A pilot, randomized, feasibility study to improve health self-management behaviors in older adults with multiple chronic conditions and functional limitations: Protocol for the Behavioral Activation and Occupational Therapy Trial (BA+OT) Journal of Multimorbidity and Comorbidity Volume 13: 1–7 © The Author(s) 2023 Article reuse guidelines: sagepub.com/journals-permissions DOI: 10.1177/26335565231163037 journals.sagepub.com/home/cob SAGE

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#### Abstract

**Background:** Approximately 45% of older adults in the U.S. have 2 or more chronic health conditions (e.g., arthritis, hypertension, diabetes) in addition to functional limitations that prevent performance of health self-management activities. Self-management continues to be the gold standard for managing MCC, but functional limitations create difficulty with these activities (e.g., physical activity, symptom monitoring). Restricted self-management accelerates the downward spiral of disability and accumulating chronic conditions which, in turn, increases rates of institutionalization and death by 5-fold. Currently, there are no tested interventions designed to improve independence in health self-management activities in older adults with MCC and functional limitations. Research suggests that older adults are more likely to change behavior with interventions that assist with planning health-promoting daily activities, especially when contending with complex medical regimens and functional limitations. Our team asserts that combining occupational therapy (OT) and behavioral activation (BA) shows promise to improve health self-management in populations with chronic conditions and/or functional limitations. This innovative combination uses the goal setting, scheduling/monitoring activities, and problem-solving components of the BA approach as well as the environmental modification, activity adaptation, and focus on daily routines from OT practice.

**Objectives:** We will test the effect of this combined approach in a Stage I, randomized controlled pilot feasibility study compared to enhanced usual care. We will recruit 40 older adults with MCC and functional limitation and randomize 20 to the PI- delivered BA-OT protocol. This research will inform modification and larger-scale testing of this novel intervention.

# Keywords

Chronic illness, multimorbidity, disability, intervention

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# Introduction

# Increasing burden of MCC-related functional impairments

MCC is disabling and costly for the individual and the health system.<sup>1</sup> Older adults with MCC, the presence of 2 or more chronic conditions, have poor health outcomes,<sup>2</sup> poor quality of life,<sup>3</sup> high health care costs,<sup>4</sup> and high health care utilization<sup>4</sup> including potentially avoidable hospital readmissions.<sup>5</sup> Common chronic conditions include type 2 diabetes (T2D), arthritis, heart disease, lung disease, and kidney disease; each of these conditions has separate recommendations for healthy eating, physical activity, pharmacological management, and monitoring symptoms and disease progression.<sup>6</sup> Approximately half of older adults with MCC report having functional limitations,<sup>7</sup> which compounds the difficulties in managing MCC and accelerates aging and disability processes (See Figure 1). Our best tool against this spiral of accelerated aging and disability is self-management, however, having MCC and functional limitations complicates the self-management process, due to the involvement of multiple health care providers, time consuming and conflicting treatment recommendations, and difficulty performing daily health selfmanagement activities.6

# Existing chronic condition self-management programs

Most empirically tested chronic condition self-management programs are not designed for individuals with MCC or functional limitations.<sup>8</sup> First, these programs typically address single diseases, ignoring the complexity that comes with managing MCC.<sup>1</sup> In fact, having MCC is frequently listed as an exclusion criteria in clinical trials.<sup>9</sup> Second, selfmanagement programs are designed to change individual behaviors, typically using a combination of disease-specific education and behavior change techniques. Functional limitations are a frequently reported barrier to success in self-management programs<sup>10</sup> because, in addition to individual behavior, multiple intervention foci are required to address the environment and attributes of the selfmanagement activity.11 Further, despite recognition that integration of self-management activities into daily routines leads to optimal uptake and maintenance of behaviors,<sup>12</sup> widely-used self-management programs do not contain this powerful task integration component.<sup>13</sup> Typical selfmanagement support programs may effect change in individuals without MCC or functional limitations, but this added complexity requires individual-tailoring that combines the potent motivational elements of behavioral activation (BA) and holistic-minded expertise of occupational therapy (OT).



**Figure 1.** Accelerated aging consequences of MCC and functional limitations. **BA-OT** may interrupt this cycle to increase independence in daily health self-management activities.

