STUDY PROTOCOL

Mindful Movement for Physical Activity and Wellbeing in Older Adults: A Community Based Randomized Hybrid Effectiveness-Implementation Study

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TOOL REVISION HISTORY

Version Number	Version Date	History	Summary of Revisions Made	Protocol Section	Impacted Regulatory and Oversight	Impacted Regulatory/Oversight, Approval Date(s)
V1.0	Nov 7, 2016	Revised proposal as protocol to UMN IRB	NA	NA	NA	IRB: 12/10/16 Required transition to Ethos submitted 8/4/2017; approved 10/24/17
		Clarification of eligibility criteria (baseline physical activity levels, disabilities)	Inclusion Criteria. Clarification re: physical activity BL levels and disabilities. -Added: self-report of <140minutes of MVPA per week (in 10 minute bouts) in the past 3 months at initial screen and BL1. -Changed: Accelerometer recorded <150 minutes to <100 minutes of MVPA.	NA	NA	NCCIH:02/16/17
		Clarification of eligibility criteria (contraindications to mindfulness)	Exclusion Criteria -Added contraindications to participating in a mindfulness intervention (e.g. severe mental health disorders)	NA	NA	NCCIH:02/16/17
		Notice of Award and approved Transition Milestones and R33 Specific Aims	See below	NA	NA	NCCIH: 03/01/17
		Key Personnel Change	Pamela Jo Johnson removed from Key Personnel due to no longer employed at institution (04//26/16)	Study Team Roster	UMN IRB	NCCIH: 04/27/17

V2.0	Nov 13, 2017	Revised V1.0 protocol to accommodate NCCIH template and reflect developments from Planning Phase; will submit to UMN IRB once NCCIH approval received	Revised Specific Aims to include NCCIH approved Transition Milestones in R21; original 2 specific aims expanded to 3 to accommodate Transition Milestones	1. Study Objectiv es	DSMP; UMN IRB	NCCIH: 12/15/17

Version Number	Version Date	History	Summary of Revisions Made	Protocol Section	Impacted Regulatory and Oversight	Impacted Regulatory/Oversight, Approval Date(s)
V2.0	Nov 13, 2017	Clarification of eligibility criteria (Participant Level- pregnancy, contraindications to mindfulness practices, concurrent participation in similar interventions)	Exclusion Criteria (Participant-level) -Added: pregnancy -Operationalized: contraindications to mindfulness practices (e.g. severe mental health disorders) for appropriate screening to optimize patient safety -Added: Current or upcoming participation in educational programs similar to those under study in terms of content (e.g. mindfulness based, general health) format (e.g. group sessions, facilitator led) and length of delivery (1-1.5 hours per week x 4-8 weeks) to the experimental and control interventions offered in the study.	4. Selection and Enrollment of Participants	DSMP; UMN IRB	NCCIH: 12/15/17
		Clarification of eligibility (Facility, Organizational Levels)	Inclusion Criteria -Clarified: Facility level must work at the YMCA (e.g. staff), but are not in leadership positions, and willing to participate in qualitative data collection; Organizational are defined as individuals at the YMCA who influence the strategic planning of the organization (e.g. hold leadership positions) and willing to participate in qualitative data collection.	4. Selection and Enrollment of Participants		NCCIH: 12/15/17
V2.0	Nov 13, 2017	Interventions	-Changed from 10 classes over 12 weeks to 8 classes over 8 weeks	5. Study Interventions	DSMP; UMN IRB; Consent Form	NCCIH: 12/15/17
V2.0	Nov 13, 2017	Interventions	-Added: use of video of content experts within class sessions	5. Study Interventions	DSMP; UMN IRB	NCCIH: 12/15/17

Version Number	Version Date	History	Summary of Revisions Made	Protocol Section	Impacted Regulatory and Oversigh	Impacted Regulatory/Oversight,
V2.0	Nov 13, 2017	Interventions	-Changed: Name of control interventions from 10 Keys to Healthy Aging to10 Keys to Health and Wellbeing. -Updated with new scientific evidence; adapted program wording, messaging to be consistent with community partner's	5. Study Interventions	DSMP; UMN IRB; Consent Form	NCCIH: 12/15/17
V2.0	Nov 13, 2017	Screening	-Changed: initial phone screen to be done either on phone OR online	6. Study Procedures	UMN IRB	NCCIH: 12/15/17
V2.0	Nov 13, 2017	Evaluation	-Added: social connection/assurance outcome measure	9. Statistical Considerations; 9.5 Outcomes	DSMP; UMN IRB	NCCIH: 12/15/17
V2.0	Nov 13, 2017	Evaluation	-Added open ended survey questions, field notes, as a qualitative data collection methods	9. Statistical Considerations; 9.5 Outcomes	DSMP; UMN IRB	NCCIH: 12/15/17
V2.0	Nov 13, 2017	Evaluation	-Changed: end of intervention follow up changed from 12 weeks to 9 weeks to align with modified intervention period	6. Study Procedures; 9. Statistical Considerations; 9.5 Outcomes	DSMP; UMN IRB	NCCIH: 12/15/17
V2.0	Nov 13, 2017	Participant compensation	Changed: participant compensation to align with modified participation period (12 weeks to 8 weeks)	4. Selection and Enrollment of Participants	DSMP; UMN IRB; Consent Form	NCCIH: 12/15/17
V2.0	Nov 13, 2017	Screening	Informed consent process will now occur in a group setting and/or one-on-one with participants. Previously, informed consent occurred one-on-one with the PI, or designee.	4. Selection and Enrollment of Participants	DSMP; UMN IRB	NCCIH: 12/15/17
V2.0	Nov 13, 2017	Key Personnel Change	Added: Craig Schulz to Key Personnel	Study Team Roster	UMN IRB	NCCIH: 12/15/17

V2.0	Nov 13, 2017	Key Personnel Change	Changed: Linda Hanson from Non-Key to Key Personnel	Study Team Roster	UMN IRB	NCCIH: 12/15/17
V2.0	Nov 13, 2017	Key Personnel Change	Changed: Brent Leininger from Non-Key to Key Personnel	Study Team Roster	UMN IRB	NCCIH: 12/15/17
V2.0	Mar 5, 2018	Updated Research Staff	Included McGargness and Ziegler as facilitators	Study Team Roster	UMN IRB	NCCIH: NA
V3	Mar 29, 2018	Change to Inclusion Criteria	Self-report of <140 minutes of MVPA per week (in 10 minute bouts, in the past 3 months at phone screen and BL1) AND accelerometer recorded <100 minutes of MVPA (in 10 minute bouts, between BL1 and BL2) changed to Self-report of <140 minutes of MVPA per week (in 10 minute bouts, in the past 3 months at initial screen and BL1) OR accelerometer recorded <100 minutes of MVPA (in 10 minute bouts, between BL1 and BL2)	4. Selection and Enrollment of Participants	UMN IRB	NCCIH: 3/28/17 (email from program officer)
V4	Nov 28, 2018	Change to Inclusion Criteria	Self-report of <140 minutes of MVPA per week (in 10 minute bouts, in the past 3 months at initial screen and BL1) OR accelerometer recorded changed to Self-report of <140 minutes of MVPA per week (in 10 minute bouts, in the past 3 months at phone screen and BL1) AND accelerometer recorded <100 minutes of MVPA (in 10 minute bouts, between BL1 and BL2)	4. Selection and Enrollment of Participants	UMN IRB	NCCIH: 2/19/19 IRB: 3/8/19
V4	Nov 28, 2018	Change to Intervention	Changed: Name of control interventions from 10 Keys to Health and Wellbeing to Keys to Health and Wellbeing	5. Study Interventions	UMN IRB	NCCIH: 2/19/19 IRB: 3/8/19
V4	Nov 28, 2018	Key Personnel Change	Changed: Alex Haley, Douglas Kennedy from non-Key to Key Personnel	Study Team Roster	UMN IRB	NCCIH: 2/19/19 IRB: 3/8/19

V4	Nov 28, 2018	Updated recruitment methods	Updated recruitment methods to include CTSI Clinical Data Repository, community listening and information sessions to enhance minority recruitment	4. Selection and Enrollment of Participants		NCCIH: 2/19/19 IRB: 3/8/19
V4	Nov 28, 2018	Change to Exclusion Criteria	Serious mental health or brain conditions (bipolar disorder, schizophrenia, psychotic disorder or problems, Alzheimer's, dementia, major depressive disorder). to Serious mental health or brain conditions (bipolar disorder, schizophrenia, psychotic disorder or problems, Alzheimer's, dementia, major depressive disorder). Self-report of diagnosis by a health provider AND health care provider does not provide clearance to participate	4. Selection and Enrollment of Participants	UMN IRB	NCCIH: 2/19/19 IRB: 3/8/19
V4	Nov 28, 2018	Update to Sample Size considerations	Updated variability estimates, between group differences; no change to sample size	9. Statistical considerations	UMN IRB	NCCIH: 2/19/19 IRB: 3/8/19
V4	Nov 28, 2018	Update to Focus on R33 Activities	Removed R21 activities so protocol focuses solely on R33 activities	All	UMN IRB	NCCIH: 2/19/19 IRB: 3/8/19
V5	Mar 13, 2019	Update to Recruitment of Candidate Participants	Clarified timing of Community Listening Sessions and Study Information Meetings	4.3 Study Enrollment Procedures	UMN IRB NCCIH	NCCIH: 3/26/19 IRB: 4/18/19
V6	May 16, 2019	Update to 6.2.2	Enrolled individuals will commence their allocated intervention up to 10 business days post randomization versus 7-10 business days post-randomization.	6.2.2 Enrollment, Baseline, and Randomization	UMN IRB NCCIH	NCCIH: 7/17/19 IRB: 8/6/2019
V6	May 16, 2019	Update to 6.2.4	Week 9 Follow-Up data can be collected between -7 and + 15 business days following W9 date; Added "if applicable" to AE form at all time points	6.2.4 Follow-Up	UMN IRB NCCIH	NCCIH: 7/17/19 IRB: 8/6/2019

V6	May 16, 2019	Schedule of Evaluations	Added study completion form	6.1-Schedule of Evaluations	UMN IRB NCCIH	NCCIH: 7/17/19 IRB: 8/6/2019
V6	May 16, 2019	Schedule of Evaluations & Adverse Events	Table updated to be congruent with text in section 7. AEs will be collected post-randomization. This is consistent with the DSMP. The Safety Officer (DSMB) will adjudicate events, with input as needed, from the PI or designee. Study related AE/SAEs will be followed to stabilization/resolution post end of study participation. Information in this section is redundant and covered in section 7.4.2	6.1-Schedule of Evaluations 7.4 Adverse Events and Serious Adverse Events & 7.4.1 Characteristics of an Adverse Event 7.4.2 Time Period and Frequency Collection and Time Period. 7.6 omitted	UMN IRB NCCIH	NCCIH: NCCIH: 7/17/19 IRB: 8/6/2019
V6	May 16, 2019	Monitoring	Non-SAEs will be reported to the IRB annually as part of the continuing review process	10.3.6 Monitoring	UMN IRB NCCIH	NCCIH: 7/17/19 IRB: 8/6/2019
V6	May 16, 2019	Protocol Deviations	Removed reference to protocol deviations in 10.3.4. Added a definition of protocol deviation and included a list of examples	10.3.5 Protocol Deviations	UMN IRB NCCIH	NCCIH: 7/17/19 IRB: 8/6/2019
V6	May 16, 2019	Participating Sites	Added Maplewood YMCA	NA	UMN IRB NCCIH	NCCIH: 7/17/19
V6	May 16, 2019	Intervention logistics	Clarified that classes may proceed with less than 8, or more than 16 persons. The PI will make the final determination as to whether or not a smaller or larger class is appropriate.	5.2.3 Intervention logistics	UMN IRB NCCIH	NCCIH: 7/17/19 IRB: 8/6/2019
V6	May 16, 2019	Schedule of Evaluations; Outcomes, Enrollment, Baseline, Randomization	Added outcome measure: interoceptive awareness. To be collected at baseline, W9, W26, and W52	6. Study Procedures; 9.5 Outcomes; 6.2.2 Enrollment, Baseline & Randomization	UMN IRB NCCIH	NCCIH: 7/17/19 IRB: 8/6/2019

V6	May 16, 2019	Consent Procedures	Included language that describes when participants will be re-consented	4.3.4 Consent Procedures	UMN IRB NCCIH	NCCIH: 7/17/19 IRB: 8/6/2019
V6	May 16, 2019	Outcomes	Vector magnitude (≥ 2751 CPM was changed to ≥ 2752 CPM)	9.5 Outcomes	UMN IRB NCCIH	NCCIH: 7/17/19 IRB: 8/6/2019
V6	June 27, 2019	Data analysis	Clarified how clustering effect will be assessed in the analysis	9.6 Data Analyses	NCCIH	NCCIH: 7/17/19
V7	March 2020	Intervention Logistics	Participant can attend intervention sessions at the remotely using UMN approved, HIPAA compliant videoconferencing due to concerns; changes made due to COVID-19 outbreak.	5.1.1 Intervention Administration/Duration	UMN IRB NCCIH	IRB: 4/6/2020
V7	March 2020	Outcomes	Week 26 Follow-Up data can be collected between -7 and + 60 business days following W26 time point; changes made due to COVID-19 outbreak.	6.2.4 Follow-Up	UMN IRB NCCIH	IRB: 4/6/2020
V8	April 2020	Outcomes	COVID-19 Impact and Zoom questions added	9.5 Outcomes 6.1 Schedule of Evaluations	UMN IRB	IRB: 4/21/2020
V9	June 2020		All references to in-person screening, interventions, training, and follow-up visits were removed. These are replaced by remote visits done by phone and/or videoconference.	Multiple sections of the protocol.	UMN IRB previously approved	NCCIH: NA
V9	June 2020		Included Young and Schroeder as facilitators; removed Ziegler.	Updated Study Team Roster	UMN IRB previously approved	NCCIH: NA
V9	June 2020		Updated Participating Sites section	NA	UMN IRB NCCIH	NCCIH: 9/2/2020 IRB: 9/28/2020
V9	June 2020		MMSE will now be conducted only on participants with suspected cognitive decline versus all participants to decrease burden.	4.2.1 Inclusion Criteria	UMN IRB NCCIH	NCCIH: 9/2/2020 IRB: 9/28/2020

