cold therapy to reduce the soreness. If these approaches do not alleviate the soreness, we will advise the use of OTC pain relievers (e.g., aspirin, acetaminophen, ibuprofen), unless contraindicated. It is anticipated that some subjects will experience soreness during the first few days of exercise, but since the recommended intensity is moderate we expect the symptoms will be minor and transient.
- Although some minor to moderate orthopedic injuries may occur during the exercise program (primarily lower body musculoskeletal injuries such as muscle sprains, tendonitis, shin splints) given the moderate intensity and gradual increase of the exercise prescription we do not expect any severe injuries. Subjects who experience minor to moderate orthopedic injuries will be allowed to remain in the study and return to exercise as tolerated.
- Participants may feel uncomfortable about answering questions that are being asked group-based classes or individualized support sessions. Participants are not required to answer any questions. To minimize this risk, we will notify participants that they are not required to answer any questions and that they may choose to leave the interview at any time. In addition, participants can ask to pause the recording at any time. Lastly, we will allow participants to send a chat privately to the interview moderator if they want to write down any thoughts or reactions that they would prefer not to share out loud, or that they didn't have a chance to say.

Qualitative Data:
Description: At the end of the 12-week field trial participant partners will be asked to participate in a 90-minute semi-structured focus group, and the RD partner will be asked to participate in a 60-minute semi-structured interview. The focus group and interview will be conducted remotely, via Zoom Videoconferencing, a web conference software with full HD video and audio capability, or in-

person. Zoom has wireless sharing, enabling users to access the platform via desktop or mobile device. Participants will have the option to connect to audio via phone or computer and can use their real name or a nickname or alias during the interview discussion to protect their privacy. Use of a web camera will be optional, with the understanding that it could reduce privacy. During the focus group or interview process, we will make every effort to protect subject privacy by only using first names in the group discussion. Any names included in the transcription will be changed to a de-identified study ID. The identity of subjects and the data acquired as a result of this study will be treated with professional standards of confidentiality. Only members of the research team will have access to information collected from the participants.

Digitally recorded interview data will be sent to an outside company to be transcribed verbatim. Once we have verified the written documents, the recordings will be deleted. The typed transcriptions will be kept on a password-protected university server and any printed copies will be kept in a locked file cabinet in Dr. Ostendorf's locked office. Data records will be maintained for at least 5 years after the publication of results. At that time, the PI may destroy the data records by deleting them from electronic media and by shredding paper documents, but some of the data records may be retained indefinitely.

Sharing of data among investigators within the institution is typically facilitated either by providing a password for the database or by electronic transmissions. All members of the research group have individual computers that are part of the institution network with institutional oversight of security. Files that contain data that could jeopardize blinding to treatment code are password-protected to restrict access. Electronic transfer, in a manner that is compliant with regulations, typically facilitates sharing of data with investigators or monitoring personnel outside the institution.

Semi-structured Focus Group: Topics that will be addressed in this focus group include participant experience with the *Move+* program including feasibility/acceptability of each *Move+* intervention component, assessment of cultural relevance, and feedback to refine *Move+* components. Additional topics include facilitators and barriers for receiving the *Move+* program. The study team will make decisions on the final *Move+* program content based on research partner feedback. Thus, the final *Move+* program content will reflect the wants and needs of the research partners. We will code for research partner comments that would result in a revision within each transcript. We will discuss all potential revisions within our study team meetings and collectively decide on which revisions to make outright, which revisions to develop a prototype for and go back to research partners for input, and which revisions to discard. As a study team, we will ensure that all revisions made to the program features are aligned with retain fidelity of the Self-Determination Theory.

Semi-structured 60-minute Interviews: Topics that will be addressed in this focus group include RD experience with delivering the *Move+* program including feasibility/acceptability of each *Move+* intervention component, assessment of cultural relevance, and feedback to refine *Move+* components. Additional topics include facilitators and barriers for delivering the *Move+* program.

