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Research Article

Addressing Physical, Functional, and Physiological Outcomes in Older Adults using an Integrated mHealth Intervention "Active for Life": A Pilot Randomized Controlled Trial

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Abstract

Objective: We evaluated components of an integrated, mobile health-based intervention "Activate for Life" (AFL) on health outcomes in lower-income older adults (≥ 60 years). **Methods:** AFL incorporates balance (Otago; OG), physical strength (Gentle Yoga and yogic Breathing; GYYB), and mental engagement (Behavioral Activation; BA) components. Thirty participants were randomly allocated to one of three study arms (n=10): OG (Arm 1), OG+GYYB (Arm 2), or OG+GYYB+BA (Arm 3; a.k.a. "full AFL"). Participants were evaluated for physical, functional, and physiological endpoints at baseline and post-intervention (12-weeks and/or 3-month follow up). **Results:** Improvements in pain interference and 1,5- anhydroglucitol biomarker levels over time were noted for all arms. No significant changes were observed for other physical, functional, or physiological measures. **Discussion**. This study illustrates potential benefits of the AFL intervention on the health of lower-income older adults. Lessons learned from this pilot trial will inform design improvements for a large-scale randomized controlled trial.

Keywords: Aging; Pain; Fatigue; Intervention; Physical activity; Low income; Mobile health

Introduction

A growing number of older adults in the United States (U.S.) are in poor health and are financially ill-equipped to address the myriad physical, psychological, and environmental factors that impede healthy aging [1]. Approximately 50 million U.S. adults are over the age of 65 and more than 80 percent report having one or more chronic conditions such as arthritis, diabetes, or hypertension [2,3]. In 2017, the most recent date for which data are available, 4.7 million (9.2 percent) older adults were estimated to live in poverty based upon the U.S. Census Bureau's official poverty measure [4]. While the proportion of older persons living in poverty has declined in the last 50 years, the number of aged poor has increased as the population of older individuals has grown [5]. By 2060, adults over the age of 65 are expected to represent 25 percent of the U.S. population [3].

Evidence suggests that lower-income, older adults are at higher risk for experiencing debilitating symptoms of pain and fatigue compared to the general population [6,7]. Of the estimated 50 million people in the U.S. who report suffering from chronic pain, a high prevalence (>25 percent) occurs in persons of advanced age who are living near the poverty threshold [8]. Fatigue, which can include both mental and physical qualities, is estimated to occur in approximately one-third of adults over 50 years of age [9]. In a cross sectional study of older, community-dwelling primary care patients, fatigue was associated with worse health and functional status compared to patients not reporting symptoms [10]. Similarly, chronic pain has been linked to restrictions in mobility, depression, and poor perceived health [11], while pain associated with higher fatigue placed older adults at increased risk of dementia, injury from falls, and mortality [12-15]. Chronic pain and fatigue can also accompany, or be exacerbated by, the presence of chronic illness. This can exact a heavy toll on an older person's quality of life, complicating their medical care, ability to manage disease symptoms, or activities of daily living [15].

Non-pharmacological interventions that counter age-related physical and psychological deterioration may be effective for alleviating symptoms of pain and fatigue and enhancing function in older adults. Multi-modal interventions incorporating exercise rehabilitation components were found to be more effective than usual care for decreasing pain and disability among older adults suffering from chronic musculoskeletal disorders [16]. Similarly, moderate intensity exercise programs focusing on daily mobility (i.e., functional walking) and balance produced positive outcomes for preventing falls and improving physical performance in older persons not exhibiting frailty [17,18]. Attention to mindfulness and mental health is another important consideration in older individuals, as late life depression can exert compounding effects on physical health. A recent meta-analysis of randomized controlled trials (RCTs 2008-2018) targeting community-dwelling older adults showed improvements related to fatigue in response to both behavioral and mental health interventions (e.g., meditation, muscle relaxation, yoga, and cognitive behavioral therapy) [19]. Yogic breathing techniques that promote awareness and progressive relaxation can also have positive effects on neurocognition, enhancing perceptions of self-control and promoting pain reduction [20,21]. Finally, behavioral strategies that facilitate supportive interactions and participation in enjoyable activities have also been shown to reduce depression and increase healthy behavior in older adults [22].

