Lifestyle Physical Activity and Cognitive Training Interventions: Preventing Memory Loss in Older Women With Cardiovascular Disease

NCT04556305

01.26.2021

***MindMoves* R01NR018443**
Overall Protocol
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4.2 Study Design

A 2x2 factorial design will be used to test the separate and combined effects of two biobehavioral interventions: *Move* and *Mind*. A factorial design lets us examine the interactive effects of a multi-component intervention, in which the interactive effect of the combined intervention is greater than the sum of each of the intervention main effects.

In the 2x2 factorial design, participants are randomized to 1 of 4 combinations of the 2 interventions being tested: (1) *Move*, (2) *Mind*, (3) *MindMoves*, and (4) usual care control. *Move*[51,92,153–155,164–166] is a lifestyle physical activity program originally designed for community-dwelling women, tested for feasibility in older women with CVD, and redesigned to meet their needs and preferences. *Move* includes a personal physical activity goal with self-monitoring and five group meetings over 24 weeks based on social cognitive theory. *Mind* is the 36-hour BrainHQ cognitive training program[48,105,113,167,168] modified for delivery in a lifestyle-focused tablet form over 24 weeks.

Data collection appointments are conducted at baseline and post-intervention at 24 (D2), 48 (D3), and 72 weeks (D4). Participants can continue to self-monitor steps in *Move* and will have access to the BrainHQ program in *Mind* following the end of the 24-week intervention. This will allow us to explore if continued use of these commercially available products predicts memory change, and to predict individuals more likely to maintain the physical activity and cognitive training. The usual care control group was selected to provide a comparison with older women not receiving the *Move, Mind,* or the combined *MindMoves* intervention.

4.2.a Narrative Study Description and Protocol

A. Introduction

The COVID-19 crisis has undoubtedly affected biobehavioral research. Older adults and those with chronic health problems are at greater risk for increased severity of symptoms and poor outcomes compared to younger populations or those without chronic health problems. Thus, our sample of women aged 65 years and older with cardiovascular disease (CVD) are considered a high-risk population during the current pandemic. We anticipate that we may face significant challenges if we were to follow the original protocol. Overall, our goal is to successfully fulfill the aims of the original proposed study, following the original timeline while keeping our participants and research staff safe. However, we realize that the current pandemic will have lasting effects for our patient population even as risk of infection declines. Our patient population may not feel comfortable coming to the clinic for study visits or attending in-person intervention group meetings despite the initial pandemic being over. Thus, we will have

alternative methods that can enable our team to successfully conduct the study. In this protocol, we will compare our original strategies versus the alternative strategies that will be utilized to decrease risk to patients throughout screening, data collection, and the intervention. Our alternative strategies aim to accommodate older women who may be at risk to leave the home after the current restrictions are lifted, or may feel more comfortable avoiding the clinic setting.

B. Recruitment and Screening

Participants (*N* = 254) are women ≥ 65 years with CVD, who are recruited from the Rush Heart Center for Women (Center). The Center was the first heart program in Chicago devoted exclusively to women. There are two modes of entry into the study: (1) referral by the Center cardiology provider; (2) participants will self-refer for participation in the study after reviewing study materials posted at the Center clinic sites; and (3) patients who are 65 years or older, women, and have seen the Rush cardiology practice since March 2019 will be mailed letters introducing the study. All participants require approval from their cardiology provider. Approval will be obtained using the parmedx questions, that will be sent via redcap link in the Epic messaging. The parmedx allows providers to select if they approve of a patient's participation in a moderate physical activity program.

B1a. Original recruitment strategy. We will build on successful recruitment strategies used in our prior preliminary studies. Recruitment will proceed simultaneously at both sites.

Dr. Halloway (PI) will conduct information sessions at the primary care recruitment sites (or via WebEx or Zoom virtual meetings) prior to the launch of the study. Information sessions will be conducted at regularly scheduled provider meetings and the information will be distributed via email. We expect these information sessions to last approximately 10-15 minutes. The content of the information sessions will include the purpose and procedures of the study and how to refer interested patients to the study team for additional introduction and screening. After the initial study information sessions, we will send out monthly email reminders regarding the study and attend quarterly staff meetings to reinforce referral processes. Dr. Volgman practices at both of the Center clinic recruitment sites. Dr. Halloway and Volgman will monitor procedures weekly. When a provider decides to make a referral to the study, they will provide the patient with a study information flyer and interest form. The providers will be instructed to explain to patients the purpose of the study, state that participation does not impact care received at the clinic, explain that data will not be associated to the electronic health record (EHR), and describe that they can receive more specific details regarding the study by completing the interest form.