Justification and Risks: Participating in a focus group or interview poses minimal risk. In addition, the subject matter of the interviews, *Move+* acceptability/feasibility, is non-sensitive. This measure is required to assess our primary study outcome of interest: feasibility and acceptability of the *Move+* program. As with all clinical research studies, there is the general risk of breach of confidentiality or data security. To minimize this risk, only the minimal necessary data will be collected, and we will follow thorough procedures to maintain confidentiality. As part of the verbal consent process before each interview, we will ensure that each participant agrees that anything of a personal nature that is mentioned in the room will not be repeated to others outside of the discussion group. If anyone is not willing to give their consent to confidentiality, they may be excused from the group. The risks to the subjects, including potential psychological risks from interview questions are minimal. Participants may feel uncomfortable about answering questions that are being asked in the interviews. Participants are not required to answer any questions. To

minimize this risk, we will notify participants that they are not required to answer any interview questions and that they may choose to leave the interview at any time. In addition, participants can ask to pause the recording at any time. Lastly, we will allow participants to send a chat privately to the interview moderator if they want to write down any thoughts or reactions that they would prefer not to share out loud, or that they didn't have a chance to say. If interviews are held in-person instead of remotely via Zoom Videoconferencing, we will hand out note cards to each participant that will be collected at the end of the session. These note cards can be used for participants to write down any thoughts or reactions that they would prefer not to share out loud, that they prefer not to be recorded, or that they didn't have a chance to say. There is a slight risk of a time burden associated with participating in engagement activities. Subjects enrolled in this study will potentially benefit by learning information about strategies to improve their adherence to physical activity goals. The potential benefits of the study to the adult population may be significant. This study is expected to lead to an enhanced understanding of, and possibly new therapeutic treatments for, obesity treatment/prevention. In light of these potential benefits, the risks to subjects are acceptable.

Outcome Questionnaires:
Description: The following questionnaires listed below will be used to assess the primary and other pre-specified outcomes of the study.

- **REDCap Survey on Design Features:** After the focus group occurs, research partners may be asked to complete a REDCap survey that asks for partner input on design changes for the *Move+* program components. Research partners may be asked to select between two design options for a program component feature that is being considered for revision. Whichever option is preferred by more research partners will be selected for the refined *Move+* program components. Program features that are selected by the majority of research partners will be used in the refined *Move+* program components. If a feature splits users 50/50 then we will make revisions to the design options and re-survey research partners. If research partners continue to be split on a feature, we will not go past 4 iterative cycles of this, and the study team will make final decisions on program features, giving priority to the features that best operationalize Self-Determination Theory.
- **Acceptability of Intervention Measure (AIM):** At the end of the 12-week field trial, research partners will be asked to evaluate each *Move+* component using the AIM[51] with a 1-5 Likert scale (1=Completely Disagree, 5=Completely Agree). The AIM is a 4-item questionnaire that asks research partners about whether the intervention component meets their approval, is appealing, whether they like it, and whether they welcome it's use. The AIM demonstrated strong psychometric properties including content validity, discriminant content validity, reliability, structural validity, structural invariance, known-groups validity, and responsiveness to change.
- **Intervention Appropriateness Measure (IAM):** At the end of the 12-week field trial, research partners will be asked to evaluate each *Move+* component using the IAM[51] with a 1-5 Likert scale (1=Completely Disagree, 5=Completely Agree). The IAM is a 4-item questionnaire that asks partners about whether the intervention component seems fitting, suitable, applicable, and/or like a good match. The IAM demonstrated strong psychometric properties including content validity, discriminant content validity, reliability, structural validity, structural invariance, known-groups validity, and responsiveness to change.
- **Feasibility of Intervention Measure (FIM):** At the end of the 12-week field trial, research partners will be asked to evaluate each *Move+* component using the FIM[51] with a 1-5 Likert scale (1=Completely Disagree, 5=Completely Agree). The FIM is a 4-item questionnaire that asks partners about whether the intervention component seems implementable, seems possible, seems doable, and seems easy to use. The FIM demonstrated strong psychometric properties including content validity,

discriminant content validity, reliability, structural validity, structural invariance, known-groups validity, and responsiveness to change.