V9	June 2020		Participants will be excluded if they cannot commit to attending >70% of intervention sessions via videoconference) Major anxiety disorder added to contraindications to mindfulness practices per UMN IRB RNI00004599	4.2.2 Exclusion Criteria	UMN IRB NCCIH	NCCIH: 9/2/2020 IRB: 9/28/2020
V9	June 2020		Recruitment plans updated to include remote recruitment initiatives	4.3.2 Recruitment of Candidates	UMN IRB NCCIH	NCCIH: 9/2/2020 IRB: 9/28/2020
V9	June 2020		Compensation increased to $210.00. An extra $10 was included to account for the pre-intervention orientation (W0).	4.3.2 Recruitment of Candidates	UMN IRB NCCIH	NCCIH: 9/2/2020 IRB: 9/28/2020
V9	June 2020		Consent procedures updated to include e-Consent. Participants who cannot e-Consent will be mailed a consent formed to sign and mail back if they want to participate. Reference to in-person consent procedures was removed.	4.3.4 Consent procedures	UMN IRB NCCIH	NCCIH: 9/2/2020 IRB: 9/28/2020
V9	June 2020		We updated how the data analysis will account for class effects with the transition away from physical sites to remote intervention delivery.	4.3.5 Randomization procedures 9.2.2 Randomization/Treatment Assignment Procedures 9.6 Analysis	UMN IRB NCCIH	NCCIH: 9/2/2020 IRB: 9/28/2020
V9	June 2020		A W0 orientation session prior to the start of the intervention sessions has been implemented to orient participants to the video-conference, virtual group environment. Participants will receive reminders prior to each session. Participants will receive additional information including tips to ensure optimal learning, comfort and safety	6.2.4 Intervention & Follow-up 5.1.1. Administration & Duration	UMN IRB NCCIH	NCCIH: 9/2/2020 IRB: 9/28/2020
V9	June 2020		All training will be conducted remotely.	5.1.4 Intervention Training	UMN IRB NCCIH	NCCIH: 9/2/2020 IRB: 9/28/2020

V9	June 2020		Intervention fidelity will not be done in-person and sessions will not be audio-recorded. Zoom interface at UMN does not allow recording of PHI.	5.2.2 Intervention fidelity	UMN IRB NCCIH	NCCIH: 9/2/2020 IRB: 9/28/2020
V9	June 2020		Participants will be given instructions on how to participate remotely. Participants will be asked about Zoom experience, tech needs and capabilities, and waist size Participants BL exams will be done via videoconference and/or phone Deaconess completed by participants prior to BL or during BL evaluation Accelerometers will be mailed to participants. Participants will mail accelerometers back to the UMN in postage paid envelope. Anthropometrics will be collected via self-report	6.2.1 Screening Evaluation	UMN IRB NCCIH	NCCIH: 9/2/2020 IRB: 9/28/2020
V9	June 2020		Additional detail added regarding options for participants to decline taking part in session activities, especially group discussions, in response to UMN IRB RNI00004599.	7. 3 Methods & Timing for Assessing, Recording, and Analyzing Safety parameters	UMN IRB NCCIH	NCCIH: 9/2/2020 IRB: 9/28/2020
V9	June 2020		Adaptations of Working Alliance Inventory (WAI) and Telehealth Usability Questionnaire added at Week 9.	9.5 Outcomes 6.1 Schedule of Evaluations	UMN IRB NCCIH	NCCIH: 9/2/2020 IRB: 9/28/2020
V9	June 2020		A secondary analysis in response to COVID-19 will be conducted. Remote screening and intervention delivery will be treated as a distinct "site" within the analysis.	9.6 Analysis	UMN IRB NCCIH	NCCIH: 9/2/2020 IRB: 9/28/2020
V9	June 2020		The first baseline evaluation will take place up to 90 days after the initial screen described above. Was previously 150 days.	6.2.1 Screening evaluation	UMN IRB NCCIH	NCCIH: 9/2/2020 IRB: 9/28/2020

V9	June 2020		Updated monitoring section to include a description of remote monitoring by Westat	10.3.6 Monitoring	UMN IRB NCCIH	NCCIH: 9/2/2020 IRB: 9/28/2020
V9	Oct 2020		Covid impact questionnaire may be asked during the screening process. This question was previously approved and may be collected post-intervention	6.1 Schedule of Evaluations	UMN IRB	IRB: 11/4/2020
V10	Feb 2021		Changed Feinstein to Folstein (in reference to the MMSE) – Feinstein was a typo.	4.2. Eligibility Criteria	UMN IRB	IRB:3/1/2021
V10	Feb 2021		BL2 can occur 7-28 business days after BL1 to allow additional time for mailing, receiving and processing accelerometers.	6.2.1 Screening Evaluation	UMN IRB	IRB:3/1/2021
V10	Feb 2021		Enrolled individuals will commence their allocated intervention up to 14 business days post randomization.	6.2.2 Enrollment, Baseline & Randomization	UMN IRB	IRB:3/1/2021
V10	Feb 2021		Added Oliver Ang and Don Thorpe. These UMN staff were approved by the IRB previously to work on the study.Protocol updated to include their names. Updated contact information for research staff	Study Team Roster	UMN IRB	IRB:3/1/2021

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TABLE OF CONTENTS

ABBREVIATIONS/DEFINITIONS

- *UMN/University of Minnesota*
- *YMCA GTC/YMCA Greater Twin Cities*
- *RCT/Randomized Controlled Trial*
- *MBI/Mindfulness Based Intervention*
- *MBSR/Mindfulness Based Stress Reduction*
- *PRECIS/Pragmatic-Explanatory Continuum Indicator Summary*
- *RE-AIM/Reach, Effectiveness, Adoption, Implementation, and Maintenance*
- *MMSE/Mini-mental status score*
- *W/ Week*
- *MVPA/Moderate Vigorous Physical Activity*
- *SA/Sedentary Activity*
- *SEE/Self-efficacy for exercise*

- *OEE_2/ Outcome Expectations for Exercise-2*
- *CPM/Counts per minute*
- *PAR-Q/ Physical Activity Readiness Questionnaire*
- *MAAS/Mindful Attention Awareness Scale*
- *FMI/Freiberg Mindfulness Inventory*
- *IPAQ-International Physical Activity Questionnaire*
- *REDCap/Research Electronic Data Capture*
- *AE/Adverse Event*
- *SAE/Serious Adverse Event*
- *MET/ Metabolic Equivalent of Task*
- *USPS/ United States Postal Service*
- *BL/Baseline*
- *BL1/Baseline visit 1*
- *BL2/Baseline visit 2*
- *DOB/Date of Birth*
- *HSR/Human Subjects Research*
- *TUQ/Telehealth Usability Questionnaire*
- *WAI/Working Alliance Inventory*
- *e-Consent/electronic consent*
- *W0/ Week 0*

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Due to the COVID-19 pandemic, all in-person study sessions (i.e., screening activities, intervention and follow-up visits) will be conducted remotely. Participants will be recruited through all YMCA Twin Cities locations. Individual YMCA locations are not listed, instead the main office (YMCA Twin Cities) is listed.

PRÉCIS

Study Title

Mindful Movement for Physical Activity and Wellbeing in Older Adults: A Community Based Randomized Hybrid Effectiveness-Implementation Study

Objectives

The broad long-term objective of this research is to optimize physical activity levels in middle to older age adults (≥50 years) using an integrated mindfulness and behavioral approach, which can be scaled for dissemination nationwide. We will work with the YMCA Greater Twin Cities, a community based organization. To overcome the problematic lag between research discovery and translation, we will use an innovative hybrid effectiveness-implementation design.

Design and Outcomes

We will conduct a Randomized Controlled Trial (RCT, n=182) to determine the relative effectiveness of two educational programs, Mindful Movement versus Keys to Health & Wellbeing (Aim 1) by assessing the following:

- Primary physical activity outcome: time spent per week in ≥ 10 minute bouts of moderate-vigorous physical activity (MVPA) at 9 weeks;
- Secondary physical activity outcomes: time spent per week in ≥ 10 minute bouts of MVPA at 26 and 52 weeks; time spent per week in MVPA and sedentary activity; and steps per day at 9, 26, and 52 weeks.
- Secondary self-report measures: quality of life, exercise self-efficacy and expectations, mindfulness, wellbeing, bodily pain, physical activity, social connectedness and assurance, intervention satisfaction, and adverse events at 9, 26, and 52 weeks.

To facilitate interpretation of the RCT results and provide resources for translation and sustainability, we will collect and describe complete contextual data within the RCT at the participant, facility and organizational levels and create a web-based implementation toolkit that can be used by other sites (Aim 2).

Interventions and Duration

The duration of the interventions is 8 weeks. One additional week, a pre-intervention session, (i.e., Week 0) is included to introduce & orient participants to the remote Zoom, group environment. The interventions are group educational programs, Mindful Movement (experimental intervention) versus Keys to Health & Wellbeing (control intervention), both facilitated by YMCA staff facilitators.

Sample Size and Population

We will enroll 182 participants 50 years of age and older.

1. STUDY OBJECTIVES

1.1 Overview

Physical inactivity is a significant public health problem associated with increased risk of disabling medical conditions, chronic disease and mortality, as well as diminished wellbeing.[1-3] Despite recommendations to engage in at least 150 minutes per week of moderate to vigorous physical activity (MVPA), most older adults do not.[4,5] There is also growing attention on the detrimental health effects of sedentary, very low energy activities.[6-8] There are many theoretical mechanisms underlying older adults' physical and sedentary behaviors,

which when considered in aggregate relate to individuals' capacity, motivation, and opportunity.[9] Specific theory based behavioral strategies, especially those that are self-regulatory and provide social support, have demonstrated effectiveness in positively affecting health and activity behaviors.[7,10,11] Emerging evidence also suggests mindfulness based interventions (MBI), incorporating mindfulness meditation, can be helpful for addressing challenges related to initiating and engaging in health behaviors[12-14] including physical activity.[15,16] With a focus on non-judgmental, present-oriented awareness, MBIs can facilitate self-regulation of attention on immediate experiences, thoughts and emotions with an orientation of openness, curiosity, and acceptance.[17] MBIs may also help older adults' navigate common negative exercise-related experiences, expectations, and beliefs. However, there is a void in research examining MBIs for health behaviors including physical and sedentary activities.

The broad long-term objective of this research is to optimize physical activity levels in middle to older age adults (≥50 years) through *Mindful Movement*, an integrated mindfulness and behavioral approach, which can be scaled for dissemination nationwide. We will work with the YMCA Greater Twin Cities, a community based organization, which provides opportunities to "build healthy spirit, mind, and body for all" and has made healthy aging a strategic priority. Together, with a multi-disciplinary team, we will refine and test a multi-level "Mindful Movement" program comprised of mindfulness practices and evidence based behavioral strategies to facilitate activity related behaviors. To overcome the problematic lag between research discovery and translation, we will use an innovative hybrid effectiveness- implementation design[18] comparing Mindful Movement to a Keys to Health & Wellbeing education program adapted from previous research.[19]

1.2 Primary Objective

Aim 1: To determine the relative effectiveness of 8 weeks of Mindful Movement versus Keys to Health & Wellbeing in a Randomized Controlled Trial (RCT, n=182) as measured by changes in primary physical activity outcome: time spent per week in ≥10 minute bouts of moderate-vigorous physical activity (MVPA) at 9 weeks.

1.3 Secondary Objectives

Aim 2: To determine the relative effectiveness of the two interventions as measured by changes in:

a. Secondary physical activity outcomes: time spent per week in ≥ 10 minute bouts of MVPA at 26 and 52 weeks; time spent per week in MVPA and sedentary activity; and steps per day at 9, 26, and 52 weeks.

b. Secondary self-report measures: quality of life, exercise self-efficacy and expectations, mindfulness, wellbeing, bodily pain, physical activity, social connectedness and assurance, intervention satisfaction, and adverse events at 9, 26, and 52 weeks.

Aim 3: To facilitate interpretation of RCT results and provide resources for translation and sustainability by:

a. Collecting contextual information to inform eventual broad scale intervention implementation. This includes assessment of participants (including follow up rates for self-reported outcomes, and barriers and facilitators to intervention and study participation); facility (including staff adherence to recruitment and intervention protocols; confidence in protocol and intervention delivery; perceived barriers and facilitators to intervention and study implementation); and organizational (including leadership views regarding intervention and study relevance, practicality, affordability, and acceptability; intervention related costs).

b. Creating a web-based implementation toolkit that can be used by other sites.

1.1 Hypotheses

Our ***primary hypothesis*** is that there will be a significant advantage (≥56 minutes) in terms of the primary outcome measure, weekly minutes spent in ≥10 minute bouts of MVPA for Mindful Movement over the Keys to Health & Wellbeing.

Our ***secondary hypotheses*** are:

- There will be a significant advantages of Mindful Movement over Keys to Health & Wellbeing in terms of the secondary objective outcome measures of time spent per week in ≥ 10 minute bouts of MVPA; time spent per week in MVPA and sedentary activity; and steps per day
- There will be significant advantages of Mindful Movement over Keys to Health & Wellbeing in terms of the secondary self-reported outcomes: quality of life, exercise self-efficacy and expectations, mindfulness, wellbeing, bodily pain and physical activity
- There will be no significant advantages of Mindful Movement over Keys to Health & Wellbeing in terms of the secondary self-reported outcomes of social connectedness and assurance, and intervention satisfaction

2. BACKGROUND AND RATIONALE

2.1 Background on Condition, Disease, or Other Primary Study Focus

This project addresses the significant challenge of engaging middle to older age adults in physical activity. By using a rigorous hybrid randomized effectiveness-implementation design, we will test a 'Mindful Movement' program with our collaborators at the YMCA Greater Twin Cities (YMCA GTC), the third largest YMCA in the United States. The YMCA's strategic priorities include improving wellbeing through all stages of life and developing socially responsible communities by embracing diversity and inclusion. With a membership of more than 300,000 locally and 22 million nationally and the ability to attract non- members, the YMCA has great reach. Furthermore, the YMCA's commitment to providing geographically and financially accessible resources and facilities greatly enhances the potential for this project to positively impact the physical activity, health, and wellbeing of a large and diverse population.