Telehealth approaches may be a promising avenue to improve access to interventions that would help alleviate pain and fatigue in lower-income, community dwelling older adults. While studies suggest that non-pharmacological interventions can improve health outcomes in older persons, many such programs are out of reach for those under financial hardship [23]. Telehealth technology that includes mobile health options (mHealth, or "the use of mobile wireless technologies for public health") [24] could help overcome many geographic, logistical, and financial access barriers. More than 90 percent of persons over 60 years old in the U.S. own a personal mobile phone [25] that would permit delivery of medical services, education, clinical instructions, and social engagement [26] to aged individuals within their own homes or healthcare environments. Further, evidence supports the acceptability and benefits of mHealth platforms for enhancing physical and psychosocial health among older persons [27-29]. Telehealth can also be easily adapted to integrated models that address specific challenges important for achieving optimal patient outcomes.

The purpose of this pilot study was to generate preliminary data on the effects of a physical / behavioral, mHealth-delivered intervention *"Activate for Life"* (AFL) for improving pain and fatigue symptoms in lower-income older adults. AFL incorporates three evidence-based components that promote self-management of pain and fatigue symptoms: Otago (OG) for Balance Training, Gentle Yoga and Yogic Breathing (GYYB) for muscle strengthening and mindfulness guidance, and Behavioral Activation (BA) that addresses affective state and motivation.

These three evidence-based components were evaluated on:

1) physical (e.g., pain intensity, fatigue, and pain medications use),
2) functional (walking, balance)
3) physiological (cortisol and 1,5-anydroglucitol biomarkers of stress) outcomes.

Materials and Methods

Setting and participants

Participants in this study were lower-income older adults (≥ 60 years) living in either subsidized housing facilities or their own homes. Subsidized facilities included those under non-profits such as the Humanities Foundation and Housing and Urban Development programs located in urban and suburban communities in South Carolina. Recruitment occurred through flyers placed in the housing facilities and through word of mouth. Inclusion criteria for study participants were: English-speaking; male or female adults aged 60 years or more; meeting the criteria for lower-income status in the State of South Carolina (≤ 150 percent of the official poverty threshold); ambulatory; reporting pain and fatigue (measured using the PROMIS Pain Interference short form 6b, the PROMIS Pain Behavior short form 6a, and the PROMIS Fatigue short form 6a); had access to the Internet; and willing to utilize a tablet device for delivery of study information and data collection (e.g., blood pressure monitoring). Excluded from the study were older adults who had significant cognitive impairment

or dementia (a score between 0-2 as measured by the Mini-Cog); who were unable or unwilling to give consent; who had a physical disability resulting in an inability to ambulate 150 feet, with or without the assistance of another individual or assistive device; or who were unable to operate the provided tablet device. Those meeting all eligibility requirements were enrolled in the study. All baseline questionnaires were administered electronically using the tablet after obtaining written informed consent from all study participants.

Study Design

For this 12-week pilot trial, we employed a randomized trial design and 3x2 repeated measures (intervention x time, pre-intervention vs post-intervention) approach to compare outcomes among participant groups in Arm 1 (OG), Arm 2 (OG + GYYB), and Arm 3 (OG + GYYB + BA; all three components together comprise the "full AFL" intervention). We originally specified 3 assessment time points that were pre-intervention, post-intervention at week 12, and post-intervention at 3-month follow-up (24 weeks from baseline). Written informed consents were obtained from all study participants. After signing the informed consent document, participants (N = 30) were randomly allocated to one of the 3 study arms using the Research Electronic Data Capture (REDCap) application. Study data were obtained at baseline, post-intervention (12-weeks), and at 3-month follow-up (Figure 1). This study design was approved on June 5, 2018 by the Medical University of South Carolina (MUSC) Institutional Review Board (approval #Pro00076835) and registered at ClinicalTrials.gov (identifier NCT03853148) released February 22, 2019. Recruitment and enrollment commenced March 2019 and the study was completed August 2020 when the final participant completed the 3-month follow-up.

