Official Title: Movement-Oriented Behavioral Activation (MOBA) to Reduce Stationary Behavior

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Aim 1: Determine feasibility and acceptability of a 10-week group MOBA intervention for individuals with excessive stationary behavior compared to waitlist control.
Aim 2: Assess activity and mobility changes following a 10-week group MOBA intervention for individuals with excessive stationary behavior compared to waitlist control.

Hypothesis: Individuals completing MOBA will have greater (1) improvement in physical performance, (2) reduction in sedentary time, and (3) increase in daily step count after 12 weeks compared to the control group.
Aim 3: Examine changes in activation, avoidance, and perceived barriers to physical activity after a 12-week group MOBA intervention for individuals with excessive stationary behavior compared to waitlist control.

Hypothesis: Individuals completing MOBA will have greater (1) increase in activation, (2) decrease in avoidance, and (3) decrease in self-reported barriers to physical activity after 12 weeks compared to the control group.

Background & Significance

- Should support the scientific aims of the research

Stationary behavior, defined as excessive sitting and/or standing without ambulation, is associated with multiple morbidities acquired by adults through the lifespan that lead to loss of mobility and diminished functional independence in older adulthood. The prolonged lack of movement that characterizes stationary behavior is associated with health risks independent of the health benefits of exercise. The attributes and antecedents of stationary behavior are distinct from exercise as well. This highlights a **critical need** for interventions that are specific to encouraging the regular movement-oriented behaviors needed to reduce the risks of prolonged stationary time, and which account for the key settings where these behaviors occur. Identifying and engaging the behavioral mechanisms that uniquely drive stationary behavior across settings will be essential to achieving lasting behavioral change.
Prevailing approaches to changing stationary activity have two weakness: they are overeliant on external motivators to produce behavior change, and they devote insufficient attention to the range of settings in which the behaviors occur. The current study is grounded in reinforcement sensitivity theory (RST), which was developed to explain internal motivational processes in responding to environmental stimuli. RST encompasses two primary motivational systems: the behavioral inhibition system (BIS) and the behavioral activation system (BAS). The BIS guides behavior in response to aversively conditioned stimuli, whereas the BAS guides behavior in response to rewarding stimuli. From the perspective of RST, excessive stationary behavior reflects a learned avoidance of movement resulting from aversive barriers to activity and lack of contact with rewards that activate alternative responses. The rationale of the proposed study is that an intervention based on behavioral activation therapy (BA), which was originally developed to treat depression, can reduce the avoidance that perpetuates stationary behavior by systematically engaging individuals in personally valued and rewarding non-stationary alternatives.

The **significance** of the proposed study, "*Movement-Oriented Behavioral Activation (MOBA) to Reduce Stationary Behavior*," is that it addresses an important public health need for a cross-cutting intervention to reduce stationary behavior. It is significant that the intervention occurs in the setting of an occupational health program, which provides close contact to work-related risk factors like stationary behavior. The significance of the occupational health approach is also related to the pilot cohort, which will be predominantly African American. Unequal access to preventative health services among minorities is a problem in this country, and workplace interventions can be an important strategy in addressing this disparity. Our choice to target stationary behavior rather than the conventional sedentary behavior (excessive sitting) is significant as well. Emerging evidence indicates that prolonged passive standing is as common in workplaces as excessive sitting and has comparable risks to health and mobility; thus, interventions targeting change in the common risk behavior-- lack of ambulatory movement-- will be more potent and translatable than those targeting either behavior alone. The significance of the proposed research is enhanced by **innovative elements:** 1) MOBA is a novel approach to changing stationary behavior, particularly the intrinsic, person-centered principles of behavior change that are underemphasized in existing interventions; and 2) the intervention is innovative in its inclusion of an ecological framework, the Behavior Settings Model, which allows closer contact between personally valued activities and the multiple settings in which stationary behaviors occur.

Design & Procedures

- Describe the study, providing detail regarding the study intervention (drug, device, physical procedures, manipulation of the subject or the subject's environment, etc.). Discuss justifications for

placebo control, discontinuation or delay of standard therapies, and washout periods if applicable. Identify procedures, tests and interventions performed exclusively for research purposes or more frequently than standard of care. Include alternative therapies, concurrent therapies discontinued per protocol, risk benefit ratio, and use of tissue/specimens. Discuss monitoring during washout periods if applicable. Include brief description of follow-up, if any.