Physical inactivity is a global health concern with profound consequences. Physical inactivity has reached pandemic proportions,[20,21] and is defined as a level insufficient to meet current recommendations for at least some health benefits (≥ 3.3 METs: 150 minutes of moderate aerobic physical activity per week OR ≥ 6.0 METs: 75 minutes of vigorous aerobic physical activity per week OR an equivalent combination of both, with bouts of activity at least 10 minutes in duration). With nearly a third of the world's population failing to meet minimal recommended physical activity levels,[22] the health and economic consequences are sobering. The negative impacts of physical inactivity approximate those of smoking and obesity,[21] and it has been estimated that up to 10% of all deaths from non- communicable diseases are due to insufficient physical activity.[21] In the US, costs attributable to physical inactivity were $500 billion in 2003 and estimated to exceed $700 billion in 2008.[23] Conversely, there are many positive benefits of physical activity, including reduced risk of chronic diseases and falls, and improved function, quality of life, and wellbeing.[20,21] It has been estimated that inactive American adults could gain up to 4 added years from age 50 by becoming active[21,24,25] and that even modest activity (e.g. 15-30 minutes per day of brisk walking) would confer health benefits.[1,20,26]

Sedentary activities carry important health risks independent of physical activity. While substantial attention has been paid to physical inactivity, it is only relatively recently that focus has been placed on sedentary behaviors, defined as engagement in very low energy activities (<1.5 METS) including sitting or reclining at work, home or during commuting and leisure times. Time spent sedentary has been associated with higher risk of physical frailty,[6] metabolic syndromes, and mortality.[7,8] Noteworthy is that participation in high levels of MVPA fails to fully mitigate risks of prolonged sedentariness.[6,7] These studies suggest that interventions should not only target increased physical activity but also concomitant reductions in sedentary behaviors.

Physical inactivity and sedentary behavior is a major concern for middle to older age adults. With the U.S. older adult population rapidly growing, increased attention is being paid to middle to older age adults' physical and sedentary behaviors.[27] Physical activity recommendations for older individuals are the same as for their younger counterparts.[1,20,26] A total of 150 minutes per week in MVPA is recommended for some health benefits, and 300 minutes per week is recommended for greater health benefits.[28] Regular walking is among the most common physical activities engaged by older adults, and generally meets the criteria for moderate intensity physical activity.[29] Recent evidence shows the majority of middle age to older adults fall alarmingly short of recommendations for physical and sedentary activities. In the recently published work by Hooker et al,[4] 75-90% of time was spent engaged in sedentary behavior, 10-23% in light physical activity, and only 0-2% in MVPA. Only 3 to 12% of participants reached $\geq$ 150 min/week using the recommended 10 minute bout criterion.[4]

Qualitative studies have found that many older adults associate exercise with potentially negative effects.[30] Further, some carry the belief that health declines are inevitable, leading to less investment in preventive behaviors, and subsequent health declines.[31] Importantly, older adults with multiple chronic conditions (a common occurrence with advancing age[32]) are at higher risk for negative perceptions about aging, and sedentary behavior. These perceptions contrast with recommendations for exercise (including aerobic forms) irrespective of age, comorbidity, pain severity, and disability.[33]

2.2 Study Rationale

There is evidence to support several behavioral strategies for optimizing physical activity. Initiating and sustaining engagement in physical activity is complex, and is influenced by many factors.[9] One model of behavior useful for understanding physical and sedentary activities is the COM-B model, which addresses capabilities, opportunities, and motivations related to behavior. **Capability** refers to the abilities required to enact a behavior and **opportunity** refers to the physical and social environment that facilitates the behavior. **Motivations** include reflective mechanisms (e.g. beliefs about what is good and bad, conscious intentions, decisions, and plans) and automatic mechanisms (e.g. emotional responses, desires, impulses, and habits resulting from associative learning and physiological states) that facilitate or inhibit behaviors.[9]

Systematic reviews of behavioral interventions for promoting changes in physical activity have found evidence for social support and the use of well-described behavior techniques, particularly those focused on self-regulation (e.g. goal setting, prompting, self-monitoring, providing feedback on performance, and goal review).[10,34] Of note is the recommendation that individual behavior techniques be combined as part of a coherent intervention in which theory, strategies, and goals are aligned.[9,10,35]

Research is beginning to emerge using this approach in older adult populations. In the RCT by Burke et al (n=478),[36] a 6 month, home based intervention which included an informational booklet, goal setting, e-mail and phone reminders, resulted in significant improvement in self- reported physical activity in 60-70 year old participants. A recent cluster RCT of nearly 300 individuals 60-75 years of age[37] tested a program focused on key behavioral strategies (goal- setting, self-monitoring, building self-efficacy social support, barrier and relapse prevention, and habit building) to encourage walking. A significant increase compared to the control was observed in daily steps and 10 minute bouts of MVPA at 3 and 12 months, with no adverse events. These studies suggest that behavioral strategies to enhance physical activity are appropriate for use in older adults, and warrant further investigation.

Mindfulness based interventions (MBIs) are among the top five commonly used complementary and integrative health (CIH) practices in the U.S.[38] Mindfulness Based Stress Reduction (MBSR) is the most popular and formalized of the mindfulness programs, stemming from Jon Kabat-Zinn's early work that introduced systematic, secular training in mindfulness.[17,39] MBSR and many MBIs, are offered as group format interventions focused on education, training, practice and social support in mindfulness meditation. Mindfulness is considered a 'meta-cognitive' skill (cognition about one's cognition)[40] which has been described as "the awareness that arises by paying attention, on purpose, and non-judgmentally, to present moment experience".[41] Mindfulness can be developed through meditation training and practice aimed at enhancing **attention regulation, body awareness, emotional regulation**, and **shifts in self-perception**,[42] all potentially important and useful skills for engaging in healthy behaviors.

The number of studies investigating MBIs is rapidly increasing and there is growing evidence for MBIs' synergistic neurobiological and behavioral mechanisms. This includes mechanistic studies demonstrating the ability of MBIs to positively affect brain regions and functions necessary for regulating attention, emotion and pain, as well as body awareness and self-perception.[42,43] While a recent evidence map of 81 systematic reviews of MBIs[44] has found generally positive clinical outcomes for a range of health issues, there is a scarcity of research focused on investigating the effectiveness of MBIs for enhancing optimal health behaviors.

However, the little research that has been performed is promising. Emerging evidence suggests MBIs incorporating mindfulness meditation, can be helpful for addressing challenges related to initiating and engaging in health behaviors.[12,13,45] This includes promising work incorporating MBIs to enhance physical activity.[15,16] A small randomized controlled trial (RCT) of 19-64 year olds (n=62) found that 4, 2 hour MBI workshops resulted in significant increases in self-reported physical activity at 6 months compared to controls. Another recent RCT of 30-50 year olds[15] (n=138), found that 9, 90 minute sessions of mindfulness combined with Acceptance and Commitment Therapy improved physical activity self-efficacy and discomfort acceptance compared to feedback alone. And while no studies have yet examined MBIs for encouraging physical activity behaviors for mid to older age adults exclusively, preliminary qualitative research found that older adults (mean age 74 years) with low back pain who participated in an 8 week MBSR program, perceived beneficial changes in body awareness resulting in behavior change.[46] Overall, the encouraging results of these studies, coupled with the growing evidence base regarding MBIs neurobiological and behavioral mechanisms, suggest it is the right time for rigorous studies coupling mindfulness approaches with evidence-based behavioral strategies for ameliorating physical inactivity and sedentary behaviors in mid to older age adults.

There are several theoretical mechanisms by which mindfulness skills may improve physical activity. Barriers to physical activity often include entrenched ideas, including beliefs that exercise is painful and even physically harmful.[47] In practicing movement with mindfulness, participants learn to intentionally pay

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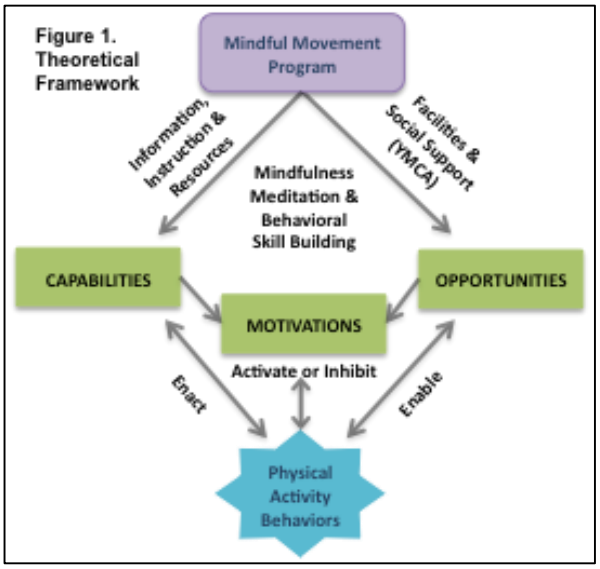

attention (**attention regulation**) to their physical sensations (increasing **body awareness**), with an attitude of friendliness and curiosity. This can lead to **shifts in perception** in which MBI participants are surprised and even pleased as enjoyable sensations of movement come to the foreground of their attention, discomfort or pain shifts to the background. Such shifts could result in shaping behaviors or actions towards physical activity engagement rather than avoidance. cognitive flexibility afforded by mindfulness may also the way for the application of other behavioral skills, including value based goal-setting and action planning. Non- judgmental awareness may aid in relapse management, where relapses are viewed with neutrality and compassion.[47] Further, coupling muscular activity with an internally directed focus can facilitate interoceptive attention to bodily sensations.[48,49 50-52] This suggests that mindfulness techniques are indeed well suited to integrate with all types of physical activity, with potential reciprocal effects (e.g. mindfulness can facilitate activity, and activity can facilitate mindfulness).[12]

MBIs could also lead to increased physical activity through attenuation of other common barriers including avoidant impulses and habitual thinking which prevent initiation, engagement, and maintenance.[47,53,54] By encouraging individuals to become aware, they can open to the possibility that allowing such habits to dictate behavior is contrary to wellbeing. Further, in facilitating a time interval where one is able to observe thoughts, feelings and sensations non-judgmentally, as opposed to negatively, mindfulness can lead to the formation of different appraisals and behavioral choices (e.g. engaging in activity versus avoiding it, etc).[13] Thus, through practice in mindfulness, mid to older age adults can moderate activities appropriate for themselves. They can also actively *respond to* rather than automatically *react to* the emotions (**emotional regulation)** or thoughts that may arise when confronted with barriers to physical activity engagement. Overall, our underlying **theoretical framework** for the Mindful Movement Program can be summarized using the COM-B model.[9] By providing education, training and practice in mindfulness meditation, and evidence-based behavioral strategies, we will enhance mid to older age adults' **capabilities** and skills required to engage in healthy physical activity behaviors. These will serve to activate positive **motivations** including those that are reflective (e.g. beliefs, conscious intentions, decisions, and plans) and automatic (e.g. emotional responses, desires, impulses, and habits) and inhibit negative ones. Importantly, by integrating the program within the YMCA, a community based organization that offers geographically and financially accessible resources and facilities in socially supportive environments, we will provide mid-older age adults from all backgrounds **opportunities** to facilitate physical activity related behaviors, and enhance their overall health and wellbeing.

3. STUDY DESIGN

To speed the translation of research to practice there has been increasing interest in study designs and strategies that work to balance methodological rigor with generalizability. This includes the emergence of hybrid effectiveness-implementation designs,[18] and other frameworks,[55] which blend rigorous clinical research approaches alongside implementation research methods to facilitate adoption by providers and systems.

We will use a hybrid randomized design which simultaneously tests the intervention and the implementation using rigorous methods to provide valid estimates.[18] To facilitate the future implementation of the Mindful Movement intervention to YMCA and other community based settings, we used the "Reach, Effectiveness, Adoption, Implementation and Maintenance" RE- AIM framework to inform the design.[55]

3.1 Overview

This is a randomized controlled trial. It uses a hybrid effectiveness-implementation approach and is informed by the RE-AIM framework, to facilitate intervention uptake and sustainability.[18,55] This study has the following aims:

Aim 1. To determine the relative effectiveness of 8 weeks of Mindful Movement versus Keys to Health & Wellbeing (n=182) as measured by changes in primary physical activity outcome: time spent per week in ≥10 minute bouts of moderate-vigorous physical activity (MVPA) at 9 weeks.

Aim 2. To determine the relative effectiveness of the two interventions as measured by changes in:

a. Secondary physical activity outcomes: time spent per week in ≥ 10 minute bouts of MVPA at 26 and 52 weeks; time spent per week in MVPA and sedentary activity; and steps per day at 9, 26, and 52 weeks.
b. Secondary self-report measures: quality of life, exercise self-efficacy and expectations, mindfulness, wellbeing, bodily pain, physical activity, social connectedness and assurance, intervention satisfaction, and adverse events at 9, 26, and 52 weeks.

Aim 3. To facilitate interpretation of RCT results and provide resources for translation and sustainability by:

a. Collecting contextual information to inform eventual broad scale intervention implementation. This includes assessment of participants (including follow up rates for self-reported outcomes, and barriers and facilitators to intervention and study participation); facility (including staff adherence to recruitment and intervention protocols; confidence in protocol and intervention delivery; perceived barriers and facilitators to intervention and study implementation); and organizational (including leadership views regarding intervention and study relevance, practicality, affordability, and acceptability; intervention related costs).
b. Creating a web-based implementation toolkit that can be used by other sites.

4. SELECTION AND ENROLLMENT OF PARTICIPANTS

4.1 Definition of "Participants"

The nature of a hybrid effectiveness/implementation design warrants participation of subjects at different levels.

Participant level. Participants will be randomly allocated to participate in experimental (Mindful Movement) or control (Keys to Health & Wellbeing) interventions, and will take part in baseline and post- intervention quantitative and qualitative data collection activities.

Facility level. These individuals include those who work at the YMCA (e.g. staff), but are not in leadership positions. These individuals will be asked to volunteer to participate in qualitative data collection to provide important contextual information that could affect implementation of the

interventions in the long term.

Organizational level. These individuals have the potential to influence YMCA's strategic planning (e.g. hold leadership positions). Similar to the facility level subjects, these individuals will be asked to volunteer to participate in qualitative data collection to provide important contextual information that could affect implementation of the interventions in the long term.