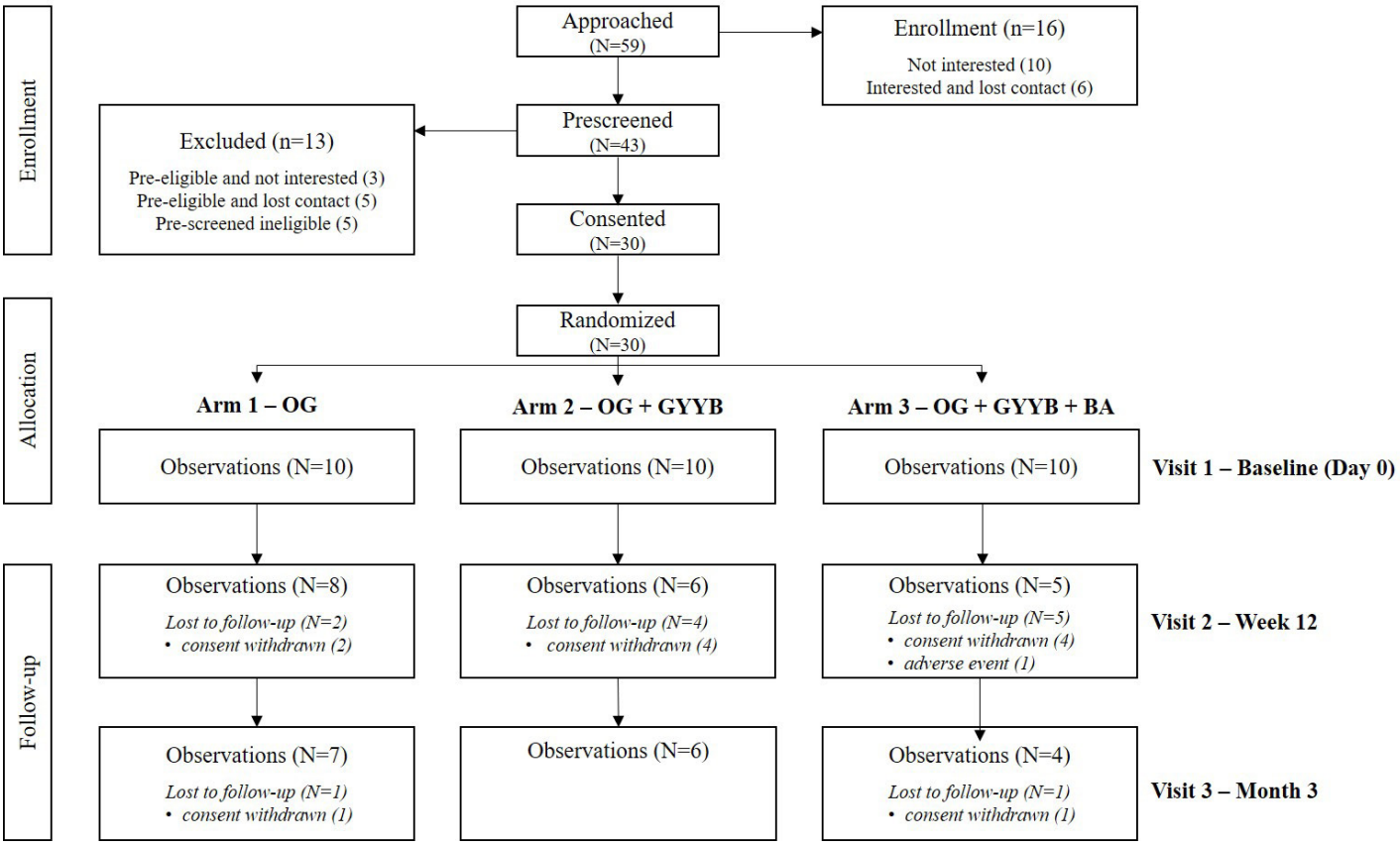

Figure 1: Flow diagram of the pilot randomized trial that included three study arms of participants receiving Otago (OG) alone or in combination with Gentle Yoga and Yogic Breathing (GYYB) and Behavioral Activation (BA) Intervention Components.

Randomization: In this small pilot trial, we recruited participants from three different sites to avoid cross-contamination of study groups. A computer-generated randomization scheme designed by our statistician (J.B.) was used by the study coordinator to randomly assign enrolled patients documented in the REDCap study database to one of the three arms, each of which received equal numbers of participants (n = 10). This trial was not powered to test or confirm hypotheses; rather, these analyses were considered hypothesis generating and descriptive.

Procedures

The study coordinator contacted each participant to set up a home visit for obtaining written informed consent and enrollment. After randomization, participants were allocated in a concealed manner (i.e., participants did not know to which of the three study arms the others were assigned), were oriented to study procedures, and baseline demographic, physical, functional, and physiological data were collected by the study coordinator. There were no more than 2 personnel directly involved with participants at any given time: the study coordinator, who followed participants in all 3 study arms, and a behavioral therapist who administered the AFL intervention to participants in Arm 3. The principal investigator (T.K) provided study oversight for study personnel who were blinded to study assignment. The mHealth application used in this study was developed under the MUSC Technology Applications Center for Healthful Lifestyles (TACHL) and designed for use on a tablet