Study information flyers will be posted in the waiting area and in the exam rooms of the Center clinic recruitment sites. The flyers and interest form will provide a description of the study and options for learning more about the study and expressing interest in participating. An interest form that includes the patient name, contact phone number, and best time to contact will be

attached to the flyer. If patients do not wish to complete the interest form at that time, they can contact the study team by one of the other methods included on the information card (i.e., email or study phone number). Providers will communicate that participation in the study does not impact care received at the Center. Interested patients will be contacted by telephone by the study staff. During the first phone contact, the study staff will assess for preliminary eligibility of prospective patients for the study and set up a secondary, in-person screening appointment.

Due to the current pandemic, we anticipate that patients may be less likely to schedule and come to the Center for their regular cardiology visits. Therefore, we propose an alternative strategy (option #3 above) in order to meet our recruitment goals.

B1b. Alternative recruitment strategy. We will leverage an alternative recruitment strategy to capture patients that may not be pursuing in-person cardiology appointments and may not be utilizing telehealth throughout the current COVID-19 pandemic. The Rush Bioinformatics and Biostatistics Core (Core) regularly extracts Rush EHR data. Currently, inclusion/exclusion criteria for data extraction include the following: age (65 years and older), female sex, and a completed appointment with a RUSH cardiology provider since March 2019 (approximately one year prior to the Illinois stay-at-place order). This will allow us to efficiently identify current patients of Center cardiologists who are actively under the care of the providers. EHR data elements to be regularly extracted may include all or a subset of the following: contact information (full names, address line 1 and line 2, city, state, zip, geographic coordinates if available, phone number(s), email address), demographics (date of birth, sex, race, ethnicity), current cardiology provider, vitals (height, weight, BMI, blood pressure, heart rate, etc.), diagnosis, drug prescriptions, and laboratory tests. The Core develops and assigns site and screening identification number for each patient in the data extraction(s). Data extraction results in spreadsheet(s) that include participant first and last name, associated screening ID, address, city, state, and zip code.

Following Dillman's methods for research and internet mailings, Dr. Volgman will send the identified patients a letter to introduce the study, present a summary of the interventions and procedures, provide the phone number and email for the research team, and inform that the patient can expect phone and email contacts from the research team.[57] In these letters, Dr. Volgman will also state that patients can call or email the research team for additional information or if the patient does not wish to be contacted. After 10 days following the initial mailing, the research team will begin calling and emailing patients. This alternative recruitment strategy is being successfully employed in the ongoing nationwide U.S. POINTER trial (RUSH is a current U.S. POINTER sites).

Recruitment begins when (1) the patient completes a paper or online interest form (indicating consent-to be-contacted), (2) the patient directly contacts the study staff indicating their interest in participating in the study, or (3) the patient identified by the EHR spreadsheet receives the recruitment letter in the mail. The paper forms will be kept at the front desk of the practice and kept in a sealed envelope. Study team members, not affiliated with the practices, will collect the interest forms. The study staff will conduct a preliminary telephone screening for all patients to assess eligibility for participation. A secure Microsoft Access database on the RUSH server will be used to track patient recruitment and communications.

B2a. Original screening protocol.

Original preliminary screening. When screened for eligibility, we will assign an ID to the potential participant. Interested patients will be contacted by phone to receive an overview of the study and complete preliminary screening (age, English language fluency, cardiology provider, hearing loss, disability, Bluetooth capable device, current physical activity level, current cognitive activity level). Participants will also confirm best phone number for contact and an email address. If eligible following the preliminary screening, the interested patient will be scheduled for a secondary screening appointment in person. After the patient's preliminary eligibility status is confirmed, a secondary screening appointment will be made. An electronic copy of the informed consent/authorization will be emailed to the participant. Staff data collectors will then schedule an in-person, secondary screening appointment with the data collectors to provide complete the secondary screening. They will be given a choice of meeting at a private room at RUMC or ROPH or a setting that is convenient to them.

Alternative preliminary screening. No changes.