4.2 Eligibility Criteria

All participant level subjects taking part in the RCT must meet all of the inclusion criteria and none of the exclusion criteria by the time of enrollment (randomization at or following BL2) to participate in this study.

4.2.1 Inclusion Criteria

Inclusion criteria are summarized below; see manual of operations for further operationalization:

- ≥ 50 years of age (as of date of initial screen, confirmed with date of birth).
- Accelerometer wear time ≥10 hours on at least 4 days in a 7 consecutive day period between BL1 and BL2.
- Self-report of <140 minutes of MVPA per week (in 10 minute bouts, in the past 3 months at initial screen and BL1) AND accelerometer recorded <100 minutes of MVPA (in 10 minute bouts, between BL1 and BL2).
- Independent self-ambulation (without assistance of another individual; can use mobility aid such as a cane, walker, scooter or wheelchair).
- Provides informed consent (signed consent form and demonstrated understanding using Modified Deaconess Questionnaire).
- Folstein Mini Mental Status Exam (MMSE) ≥ 24 for those with suspected cognitive decline.

Additionally, the following describes inclusion criteria for the other subject levels who provide important contextual information required as part of the hybrid effectiveness/implementation design and RE-AIM framework.

- Potential participant level subjects must be 50 years of age and older and willing to participate in qualitative data collection.
- Facility level subjects must work at the YMCA (e.g. staff), but are not in leadership positions, and willing to participate in qualitative data collection.
- Organizational level subjects are defined as individuals at the YMCA who influence the strategic planning of the organization (e.g. hold leadership positions) and willing to participate in qualitative data collection.

4.2.2 Exclusion Criteria

Exclusion criteria are summarized below; see manual of operations for further operationalization:

- Pregnancy (self-report of current pregnancy or trying to get pregnant)

- Unwilling or unable to participate in study activities (not able and willing to attend baseline study visits; not able and willing to wear the accelerometer daily for at least 10 hours per day on 7 days; not able and willing to complete self-report questionnaires unassisted, using electronic or paper formats, [includes English literacy]; cannot commit to attending >70% of intervention sessions via videoconference*)
- Current or upcoming participation in educational programs similar to those under study
- Medical restrictions to increasing MVPA (Participant self-report AND health care provider does not provide clearance to participate)**
- Terminal illness
- Contraindications to mindfulness practices:
    - Serious mental health or brain conditions (bipolar disorder, schizophrenia, psychotic disorder or problems, Alzheimer's, dementia, major depressive disorder, major anxiety disorders). Self-report of diagnosis by a health provider AND health care provider does not provide clearance to participate**
    - Suicidality (score of $\geq$2 on the suicidal ideation screen from the Quick Inventory of Depressive Symptomatology-Self Report (QIDS-SR)[56]
    - Substance abuse (self-report of substance abuse at time of screening as measured by affirmative responses to screening questions of drinking more alcohol or using more drugs than intended in the past 6 months AND feeling the need to cut down on alcohol use or drugs)
    - PTSD (self-report of diagnosis of PTSD AND health care provider does not provide clearance to participate)**
    - Seizure disorder. Self-report of diagnosis by a health provider AND health care provider does not provide clearance to participate**

*Participants can participate even if they do not have the appropriate electronic hardware and/or internet access. These individuals will be identified during screening and provided the necessary technology resources (e.g. computer tablet, mobile hot spot device, etc.). Electronic devices will be formatted by UMN staff to allow participants to participate in screening activities, the study interventions, and data collection. Enrolled participants can keep this equipment. Participants who disqualify during the screening process will be asked to send the equipment back to the university in a postage-paid package.

To reduce potentially negative impacts on recruitment we will only send devices/tablets to individuals who have completed a thorough initial screening; this will minimize the amount of mailing back and forth of devices since the majority of individuals will likely qualify at this point. Additionally, the time window between initial screening and baseline 1 is sufficiently long enough (90 days) to accommodate shipping and returns.

We feel there is an advantage of having potential participants try using Zoom prior to randomization; by experiencing the Zoom environment they can make better informed decisions regarding participation. In doing so, we anticipate increased intervention engagement and fewer withdrawals.

** Healthcare provider clearance: participants who may have contraindications to mindfulness practices or medical restrictions to increasing MVPA (as determined by assessment of inclusion/exclusion criteria during screening) need written clearance from their medical provider to participate in the study. The medical waiver includes information about the study purpose, the funding agency, a list of potential risks and contact information for the study team. Participants are instructed to review the waiver with their medical team and return the signed waiver (by mail, fax or scanned) to the study team prior to randomization. Medical waivers are secured in the participant's research file. Those who are not able to obtain this necessary clearance cannot participate.

4.3 Study Enrollment Procedures

4.3.1 Identification of Candidate Participants

Participants will self-identify in response to various solicitation methods (see below). Private medical or protected records will not be accessed for screening. Participants will be recruited from the Twin Cities and surrounding metropolitan communities.

4.3.2 Recruitment of Candidate Participants

Participant level subjects: Consistent with normal YMCA practices and to enhance our reach to a diverse study population, we will recruit from all YMCA sites in the Twin Cities, as well as in the general community. We will reach Twin Cities wide YMCA members through routine communication channels including monthly general news emails; 'healthy aging focus' e-mails to target age groups; the YMCA website and social media; announcements in ongoing YMCA classes; and posters distributed within the YMCA facilities. We will also recruit non-members from the general community via the YMCA's usual marketing methods (e.g. postal mailings), and will work in collaboration with local clinics and other community partners, located in proximity to the participating YMCA sites to facilitate referrals. Additionally, we will use existing data from the UMN Clinical and Translational Science Institute (CTSI, NIH UL1TR000114) Clinical Data Repository (CDR) hosted by the Academic Health Center Information Exchange (AHC IE). This data originates from the Electronic Health Records of patients of Fairview Health Services and University of Minnesota Physicians and currently includes over 2.3 million patients who have consented to have their data used for research. Eligibility criteria in this study will be applied to the data repository.

In addition, recruitment of Facility Level Subjects (YMCA staff) to participate in qualitative data collection will occur through system-wide and targeted e-mails, newsletters, routine organizational meetings and special presentations (in-person or remotely via tele-and videoconferencing). Recruitment of Organizational Level Subjects (YMCA Twin Cities leadership, including decision makers and board members) will occur via routine meetings and communications (in-person or remotely e.g., via tele-and videoconferencing), special presentations and targeted e-mails.

Minority Recruitment Efforts:
Based on data gathered in the R21 phase, we learned that greater attention needs to be paid to addressing the barriers that currently exist to minority participation in research, as well as mindfulness based interventions. Common barriers include distrust of research, (e.g., fears about study procedures, lack of knowledge regarding mindfulness and wellbeing interventions, etc.), little perceived benefit to community, and conflicting time demands. To address these barriers we have updated our recruitment plans. This includes working closely with YMCA leadership (Dr. Hedy Lemar Walls, Chief Social Responsibility Officer-YMCA of the Greater Twin Cities, Bruce Yang Director of Social Responsibility-YMCA of the Greater Twin Cities) to coordinate

community listening sessions and additional study information meetings.

Community listening sessions: we have dedicated investigator and staff to meet in-person or remotely (e.g., via tele-and videoconferencing) with community stakeholders to better understand community needs, align values, and share information about the study and potential benefits of community participation. Identification of the stakeholders and facilitation of the community listening sessions will be conducted in partnership with the YMCA leadership (e.g. Dr. Lemar Walls and Mr.Yang). Listening sessions began in the R21 phase, and will continue through the R33, as screening and interventions continue to be implemented at the participating YMCA sites (see approved SARP). Information gained in the listening sessions have been and will be used to inform revisions to recruitment related study materials (e.g. flyers, newsletters, informational meeting materials, etc.). The timing of community listening sessions will continue to be coordinated in a manner that allows for necessary approvals prior to use (e.g. participant-facing R33 materials require IRB approvals, and any affected changes to the R33 protocol require NCCIH and IRB approvals).

Study information meetings: we have dedicated investigator and staff to perform study information meetings (in person or remotely via tele- and videoconferencing) to enhance outreach and recruitment at YMCA sites that typically draw from minority communities. Study information meetings will be held 1-12 weeks prior to the beginning of screening from specific YMCA sites as well as with interested community partners (see approved SARP). Study personnel will provide information about the study, research procedures and terminology, and offer an opportunity for potential participants and family members to ask questions. To better navigate the time constraints of potential participants, the informational meetings will be held at convenient times (e.g. in the evenings following work hours). IRB approved study materials and information provided in these meetings will be guided by recommendations from the community listening sessions (as described above).

In addition, we will seek guidance from the University of Minnesota's (UMN) Recruitment Center to ensure a diverse study population. The Recruitment Center assist researchers with attaining recruitment goals using UMN partnerships, technologies and resources. StudyFinder, for example, extracts data from UMN affiliated enrolling studies listed on ClinicalTrials.gov and provides potential participants a simple way to identify studies that need volunteers. ResearchMatch is an electronic volunteer recruitment registry that also provides information about UMN studies and allows persons interested in research participation to self- register. Strategies include advertising in minority-oriented community newspapers (e.g., Latino American Today, Hmong Times) and hanging posters and flyers in University of Minnesota and other community clinics serving large minority populations.

The YMCA also has numerous partnerships with organizations in the Twin Cities who represent women and minorities and are in close proximity to participating YMCA sites. This includes the Native American Community Clinic; Smileys Family Medicine Clinics (serving a large Somali population), and Westside Community Clinic (also known as La Clinica serving a predominantly Hispanic population). Further, the YMCA's Diversity, Inclusion, and Global (DIG) Council which is charged with the responsibility for creating a welcoming and accessible environment to participants of all ages, genders, cultures, abilities and backgrounds, will serve as a resource for reaching out to minorities for the project.

Compensation: All program fees are paid for by the study. Participants will be compensated for time associated with participating in this study sessions after they are enrolled. The maximum compensation for completing all study sessions is 210.00. Details of compensation procedures are included in the manual of operations and are addressed in the informed consent form.

4.3.3 Documentation Procedures

A comprehensive list of all subjects screened, how they heard about the study, whether or not they were enrolled, and the reasons for ineligibility or non-participation (if applicable) will be maintained electronically.

4.3.4 Consent Procedures

Consent will be sought from all participants by the PI, or designees (e.g. trained study staff). All individuals seeking consent from potential study candidates are required to complete the University of Minnesota's Human Subjects and HIPAA related training. Documentation of consent at the following levels will be recorded by study staff in REDCap. In addition a paper or electronic copy of the signed and dated consent form will be secured for participant level participants.

Participants will be re-consented (including documentation of written consent) if they elect to participate in a different wave other than when the original consent was obtained.

Initial screen (online or by phone). Participants will provide verbal or electronic consent during the initial screen which will be documented in REDCap. Information provided by the participants will be used to assess whether or not they are eligible for a screening appointment (BL1). Prior to baseline screening, consent materials and other study related information will be sent to the study participant by post or e-mail.

Baseline screening. Two screening evaluations will take place remotely via UMN supported, HIPAA secure videoconference (i.e., Zoom) and/or phone and will include the following consent procedures.

- First baseline visit (BL1). Participants will review consent materials on their own prior to this visit. They will receive information about the study purpose, expectations for participation, risks and benefits, the voluntary nature of participation, confidentiality of information provided, research related injury etc. This information will be reviewed with potential subjects in a group setting or one-on-one.

- Participants will be asked a series of questions (based on the Modified Deaconess Questionnaire) to assess their understanding of the research (i.e. prior to and/or during the BL1 evaluation). Staff will review participant responses and invite participants to ask questions prior to signing the consent form at BL1. Participants will e-sign the consent form in REDCap directly. Participants who do not have the ability to e-sign the consent form in REDCap (e.g., they do not have an electronic device) will be mailed a paper consent form. They will be instructed to sign the paper consent form and mail it back in a postage paid envelope. Once consent is obtained, additional screening activities will occur.

- Second baseline screening (BL2). Participants will meet with study staff who will answer questions, provide clarification and reaffirm consent verbally. Confirmation of verbal consent will be documented at BL2 in REDCap.

Documentation: Signed paper consent forms are secured in a locked filing cabinet at the Integrative Health Wellbeing Research Program offices at the University of Minnesota. Electronic consent forms are captured & stored in REDCap. Those who consent electronically will not have a paper consent form.

Revisions: Changes to the consent form may be initiated by staff, investigators, the DSMB or the IRB because of the need for clarification or changes to the protocols. Changes will be approved by the study PI and then submitted to the IRB for approval.

Training in Consent Procedures. In addition to the required institutional training in human subjects protection, prior to initiation of participant enrollment (and annually thereafter), all study staff will be required to undergo project specific human subjects training relevant to their role and be certified by the PI (or Co-I designee). Training will include: review of the key elements of the consent form including potential benefits, risks and alternatives to study participation, voluntary nature of participation, confidentiality, and disclosure of new information using standardized scripts. These will be reviewed and applied in practice scenarios. As part of the certification process, research staff will be required to participate in mock scenarios created by the PI or designees which address key elements of consent, including e-consent. Additional details are described in the manual of operations.

4.3.5 Randomization Procedures

Eligible participants will be randomized using the web-based Randomizing Module in REDCap.[12] We will use two strata for age (50-69 and 70+) and separate strata for sites. This will include "online sites/groups" for participants enrolled during specific time-intervals corresponding to treatment cohorts/classes after the transition to remote intervention delivery). Block randomization will be used with random sized blocks, varying between 4 and 6, and a 1:1 allocation ratio, to ensure group balance. Randomization will occur at the second, screening appointment (BL2) following inclusion/exclusion criteria confirmation (see 6.2.1 and 6.2.2).

5. STUDY INTERVENTIONS

5.1 Interventions, Administration, and Duration

We have used intervention mapping[9,57,58] to align evidence-based behavioral theories and strategies with project objectives and stakeholder needs (at the participant, facility and organizational levels).

5.1.1 Administration and Duration

All intervention sessions will take place remotely via HIPAA secure videoconference (i.e., Zoom).

The experimental and control interventions will be 8, 90-minute, remote group sessions over 8 weeks to meet the needs of middle to older age participants. This format is consistent with other YMCA programs, and will facilitate long term sustainability.