device. The application guided participants through OG and GYYB programs. Participants also used the application to log daily study activities and provide responses to questions regarding levels of pain, fatigue, exercise, and use of medications taken for pain. Additionally, the application collected pulse and blood pressure (BP) data from a wearable tracking Bluetooth®-connected device (Garmin, Olathe, Kansas, USA).

Otago: OG is an evidence-based muscle strengthening and balance retraining program endorsed by the Centers for Disease Control as an effective fall intervention program [30]. The OG program (Arms 1, 2, and 3) encompasses a series of 17 warm-up exercises followed by additional exercises such as walking heal-to-toe, backwards, in a figure eight pattern, and side stepping to improve strength and balance. OG videos were embedded in the mHealth application and participants were instructed to follow along. Participants were also encouraged to perform the full set of exercises at least five times per week over the 12-week study period using a cane, chair, or table as needed for stability and safety.

Gentle Yoga and Yogic Breathing: The GYYB component (Arms 2 and 3) was designed by a study team member (S.B.) who is certified by the International Association of Yoga Therapists. The goal of the GYYB component is to improve overall flexibility, bodily control, and mindfulness in movements for older persons with limited mobility based on principles of integral yoga [31]. The study team previously developed a one-hour GYYB video reviewing: 1) yoga postures that participants could practice sitting on a chair while watching the video on their tablet devices (30 minutes) followed by 2) yogic breathing exercises (30 minutes) [32,33]. Participants were encouraged to perform GYYB daily for 12 weeks.