- **Weekly Survey:** Every week during the 12-week field trial, patient partners will be asked to rate their satisfaction with specific program components that they received using a 1-10 Likert scale (1=Strongly Dislike, 10=Strongly Like), to describe their engagement with the virtual fitness membership and rate the classes they tried, and to provide any input for refinement/improvement.
- **Net Promoter Score (NPS):** At the end of the 12-week field trial, research partners will be asked to evaluate each *Move+* component using the NPS. The NPS is a single question with a 1-10 Likert scale: How likely is it that you would recommend the *Move+* component to a friend or colleague? Respondents are grouped as follows: 1) promoters (score 9-10) are loyal enthusiasts who will keep referring others and fueling growth, 2) passives (score 7-8) are satisfied but unenthusiastic customers who are vulnerable to competitive offerings, and 3) detractors (score 0-6) are unhappy customers who can impede growth with negative word-of-mouth. The final NPS score is calculated as % promoters - % detractors. NPS scores range from -100 to +100, with scores >0 indicating good acceptability.
- **Perceived Characteristics of Intervention Scale (PCIS):** At the end of the 12-week field trial, the RD partner will be asked to complete the PCIS (e.g., completed in both phases 1-2). The PCIS is a 20-item scale that measures trialability, relative advantage, compatibility, complexity, potential for intervention adaptation, etc. The PCIS is a reliable measure of perceived characteristics of interventions, with some preliminary support for its validity.[52] Participant partners will not be asked to complete this scale.
- **Organizational Readiness for Knowledge Translation (OR4KT) Questionnaire:** At the end of the 12-week field trial, the RD partner will be asked to complete the OR4KT. The OR4KT is a 59-item survey that measures setting-level factors that influence program adoption (organizational climate for change, organizational contextual factors, organizational willingness to adjust to changes, leadership, organizational support, and motivation).[53] Subscales are grouped into 6 dimensions: 1) Organizational climate for change (10 items), 2) organizational contextual factors (10 items), 3) Change content (9 items), 4) Leadership (10 items), 5) Organizational support (10 items), and 6) motivation (10 items), followed by 1 open-ended question. The validity and reliability of the OR4KT will be assessed in real-life contexts of implementation of evidence-based changes in healthcare.[53] Participant partners will not be asked to complete this scale.
- **Global Physical Activity Questionnaire (GPAQ) [69, 70]:** At baseline and week 12, patient partners will be asked to complete the GPAQ with showcards. The GPAQ is a 16-item interview-based questionnaire, where a research staff member will ask participants to estimate time spent doing different types of physical activity in a typical week. The research staff member will use showcards to help the participant understand types of activities considered moderate vs. vigorous intensity.
- **Basic Psychological Need Satisfaction and Frustration Scale - Exercise (BPNSFS-E)[54]:** At week 12, patient partners and provider partners will be asked to complete the BPNSFS-E. The BPNSFS-E is a SDT-based questionnaire. It assesses satisfaction vs. frustration with basic psychological needs for autonomy, competence, and relatedness with regards to exercise through 12 items (e.g., "The way I exercise is in agreement with my choices and interests") and a five-point Likert scale, where 1 = "I don't agree at all" and 5 = "I completely agree"). This 24-item questionnaire has demonstrated validity[71] and gender invariance.[72]
- **Behavioral Regulations for Exercise Questionnaire (BREQ-3)**[55]: At baseline and week 12, patient partners will be asked to complete the BREQ-3. The BREQ-3 is SDT-based and provides separate scores for each behavioral regulation for exercise (amotivation, external, introjected, identified, integrated, and intrinsic). There are 24-

items with responses that range from 0="Not true for Me" and 4="Very true for Me." It has demonstrated validity and reliability.[55, 73]