Overview.
The study uses randomized waitlist-control design. We propose to randomly assign half of participants to (a) 10 weeks of MOBA intervention, and half of participants to (b) a 10-week waitlist, followed by 10 weeks of MOBA.

Intervention. MOBA is adapted from established protocols to integrate traditional behavioral activation (BA) principles with strategies to incorporate values-based, goal-directed movement into daily routines. The BA content of MOBA is adapted from co-investigator Dr. Smoski's intervention Behavioral Activation Therapy for Anhedonia (BATA). MOBA reduces depression-related content relative to BATA and increases focus on values that engage individuals in movement-related activity. MOBA is designed as a group intervention to leverage the reward value of social contact, and the positive influence of group problem-solving and accountability on behavior change. MOBA preserves the principles and general sequence of sessions used in BATA, but incorporates movement-oriented content: (a) provide psychoeducation about risks of physical inactivity, behavioral barriers to activity, and rationale for the treatment approach; (b) explore personal values, non-stationary, movement-oriented activities that support those values, and a hierarchical plan for goal attainment; (c) identify and assign weekly activities related to the valued goals; (d) address common barriers to engagement with valued activities including avoidance, low behavioral initiation, and an overemphasis on felt motivation as a prerequisite for action; and (e) monitor, support, and reward achieving behavioral goals. Content unique to MOBA includes: 1) demonstration and participation in physical activities that provide alternatives to stationary behavior, including select activities used in a previous study with the Dining Services cohort (e.g., stairs, body-weight squats, knee raises), and 2) generation of person-centered strategies for integrating movement-oriented activities into daily routines across the three domains of the Behavior Settings Model: 1) workplace sitting/prolonged standing, 2) screen-focused home activities, 3) time spent sitting in automobiles. Weeks 1-4 address topics a-c; weeks 5-12 address topics d-e. MOBA will be facilitated by a clinician (Dr. Potter) and a wellness educator (Dr. Tittle), who will be trained on the MOBA treatment manual. The facilitators' role is to provide teaching, support, encouragement, and guidance throughout the intervention. Weekly sessions will take place in a dedicated conference room near the workplace, during the last hour of the workday (4-5 pm), and is counted as paid time at work.

Assessments.
Pre-intervention focus group. Separately, and prior to the enrollment in the intervention, we plan to conduct a small focus group of individuals (N = 8-10) from the Duke Dining Service staff in order to (1) better understand perspectives and experience with physical activity; (2) gauge interest in aspects of the study, and (3) understand format preferences for presenting and collecting information. The goal is to gather information to improve delivery of the intervention to participant stakeholders. Individuals who participate in the focus group are not under any obligation to participate in the intervention.

Feasibility and acceptability. We plan to collect multiple sources of information to provide information about feasibility and acceptability:
(1) We will document our challenges and decisions across all aspects of the study (e.g., recruitment, engagement, obstacles to enrollment) to optimize the translation of our findings; (2) We will collect descriptive data on adherence and participant engagement; (3) We will collect and characterize descriptive information on experience, perceived benefits, and satisfaction; (4) We will conduct focus groups with participants, and those who declined to participate, to better understand "what worked" and "what needs work" with respect to the intervention. We will consult with Duke Roybal Center intervention experts for input on our approach. Fidelity to the treatment will be assessed by Dr. Smoski, who does not lead groups, but will review taped sessions to document adherence (e.g., whether content described in treatment manual is presented during sessions).

Mobility testing. Short Physical Performance Battery (SPPB) will assess lower extremity function and mobility.[11] The 6-Minute Walk Test (6MWT) will assess functional exercise capacity. These measures will occur at Baseline and Week 10.

Mechanisms of change. The Behavioral Activation in Depression Scale (BADS) will assess state characteristics of avoidance and activation. This measure will be administered at baseline and week 5. The Barriers to Being Active Quiz will assess perceived barriers to regular movement-oriented activity. These measures will be administered at baseline and post-intervention.