*Rationale for BA*. With the BA approach, practitioners coach clients to engage in activities that will lead to a more rewarding life.<sup>14</sup> By <u>scheduling and performing meaningful</u> daily activity and monitoring the results, participants begin to connect accomplishments to feelings of success. This process engages an upward cycle of goal attainment that can develop active self-managers.<sup>14,15</sup> BA is a powerful tool for building mastery and motivation to change.<sup>16</sup> However, on its own, the BA approach does not develop skills needed to continue to perform daily activity in the presence of functional limitations, a condition that forces individuals to modify or adapt how they complete daily activity.

Rationale for OT. Occupational therapists bring a unique expertise to health self-management by supporting performance of health-promoting activities, such as medication management and exercise.<sup>17</sup> Occupational therapy researchers have demonstrated an established track record of interventions that improve health management, wellness and prevention of chronic illness and disability<sup>18</sup> making OT a strong additive approach to a BA intervention. Using an OT conceptual practice model (the Person-Environment-Occupation-Performance Model), occupational therapists assist clients through modifications to the environment, adaptations to the activity, adjustments to daily routines and roles, and remediation of functional limitations.<sup>19</sup> Many intervention outcomes in trials for older adults with MCC are difficult to improve (e.g., organization of care delivery, quality of life); however, studies that specifically target functional outcomes (i.e., independence in daily activity) show promise.<sup>20</sup> Improved independence in health selfmanagement activities is a proximal and modifiable outcome that has potential to drive the upward cycle of mastery and motivation.

Integration of BA and OT components. With the BA-OT approach, the PI will use an evidence-based 4-step process (GOAL-PLAN-DO-CHECK: Figure 2) to assist the older adults to develop strategies to plan and execute daily health self-management activities.<sup>21,22</sup> BA-OT teaches older adults with MCC and functional limitations to 1) set achieveable and meaningful activity goals, 2) engage in action planning that includes brainstorming strategies to overcome barriers, 3) evaluate the results after performing the activity, and 4) modify the plan or choose a new goal, then generalize strategies to new problems. Our approach to improving independence in health self-management is consistent with self-regulation models that emphasize congruence between goals, client-level factors, and broader circumstances (e.g., environmental and activity demands).<sup>23</sup> By assisting participants to develop daily routines and integrate safe health self-management activities into these routines, occupational therapists provide strategies that support adaptation in the face of stressful situations.<sup>24</sup> We hypothesize that by deliberately targeting improved independence in meaningful self-management activities, and then habitualizing those activities into daily routines, these activities become routinized health behaviors. With time, sustained engagement in these routines is part of healthy self-management. Participants may choose goals such as creating, adapting, and integrating an exercise plan or, or exploring assistive devices and strategies for safe and healthy meal preparation to ensure adequate nutritional intake.

Our hypothesis regarding the translation of health promoting activities into sustained engagement in selfmanagement arose from clinical and research observations. Previous research revealed increased complexity of medical management was related to decreased daily activity individuals with chronic conditions.<sup>25</sup> Follow-up qualitative studies<sup>26</sup> strengthened existing evidence<sup>12,27</sup> that inability to translate self-management recommendations into everyday life and existing routines is an enormous barrier.<sup>26</sup> Research has recently characterized deficits in daily activity<sup>28</sup> and functional mobility<sup>25</sup> for older adults with MCC. In addition, having a stable daily routine is a primary contributor to good medication management<sup>25</sup> and participation in meaningful daily activities.<sup>25</sup> Based on empirical evidence and a strong theoretical foundation, our intervention has potential to improve independence in health self-management activities and prevent further disease and functional decline in older adults with MCC and functional limitations.

#### Objectives

**Specific Aim 1:** Collect preliminary data to test the effect of BA-OT for improving independence in health self-management activities for older adults with MCC and functional limitation compared to enhanced usual care.

Step 1	GOAL	Goal Setting
Step 2	PLAN	Action planning Activity scheduling Examine and develop daily routines Problem Solving Modify environment Adapt activity
Step 3	DO	Client does the activity with OT
Step 4	CHECK	Activity monitoring Change the Action Plan or choose a new goal Problem Solving Modify environment Adapt activity Generalize strategy to other problems
Green: Both BA and OT, <mark>Blue:</mark> BA approach, <mark>Yellow:</mark> OT expertise		

Figure 2. Active ingredients of intervention.

**Hypothesis**: Older adults who receive BA-OT will demonstrate improved independence in health self-management activity as measured by the self-report Canadian Occupational Performance Measure<sup>29</sup> and the Self-Management Assessment Scale.<sup>30</sup> **Rationale:** Though similar interventions have shown promise in populations with different disease courses,<sup>21,22,31</sup> BA-OT has not been tested in older adults with MCC and functional limitations.