Behavioral Activation: BA (Arm 3 only; a.k.a. the "full AFL" intervention) incorporates structured strategies for increasing patients' engagement in values-based, social, and healthy activities, such as interacting with supportive family and friends, that are likely to produce reinforcement in the natural environment [34]. Daily planners and worksheets are used in conjunction with talk therapy to identify, plan, and rate behaviors that are easily incorporated into daily activities. Participants in Arm 3 began with a weekly self-monitoring of activities and recorded these via hand-written study logs. These data served as a foundation to orient the participant to the quality and quantity of his or her day-to-day activities. These participants were also scheduled to meet with a Master's-prepared behavioral therapist every other week over the course of the 12-week study course (n=5 visits) via Vidyo [visual communication software (Enghouse, Hackensack, NJ)]. During the baseline assessment, the behavioral therapist reviewed with the participant their general values and examples of specific behaviors that would 'demonstrate' each value. A list of demonstrable behaviors was compiled and used to generate 10 to 20 highly defined, value-based, reinforcing activities. These were then combined with activities outlined in the OG and GYYB components to generate a "master list" of activities for the AFL intervention. At each visit, the participant and therapist would tailor and discuss values-based activities that needed to be completed. The goal was for each participant to complete activities within the two days following their session conducted with the behavioral therapist.

Measures: Physical outcomes were pain and fatigue measured with Patient Reported Outcome Measurement Information System (PROMIS) instruments obtained from the NIH Toolbox® for Assessment of Neurological and Behavioral Function (NIH Toolbox) [35-37]. For self-reported pain, we used PROMIS Pain Interference 6b (6 items - consequences of pain on one's life), Pain Intensity 3a (3 items-how much one hurts), and Pain Behavior 6a (6 items – verbal and nonverbal actions that indicate one is experiencing pain) short forms incorporating 5-point Likert scales that allow participants to rate their symptoms over the prior seven-day period. The PROMIS Fatigue 6a form encompasses 6 items that assess the experience of fatigue and interference on daily activities [38]. All instruments have well-established psychometric properties for use in older adults [39,40]. Raw scores are converted to t-scores with a mean of 50 and a standard deviation of 10 and are normalized to the general U.S. population [36]. Higher scores indicate more severe symptoms. An 11-point numeric rating scale

(0-10, with 10 indicating the highest possible level of pain) was also used to assess daily pain levels and data were recorded through the tablet-based mHealth application. Pain medication usage was also evaluated and monitored via the mHealth app.

Functional outcomes were measured using the 10-item PROMIS Physical Function 10b instrument that assesses sit-to-stand, walking, and balance abilities as well as self-reported physical abilities including mobility, upper and lower extremity strength, core strength, and activities of daily living [41,42]. Lower scores on the 10b form indicate a greater degree of impaired function. Additionally, the two-minute walk test was used to measure walking distance in feet over a timed two-minute period [43]. The 30-second (s) chair test [44] was used to measure lower body strength by counting the number of times an individual can transition from a full seated to a full standing position after 30 s have elapsed. Balance was assessed using the Berg Balance Scale, which includes 14 tests (e.g., sit-to-stand, standing on one leg, stepping over obstacles). Each task is worth 0-2 points. Higher scores indicate better balance and lower fall risk [45,46]. Resting BP, post BP, and pulse were measured both before and after the 30-s chair test using a BP device attached to the tablet.

Physiological measures included salivary cortisol and 1,5-anhydroglucitol (AG) biomarker levels. Cortisol is an indicator of hypothalamus-pituitary-adrenal (HPA) axis activity that represents the dominance of the sympathetic nervous system (i.e., a measure of psychosomatic stress) [47]. Aging is associated with increased levels of salivary cortisol [48]. 1,5-AG is a biomarker for glycemic metabolism and is reduced with age [49]. Clinical and preclinical studies suggest exercise could enhance 1.5-AG [50]. For measurement of biomarkers, saliva was collected upon rising in the morning through passive drooling into a sterile tube. Cortisol (Invitrogen, Catalog Number EIAHCOR) and 1,5-AG (MyBioSource, Catalog Number MB723128) were analyzed by ELISA in single batches (two technical replicates per sample) using commercially available reagents. Cortisol reference values were: 3.7-9.5 ng/mL (morning), 1.2-3.0 ng/mL (noon), 0.6-1.9 ng/mL (evening), 0.4-1.0 ng/mL (bedtime). The normal reference value for 1,5 AG is ≥ 14.0 μg/ml.