- **Single Category Implicit Association Test (SC-IAT)[56]:** At baseline and week 12, patient partners will be asked to complete the SC-IAT. The SC-IAT is a computerized, time sorting task, which asks participants to rapidly indicate, whether each presented PA stimulus belongs to one of two attributes (good/bad). The SC-IAT for physical activity has shown satisfactory internal consistency (i.e., reliability of the outcome score of trials within the same test)[74, 75] Three scores will be calculated: *D-Score*, *DW-Score*, and *IP-Score*.
- **Vividness of Movement Imagery Questionnaire (VMIA-2)[76]:** At baseline and week 12, patient partners will be asked to complete the VMIA-2. The VMIA-2 is a 12-item questionnaire where participants rate each mental image in 3 ways (internal visual imagery, external visual imagery, and kinesthetic imagery) from 1 (perfectly clear and vivid) to 5 (no image at all).
- **Movement Imagery Questionnaire (MIQ-3)[77]:** At baseline and week 12, patient partners will be asked to complete the MIQ-3. The MIQ-3 is a 12-item questionnaire to assess an individual's ability to image four movements using internal visual imagery, external visual imagery, and kinesthetic imagery.
- **Internalization of Weight Bias (WBIS-M):** At baseline and week 12, patient partners will be asked to complete the WBIS-M. We will measure internalization of weight bias using the Weight Bias Internalization Scale – Modified (WBIS-M)[57]. This scale consists of 11 items and uses a 7-point Likert scale (1=strongly disagree; 7=strongly agree). WBIS-M has demonstrated high internal consistency and strong construct validity. The WBIS-M also demonstrated significant correlations with body image, eating pathology, self-esteem, and symptoms of anxiety and depression, and was associated with these outcomes distinctly from anti-fat attitudes and BMI[57].
- **Body dissatisfaction:** At baseline and week 12, patient partners will be asked to rate their degree of body dissatisfaction. We will measure this using the Figure Rating Scale (FRS) developed by Stunkard et al[78]. Respondents are asked to choose the image that better represents their actual size. Then, they are asked to choose which image represents their ideal body size. The first is considered a measure of perception of one's body (current body image); the second is understood as an adherence to the ideals of beauty socially shared in the culture to which the respondent belongs (ideal body image). The discrepancy between the two is considered a good measure of body dissatisfaction. Positive scores are indicative of the desire to have a larger body size, while the negative ones are indicative of the desire to be thinner. The FRS has indicated good test—retest reliability and moderate correlations with other measures of body image dissatisfaction, eating disturbance, and overall self-esteem.[79]
- **Identity**: At baseline and week 12, patient partners will be asked to rate their level of agreement for each physical activity identity statement. This will be measured using the Behavior Based Identity Questionnaire, which consists of 4 items. [80]
- **Physical Activity Habit Strength**: At baseline and week 12, patient partners will be asked to rate their level of agreement for each physical activity habit statement. The Self-Report Index of Habit (SRHI) Index Strength involves 12-items that assesses physical activity habit strength and automaticity[81, 82].
- **Dietary Intake Assessment**: Dietary energy and fat intake will be assessed with a 3-day dietary record. Participants will be asked to log food intake over 3 days including a weekend day.
- **Environment:** Participants will be asked to report their home address, work address, and any changes in these addresses over the 12-week intervention. Home address and work address will be used to obtain census level data about the area in which they live and work, like access to parks and grocery stores.

- **Medication Review:** We will ask patient partners about the medications they are taking at baseline and week 12.

Justification and Risks: These questionnaires are required to assess the primary outcomes of acceptability and feasibility and other pre-specified outcomes of changes in SDT-based constructs and additional behavioral and psychosocial outcomes. Subjects may find it inconvenient to complete the surveys. There are no known risks associated with these procedures.

Additional, Other Pre-Specified Outcome Measures:
Anthropometric Measures
Description: Body weight will be measured using a digital scale accurate to ±0.1 kg at baseline and week 12. Height will be measured to the nearest 1 mm with a stadiometer at baseline. Blood pressure will be measured with an automatic sphygmomanometer (average of 2 seated values taken after 5 min rest) at baseline and week 12. Waist circumference will be measured at baseline and week 12 with a tape measure just over the iliac crest.

Justification and Risks: These measures are required to assess our primary study outcomes of change in weight and BMI and there are no risks associated with these procedures.