**Specific Aim 2:** Examine the feasibility of recruitment and delivery of the BA-OT intervention with older adults with MCC and functional limitation. Quantitative feasibility measures include recruitment rates, proportions of participants who initiate and complete the intervention, and adherence to study procedures. In-depth qualitative interviews will be conducted to understand acceptability and suitability of the intervention. **Rationale:** Similar interventions have been successful, but not with older adults with MCC and functional limitations, a group that is difficult to treat. We will begin answer the critical question "can it work?" and seek evidence to inform adaptation to a larger study.

Combining these two approaches to address the persistent problem of health self-management in this population is novel and promising. This specific combination of active ingredients has the potential to prevent functional limitations and costly hospitalizations and may reduce disability in older adults with MCC. This project will inform the modification and testing of BA-OT with a larger sample, as well as generating preliminary data for a collaborative federal grant submission.

# Methods

#### Intervention design

This is a single-blind, pilot feasibility randomized trial (Stage  $I^{32}$ ) comparing BA-OT (n = 20) to enhanced usual care (n = 20). Due to the nature of the intervention, it is not possible to conceal allocation to BA-OT, however, the unbiased study evaluator will be blinded to participation condition.

# Participants and recruitment

Forty older adults (aged 60+) will be randomized to the intervention or control groups. Eligible participants will have  $\geq 2$  chronic conditions (using ICD-10 list of 21 chronic conditions<sup>33</sup>) and  $\geq 1$  functional limitation (as measured by the Work and Social Adjustment Scale<sup>34</sup>), intention to set  $\geq 1$  physical activity goal, and live within 15 miles of the OU Schusterman Center. Participants are ineligible if they have a life expectancy <6 months, a progressive neurological condition, are in active treatment for cancer, are not English-speaking, have moderate-severe cognitive impairment (measured by score <19 on the Telephone-Montreal

Cognitive Assessment: T-MOCA<sup>35</sup>), have current or history of severe mental illness (i.e., schizophrenia, bipolar disorder), or are in concurrent treatment with physical or occupational therapy. The intervention sample size of 20, given 80% retention at 3 months (n = 16), will result in > 95% power to detect change between pre- and post-tests on the primary outcome, the Canadian Occupational Performance Measure (COPM: MCID = 3.0, SD = 2.0).<sup>29</sup> The primary recruitment strategy will be referrals from collaborating physicians at OU Health's Schusterman Center Internal Medicine. If additional recruitment strategies are needed, the PI will use 'direct-to-consumer' approaches, including presentations to local senior organizations, and advertisements in senior newsletters.

Assessments. Research staff will establish study eligibility, consent, and gather demographic and clinical characteristics (age, chronic medical conditions, years of education, marital status, race/ethnicity, medications). Baseline assessment interviews will be conducted by the PI.

The primary outcome is independence in health selfmanagement activities, as measured by the COPM and the Self-Management Assessment Scale (SMASc).<sup>30</sup> The COPM was designed to facilitate goal setting and detect change in self-report performance of daily activity.<sup>36</sup> The COPM is valid, reliable, clinically useful, and responsive in community-dwelling older adults.<sup>29</sup> The SMASc, an assessment for measuring effective self-management of chronic conditions, is valid, reliable, and sensitive to change in a sample with T2D and other chronic conditions.<sup>30</sup>

Given that MCC and depression often coexist,<sup>37</sup> improvements in mood will be assessed using the Behavioral Activation for Depression Scale (BADS).<sup>38</sup> The BADS has good factor structure, internal consistency, construct validity, and test-retest reliability in community-dwelling adults.<sup>39</sup>

A major determinant of success in chronic condition selfmanagement is self-efficacy.<sup>40</sup> The PROMIS© Measures for Self-Efficacy for Managing Chronic Conditions are highly validated and reliable with good internal consistency in multiple samples with chronic conditions.<sup>40,41</sup>

Research staff will collect quantitative feasibility measures including recruitment rates, proportions of participants who initiate and complete the intervention, and adherence to study procedures. In addition, qualitative information regarding suitability and acceptability of the study procedures and intervention will be collected by the unbiased study evaluator at 10 weeks and 22 weeks. Fidelity of the PI-delivered intervention will be ensured using established procedures for checklist assessment methods.<sup>22</sup>