Data Analysis: Data were analyzed using IBM SPSS Version 26.0. Descriptive analysis was conducted for each outcome variable within each of the three intervention arms as well as across the full study sample. Repeated measures analysis of variance (ANOVA) was used to determine significant differences in outcomes between groups and effect size via Partial Eta^2 is presented (Supplemental Material). Due to the high proportion of missing data (about 43 percent), a single post-intervention measurement value was determined for each measure based on either the week 12 observation, the 3-month follow-up observation, or, if data were present for both, the average between the two time points. This method was considered more conservative than conducting mean substitution. Differences were considered statistically significant for p-values < 0.05.

Results

Among the 59 older persons invited to participate in the study, 30 were consented and enrolled. Baseline demographic characteristics of the study population are summarized in Tables 1 and 2. The majority of participants (mean age = 70.6 years) were retired (63 percent), Black, and female. Retention rates were lowest for Arm 3 at Visit 2 (week 12, or study completion; 50 percent) and Visit 3 (3-month follow-up; 40 percent) (Figure 1). Consistent with the pilot nature of this study, data trends were analyzed for each group to generate a preliminary picture of intervention effects. Changes in physical, functional, and physiological measures were not found to be statistically significant across groups or over time (Tables S1-15 in Supplemental Data). Results from this study will inform power estimates for a future RCT investigating AFL efficacy in a larger study population.

	Arm 1 n = 10		**Arm 2 n = 10**		**Arm 3 n = 10**		**Total N = 30**	
Variable	M	SD	M	SD	M	SD	M	SD
Age (years)	73.4	5.6	68.5	7.5	69.8	5.4	70.6	6.4
Body mass index	34.7	5.7	29.7	7.5	34.3	6.7	32.9	6.8

Table 1: Participant Mean Age and Body Mass Index at Enrollment M = mean; SD = Standard deviation.

	Arm 1 n = 10		**Arm 2 n = 10**		**Arm 3 n = 10**		**Total N = 30**	
Variable	n	Percent	n	Percent	n	Percent	n	Percent
Sex								
Male	3	0.30	3	0.30	3	0.30	9	0.30
Female	7	0.70	7	0.70	7	0.70	21	0.70
Race								
White	5	0.50	5	0.50	2	0.20	12	0.40
African American/Black	5	0.50	5	0.50	8	0.80	18	0.60
Ethnicity								
Not Hispanic or Latino	10	1.00	10	1.00	10	1.00	30	1.00
Education								
Grade 12 or less	3	0.30	1	0.10	3	0.30	7	0.23
High school diploma	1	0.10	3	0.30	2	0.20	6	0.20
Some College or More	6	0.60	6	0.60	5	0.50	17	0.57
Employment								
Disabled	1	0.10	3	0.30	3	0.30	7	0.23
Retired	8	0.80	6	0.60	5	0.50	19	0.63
*Other	1	0.10	1	0.10	2	0.20	4	0.13
Medication use								
Antihypertensive	5	0.50	8	0.80	5	0.50	18	0.60
Cholesterol	6	0.60	5	0.50	8	0.80	19	0.63
Diabetes	4	0.40	4	0.40	2	0.20	10	0.33
Pain	7	0.70	4	0.40	3	0.30	14	0.47

Table 2: Participant Demographics and Other Characteristics *Employment category Other: Keeping House, Working Now.

Physical Outcomes: Over the study period, participants in Arms 1 and 2 reported more instances of pain and pain medication usage compared to Arm 3 reported through the mHealth tablet application. While mHealth data for Arm 1 and Arm 2 are consistent with elevated PROMIS Pain Intensity scores at all study visits (and slight increase on the post-intervention) (Table 3), pain level trends in Arm 3 remained unchanged. Pain Behavior, Pain Interference and Pain Intensity scores remained relatively stable from baseline to post-intervention for all Arms (Table 3). Although PROMIS Fatigue score changes were not statistically significant, there was a slight

increase in Arm 3 over time. Observations for these outcome variables are consistent with the total mean score for PROMIS measures in older adults (50 ± 10).