Original secondary screening. At the beginning of the secondary screening appointment, the data collector will complete the informed consent and HIPAA research authorization process. The data collector will read the informed consent/authorization to the participant and the participant will have time to ask questions (10-15 minutes total). The informed consent and HIPAA research authorization process will be completed prior to any additional screening or data collection. During the informed consent and HIPAA research authorization process, participants will be asked for permission for the data collector to review the EHR for additional screening items. Following informed consent, participants will be screened for cognitive status (Montreal Cognitive Assessment), and will complete the Physical Activity Readiness Questionnaire. Data collectors will then review the EHR for the following criteria: diagnosis of CVD, blood pressure ≤ 160 or diastolic ≤ 100 mm Hg at the last clinic visit, hemoglobin A1C < 9.0 in the past six months, no diagnosis of neurological disease, no stroke in the past three months, no stage 5 renal disease on dialysis, and medications (no anti-psychotics).

If a participant is not eligible for the study based on secondary screening, the participant is considered as a screen failure. Eligible patients who agree to participate and are eligible at all stages of screening will complete baseline data collection appointments, either directly following secondary screening, or at a separate appointment in a private room at RUMC or ROPH.

B2b. Alternative screening protocol.

Alternative secondary screening. We will both mail a paper copy as well as email a digital copy of the informed consent/authorization form to the patient following a positive preliminary screening appointment. We will complete the secondary screening appointment over the phone instead of in-person. At the beginning of the secondary screening appointment, the data collector will verify the patient's full name and date of birth to verify identify. Then the data collector will read the information consent/authorization to the participant, explaining all

components, and the participant will be asked to read along to the paper copy they received in the mail and/or the electronic copy they received via email. The participant will have time to ask questions (10-15 minutes total for the informed consent/authorization process). The informed consent and HIPAA research authorization process will be completed prior to any additional screening or data collection. During the informed consent and HIPAA research authorization process, participants will be asked for permission for the data collector to review the electronic health record for additional screening items. The data collector will utilize the following smart phrase to document the informed consent process in Microsoft Access:

"On {Date and Time} the patient was consented for the {Title of study/Protocol number} study. The protocol and consent form were reviewed with the patient, including the risks, benefits and alternative treatment options. Time was given for questions to be asked and answered with the patient. The patient demonstrated a good understanding of the study and participation. The patient was given a copy of the signed consent prior to the start of study related procedures. {Name of person consenting} consented this patient."

In addition, the following checklist will be used to ensure that the data collector is fully discussing all components of the informed consent and authorization, including but not limited to purpose, procedures, risks/benefits, alternatives to participation:

RUSH UNIVERSITY MEDICAL CENTER	**INFORMED CONSENT PROCESS DOCUMENTATION**
	Subject ID: _____

ORA#	Study Title:
Consent Version Date:	
Approval Date of Consent:	
Expiration Date of Consent:	
Study Principal Investigator(PI)I:	

Study and Consent discussed with:
___ Subject
___ Legally Authorized Representative (LAR)
___ Family Members
___ Other

Key information presented to subject first?	☐ YES	☐ NO
Purpose of study discussed with subject?	☐ YES	☐ NO
Procedures discussed with subject?	☐ YES	☐ NO
Risks and Benefits discussed with subject?	☐ YES	☐ NO
All of subject's or LAR's questions were answered?	☐ YES	☐ NO
Subject or LAR verbalized understanding of consent?	☐ YES	☐ NO

Subject: ☐ Agrees to Participate ☐ Declined Participation ☐ Wants to meet for further discussion		
Consent signed prior to any study related procedures?	☐ YES	☐ NO
A copy of the executed study consent form was given to subject?	☐ YES	☐ NO
Is the subject currently enrolled in any other study?	☐ YES	☐ NO
Does the subject have any special needs? If Yes, describe in comments section below	☐ YES	☐ NO
Does the subject meet all Inclusion and no exclusion criteria for the study?	☐ YES	☐ NO
Comments:		

Signature of Person Obtaining Consent:	Date and Time:

Following informed consent, participants will undergo secondary screening, including cognitive status (Montreal Cognitive Assessment) and will complete the Physical Activity Readiness Questionnaire. Data collectors will then review the electronic health record for the following criteria: diagnosis of CVD, blood pressure ≤ 160 or diastolic ≤ 100 mm Hg at the last clinic visit, hemoglobin A1C < 9.0 in the past six months, no diagnosis of neurological disease, no stroke in the past three months, no stage 5 renal disease on dialysis, and medications (no anti-psychotics). In this alternative screening protocol, all of the secondary screening will occur over the phone. If a participant is not eligible for the study based on secondary screening, the participant is considered as a screen failure.