Study procedure. Following screening by trained research staff and enrollment in the study, participants will be 1: 1 randomized into either BA-OT or enhanced usual care

control group. Baseline assessments for all participants will be collected by the PI. Following baseline assessment, the PL a BA-trained, licensed occupational therapist will deliver a 10-session manualized program in the participants' homes to ensure optimal uptake of the active ingredients and integration into daily life routines. This intervention will occur over 10 weeks; in similar studies, 10 weeks is sufficient to make behavior changes.<sup>42</sup> The intervention manual will include educational materials for the 4-step approach, and worksheets for goal setting and developing daily routines. In the 1<sup>st</sup> BA-OT session, the PI will collect baseline assessments and use COPM data to facilitate goal setting. The top 5 participant-selected goals chosen will be the subject of the 4-step process in sessions 2 - 10. At least one goal must be related to improving physical activity routines; each participant will receive a Fitbit Charge 5 to self-monitor fitness progress. The unbiased evaluator will carry out follow-up assessments at 10 weeks and 22 weeks with participants in both conditions. The enhanced usual care control group will receive the same assessment battery, a Fitbit Charge 5 with 1 hour training, and a handout about living with chronic conditions.

Attrition management. Participant attrition is a risk we will work to mitigate. First, by collaborating with the primary care physician for referrals, we will build participant trust in the intervention. Second, to reduce participant burden, we will offer flexible appointment times in the homes of participants and research staff will make reminder calls prior to appointments. Lastly, we are providing remuneration for each testing event. In the unforeseen event of loss of the unbiased study evaluator the PI will use funds to purchase an occupational therapist colleague's time for follow-up testing.

Data management and planned analyses. Data capture, quality assurance, management and processing will be consolidated in Research Electronic Data Capture (RED-Cap); including direct data entry of screening information by study personnel and double data entry of assessments by study personnel. We will test for baseline differences between groups in demographic and clinical characteristics and assessments.

Data Analysis for Aim 1. To test within-group effects, mean changes in pre-post intervention (at 10 and 22 weeks) in COPM and SMASc scores will be assessed using a repeated measures ANOVA with a 2-sided 0.05 alpha level. Non-parametric approaches will be used if ANOVA assumptions are not satisfied. For between-group effects, we will use independent t-tests at each time point. T-test results will provide parameter estimates, standard errors, and 95% confidence intervals, which we will use to determine the magnitude of intervention effect. If necessary, we will use a non-parametric equivalent. Statistical significance will be based on an alpha level of  $\leq 0.05$ .

Data Analysis for Aim 2. We will use rates and proportions as appropriate to calculate quantitative feasibility benchmarks. We will also categorize reasons for nonparticipation, withdrawal, or missed visits. For qualitative feasibility, the unbiased study evaluator will record responses to questions about suitability and acceptability of the intervention. The PI (a trained qualitative investigator) and research staff will use thematic analysis to identify suitability and acceptability of the intervention as well as suggested modifications.<sup>43</sup>

A plan to maintain participants' safety and prevent injury has been developed for the study. Occupational therapists are trained to support older adults to safely execute daily activity in the presence of functional limitations. To prevent illness, we will follow CDC recommendations for COVID-19 safety for home health workers, including prophylaxis use and testing as necessary. This research study, all participant education and recruitment materials, and other documents have been approved by the Institutional Review board at the University of Oklahoma health Sciences Center (approval # 14683). This protocol is registered on Clinicaltrials.gov (registration # NCT05600465) This manuscript was prepared using the Standard Protocol Items: Recommendations for Intervention Trials (SPIRIT) Statement, which provides guidance on reporting study protocols. <sup>44</sup> Any modifications to the protocol which impact the conduct of the study will require an amendment to be submitted to the Institutional Review Board and may require approval from the study funder, the Presbyterian Health Foundation. This protocol was submitted for publication 12/21/22, this publication represents version 1 of the protocol.

### Discussion

This research will begin to fill a current gap in service delivery for older adults with multiple chronic conditions and functional limitations by providing an evidence-based, practical, and eventually billable intervention that can help decrease functional limitations and improve health selfmanagement behaviors. The findings of this study will be disseminated via publication and presentation to healthcare professionals and other stakeholders as well as relevant professional societies. This pilot study will inform modification and development of this intervention to a full-scale randomized controlled trial.

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#### **Declaration of conflicting interests**

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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#### **Ethical statement**

We obtained approval from the Institutional Review Board of the University of Oklahoma Health Sciences Center. Approval # 14683.

#### Informed consent

Participants provide written informed consent.

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