Patterns of PA and Sedentary Behavior
Description: The activPALv4 (PALTechnologies, Glasgow, Scotland) will be used to estimate time spent in moderate-to-vigorous PA (MVPA), light activity, and sedentary behavior over a 7-day period at baseline and approximately week 12. The activPAL is a small (23.5 x 43 x 5 mm) and light (10 grams) device that uses accelerometer-derived information about thigh position to estimate time spent in different body positions (i.e., sitting/lying, standing and stepping). The device is attached to the anterior thigh and is waterproofed by wrapping in a nitrile sleeve. Thus, it can be worn during bathing and overnight, allowing for 24-hour measurement of wake and sleep behavior. The activPAL was used in Dr. Catenacci's K23 DK078913 in 114 participants; the device was well-tolerated with wear time averaging >23 hours/day[83]. The time-stamped "event" data file from the activPAL software will be used to determine time spent sitting, standing, and stepping per day. Using the activPAL program, the event data file will be converted to a second-by-second file and additional metrics of sedentary behavior (e.g., breaks in sedentary time, average duration of sedentary bouts, sleep time) and time in PA intensity category (sedentary, light and MVPA) will be estimated. The activPAL estimates EE (METs) by 1) assigning MET values to sitting/lying and standing events and 2) estimating METs for stepping events. Many studies have validated the activPAL for use in children, adolescents, and adults and report very high levels of accuracy (99-100%) and no adverse events[84-90]. Participants will also be asked to log all exercise during the 7-day period they wear the activity monitor.

Justification and Risks: This measure is necessary to obtain an assessment of patterns of free-living physical activity, and sedentary behavior. Subjects may find wearing the monitors inconvenient. Rarely, mild to moderate skin irritation or rash can occur due to the activity monitors. If this occurs, the monitor will be discontinued, and the subject evaluated by the study PI.

3 Minute Step Test (TMST)
Description: A TMST will be obtained as a surrogate measure of cardiorespiratory fitness. In accordance with the YMCA TMST protocol[58] participants will step on and off a 30.5 cm (12 inch) step 24 times per minute for 3 minutes. They will be aided by an electronic metronome set at 96 beats per minute which they are to match with 96 steps (24 ascent-descent cycles) per minute. At one-minute intervals participants will be told "you are doing well" and the time remaining was indicated. Immediately after completion of the test participants rate their perceived exertion using the Borg (6 to 20) perceived exertion scale. Their cumulative heart rate will be determined by auscultation with a stethoscope during the first minute after test completion.

Justification and Risks: The TMST predicts 50-90% of the variance in fitness as assessed by exercise treadmill V02 max testing and is thus an inexpensive surrogate for cardiorespiratory fitness, an important metabolic outcome measure. The TMST is also recommended by the ADOPT working group as an important predictor of response within weight loss interventional studies. The primary risks associated with the TMST are likely to be fatigue, shortness of breath, or muscle soreness during or after the test. It is expected that when these symptoms occur, they will be minor and brief. During the TMST there is a small risk subjects may experience musculoskeletal injuries. During the TMST there is a small risk subjects may trip or fall. During the TMST is a very small risk subjects will experience cardiovascular symptoms such as chest pain, shortness of breath, dizziness, syncope, or lower extremity claudication. Study staff will monitor the test and the test will be stopped if subjects experience any of these symptoms and subjects will be referred to their PCP or to the emergency room for further evaluation depending on the severity of symptoms. Risks of the TMST will be minimized by ensuring all subjects meet the specific study inclusion/exclusion criteria. Subjects will have previously undergone a medical screening including medical history interview and physical exam, and assessment of blood pressure.

D. Potential Scientific Problems:

Making correct inferences when coding qualitative data: There is a risk of making incorrect inferences when coding the qualitative data. However, we will use an iterative process that involves moving back and forth between raw data and emerging themes multiple times, to ensure that participants' experiences are accurately captured. We use a team-based approach to code the qualitative data.