C. Data Collection and Intervention Orientation

Participant tracking (phone calls, appointments completed, contact information) will be completed in Microsoft Access. The Access database will be password-protected and will be on the secure Rush server. Participants will complete informed consent procedures on the phone, and the informed consent process checklist will be recorded in Microsoft Access. Participants will complete all baseline survey measures using REDcap. All digital files will be saved using a unique identifier for each participant. The data collector will read all questionnaires to participants and administer the performance-based neurocognitive tests using an iPad tablet.

C1. Original Baseline (D1) Protocol. At the baseline (D1) appointments, participants will complete questionnaires, performance-based neurocognitive tests, and measurements of weight, height, and BP. Participants will wear an ActiGraph accelerometer on the hip to measure physical activity during waking hours for seven days, and then return the device to staff in a prepaid, padded envelope with tracking information. Return demonstration will be used to ensure proper accelerometer placement. Participants will receive a reminder text message and phone call two days following the data collection appointment to remind them to wear the accelerometer. Participants will have blood drawn at the outpatient laboratory after an 8-hour fast between 8am and 10am[235] for serum biomarker levels and genotyping.

C2. Alternative Baseline (D1) Protocol. Baseline appointments (D1) will have both phone and in-person components. First in-person data collection will be scheduled. The in-person data collection appointment will occur in the participants' home. Prior to the in-person appointment, the data collector will ask if the participant or anyone that the participant is living with has symptoms of a respiratory infection including fever, shortness of breath, or cough. If the participant reports positive symptoms, then the in-person appointment will be rescheduled. The data collector will wear a gown, gloves, and mask to data collection appointments. At the in-person part of the appointment, participants will complete measurements of weight, height, BP, and step test, and the data collector will draw blood samples after an 8-hour fast between 8am and 10am[235] for serum biomarker levels and genotyping. Either at the outpatient laboratory or in the participant's home, participants will prick their finger once to obtain 4 blood spots (with additional pricks if necessary to obtain the 4 blood spots), and smear those blood spots on a card, also for serum biomarker levels and genotyping. Both blood samples will be taken back to the Rush Biomarker Core for processing. Participants will wear an ActiGraph accelerometer on the hip to measure physical activity during waking hours for seven days, and then return the device to staff in a prepaid, padded envelope with tracking information. Return demonstration will be used to ensure proper accelerometer placement. Participants will receive a reminder text message and phone call two days following the data collection appointment to remind them to wear the accelerometer. Participants will be given a questionnaire response booklet that will be used during the phone data collection component.

Then phone data collection will consist of the data collector administering questionnaires and performance-based neurocognitive tests.

C3. Randomization. Participants will then be randomized to a condition and complete intervention orientation by the interventionist. Because the *Move* intervention is group-based, all participants will be cluster-randomized by clinic recruitment site and will return to the same site five times over 24 weeks for group meetings. At the 24-, 48-, and 72-week data collection appointments, participants will return to the site to complete appropriate measures, wear the ActiGraph for seven days, and return it as described above. The data collector will be naïve to the randomization condition. Beginning in week 27 of Year 1, 7 weeks are allocated to recruit and complete baseline data collection appointments with 10-11 patients from each of the 2 clinic recruitment sites (1–2 patients per site per week). Once all 10-11 participants have been recruited for a site, participants are randomized and told of their study condition (*Move*, *Mind*,

MindMoves, and usual care control) at their respective intervention orientations. Recruitment then begins for the next cohort of 10-11 participants at each site.

C4. Intervention Orientation. Intervention Orientation will occur following randomization during a separate orientation appointment conducted by the interventionist. The Intervention Orientation will occur at a location convenient to the participant. In the alternative intervention orientation protocol, all appointments will occur at the participants' homes, and contact will be minimized.

Original intervention orientation protocol. Participants receiving *Move* use their personal Bluetooth-capable device to self-monitor or track goals in the Fitbit application (app). Participants complete an individual intervention orientation with the interventionist, where the Fitbit is synced with their own device to track progress. Participants receive training on Fitbit use, its app, and troubleshooting. The interventionist uses a skills checklist to demonstrate correct use and have participants demonstrate their understanding. Written directions with pictures are provided. There will be a designated tech support staff member. The Fitbit is wrist-worn during all hours except when swimming or bathing.[158] Participants will first wear a Fitbit Charge HR with the monitor display blinded for seven consecutive days to obtain data for determining their initial goal. Interventionists will instruct participants to attend the five group meetings that occur in conference rooms at RUMC or ROPH. Participants receive weekly phone calls from interventionists to remind them to complete their intervention components. Participants will receive their first step and moderate-vigorous physical activity goals at Group Meeting 1.