Both experimental and control interventions will include the following standard elements:

- An up to 90 minute orientation session prior to the start of the intervention sessions (i.e. Week 0) to get oriented to the video-conference environment. This will include practicing using the video conferencing application and tips for setting up one's space for an optimal experience. Trained study staff will also be available to assist participants in solving technical problems.
- Narrated videos presenting course concepts presented by a content expert. Videos will be interspersed with group discussions led by a YMCA staff facilitator and intervention specific activities (see Section 5.1.2 and 5.1.3).
- Standard informational materials (web-based and print workbook) aimed at increasing knowledge of national physical activity guidelines for older adults[1] as well as recommendations for activities to be done at home, in the community and through the YMCA. This will include short bouts of exercise

frequently throughout the day, as well as suggestions for a range of indoor and outdoor options including walking, jogging, dancing, aerobic exercise classes, and use of stationary aerobic machines appropriate for different fitness levels. Additional information will include participation tips to ensure optimal learning, comfort and safety (see section 7.3).

- Weekly reminder emails prior to each session along with instructions on how to participate in the study remotely (e.g., Zoom instructions)

5.1.2 Experimental Intervention: Mindful Movement

The Mindful Movement program is adapted from the widely used Mindfulness Based Stress Reduction Program (MBSR)[41], with which the project collaborators have considerable experience.[59-63] The program will focus on enhancing individuals' mindfulness capabilities and skills, specifically attention regulation, body awareness, emotional regulation, and shifts in self-perception,[42] by providing opportunities for education, practice, and social support in mindfulness practices to facilitate physical activity (see Figure 1 for Theoretical Framework).

The class format will include the following elements in addition to the standard elements described above: narrated videos of a trained mindfulness instructor presenting mindful movement related course concepts and guided meditations. Videos will be interspersed with facilitator led group discussions and mindful movement exercises.

Participants will be introduced to specific content including mindfulness practices and meditation techniques such as directed breathing and mindful awareness of thoughts and sensations during sitting, walking, lying down and other postures,[41,64] as well as other contemplative (e.g. mindful) physical movements. Evidence-based behavioral strategies will be incorporated into the session content including goal setting, self-monitoring, social support, relapse management, follow up prompts, and feedback.[10,34] Support resources include a workbook to help set and monitor achievable goals for daily mindfulness practices and physical activity that builds up to 300 minutes (in 10 minute bouts) per week. The narrated videos (presented in the class sessions), as well as customized mindful movement videos and mindfulness meditation recordings (ranging from 5-20 minutes to accommodate individual participant abilities and preferences) will be provided on a webpage to facilitate practice. Further details regarding delivery of the Mindful Movement intervention are provided in the manual of operations.

5.1.3 Control Intervention: Keys to Health & Wellbeing

We have adapted an existing education program "Keys to Health & Wellbeing to Healthy Aging" to use as the comparison intervention, which will be delivered in a similar manner as the experimental group to control for time and attention. The Keys to Health & Wellbeing program is adapted from a community-based educational program[19] used previously by members of our team as a comparison group for a mindfulness intervention.[63] The program provides participants useful content focused on ways to improve overall health. We have changed the name of the program to reflect our community partner's current messaging which de-emphasizes focus on age, and re-emphasizes wellbeing for all. Further, we have updated the program content to include recent scientific evidence and resources that include health related topics requested by older adults at the YMCA.

The class format will include the following elements in addition to the standard elements described above: narrated videos by a content expert presenting health related-related information. Videos will be interspersed with YMCA staff facilitator led group discussions and workbook exercises focused on things participants can do themselves to improve their overall health and wellbeing. Participants will be introduced to general health

content including information regarding self-care tips for common health conditions and maintaining their social and mental health.

Support resources include a workbook to help set and monitor achievable goals for applying the general health practices suggested by the program. The narrated videos (presented in the class sessions), as well as informational links, will be provided on a webpage to facilitate application of the information presented. Further details regarding delivery of the Keys to Health & Wellbeing intervention are provided in the manual of operations.

5.1.4 Intervention Training

YMCA staff will serve as intervention facilitators for the group interventions sessions. Facilitators will not be required to be certified in mindfulness (e.g. MBSR) or to have significant content expertise in the concepts related to the interventions (e.g. mindfulness and overall health and wellbeing) as this is not a reasonable expectation for YMCA staff. YMCA staff facilitators are expected to be trained sufficiently to understand the content to facilitate intervention sessions and to provide participant support in remote environments (e.g. videoconferencing). This approach has multiple advantages. First, it will facilitate consistency and fidelity across study cohorts and prevent cross-contamination (see section 5.2.2 below). Secondly, by refraining from a program that requires extensive training and certification of facilitators (which is what is required for MBSR instructor certification), there is a greater likelihood that the intervention can be adopted and sustained in YMCA settings.

The PI, her designees and experienced content experts, will train YMCA staff to facilitate the intervention sessions to ensure participant safety and methodological rigor, and enhance long- term feasibility and sustainability at the YMCA. Further details regarding intervention training are provided in the manual of operations.

Training of YMCA staff facilitators will include:

- Human subjects protection and HIPAA training as required by the University of Minnesota
- Study specific human subjects protection training
- Review of rationale for experimental and control interventions and the importance of maintaining equipoise (note: blinding of facilitators is not possible)
- Facilitation of interventions including review of key concepts and practices, and practical application through mock scenarios

5.2 Handling of Study Interventions

5.2.1 Accountability Records

For each session, facilitators will complete the intervention administration form in REDCap. The form documents participant attendance, adverse events, and includes a checklist of the elements covered in sessions (see Section 6.2.4) and any reasons for facilitators deviating from protocol. This will be reviewed by study staff and presented in a summary format to the investigators for review on a routine basis.

5.2.2 Intervention Fidelity

Intervention fidelity will be assessed by the PI's designees using fidelity instruments that address whether or not

content elements of intervention sessions were addressed, facilitator enthusiasm and other factors that could affect outcomes. At least 15% of the sessions will be assessed for fidelity. We will use adapted fidelity instruments used in previous studies. Fidelity of intervention delivery will also be assessed by review of session checklists completed by the facilitators. Fidelity procedures and instruments are further described in the manual of operations.

5.2.3 Intervention Logistics (Group Size, Cohort Management)

We anticipate the minimum class size will be 8 persons and the maximum will be 16 (which approximates existing YMCA and other mindfulness programs). However, classes may proceed with less than 8, or more than 16 persons. The PI will make the final determination as to whether or not a smaller or larger class is appropriate.

5.3 Concomitant Interventions

5.3.1 Allowed Interventions

Participants are allowed and encouraged to take part in physical activity and other interventions as they normally would, that are necessary for managing their health.

5.3.2 Prohibited Interventions

Participants will be excluded from participating in the study if at the time of enrollment, they are participating or plan to participate over the 8-week intervention period in the following: formal educational programs similar in terms of content (e.g. mindfulness based, general health), format (e.g. group sessions, facilitator led), and length of delivery (1.5 hours per week x 4-8 weeks) to the experimental and control interventions offered in the study.

5.4 Adherence Assessment

Adherence to the intervention regimen is defined as follows:

- ≥70% of enrolled participants adhere to the interventions (defined as attending 6/8 sessions, as measured by the YMCA staff facilitator and entered on the intervention administration form).
- ≥70% of enrolled participants report participation in assigned intervention-specific 'home practices' ≥3 days per week (as measured on the post-intervention W9 self-report questionnaire)
- ≥80% of enrolled participants satisfied with experimental and control interventions (as measured on the post-intervention W9 self-report questionnaire)

6. STUDY PROCEDURES

The Schedule of Evaluations is presented in Table 1.

6.1 Schedule of Evaluations

TABLE 1. SCHEDULE OF EVALUATIONS for RCT Participants						
	Initial Screen	BL1	BL2	Intervention Sessions 1-8	W9 Follow-Up	W26 & W52 Follow Up
Informed consent	x	x	x			
SRQ Demographics	x	x				
SRQ Health characteristics	x	x				
Anthropometrics		x				
Accelerometer		x	x		x	x
SRQ Quality of life		x			x	x
SRQ Exercise self-efficacy		x			x	x
SRQ Exercise expectations		x			x	x
SRQ Mindfulness			x		x	x
SRQ Wellbeing			x		x	x
SRQ Bodily pain		x			x	x
SRQ Physical activity		x			x	x
SRQ Social connectedness & assurance			x		x	x
SRQ Intervention satisfaction					x	x
SRQ Home practice and engagement					x	x
SRQ Qualitative data	x	x	x		x	x
SRQ Interoceptive Awareness			x		x	x
SRQ COVID-19 Impact/Zoom	x		x		x *	x *
SRQ Working Alliance Inventory					x	
SRQ Telehealth Usability Questionnaire					x	
Inclusion/Exclusion Criteria	x	x	x			
Enrollment/Randomization			x			
Intervention Administration Form				x		
Intervention Fidelity Form				x		
Adverse events (AE)				x	x	x
Study Completion Form						x
KEY: BL=baseline; W=week; SRQ=Self-report questionnaire; MVPA=moderate-vigorous physical activity; SA=sedentary activity. *Impacted participants will be queried.						

6.2 Description of Evaluations

Table 1 summarizes the screening and follow up evaluations (participant-level subjects).

6.2.1 Screening Evaluation

During the screening process and prior to additional study visits post enrollment (if applicable), participants will be given instructions on how to participate in the study remotely. These instructions will include instruction sheets and tutorial videos for how to use videoconferencing applications. These will be sent via email, mail and/or reviewed during screening evaluations.

Initial Screen. Potential participants will be initially screened for eligibility using direct electronic data entry in REDCap administered to the participant through a web-based survey interface or a phone screen with trained study staff. Both processes will include an introduction to the study and participants will be required to provide verbal or electronic *informed consent* (see 4.3.4). Participants will be asked questions pertaining to *inclusion/exclusion criteria*: age, self-reported physical activity levels, pregnancy, medical restrictions to increasing physical activity, contraindications to mindfulness practices (serious mental health condition, suicidality, substance abuse, PTSD and seizure disorders), and terminal illness. To assess which participants will need devices/equipment to participate, we will ask about electronic technology, internet access and technology related capabilities and needs. Eligible individuals will be scheduled for a first baseline evaluation. They will be asked to let study staff know prior to their BL1 visit if there are changes to their health status that may affect their eligibility. The manual of operations describes circumstances and procedures for additional screening.

BL1 (first baseline evaluation). The first baseline evaluation will take place up to 90 days after the initial screen described above. This evaluation will be conducted via Zoom and/or telephone.

- Trained study staff will perform *informed consent* (see Consent Procedures)
- The Folstein Mini-Mental Status Examination (MMSE) will be administered to participants if cognitive impairment is suspected (e.g., repeating questions, unable to respond to/follow basic instructions)
- *Inclusion/exclusion criteria* will be confirmed using eligibility checklists directly entered in REDCap by study staff.
- Self-report questionnaires will provide baseline assessment of *demographic* and *health characteristics* along with self-reported outcome questionnaires (*SRQ*s, see Section 9.5).
- Study staff will collect *anthropometric* measurements by participant self-report; waist size will also be captured to fit individuals with an *accelerometer,* which is required for the baseline objective outcome measurement of physical activity.
- Participants eligible for BL2 will be mailed accelerometer with wear and return mailing instructions (a pre-paid postage return envelope will be provided).

BL2 (second baseline evaluation). A second baseline evaluation will take place 7-28 business days after BL1. This evaluation will be conducted via video/teleconference. Study staff will

- Confirm consent and eligibility criteria
- Administer BL2 participant survey if not completed prior to BL2
- Inclusion/exclusion criteria will be confirmed using eligibility checklists completed by study

staff via direct electronic entry into REDCap.

- Final eligibility determination will occur following inclusion/exclusion criteria confirmation (see sections 4.3.5 and 6.2.2).

6.2.2 Enrollment, Baseline, and Randomization

Enrollment. Enrollment is defined as occurring at the date of randomization at which point all of the screening criteria are met and the individual has agreed to participate.

Baseline Assessments. The following baseline assessments will be performed prior to randomization and are summarized in Table 1.

Self-report questionnaires (*SRQs*) will be used to collect the following baseline variables. These are distributed between BL1 and BL2 (see Table 1) to reduce burden on participants.

- Baseline demographics. Participants will report ethnicity, race, employment status, marital status, education, YMCA membership status, household income, use of ambulatory devices (e.g. cane), experience with study interventions, YMCA membership status on the self-report questionnaire.
- Anthropometrics. Height and weight collected via participant self-report
- Baseline health characteristics including current health conditions and smoking history on the self-report questionnaire.
- Baseline SRQ outcome measures of *quality of life, exercise self-efficacy and expectations*, *mindfulness*, *wellbeing*, *bodily pain*, *physical activity*, *social connectedness and assurance*, COVID-19 impact, *interoceptive awareness*, and *intervention satisfaction* (see Section 9.5 for description of these outcome measures).Accelerometers will be used to collect objective physical activity outcomes (see 9.5); accelerometers will be mailed to qualified participants following the first baseline appointment. Participants will mail the devices back in postage-provided envelopes.

Randomization. Prior to study enrollment, the study's statistician will assign a member of his staff to create the random allocation tables according to the allocation plan (see Section 9.2), which will be administered using the randomization module in REDCap. Randomization will occur at BL2 after completion of all screening and baseline evaluations, and inclusion and exclusion criteria are verified (see Sections 4.3.5, 6.2.1 and 6.2.2). As each participant becomes eligible, project staff responsible for enrolling participants will access REDCap to obtain the electronically generated random assignment for that participant. All study personnel will be blinded to upcoming assignments. Enrolled individuals will commence their allocated intervention up to 14 business days post randomization.

6.2.3 Blinding

Blinded Personnel: The PI, select co-investigators, and the study statistician will be blinded until the database is locked. The study's statistician will assign a member of his staff to create the random allocation tables according to the allocation plan, which will be administered using the randomization module in REDCap.

Unblinded Personnel: The Project Director and Coordinator, YMCA staff facilitators, and data manager will not be blinded to study interventions. The Project Director and Coordinator facilitate

scheduling and tracking of participants to ensure timely participation in intervention and other study activities. The YMCA staff facilitators conduct the remote intervention sessions. Unblinded personnel will not participate in data preparation or analyses.