Compliance with *Move+* Intervention: We recognize adherence to PA will not be perfect and we do not expect it to be. The research question we seek to address is not whether participants will fully adhere to the *Move+* program, but rather whether the *Move+* program components are acceptable and feasible.

F. Data Analysis Plan:

F.1 Quantitative Data Analyses: Descriptive statistics will be performed on scale ratings with aspects of the *Move+* program. Aspects of the *Move+* program with less acceptable ratings will be targeted for refinement. Average scores <0 for the Net Promoter Score®, or <3 on any scale from the PCIS will indicate areas for refinement. Demographic information will be analyzed using descriptive statistics. We will also explore within-person changes in other pre-specified outcome measures from baseline to 12 weeks (e.g., PA, weight, waist circumference, blood pressure, cardiovascular fitness) using a paired samples t-test. Normality assumptions will be evaluated, and transformations used (e.g., square root and log) as appropriate. P-values <0.05 will be considered significant. No interim analysis is planned.

F.2 Qualitative Data Analyses: Qualitative data from each cycle will be transcribed verbatim and analyzed using a rapid qualitative analysis approach and a traditional content analytical approach. The qualitative data software program ATLAS.ti will be used for data organization, management, and analysis. Consistent with established qualitative methodology, analysis of interview data will be a continuous, iterative process, beginning with initial data collection and continuing throughout and beyond the data generation period.[91-93] We will use a rapid qualitative analysis to understand themes around specific domains (acceptability, feasibility, areas for improvement)[94]. A rapid qualitative analysis involves the use of a templated summary to summarize each transcript. Once templated summaries are complete, they are further condensed into a matrix to identify key points, potential themes, quality and consistency of data collection, directions for further data collection and analysis. A rapid qualitative analysis is used to obtain a quick understanding of what is in the data. In addition, order to achieve immersion, transcripts will be read

multiple times using a deductive approach guided by the Practical Robust Implementation and Sustainability Model (PRISM) and RE-AIM (Reach, Effectiveness, Adoption, Implementation, and Maintenance) frameworks[95, 96], as well as an inductive, emergent approach in order to emphasize respondent perspectives and deemphasize investigator speculations[93]. Each transcript will be coded using a team-based approach (by Dr. Ostendorf and a trained Professional Research Assistant) within ATLAS.ti©. Initial codes will be established, and any questionable codes will be discussed with the study team. We will look for comments/themes of acceptability and feasibility. The PI will meet with her mentors quarterly to discuss emergent new codes, themes, and patterns.[97-99]

F.3 Mixed Methods Analyses: We will use an iterative convergent mixed methods design[100] to integrate findings from the survey results with qualitative themes to identify intervention areas for refinement. We will look for parallel constructs/themes, identify differences and similarities, and create a joint display to array the integrated results.[101, 102] We will incorporate what we learn from Aim 1 to create a *Move+* manual. Our goal is to package *Move+* in a manner that it is 1) acceptable to participants and organizations to and 2) can be feasibly integrated into any existing lifestyle weight management curriculum.

G. Summarize Knowledge to be Gained: Over two-thirds of US adults are afflicted with overweight or obesity. Obesity is a serious and increasing public health problem. Physical activity is a key modifiable behavior, which may help promote weight loss and weight loss maintenance. Despite the benefits of physical activity, the majority of adults with overweight or obesity do not meet physical activity recommendations. Participants in lifestyle interventions typically adhere to behavior change recommendations initially, but this adherence steadily declines over time. Although many factors contribute to poor physical activity adherence, absence of accessible, effective, theory-based programs that account for each person's values, motivation, and preferences remains a major barrier. The proposed study is designed to optimize a theory-based, person-centered physical activity program for adults with overweight or obesity. Developing novel approaches to improve physical activity adherence and promote weight loss and maintenance may potentially benefit many people. Identifying a feasible physical activity support program for adults with overweight or obesity could enhance our ability to treat obesity, as well as reduce the risk of chronic diseases, including cardiovascular disease. Thus, the minimal potential risks to participants are balanced by the expected knowledge to be gained from this study.

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