Participants in *Mind* will complete the BrainHQ program on iPad tablets, which will be provided to them at the intervention orientation. Behavioral tracking is used to ensure each participant is trained at the threshold level (uppermost level of her skill). Training is tailored and progressive: exercises become increasingly complex as the participant progresses through the program at a rate specific to the individual. Participants will be introduced to the tablet, including general use, charging, and troubleshooting. Participants will be instructed to complete 30-minute BrainHQ training sessions 3 times per week over the course of 24 weeks. To ensure the participant is comfortable with the tablet and BrainHQ, the interventionist will demonstrate correct use, ask the participant to demonstrate correct use, and use a skills checklist. Written directions with pictures will be provided. We will have a tech support staff member.

Participants who are assigned to *MindMoves* will complete both the *Move* and *Mind* interventions simultaneously for 24 weeks. The 24-week *MindMoves* combined intervention will consist of: (1) 5 group meetings focusing on motivation and barriers to increasing physical activity, (2) physical activity goal with Fitbit monitoring, and (3) 30-minute home-based BrainHQ cognitive training sessions on an iPad tablet 3 times per week. Interventionists will complete orientation for both *Move* and *Mind.* Participants will receive both a Fitbit and tablet to complete the combined intervention.

Participants in the usual care control group do not receive any *Mind*- or *Move*-related intervention. At the Center, providers assess and counsel patients regarding self-management and lifestyle habits at every appointment and offer the following resources (standard clinical practice for patients with CVD[143,205]): (1) referral to a dietician; (2) cardiac rehabilitation for patients with a new qualifying diagnosis;[206] (3) referral to a gym for weight management for obese patients; and (4) educational materials on risk management. Resources are offered per any change in CVD risk status. Patients are excluded in the intervention group if currently in a physical activity program or cardiac rehabilitation. The usual care condition is necessary because we hypothesize that *Move* alone and *Mind* alone will improve memory performance and serum biomarkers more than usual care.[207] We do not expect issues with attrition in this as prior physical activity studies with usual care groups have comparable drop-out rates across conditions.[89,208] There are no physical activity or cognitive training clinical guidelines specifically for older adults with CVD.[143]

Alternative Intervention Orientation Protocol. Intervention orientation content resembles the original intervention orientation protocol. However, Intervention Orientation will now occur in two stages to accommodate older women who may be at risk to leave the home after the current restrictions are lifted. For *Move,* the orientation intervention components requiring in-person contact will occur in the home. The interventionist will sync a blinded Fitbit (to establish a physical activity goal), provide a participant manual, and give an iPad that will be used for virtual group meetings. Second, the interventionist will follow-up with the remainder of the orientation over the phone. For the five group visits, the nurse interventionist will utilize the Zoom application to conduct a group meeting via video conference with the 10-11 other participants. The interventionist will follow the intervention manual for group meeting content and structure. For *Mind,* contact will be limited during the intervention orientation, which will occur in a participant's home. First, the interventionist will drop off an iPad that the participant will utilize for the BrainHQ program and the participant manual. The iPad will be previously set up, and directions with pictures will be provided. The remainder of the intervention orientation will be conducted over the phone to minimize contact.

Figure 1 displays the timeline of the delivery of the interventions (*Mind*, *Move*, *MindMoves*).

Figure 1. Timeline of Study Intervention Delivery

Intervention	**Week**				
	1	6	11	16	21
Mind: BrainHQ	30-minute sessions on tablet 3x/week				
Move: Steps	Continuous self-monitoring of steps with Fitbit				
Group meetings	1	2	3	4	5
Both: Phone calls	Weekly reminder phone calls				

Participants will receive a $40 Target gift card at each data collection time point for a possible total of $160 in Target gift cards, and will either keep their Fitbit (*Move*, *MindMoves*) or receive a Fitbit (*Mind*, usual care).

C5 Follow-up Data Collection Appointments (D2, D3, D4)

Original Follow-up Data Collection Protocol. Participants will complete questionnaires, performance-based neurocognitive tests, weight, height, and blood pressure. Similar to the baseline data collection appointments, participants will be read survey questions and data collectors will conduct the performance-based neurocognitive tests on an iPad. All measures will be collected except for the demographics and genetic factor measures. Participants will be given an ActiGraph accelerometer and instructed to wear the device on the hip during waking hours only for one week, and then will mail the device to the research staff using a prepaid, padded envelope with tracking information. Return demonstration will be used to evaluate proper accelerometer placement. Participants will receive a reminder text message and phone call two days following the data collection appointment to remind them to wear the accelerometer device. Participants will have their blood drawn at the outpatient laboratory at the respective clinic site (RUMC or ROPH) to obtain serum biomarkers and genetic factors.