Individuals authorized to break the blind: The PIs and their investigator designees are authorized to break the blind.

Circumstances for breaking the blind: This will occur when it is in the participants' safety- related interest. The primary example is a reportable adverse event.

6.2.4 Intervention & Follow Up

- **Pre-Intervention Session 0 (Week 0): Introduction to Zoom environment**
  - Documentation of attendance and elements covered in session (using the *intervention administration form*) in REDCap
  - Adverse events (using the *adverse event form*) in REDCap, if applicable

- **Intervention Sessions 1-8 (weeks 1-8)**
  - Documentation of attendance and elements covered in session (using the *intervention administration form*) in REDCap
  - Adverse events (using the *adverse event form*) in REDCap, if applicable
  - *Note at Week 8 only: distribution of *accelerometer* (see Week 9 Follow-Up)

- **Week 9 Follow-Up (week 9)** (-7 / + **15 business days)**
  - Return of *accelerometer* for measurement of physical activity (see Section 9.5)
  - Completion of *self-report questionnaire* (see Section 9.5)
  - Adverse Events (using the *adverse event form)* in REDCap, if applicable

- **Weeks 26 Follow-Up (-7 business days, + 60 business days)**
  - Return of *accelerometer* for measurement of physical activity (see Section 9.5)
  - Completion of *self-report questionnaire* (see Section 9.5)
  - Adverse Events (using the *adverse event form)* in REDCap, if applicable

6.2.5 Final Evaluation

- **Week 52 Follow-Up Visit/Final Evaluation** (week 52+/- **15 business days)**
  - Return of *accelerometer* for measurement of physical activity (see Section 9.5)
  - Completion of *self-report questionnaire* (see Section 9.5)
  - Adverse Events (using the *adverse event form*) in REDCap, if applicable

- *Study completion form* in REDCap

6.2.6 Additional Evaluation Related to Hybrid Effectiveness/Implementation Design and RE-AIM and PRECIS Frameworks

The incorporation of the hybrid effectiveness-implementation designs and RE-AIM framework,[18,55] necessitate additional data collection, which is described below.

- As part of *Aim 3*, we will gather contextual information using qualitative methods (via open-ended surveys, interviews and field notes) related to barriers and facilitators, intervention satisfaction (at participant and facility levels), protocol confidence (facility level), and intervention relevance, practicality, and affordability (organizational levels). These data will be used to inform interpretation of results regarding the Mindful Movement program's effectiveness and creation of a web-based toolkit (including Manuals of Operations, staff training materials, participants' informational materials, etc.) to facilitate dissemination of program to other sites.

7. SAFETY ASSESSMENTS

7.1 Expected adverse events by intervention

The inclusion and exclusion criteria and adverse monitoring procedures, have been developed to minimize the risk of adverse events.

Mindful Movement Program. The probability of risks occurring as a result of mindfulness based interventions is considered very low. There is a very small chance of the following adverse events occurring:

- Aggravation of PTSD symptoms associated with mindfulness and meditation practices
- Aggravation of mental health symptoms associated with mindfulness and meditation practices
- Cardiac events associated with increasing physical activity
- Minor physical discomfort associated with mindfulness and meditation practice positions and postures
- Seizures associated with mindfulness and meditation practices
- Short-lasting muscle and joint soreness associated with recommended physical activity
- Social anxiety associated with participating in group sessions

Keys to Health & Wellbeing Program. The probability of risks occurring as a result of general education programs is considered very low. There is a possibility of the following adverse events occurring:

- Cardiac events associated with increasing physical activity
- Short-lasting muscle and joint soreness associated with engagement in recommended physical activity

- Social anxiety associated with participating in group sessions

7.2 Specification of Safety Parameters

Safety of participants will be addressed in the eligibility screening that identifies persons that have contraindications to the interventions and increasing physical activity. Once enrolled, participants will be queried regarding the occurrence of adverse events (active surveillance) and reminded to report them to study staff should they occur (passive surveillance).

7.3 Methods and Timing for Assessing, Recording, and Analyzing Safety Parameters

Our methods and timing for assessing recording and analyzing safety parameters are described below. Mindfulness based interventions are generally presumed to be associated with minimal adverse events. However, similar to other fields, systematic adverse event reporting has been inadequate and the presumption of safety is not well informed by rigorous scientific evidence.[65] This is confirmed by recent systematic reviews of mindfulness based interventions noting a lack of studies in which systematic assessment of adverse events occurred.[66,67] Most mindfulness based intervention related adverse events are associated with meditation. There have been case reports and observational studies of mental health related symptoms including anxiety, panic, traumatic memory re-experiencing, and others.[65]

Given the lack of rigorous evidence regarding mindfulness based intervention related adverse events, and to ensure participant safety, we have designed our inclusion and exclusion criteria to protect individuals in which mindfulness based interventions are considered contraindicated (e.g. active PTSD, suicidality, severe mental health disorders; see Section 4.2). This is based on recommendations from The University of Massachusetts Center for Mindfulness[64] and our project's expert consultants. We will also train staff to be aware of signs of potential distress, and how to address (this is detailed in the manual of operations). Further, we will use active adverse event surveillance methods in addition to passive surveillance (see Section 7.4).

In addition we will provide:

- Explicit instructions at multiple points to participants regarding what they should do if they don't feel comfortable sharing in the group. This includes reviewing with participants:
    - It is important to take care of themselves and monitor how much information, if any, they are comfortable sharing;
    - It is fine to leave the session environment as needed;
    - It is okay to opt out or pass on any session activities, including discussions. This can be done by sending a private message to the facilitators within session or saying "pass" if called upon.

  These instructions are provided throughout the program:
    - In writing, in the workbook, which participants review with facilitators at the first session, and then are encouraged to read and use each week.
    - Verbally, by session facilitators, at the beginning of each session (as detailed in the manual of operations).
    - Verbally, by session facilitators, prior to any group discussions within the sessions (as detailed in the manual of operations).

In addition, participants are routinely encouraged to let the study team know if they have any concerns or hesitations about participating in the sessions. This includes:

- Each week enrolled participants are sent a reminder email about their upcoming intervention session. The study team will include a note encouraging participants to contact the PI/study team (i.e., respond to the email or call the study number (included in the email)) if they have any concerns about the upcoming session. All participant emails are acknowledged by a member of the study team and responded to accordingly. If a participant indicates they feel uncomfortable participating in group discussions, the session facilitator will be informed and the participant will not be called upon.

7.4 Adverse Events and Serious Adverse Events

Prior to initiation of research activities, all project personnel engaged in human subject research will be required to complete CITI Program training in HSR and every 3 years thereafter. In addition, all project personnel will receive training in the application of HSR principles as they directly apply to the project. These will be delivered via live sessions conducted by the PI, designated Co-Is, and Project Director. They will be conducted prior to commencing related activities, and at routine intervals through the life of the project (no less than annually). Content will focus on human subjects related study protocols and procedures.

YMCA staff, will not be involved in assessing, evaluating and reporting, adverse events (AEs). Instead, participating subjects will be instructed to contact the PI and/or the Project Director (or designee) with information about their event. The PI and/or the Project Director (or designee), will contact the DSMB Safety Officer, who will adjudicate the event using a standardized form in REDCap. The PI and/or the Project Director (or designee) may assist with adjudication. Additionally, YMCA staff made aware of AEs will be trained to notify the PI and Project Director in a timely manner using standardized study forms.

7.4.1 Definitions

Adverse Event. An adverse event (AE) is any untoward medical occurrence in a subject during participation in the clinical study or with use of the experimental agent being studied. An adverse finding can include a sign, symptom, abnormal assessment (laboratory test value, vital signs, electrocardiogram finding, etc.), or any combination of these regardless of relationship to participation in the study.

Unanticipated Problems. The Office for Human Research Protections (OHRP) considers unanticipated problems involving risks to subjects or others to include, in general, any incident, experience, or outcome that meets **all** of the following criteria:

- Unexpected in terms of nature, severity, or frequency given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;
- Related or possibly related to participation in the research ("possibly related" means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and

- Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

Serious Adverse Events. A serious adverse event (SAE) is one that meets one or more of the following criteria:

- Results in death
- Is life-threatening (places the subject at immediate risk of death from the event as it occurred)
- Results in inpatient hospitalization or prolongation of existing hospitalization
- Results in a persistent or significant disability or incapacity
- Results in a congenital anomaly or birth defect

7.4.2 Time Period and Frequency

Collection and Time Period. Unanticipated problems will be recorded in the data collection system throughout the study. The PI, or designee, will record all reportable events with start dates occurring any time after randomization until 7 (for non-serious AEs) or 30 days (for SAEs) after the last day of study participation. At each study visit or data collection time point, the investigator, or designee, will inquire about the occurrence of AE/SAEs since the last visit/questionnaire. Study related AE/SAEs will be followed to stabilization/resolution post end of study participation.

7.4.3 Characteristics of an Adverse Event

Relationship to Study Intervention. To assess relationship of an event to study intervention, the following guidelines are used:

- Related (Possible, Probable, Definite)
- The event is known to occur with the study intervention.
- There is a temporal relationship between the intervention and event onset.
- The event abates when the intervention is discontinued.
- The event reappears upon a re-challenge with the intervention.
- Not Related (Unlikely, Unrelated)
- There is no temporal relationship between the intervention and event onset.
- An alternate etiology has been established.

Expectedness. The Safety Officer, will be responsible for determining whether an SAE is expected or unexpected. The PI and/or designee may assist with determination, as needed. An adverse event will be considered unexpected if the nature, severity, or frequency of the event is not consistent with the risk information previously described for the intervention in the consent form.

Severity of Event. The following scale will be used to grade adverse events:

- Mild: transient or minimal symptoms; no change in activity level; no therapy or only symptomatic therapy required.

- Moderate: symptomatic; moderate change in activity level; minimal decrease in social activities; specific therapy required.
- Severe: incapacitating = ≥ 24 hours of any of the following: loss of work, bed rest, decreased social activities.
- Serious: results in death; life threatening; requires inpatient hospitalization; results in persistent or significant disability; congenital anomaly or birth defect.

7.5 Reporting Procedures

7.5.1 Unanticipated Problem Reporting

Incidents or events that meet the OHRP criteria for unanticipated problems require the creation and completion of an unanticipated problem report form. OHRP recommends that investigators include the following information when reporting an adverse event, or any other incident, experience, or outcome as an unanticipated problem to the IRB:

- Appropriate identifying information for the research protocol, such as the title, investigator's name, and the IRB project number;
- A detailed description of the adverse event, incident, experience, or outcome;
- An explanation of the basis for determining that the adverse event, incident, experience, or outcome represents an unanticipated problem;
- A description of any changes to the protocol or other corrective actions that have been taken or are proposed in response to the unanticipated problem.

To satisfy the requirement for prompt reporting, unanticipated problems will be reported using the following timeline:

- Unanticipated problems that are serious adverse events will be reported to the IRB, Independent Safety Monitor(s), and NCCIH within 7 days of the investigator becoming aware of the event.
- Any other unanticipated problem will be reported to the IRB, Independent Safety Monitor(s), and NCCIH within 14 days of the investigator becoming aware of the problem.
- All unanticipated problems should be reported to appropriate institutional officials (as required by an institution's written reporting procedures), the supporting agency head (or designee), and OHRP within one month of the IRB's receipt of the report of the problem from the investigator.

7.5.2 Adverse Event Reporting of Non-IND Studies

SAEs that are unanticipated, serious, and possibly related to the study intervention will be reported to the DSMB, IRB, and NCCIH in accordance with requirements.

- Unexpected fatal or life-threatening AEs related to the intervention will be reported to the NCCIH Program Officer, and Independent Safety Monitor(s) within 3 days of the investigator becoming aware of the event. Other serious and unexpected AEs related to the intervention will be reported within 7 days.
- Anticipated or unrelated SAEs will be handled in a less urgent manner but will be reported to the Independent Safety Monitor(s), IRB, and other oversight organizations in accordance with their requirements and will be reported to NCCIH on an annual basis.
- All other AEs documented during the course of the trial will be reported to NCCIH on an annual basis by way of inclusion in the annual report and in the annual AE summary which will be provided to NCCIH and to the Independent Monitors. The Independent Safety Monitor(s) Report will state that all AEs have been reviewed.

7.5.3 Reporting of Pregnancy

It is unlikely, but possible, given the age range of study participants that pregnancy may occur. Participants will be queried prior to enrolling regarding pregnancy status, and assessed for the study's inclusion and exclusion criteria. Medical restrictions (of any type) for increasing physical activity are exclusionary for all participants.

7.6 Safety Monitoring

A Data Safety and Monitoring Board has been assigned to perform independent study monitoring.

8. INTERVENTION DISCONTINUATION

8.1 Investigator Initiated Discontinuation

If a participant experiences a change in their health status so they no longer meet the inclusion and exclusion criteria, or if new information arises suggesting the research is unsafe for them to participate in the intervention, the PI will withdraw them from the research without their consent. It is noted that that this occurrence is unlikely, given the interventions in this study are considered to be low risk. Participants will continue to be followed up for outcomes with their permission. In the event that the participant's change in health status is temporary and they are able and willing to resume participation in the intervention, the participant will be administered relevant questions from the screening evaluations; if the participant meets the inclusion criteria, they will be allowed to continue with the intervention.

8.2 Participant Initiated Discontinuation

Participants will be asked to submit in writing to the PI (e.g. signed and dated letter or email) if they want to withdraw from the study. For reporting purposes, research staff will inquire about reasons for their withdrawal. Participants will also be asked if they're willing to complete self-report questionnaires, and participate in objective data collection (e.g., accelerometer) as a means of collecting primary and secondary outcomes. If they refuse, participants will not be contacted by the study team. A formal letter will be sent by the PI, or designee, indicating receipt of their request for withdrawal and additional provisions around data collection, if applicable. The letter will reiterate our appreciation for their participation to date and remind participants that their withdrawal will not affect their relationship with the university or the YMCA. Regulatory bodies will be provided summary information related to attrition (e.g., losses to follow-up, withdrawals etc.). Participants will not be named.