			Baseline		Post-intervention	
Variable	**Arm**	**N**	**M**	**SD**	**M**	**SD**
Pain Intensity	1	8	45.85	7.4	49.1	7.7
	2	6	42.5	11.3	45.3	7.1
	3	4	46.1	7.1	46.6	5.5
Fatigue	1	8	47.1	7.3	46.2	5.8
	2	5	46.9	16.2	47.7	8.6
	3	5	46.8	8.7	50.8	10.6
Pain Interference	1	7	54.7	6.4	52.1	7.2
	2	6	56.1	11.2	51.1	11.2
	3	4	54.4	4.3	53.3	8.3
Pain Behavior	1	7	55.2	4.6	55.9	5.8
	2	6	55.4	5.3	53.2	11.4
	3	4	54.2	3.5	57.3	5.2

Table 3: Physical Outcomes M=mean; SD=standard deviation.

Functional Outcomes: Functional measures were assessed at baseline and post-intervention using the PROMIS Physical Function short form 10b, 2-minute walk test, 30-s chair test, and Berg Balance Scale (Table 4). We also analyzed systolic and diastolic BP readings and pulse measures collected through the tablet application. Scores remained relatively stable and non-significant changes were observed for all arms in PROMIS Physical Function scores and performance in the 2-minute walking test. On the whole, post-intervention resting and 30 second BP and pulse measures were stable and no significant changes were observed. There were significant, positive improvements between baseline and post-intervention in all Arms with regards to balance (see table S12). Our findings for 2-minute walking distance are consistent with those consolidated from a meta-analysis of 4 studies that reported walk test distance weighted means of 535.1 (SD = 16.7) feet for males and 493.1 (SD = 4.3) feet for females between 70 - 79 years of age [43]. Our findings across the 2 measurement periods were well below those averages for all three Arms. There were no clinically meaningful changes noted in any group.

			Baseline		Post-intervention	
Variable	Arm	N	M	SD	M	SD
Physical function	1	7	43.9	10.8	42.9	6.8
	2	5	41.9	7.5	38.8	9.0
	3	4	46.5	5.9	45.0	8.0
2-minute walk test (feet)	1	7	307.3	81.0	289.9	63.9
	2	5	333.6	122.6	340.4	125.6
	3	4	359.0	102.2	335.0	118.0
Berg Balance Scale	1	6	48.7	5.7	50.5	4.6
	2	2	45.5	2.1	50.0	1.4
	3	2	48.5	2.1	53.0	2.4
30-s chair test Resting BP (systolic)	1	7	145.1	28.6	131.3	15.8
	2	5	121.2	10.3	135.4	6.7
	3	4	135.3	16.1	136.3	5.7
30-s chair test Resting BP (diastolic)	1	7	85.3	11.5	80.6	7.1
	2	5	77.0	5.6	81.0	7.7
	3	4	75.3	2.9	80.5	9.9
30-s chair test Resting pulse	1	7	74.1	9.7	76.3	15.0
	2	5	69.4	7.8	68.8	12.0
	3	4	75.0	14.4	75.3	11.7
30-s chair test Post BP (systolic)	1	6	145.0	36.0	136.0	16.0
	2	5	133.4	9.1	131.8	14.5
	3	4	144.8	15.6	153.5	19.7
30-s chair test Post BP (diastolic)	1	6	81.0	15.6	81.0	11.0
	2	5	76.8	10.6	75.8	9.9
	3	4	74.8	4.2	79.0	1.8

30-s chair test Post pulse	1	6	83.2	12.7	83.8	15.5
	2	5	74.6	10.6	76.0	13.9
	3	4	78.8	21.7	82.8	13.2

Table 4: Functional Outcomes BP; blood pressure; M = Mean; SD = Standard Deviation.