Alternative Follow-up Data Collection Protocol. All measures will be collected during follow-up appointments except for the demographics and genetic factor measures. Participants will complete questionnaires over the phone with the data collector, including performance-based neurocognitive tests, weight, height, and blood pressure. Similar to the baseline data collection appointments, participants will be read survey questions and data collectors will conduct the performance-based neurocognitive tests. Then an in-person data collection appointment will be scheduled. The in-person data collection appointment will occur in the participant's home. Prior to the in-person appointment, the data collector will ask if the participant or anyone that the participant is living with has symptoms of a respiratory infection including fever, shortness of breath, or cough. If the participant reports positive symptoms, then the in-person appointment will be rescheduled. The data collector will wear a gown, gloves, and mask to data collection appointments. At the in-person part of the appointment, participants will complete measurements of weight, height, BP, and step test, and the data collector will draw blood samples after an 8-hour fast between 8am and 10am[235] for serum biomarker levels. Either at the outpatient laboratory or in the participant's home, participants will also prick their finger once to obtain 4 blood spots (with additional pricks if necessary to obtain the 4 blood spots), and smear those blood spots on a card, also for serum biomarker levels. The samples will be taken back to the Rush Biomarker Core for processing. Participants will be given an ActiGraph accelerometer and instructed to wear the device on the hip during waking hours only for one week, and then will mail the device to the research staff using a prepaid, padded envelope with tracking information. Return demonstration will be used to evaluate proper accelerometer placement. Participants will receive a reminder text message and phone call two days following the data collection appointment to remind them to wear the accelerometer device.

4.2.c. Intervention Descriptions

Intervention Type:

Behavioral

Name:

Move

Description:

The *Move* intervention is a 24-week evidence-based program based on social cognitive theory. It was originally developed for midlife women and successfully maintained increased physical activity. It has since been tailored for older women with CVD to prevent or delay memory, and includes: (1) education on the importance of lifestyle physical activity for brain health, (2) increasing lifestyle physical activity while considering CVD, and (3) including a goal for increasing Fitbit "active" minutes (≥ 3 METs or moderate-intensity physical activity) to ensure participants are obtaining the beneficial aerobic fitness effects during periods of lifestyle physical activity. Core elements include a personal lifestyle physical activity goal and five group meetings. The personal physical activity goal is obtained from baseline steps and baseline "active" minute obtained from a Fitbit Charge HR 3 distributed during baseline data collection. *Move g*roup meetings, based on social cognitive theory, consist of five 90-minute visits led by a trained nurse interventionist.

Intervention Type:

Behavioral

Name:

Mind

Description:

The *Mind* intervention uses the evidence-based BrainHQ computerized cognitive training program. BrainHQ focuses on improving memory, sensory function, and working memory, and has demonstrated efficacy in improving memory among healthy older adults and adults with heart failure. BrainHQ is tailored to the individual, and program difficulty automatically progresses based on performance. BrainHQ addresses seven key core elements through six exercises that target memory, sensory function, working memory, and processing speed. Training occurs during three 30-minute sessions per week, for a total of 36 hours. Participants

will complete the BrainHQ program on an iPad tablet, which will be provided to them. Behavioral tracking is used to ensure each participant is trained at the threshold level (uppermost level of her skill). Training is tailored and progressive: exercises become increasingly complex as the participant progresses through the program at a rate specific to the individual.

Intervention Type:

Behavioral

Name:

MindMoves

Description:

Participants who are assigned to this condition will complete both the *Move* lifestyle physical activity program and the *Mind* BrainHQ cognitive training intervention simultaneously for 24 weeks. The 24-week *MindMoves* combined intervention will consist of: (1) five group meetings focusing on behavioral strategies to increasing moderate-intensity physical activity, (2) personal physical activity goal with Fitbit monitoring, and (3) three 30-minute sessions per week of home-based BrainHQ cognitive training sessions modified for use on an iPad tablet (see *Move* and *Mind* descriptions). Participants will receive both a Fitbit and iPad tablet to complete the combined *MindMoves* intervention.