Stationary behavior. With no validated questionnaire specific to stationary behavior, self-reported sedentary activity will be assessed at baseline/post-assessment, and weekly during the intervention using the Past-Day Adults' Sedentary Time questionnaire (PAST). The PAST assesses multiple domains of sedentary behavior over the past day; it was found to have the highest correlation to device-based activity compared to other questionnaires. The PAST will be administered at baseline, weekly, midpoint, and post

assessment. Device-based tracking. Participants will wear an Actigraph Actilife 6 accelerometer on the right hip for 7 days prior to MOBA participation. This period will represent the pre-intervention control activity condition for each participant. Participants will similarly wear the Actigraph for 1 week post-intervention. The main outcomes of device-based tracking will be percent change in step count per day, with secondary measures including total activity count, and physical activity energy expenditure.

MOBA intervention sessions will occur weekly.
The following questionnaires will also be administered. PHQ-9 will be collected at baseline and week 10, which is post assessment. Physical Activity Readiness will be collected at baseline. The Brief Health Questionnaire will be collected at baseline an week 10. At the final session, a MOBA Class Feedback form will be completed by the participants.

As shown in Table 1, participants will complete a baseline assessment administered by a fitness specialist that incudes questionnaires and mobility testing. These assessments will be repeated at end of the intervention. Additionally, the wait-list control group will complete a third assessment at the end of their 02-week participation in MOBA.

Table 1. Study assessments

Aim 1 (pre- and post- intervention)	**Acceptability & feasibility:** Characterize and document process measures of intervention engagement; descriptive data (e.g., % attendance, % homework completion); participant experience questionnaires, focus groups
Aim 2 (pre- and post- intervention)	**Mobility:** SPPB, 6MWT, **Activity:** Actigraph average steps per day, PAST (subjective activity)
Aim 3 (pre- and post- intervention)	**Activation/Avoidance:** BADS; **Barriers:** BBAQ
Note: Wait-list control group will be assessed at 3 timepoints: baseline (at waitlist), pre-intervention, post-intervention	

April 6, 2022 An amendment to remove the participant initials from the last page of the consent is incorporated to prevent consent deviations.
May 16, 2022 An amendment to request permission for a magazine article e.g., Work at Duke, to be written about the MOBA project. This article will include pictures of participants and interviews, if they agreed. These pictures would require a release to other purposes, such as presentations or an eventual website. It is hoped that the article could be written with the next set of assessments, which is scheduled near the end of June. By participating in the article, participant's involvement would no longer be confidential.

Selection of Subjects

- List inclusion/exclusion criteria and how subjects will be identified.

Participants. Inclusion: The pilot cohort will be composed of members of the Duke Dining Service staff age 30-64. The age range was chosen to target the critical window for establishing the long-term geroprotective benefits of increasing movement-oriented behaviors. The age range has also been expanded to allow for participation by all members of the Dining Service. The workplace cohort was chosen because their work demands are characterized by a high level of stationary activity, and because of previous success recruiting this group to participate in the Healthy Duke *Making the Connection* (MTC) wellness initiative. Additionally, 58% of this cohort reported >5 hours sitting per day, which indicates high levels of sedentary behavior in addition to stationary behavior at work. In MTC, the participating cohort was 72% female, and 80% were between age 30-64. Exclusion: 1) individuals with moderate or greater depression severity (PHQ-9 > 14); and 2) individuals with significant mobility limitation, defined as inability to complete 6 Minute-Walk Test. We plan to include rather than exclude individuals with medical comorbidities (e.g., diabetes, cardiac conditions, obesity) because this provides the most representative sample of the stationary population, and is consistent with our goal of developing a cross-cutting and translatable intervention. The Dining Services workforce is >90% African American, which is a group with disproportionately lower physical activity; and 3) individuals who answer "Yes" to any of the questions on the Physical Activity Readiness Questionnaire (PAR-Q) will be encouraged to consult with their physician before proceeding with the study. Physician clearance is not required for participation. Sample size. We plan to recruit 16 individuals for each of the two MOBA groups (N = 32), which allows for 23% attrition based on prior MTC completion rates.