9. STATISTICAL CONSIDERATIONS

9.1 General Design Issues

The reliability and validity of primary and secondary outcome measures are described in Section 9.5.2 below.

9.1.1 Hypotheses

Our ***primary hypothesis*** is that there will be a significant advantage ($\geq$56 minutes) in terms of the primary outcome measure, weekly minutes spent in $\geq$10 minute bouts of MVPA for Mindful Movement over the Keys to Health & Wellbeing.

Our **secondary hypotheses** are:

- There will be significant advantages of Mindful Movement over Keys to Health & Wellbeing in terms of the secondary objective outcome measures of time spent per week in $\geq$ 10 minute bouts of MVPA; time spent per week in MVPA and sedentary activity; and steps per day
- There will be significant advantages of Mindful Movement over Keys to Health & Wellbeing in terms of the secondary self-reported outcomes: quality of life, exercise self-efficacy and expectations, mindfulness, wellbeing, bodily pain and physical activity

- There will be no significant advantages of Mindful Movement over Keys to Health & Wellbeing in terms of the secondary self-reported outcomes of social connectedness and assurance, and intervention satisfaction.

9.2 Sample Size and Randomization

9.2.1 Sample Size

The sample size is calculated based on the primary outcome of change in minutes/week spent in ≥10-min bouts of MVPA between baseline and post-intervention (9 weeks). In the R21 pilot study, we observed a standard deviation of 57 min for ≥10-min bouts of MVPA at week 9. This is lower than what we originally anticipated from the existing literature (120 min)[73 37] which provided the best available estimate at the time the original proposal was written. These studies however are not ideal representations of the interventions and population for the proposed study. Recognizing the standard deviation estimate from the pilot study is based on a limited number of participants (n=29), we performed 5000 bootstrap replications of our pilot sample and used the upper end of the distribution as a conservative variability estimate. This yielded a standard deviation estimate of 85 minutes, which when used as an estimate at baseline and week 9 will allow for detection of a medium effect size (0.50) difference between groups, of approximately 40 minutes in 182 participants (assuming alpha = 0.05, power = 0.85, correlation (ρ) between baseline and week 9 measures of 0.54, 10% loss to follow up; STATA, StataCorp. 2015 Stata Statistical Software: Release 14. College Station, TX: StataCorp LP). Varying the strength of correlation between the baseline and week 9 measures changes the detectable differences between groups from 31 (ρ = 0.7) to 47 minutes (ρ = 0.3). Data from the R21 pilot study (ρ = 0.54) was used to estimate the correlation between baseline and week 9 MVPA measures.

9.2.2 Randomization/Treatment Assignment Procedures

Eligible individuals will be randomized using the web-based Randomizing Module in REDCap by trained study staff masked to upcoming treatment assignments. Randomization will be stratified by site (including a "online sites/groups" for participants enrolled during specific time-intervals corresponding to treatment cohorts/classes after the transition to remote intervention delivery) and age (50-69 and 70+). Block randomization will be used with random sized blocks, varying between 4 and 6, and a 1:1 allocation ratio, to ensure group balance. The study's statistician will assign a member of his staff to create the random allocation tables according to the allocation plan, which will be administered using the randomization module in REDCap. Investigators will be blinded to individual participants' group assignment until after the analysis by the study statistician is complete. Breaking the blind will occur if, in the event of a serious adverse event, expected or unexpected, it is necessary to protect patient safety and/or determine the relatedness of the event to the intervention. In these instances, the Project Director (who must remain un- blinded to coordinate individuals' participation) will provide the PI or designee the individual's specific intervention assignment. The breaking of the blind will be documented by the Project Director, and will be reported to all monitoring bodies as required.

9.3 Definition of Populations

All analyses will be conducted using the intention to treat principle. That is, all participants will be analyzed in the group to which they were randomized regardless of outside care, adherence to protocols, or compliance with follow-up.

9.4 Interim analyses and Stopping Rules

Interim analysis: No interim analysis is planned because of the very low risk of serious study- related adverse events. The DSMB reserves the right to request outcomes data and perform analysis at any time with NCCIH approval. The study statistician will provide the group assignment code to the DSMB upon request of data.

Stopping rules: There are no stopping rules. The study can be stopped by the IRB and DSMB in accordance with federal regulations (e.g., in the event of unexpected adverse events or failure to follow study protocols appropriately).

9.5 Outcomes

For Aims 1 and 2: Objective outcomes of physical activity and other secondary outcomes will be used to assess the relative effectiveness of the interventions; these outcomes are described below.

Primary physical activity outcome:

- Minutes/week spent in ≥10-min bouts of MVPA between the 7-day baseline and the 7- day end of the intervention period (9 weeks).

Secondary physical activity outcomes:

- Minutes/week spent in ≥10-min bouts MVPA from baseline to 26 and 52 weeks;
- Minutes/week spent in MVPA and sedentary activity (SA) from baseline to 9 weeks
- Step counts/day.

The physical activity outcomes will be collected by participants wearing the Actigraph GT3X+ accelerometer (hip placement). A full description of accelerometer data collection is provided in the manual of operations.

Data will be collected for seven consecutive days at baseline and weeks 9, 26 and 52.[74] The Actigraph captures integrated acceleration information as an activity count (e.g. counts per minute (CPM)), and provides an objective estimate of vertical bodily movement.[75-77] Accelerometers are recommended by authors of systematic reviews to improve the rigor of physical activity based research.[78] They offer a more valid measure of physical activity than self- report measures which tend to provide over-estimates.[79] Accelerometers are appropriate for use in older populations[80,81] and are a method of data collection for which the investigators have considerable experience.[81-83]

We will use the following thresholds to characterize levels of activity: MVPA (vector magnitude ≥2,752 CPM) and SA (vector magnitude <200 CPM). [108, 109, 110] In addition, we will conduct sensitivity analyses to assess the impact of using other thresholds for MVPA (≥1,952 CPM, ≥ 3 METs) [84,85] and SA (<100 CPM, <1.5 METs).7

Secondary self-report measures

- Quality of life will be measured using the Euroqol 5D (EQ5D), which has sound reliability and validity,[86,87] and has been used in exercise and physical activity studies of older adults.[37,81] The EQ5D captures five dimensions of health (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression) over 5 levels (no problem, slight problem, moderate problem, severe

problem, unable to perform/extreme problem). The advantage of the EQ5D over other instruments is its brevity and ease of use.

- Exercise self-efficacy will be measured using the Self-Efficacy for Exercise (SEE) scale[88] a reliable and valid measure of exercise self-efficacy tested in older adult populations. Individuals are asked to rate their confidence in their ability to exercise in each of nine situations. Confidence ratings range from 0 (not confident) to 10 (very confident).
- Exercise expectations will be measured using the Outcome Expectations for Exercise-2 (OEE-2), a 13-item instrument focused on beliefs about the positive and negative physical and mental health benefits of exercise.[88] Responses range from 1 (strongly agree) to 5 (strongly disagree). The OEE-2 has been shown to be reliable and valid in older individuals.[88]
- Dispositional mindfulness will be measured with the Mindful Attention Awareness Scale (MAAS), which has demonstrated good internal consistency, reliability, construct validity, and responsiveness.[89,90] The scale is comprised of 15 items measured on a 6-point scale (1=almost always, 6=almost never) which when combined represents a single construct of dispositional mindfulness.
- State mindfulness will be measured using the Frieberg Mindfulness Inventory (FMI) to assess mindfulness skill.[91,92] The FMI addresses 14 items with a four-point response scale (1=rarely, 4=almost always), and has been found to have good internal consistency and convergent validity.[92]
- Wellbeing will be measured using the brief 8-item Flourishing Scale[93] assessing perceived success in relationships, self-esteem, purpose, etc. It is psychometrically sound and provides a single psychological wellbeing score.
- Bodily pain (including musculoskeletal pain) is a common occurrence with aging[32,94] and may affect engagement in physical activity.[95,96] Participants will be asked to rate their pain in the past 7 days in four bodily areas (legs including foot, ankle, knee and hip; arm including hand, wrist, elbow and shoulder; back including neck, mid and low back; and other) on an 11-box numerical rating scale (0=no pain, 10=the worst pain possible). [97]
- Physical activity (self-reported) will be measured using questions adapted from the International Physical Activity Questionnaire (IPAQ) which has been tested for reliability and validity, and used in older populations.[98] The IPAQ is a nine- item instrument addressing days/week and minutes/day spent on physical activity in the past 7 days. While physical activity self-report measures tend to provide over-estimates,[79] we will explore the extent to which this is true for the population. Self-report methods are less burdensome and costly, and would be better suited for routine evaluations in the long-term.
- Social connectedness and social assurance will be measured using two 8-item questionnaires, and a six item scale (strongly agree, strongly disagree).[99]
- Interoceptive Awareness will be measured using the Multidimensional Assessment of Interoceptive Awareness survey instrument (V2). [111] To reduce participant burden, we will limit measurement to four subscales which focus on domains covered in our mindfulness intervention: noticing (which includes awareness of uncomfortable, comfortable, and neutral body sensations); attention regulation (including the ability to sustain and control attention to body sensations); emotional awareness (including awareness of the connection between body sensations and emotional states); and self-regulation (including ability to regulate distress by attention to body sensations).

- Intervention satisfaction will be collected using a question that has participant's rate their overall satisfaction ranging from completely satisfied to completely dissatisfied.
- Adherence to home practice will be collected using a question that asks the average number of days per week that participants completed the recommended home practices.
- Adverse events will be collected through both active and passive surveillance. For active surveillance, participants will be asked to report side effects by choosing from a list generated from previous studies including exercise and older adults[81,100,101] and known potential risks of mindfulness interventions.[64] Participants will rate the bothersomeness of these adverse events on an 11-box scale (0=not at all bothersome, 10=extremely bothersome). For passive surveillance, participants will be instructed to contact the PI or Project Director (see Section 7).
- COVID-19 Impact and Zoom: Covid-19 impact may be asked at baseline. Enrolled participants may be queried following the intervention phase and at long-term follow-up data collection points (e.g., W26 and W52, per the study protocol). Future enrolled participants/cohorts may not be impacted, and thus the following questions will not be relevant. The PI and study team, with the study funder (NCCIH), will determine which cohorts of participants are affected by the COVID-19 pandemic and which participants will participate in the intervention remotely via Zoom; these individuals will be asked to answer questions related to pandemic impact on physical activity (5-item Likert scale), satisfaction with Zoom (7-point Likert scale) and advantages/disadvantages of Zoom using open-ended questions.
- Working Alliance Inventory (WAI): We will measure participants' views of the working alliance with facilitators using an adaptation of the Working Alliance Inventory (WAI) Short Form C.[113] The WAI is composed of three subscales—bond, task, and goal—which are important aspects of the therapeutic alliance.
- Telehealth Usability Questionnaire (TUQ): Participants' views of the remote intervention delivery platform will be assessed using items adapted from the Telehealth Usability Questionnaire.[112] To reduce burden, we will limit measurement to items related to the perceived usefulness, ease of use, learnability, interface quality, interaction quality, and reliability of the remote delivery platform.

For *Aim 3:* we will collect participation flow data (e.g. enrollment, participation, session attendance, follow up rates, etc.) and qualitative data (using qualitative surveys and field notes) to gather the necessary contextual information related to barriers and facilitators, intervention satisfaction (at participant and facility levels), protocol confidence (facility level), and intervention relevance, practicality, and affordability (organizational levels).

9.6 Data Analyses

Outcomes data will be analyzed by a statistician masked to study group assignment.

For Aim 1 to determine the relative effectiveness of Mindful Movement versus Keys to Health & Wellbeing in a Randomized Controlled Trial (RCT, n=182) we will conduct the following analyses.

For the primary physical activity outcome: time spent per week in ≥ 10 minute bouts of moderate vigorous physical activity (MVPA) at 9 weeks;

- An intention-to- treat analysis will be used including all participants with at least one outcome measurement in the analysis.
- A mixed-model regression will be used for the primary outcome measure. The ***primary analysis*** will evaluate change in weekly minutes spent in ≥10-min bouts of MVPA using mixed model longitudinal regression (PROC MIXED in SAS) version 9.3 (SAS Institute, Cary, North Carolina). The analysis, using the baseline value as outcome, will determine between-group differences in study outcomes post-intervention period (9 weeks, the primary outcome) and at the 26 and 52 week follow up points. Clinical and demographic variables showing group differences at baseline will be used as covariates in the analysis if they are at least moderately correlated with changes in outcomes.[105] A strength of the mixed model analysis approach is the flexibility when data is missing at random.[106]
- Efforts will be made to minimize the amount of missing data, but if missing data is present, the pattern of missing data will be determined to select the most appropriate form of analysis. Imputation strategies will be considered as sensitivity analyses if data are missing not at random.[107]

The analysis will account for the correlated nature of repeated outcomes inherent in the longitudinal trial design. The variance-covariance structure that best fits the data will be used; most likely this is an AR(1) structure. From this model an overall intervention effect will be estimated (pooled across time points), as well as intervention effects at each of the post-intervention follow-up time points.[105] As a result of the pandemic, the structure of the trial has changed. Previously participants were screened at four locations (clinical sites), and randomized to either intervention or control, with the intervention carried out in group sessions within each location. In the present configuration, participants are (as before) randomized to treatment or control, but the intervention is carried out in virtual groups in specified time intervals by intervention teams that are not physical location-specific. Outcome data will be analyzed by treatment group as before, but we will include a stratifying factor: an indicator variable for the virtual group in a specified time interval to which participants are assigned (i.e. group 1, 2, 3, 4….etc.). The main analytic model will include a random effect to account for clustering due to the group intervention.

- To facilitate interpretation of trial results, an analysis will be done of group differences (including 95% confidence intervals) in proportions of participants who experienced at least a 25%, 50%, or 75% increase in minutes/week spent in ≥10-min bouts of MVPA at week 9.

For Aim 2, to determine the relative effectiveness of the two interventions as measured by secondary physical activity and self-report measures we will employ the same data analytic methods described above. In addition, we will conduct secondary analyses in response to the COVID-19 pandemic. These analyses will evaluate overall and between-group changes in objective and self-reported physical activity, key study implementation measures (e.g., intervention adherence, loss to follow-up, adverse events), and other secondary self-reported outcome measures by enrollment cohort. We anticipate 4 or more time partition strata that can be used 'as is' or grouped and included as a fixed effect in analytic models (e.g., 1. prior to MN state COVID response measures, 2. MN state 'social distancing' recommendation, 3. MN state 'stay home order', 4. More severe lockdown restrictions or a lifting of restrictions). We will also look at trends over a continuous timeline. We acknowledge that the study is likely underpowered for formal statistical inference with these added secondary analyses.