Subject Recruitment and Compensation

- Describe recruitment procedures, including who will introduce the study to potential subjects. Describe how you will ensure that subject selection is equitable and all relevant demographic groups have access to study participation (per 45 CFR 46.111(a) (3)). Include information about approximately how many DUHS subjects will be recruited. If subjects are to be compensated, provide specific prorated amounts to be provided for expenses such as travel and/or lost wages, and/or for inducement to participate.

The opportunity to participate will be presented to employees by the supervisor of East Campus Dining. The opportunity will be clearly presented as voluntary and having no bearing in employment or performance evaluations. We will work with the supervisor to facilitated recruitment through assistant managers, emails, flyers, and staff meetings.

The age diversity of the sample is guided by the research question, which is oriented toward mid-to-late middle age, and aligns with the target population of the Roybal Center, which is funding entity for this pilot study. The demographics are guided by the workforce cohort chosen for the pilot study, which is based workplace demands and past participation in successful workplace activity initiatives. However, the target population in predominantly African American, which is a demographic group that is often underrepresented in intervention research on physical activity.

The target cohort for this pilot study will be composed of Duke University employees, but not DUHS employees.

Participant Remuneration
Baseline assessment ($50), post-intervention assessment ($70), 2-month follow-up interview (32 x $20), non-participant interview (20 x $20).

We plan assessment proximate to the workplace, so there will be no travel costs. The intervention occurrs on paid time, and will not result in lost wages.

Subject's Capacity to Give Legally Effective Consent

- If subjects who do not have the capacity to give legally effective consent are included, describe how diminished capacity will be assessed. Will a periodic reassessment occur? If so, when? Will the subject be consented if the decisional capacity improves?

This is not applicable. All participants will have the capacity to give legally effective consent.

Study Interventions

- If not already presented in #4 above, describe study-related treatment or use of an investigational drug or biologic (with dosages), or device, or use of another form of intervention (i.e., either physical procedures or manipulation of the subject or the subject's environment) for research purposes.

The behavioral intervention is described above. There is no use of an investigational drug, biologic, or device.

Risk/Benefit Assessment

- Include a thorough description of how risks and discomforts will be minimized (per 45 CFR 46.111(a) (1 and 2)). Consider physical, psychological, legal, economic and social risks as applicable. If vulnerable populations are to be included (such as children, pregnant women, prisoners or cognitively impaired adults), what special precautions will be used to minimize risks to these subjects? Also identify what available alternatives the person has if he/she chooses not to participate in the study. Describe the possible benefits to the subject. What is the importance of the knowledge expected to result from the research?

Mobility and fitness testing has a low risk of complications, and the physical assessment in the study are widely used, including in populations with medical conditions and mobility limitations. All physical assessment are administer by a trained fitness specialist.

Brief low intensity activities will be taught during MOBA session, and have low risk of complications /injury. These are also taught be a trained fitness specialist. Participants will be choosing low-to-moderate physical activities in which they will voluntarily engage during their time out of work. Trained fitness specialists will provide guidance on a range or appropriate activities and progression of activity level. These voluntary activities will be expected to have low risk of complications/injury.

There may be risks, discomforts, or side effects that are not yet known.

Vulnerable populations will not be included in this study.

The possible benefits of participation in this study are expected to be improved mobility and decreased stationary behavior, which reduced multiple health and injury risks. The knowledge from the research is expected to result in a better understanding of how to motivated individuals to decrease stationary behavior and increase physical activity.

Costs to the Subject

- Describe and justify any costs that the subject will incur as a result of participation; ordinarily, subjects should not be expected to pay for research without receiving direct benefit.

We do not anticipate any costs incurred by participants as a result of participation.

Data Analysis & Statistical Considerations

- Describe endpoints and power calculations. Provide a detailed description of how study data will be analyzed, including statistical methods used, and how ineligible subjects will be handled and which subjects will be included for analysis. Include planned sample size justification. Provide estimated time to target accrual and accrual rate. Describe interim analysis including plans to stop accrual during monitoring. Phase I studies, include dose escalation schema and criteria for dose escalation with definition of MTD and DLT.

Sample size was based on previous recommendations from Lancaster et al. that targeting approximately 30 participants is a pragmatic standard for feasibility trials. While we recognize this sample size will not allow us to derive meaningful effect size estimates for between-group comparisons in this pilot study, it will be useful in determining the acceptability of the proposed intervention and deriving variance metrics (e. g., standard deviation of physical activity outcomes) for the purposes of future effect size estimation. We acknowlege that the proposed sample size is not adequate for formally testing group differences or effect size metrics. We will therefore (a) interpret these comparisons as preliminary, (b) characterize effect sizes for pre-to-post changes within each group separately, and (c) characterize group changes in actigraphy using contemporary minimum clinically important difference (MCID) metrics (e.g., 500 steps / day).

Analysis plan for Aim 1. We plan to collect multiple sources of information to provide information about feasibility and acceptability: (1) We will document our challenges and decisions across all aspects of the study (e.g., recruitment, engagement, obstacles to enrollment) to optimize the translation of our findings; (2) We will collect descriptive data on adherence and participant engagement; (3) We will collect and characterize descriptive information on experience, perceived benefits, and satisfaction; (4) We will conduct focus groups with participants, and those who declined to participate, to better understand "what worked" and "what needs work" with respect to the intervention. We will consult with Duke Roybal Center intervention experts for input on our approach. Areas of efficacy: We will use data from the PAST questionnaire to identify which domains of activity are most and least responsive to MOBA. Fidelity to the

treatment will be assessed by Dr. Smoski, who does not lead groups, but will review taped sessions to document adherence (e.g., whether content described in treatment manual is presented during sessions).

Analysis plan for Aim 2. To test Hypothesis 2, we will examine mean difference in SPPB and 6MWT between baseline and post-intervention performance (e.g., student's *t*-test). We will also examine percent change and effect size (e.g., Cohen's *d*). To test Hypothesis 2b, we will compare change in self-reported sedentary time between baseline and post-intervention. We will plot and visually examine trends of change across monthly questionnaires. Additionally, we will examine change in Actigraph measures between baseline and post-intervention. As part of this aim, we will examine the association between self-report (PAST) and device-measured activity.

Analysis plan for Aim 3. To test Hypothesis 3, we will examine mean difference, percent change, and effect size in BADS (Avoidance and Activation scales) and BBAQ total score between baseline and post-intervention assessments.

Reference Cited:
Lancaster GA, Dodd S, Williamson PR. Design and analysis of pilot studies: recommendations for good practice. *J Eval Clin Pract.* 2004;10(2):307-312.

Data & Safety Monitoring

- Summarize safety concerns, and describe the methods to monitor research subjects and their data to ensure their safety, including who will monitor the data, and the frequency of such monitoring. If a data monitoring committee will be used, describe its operation, including stopping rules and frequency of review, and if it is independent of the sponsor (per 45 CFR 46.111(a) (6)).

The study team includes three licensed clinical psychologists who will review any potential safety concerns at regular meetings, at least montly. Other staff will be asked report any potential safety concerns to the PI.

Adverse events will be systematically monitored at the time of enrollment, initiation of the study intervention, at the conclusion of the 6-month program. Although we anticipate few adverse events, we note that any intervention-related adverse events will be reviewed by the clinical team on a regular basis. For the purposes of the proposed study, an adverse event is defined as any undesired, noxious, or pathological change in a participant, as indicated by symptoms that occur in association with study participation. Pre-existing conditions that worsen during a study are considered adverse events. Serious Adverse Events (SAE) are defined as any adverse event that results in any of the following outcomes:

- Death or a life-threatening illness including active suicidal ideation/attempt (such as drug overdose)
- A persistent or significant disability/incapacity
- A requirement for hospitalization ≥24 hours

Participants will be screened with the PHQ-9 at enrollment, and those individuals with moderate or greater depression severity (PHQ-9 > 14) will be excluded; however, they will also be contacted for a wellness interview by the PI, and provided resources for care, such as Duke Personal Assistance Service.

All staff involved in the design or conduct of the study will receive and maintain the required education on the protection of human research participants prior to funding of the project. Dr. Potter, Dr. Smoski, and Dr. Smith are all licensed clinical psychologists and will be available 24/7 for emergent and/or urgent study-related issues. Primary on call availability will be with Dr. Potter, and Dr. Smoski and Dr. Smith will provide back up as needed.