For Aim 3, to facilitate interpretation of RCT results and provide resources for translation and sustainability we will analyze contextual information gathered using qualitative methods to inform eventual broad scale intervention implementation. A sample of qualitative texts will be reviewed to gain a general understanding of the data and establish preliminary codes as well as a working codebook, based on the study's underlying theoretical frameworks.[102-104] All qualitative text will then be analyzed independently using NVivo; periodic meetings will be held to revise the codebook as necessary. Representative patient quotations will be identified during the coding process; coded themes will be grouped into larger thematic categories. Themes will then be quantified by categorizing them as present or absent for each case, and presented as frequencies.[104]

10. DATA COLLECTION AND QUALITY ASSURANCE

10.1 Data Collection Forms

Case Report Forms (CRFs). CRFs will be built into REDCap. The following case report forms will be used:

- Initial screen — study registration information and data regarding initial study eligibility will be **directly** entered on this form either through self-report by participant OR trained study staff performing screening by phone.
- Screening self-report questionnaires (BL1 and BL2) — baseline self-report outcomes, health characteristics, demographics, and information on eligibility will be **directly** entered on these forms through self-report by participants
- Follow up self-report questionnaires (Weeks 9, 26, and 52) — will be **directly** entered by participants
- Eligibility determination forms (BL1 and BL2) — the eligibility determination forms will include a **mixture** of data directly entered by trained study staff and data with source documentation (e.g. verification of a signed consent form). The BL2 eligibility determination form will include stratification variables for treatment allocation.
- Anthropometrics (BL1) – **direct** entry of self-report anthropometric data (height, weight) into REDCap will be performed by trained study staff.
- Accelerometer form (BL2, Weeks 9, 26 and 52)– – trained study staff blinded to treatment assignment will record information regarding wear-time compliance and objective physical activity using scored and summarized data from Actilife as the source document.
- Intervention administration form (Sessions 1-8)— **direct** entry of session attendance will be done by trained study staff. **Direct** entry of pre-intervention session (i.e., W0) attendance will also be captured.
- Intervention fidelity form (Sessions 1-8)— **direct** entry of in-session observation done by trained study staff.
- Adverse event form (Post Enrollment: W0 - Week 52) — **direct** entry of adverse event details will be performed by trained study staff
- Study completion form (Week 52 or earlier if withdrawal) – The study completion form will

include data directly entered by trained study staff (e.g. reason for terminating study participation, number of intervention visits completed).

Source Documents. Data that will serve as source documents include:

- De-identified physical activity data collected by accelerometer and which will be downloaded via ActiLife software for secure management, processing and preparation for analysis. Ongoing ActiLife software support will be provided through ActiGraph's maintenance agreement subscription. Scored and summarized activity data will be electronically merged into the project REDCap database.
- De-identified qualitative data will be securely stored in REDCap. Collected outside of REDCap surveys (e.g. field notes from interviews) will be stored electronically on a password-protected computer located at the University of Minnesota in a locked office, maintained by the Project Director. The computer is supported and maintained by the UMN AHC-IS with regular, automatic backups.
- All paper source documents (e.g. informed consent & HIPAA combined form, medical waivers if applicable, paper version of self-report questionnaires in limited circumstances) will be stored in a locked file cabinet, in a locked office at the University of Minnesota maintained by the Project Director. The Project Director will have oversight for all paper forms and will route the forms from participating YMCA sites to the UMN. The Data Manager will log the receipt of all paper forms.
- Electronic source documents will be stored on a password protected computer at the University of Minnesota in a locked office, without public access. The computer is supported and maintained by the UMN Academic Health Center-Information system. Participant ID numbers will be used to protect participants' confidentiality.

10.2 Data Management

The Principal Investigator, Data Manager and Project Director are responsible for ensuring the accuracy, completeness and timeliness of study data. All source documents will be completed in a neat, legible manner to ensure accurate interpretation of data. Case report forms (CRFs), and source documentation will be reviewed regularly for accuracy. A description of data collection forms and schedule of evaluations are provided in sections 6.1 and 10.1.

10.2.1 Data security and storage

CRFs for this study will be entered into a REDCap database, which uses a MySQL database via a secure web interface with data checks used during data entry to ensure data quality. REDCap includes a complete suite of features to support HIPAA compliance, including a full audit trail, user-based privileges, and integration with the institutional LDAP server. The MySQL database and the web server will both be housed on secure servers operated by the University of Minnesota Academic Health Center's Information Systems group (AHC-IS). The servers are in a physically secure location on campus and are backed up nightly, with the backups stored in accordance with the AHC-IS retention schedule of daily, weekly, and monthly tapes retained for 1 month, 3 months, and 6 months, respectively. Weekly backup tapes are stored offsite. The AHC-IS servers provide a stable, secure, well-maintained, and high-capacity data storage environment, and both REDCap and MySQL are widely-used, powerful, reliable, well-supported systems. Access to the study's data in REDCap will be restricted to the members of the study team by username and password. Electronic communication with outside collaborators will involve only non-identifiable information and investigators will be blinded to group assignment until after the analysis by the study statistician is complete.

Electronic source documents will be stored on a password protected computer at the University of Minnesota in a locked office, without public access. The computer is supported and maintained by the UMN Academic Health Center-Information system. Participant ID numbers will be used to protect participants' confidentiality. All paper source documents (i.e., medical waivers) will be stored in a locked file cabinet, in a locked office at the University of Minnesota maintained by the Project Director and her designees. De-identified physical activity data collected will be downloaded via ActiLife software for secure management, processing and preparation for analysis. Ongoing ActiLife software support will be provided through ActiGraph's maintenance agreement subscription. Scored and summarized activity data will be merged with the project REDCap database.

10.3 Quality Assurance and Quality Control

10.3.1 *Quality Assurance*

The primary method of data collection for participant self-reported outcomes will be direct electronic entry through a survey interface with REDCap. Logic rules specifying the type and range of acceptable responses will be programmed into REDCap. Participants will receive an error message if they enter an invalid response. Physical activity measures (primary outcome measure) will be collected via accelerometry. Subject compliance with accelerometer data collection (e.g. wear time) will be assessed at the relevant data collection timepoints and procedures will be outlined in the study manual of operations to enhance compliance with accelerometer wear time. In addition, data regarding accelerometer wear time compliance and the validity of physical activity data will be collected and actively monitored.

10.3.2 *Quality Control*

The REDCap study database limits invalid character and out of range responses and tracks missing

responses. The Data Manager (or designee not involved in data entry) will perform quality control checks for 10% of new records on a monthly basis by reviewing source documents (i.e. physical activity measures). Quality control checks will include, but are not limited to, verification of study eligibility, completeness of data collection, physical activity measure quality, and adverse event documentation. Reports on quality control findings will be provided to the PI and study Steering Committee on no less than a monthly basis. Study operating procedures will be modified as necessary based on quality control findings. Results of ongoing quality assurance and quality control procedures will be summarized in Reports for the Data Safety and Monitoring Board.

10.3.3 *Training*

Training for study staff responsible for data collection will be conducted prior to study recruitment. Certification by the principal investigator (or designee) requires adherence to standard operating procedures for data collection outlined in the study protocol.

10.3.4 *Metrics*

Data on adherence to the study protocols will be collected by research staff and reviewed monthly by the PI and the Study Steering Committee. These include study events (e.g. baseline evaluation, enrollment, intervention, follow up, adverse event reporting) occurring within specified time frames.

The PI and Steering Committee will monitor the specific adherence metrics detailed in Section 5.4. If adherence falls below the rates, the PI will call a special meeting with the Study Steering Committee, co-investigators and others as needed (e.g. consultants), to re-assess and refine standard operating procedures to remedy the problem.

10.3.5 Protocol Deviations

A protocol deviation occurs when, without significant consequences, the activities on this study diverge from the UMN IRB approved protocol. Examples include divergence(s), that

- reduce the quality or completeness of the data,
- make the Informed Consent Form inaccurate, or
- impacts a subject's safety, rights, or welfare.

Protocol deviations include, but are not limited to the following:

- Failure for participants to complete 6/8 intervention sessions
- Failure to keep IRB approval up to date
- Outcome assessment and/or measurement not performed
- Implementing protocol modifications without obtaining prospective IRB approval;
- Conducting research during a lapse in IRB approval;
- Enrolling more subjects than what's approved in the protocol;
- Performing research procedures outside the protocol specified window;
- Failure on the part of any individual involved in research review or oversight to abide by applicable laws or regulations, or the University of Minnesota IRB policies.
- Randomization of an ineligible participant; not-adhering to inclusion/exclusion criteria;
- Failure to obtain Informed Consent or altering from the informed consent process as described in the IRB approved protocol;
- Obtaining consent using an outdated consent form;
- Performing non-exempt human subject research without obtaining prospective University IRB approval;

- Failure to report an SAE
- Wrong intervention administered to a participant

Protocol deviations will be logged by research staff in REDCap in accordance with the plan described above. Details regarding the protocol deviation including whether it resulted in an adverse event or is reportable to the IRB will be included in the log. Reports on protocol deviations will be reviewed by the PI and study Steering Committee on a regular basis. The DSMB will be provided a summary of protocol deviations in regular DSMB reports.
Study operating procedures will be modified as necessary based on review of protocol deviation summaries.

10.3.6 *Monitoring*

Internal monitoring - Automated queries will be used to assess for protocol deviations when possible (e.g. missing evaluations or evaluations performed outside of allowed timeframe, non- compliance with assigned interventions). Potential protocol deviations that cannot be identified through automatic reports will be monitored through quality control procedures outlined in section 10.3.2

External monitoring - A Data Safety and Monitoring Board has been assigned to perform independent study monitoring. The UMN IRB and NCCIH will also review study progress. The PI and the Study Steering Committee provide monthly monitoring (see Table 2).

Westat is responsible for conducting NCCIH site monitoring visits. Monitoring visits include review of regulatory/essential documents, 100% of informed consents for enrolled participants, select participant records (e.g., source documentation, case report forms, and/or database entries) including documents that contain PHI, and other relevant study materials. Due to COVID-19, Westat will conduct monitoring visits remotely in lieu of on-site monitoring visits. If it is safe to do so in the future, Westat may return to on-site (versus remote) monitoring.

Research staff will provide a current list of enrolled participant ID numbers to the monitor upon request. For the remote visit, research records, with PHI, will be uploaded by study staff to the HIPAA secure UMN Box (e.g., signed informed consent forms, HIPAA forms (if separate from the consent form), medical waivers). The Westat monitor will be given access to study documents in the UMN Box system to review per the monitoring requirements. Additional regulatory/essential documents will be uploaded to Zoom for review (e.g., IRB approval letters (notices of continuing review), delegation logs, human subjects training certificates, conflict of interest forms).

The Westat monitor will also view select records that contain PHI, in the project database, REDCap, to review remotely. UMN staff will make select records available for the Westat monitor to review via HIPAA compliant Zoom videoconference. The Zoom videoconference meeting will not be recorded. Westat will not be given access to the full REDCap database. To protect participant's confidentiality, records will be reviewed in a private space. Only the Westat monitor and designated study staff member will be invited to the videoconference review.

Table 2. Monitoring		
Data type	**Frequency of review**	**Reviewer**
Subject accrual (including compliance with protocol enrollment criteria)	Monthly	PI, Steering Committee
	Semi-annually	DSMB
Status of all enrolled subjects, as of date of reporting	Monthly	PI, Steering Committee
	Semi-annually	DSMB
Findings from ongoing quality assurance and quality control procedures	Monthly	PI, Steering Committee
	Semi-annually	DSMB
Adherence data regarding study visits and intervention	Monthly	PI, Steering Committee
	Semi-annually	DSMB
AEs and rates	Monthly	PI, Steering Committee
	Semi-annually	DSMB
	Annually	NCCIH, IRB
SAEs (unexpected and related)	Per occurrence	PI, DSMB, IRB, NIH/NCCIH
SAEs (expected or unrelated)	Per occurrence	PI, Steering Committee
	Annually	DSMB, IRB, NIH/NCCIH
Unanticipated Problems (UPIRTSO)	Per occurrence	PI, DSMB, IRB, NIH/NCCIH
Definitions: PI=Principal Investigator; DSMB=Data Safety and Monitoring Board; AE=Adverse Events; SAE=Serious Adverse Events		

11. PARTICIPANT RIGHTS AND CONFIDENTIALITY

11.1 Institutional Review Board (IRB) Review

This protocol and the informed consent document and any subsequent modifications is reviewed and approved by the IRB.

11.2 Informed Consent Forms

A signed consent (e-consent or written) form will be obtained from each participant. The consent form will describe the purpose of the study, the procedures to be followed, and the risks and benefits of participation. A copy will be given to each participant and this fact will be documented in the participant's record (REDCap). See Section 6.

11.3 Participant Confidentiality

Procedures are in place for maintaining the full confidentiality of all information collected. Participant confidentiality will be protected by securing all hard copy study files in locked filing cabinets. Electronic files containing personal identifiers will be stored on secure servers operated by the UMN AHC-IS. All study staff receive training on privacy standards for maintaining participant confidentiality. All published reports will be of summary nature and no individual subjects will be identified beyond the investigative staff involved in the project.

11.4 Study Discontinuation

The study may be discontinued at any time by the IRB, the NCCIH, the OHRP, or other government agencies

as part of their duties to ensure that research participants are protected.

12. COMMITTEES

The study has a Steering Committee which will communicate in person, by phone or electronically to monitor study activities. It consists of the PI, Data Manager, Project Director, YMCA Project Coordinator and other co- investigators and study staff as needed. The study also has an Advisory Committee of community members, consultants and practitioners who are consulted as needed. Details regarding membership and roles are provided in the manual of operations.

13. PUBLICATION OF RESEARCH FINDINGS

Polices for publication of research findings from this research will be governed by the policies and procedures developed by the Steering Committee.

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