Physiological Outcomes: By the end of the study, Arm 2 demonstrated slightly decreased levels of cortisol compared to baseline whereas Arm 1 and Arm 3 showed no change or a slight increase respectively, although not of these trends were statistically significant (Table 5). 1,5-AG levels decreased comparatively across all 3 Arms despite not being statistically significant between and within groups over the intervention time-course and were above the normal reference value of 14.0 µg/ml.

			Baseline		Post-intervention	
Variable	**Arm**	**n**	**M**	**SD**	**M**	**SD**
Cortisol (ng/mL)	1	8	3.3	2.5	3.6	2.4
	2	6	3.5	2.3	2.9	2.1
	3	4	3.0	3.2	3.5	2.0
1,5-AG (µg/mL)	1	3	36.6	19.5	31.3	14.7
	2	3	26.1	7.8	20.7	2.6
	3	5	30.6	13.7	26.7	9.9

Table 5: Physiological Outcomes M = Mean; SD = Standard Deviation.

Finally, repeated measures analysis was conducted for each of the variables presented above to compare effects of intervention over time (Supplemental files). No significant effects and/or interactions were observed.

Discussion

The primary goal of this study was to derive preliminary signals of efficacy for AFL intervention components on physical, functional, and physiological outcomes in lower income older adults. These data will drive power estimates for future investigations evaluating the efficacy of the AFL (OG + GYYB + BA) intervention on physical health and function in a larger study population. Towards this end, we separately tested each component, positing that the integrated intervention would drive significant participant improvements related to the 3 main outcomes over the 12-week study period. To the best of our knowledge, there are no prior published studies in which the efficacy of a physical / behavioral mHealth intervention on measures of pain and fatigue in lower-income older adults have been evaluated.

After delivery of the intervention, our results did show significant, positive improvements in all arms with respect to balance probably related to the Otago component as it was the common activity shared by all arms; but we observed non-significant improvements in physical outcomes (e.g., pain) among participants receiving the full AFL program (Arm 3) compared to OG alone (Arm 1) or in combination with GYYB (Arm 2). We also observed a non-significant trend towards post-intervention improvements in walking distance in Arm 3. There were no significant changes in PROMIS physical function scores for any group. Several factors may have played a role with respect to functional outcomes. First, participants in Arm 2 showed signals of greater functional impairment compared to the other two Arms at baseline. Second, some participants indicated their lack of interest for the breathing exercises, which may have negatively impacted adherence to the prescribed activities for Arms 2 and 3.

Our preliminary results suggest that addition of positive reinforcement behaviors through BA may have helped offset unintended discomfort associated with strength training through the OG series of exercises. The well-established OG Exercise Program (OEP) is known to produce functional improvements in older adults. A systematic review of data from eight studies on modified OEP formats (five were RCTs, two were quasi-experimental, and one was a qualitative study) demonstrated improved balance, general mobility, and reduced falls in 604 male and female older adults with a mean age of 76.8 years [51]. In our study, although not statistically significant, pain interference was on a decreasing trend over time in all Arms. These findings are similar to those from a study conducted by Cederbom and Arkkukangas (2019) that found pain was significantly reduced from baseline at 3, 12, and 24 months in 199 older adults who participated in a 2-year OEP fall prevention intervention [52]. Despite starting out with the highest levels of pain medication usage, participants receiving the full AFL intervention in Arm 3 reported lower rates of pain pill consumption by week 12. Participants in Arm 3 also showed less fluctuation over time with regards to their average pain rating. Behavioral activation, which is a well-established approach for improvement of late life depression [22], has been shown to produce significant reductions in self-reported measures of pain and increased physical and social functioning [53,54].

Our data suggest that OG produced minimal physiological changes regardless of the intervention mode received by participants. Cortisol levels were slightly, albeit non-significantly,

elevated by the end of the study compared to baseline in Arms 1 and 3, while 1,5-AG levels were slightly reduced in all arms. Exercise has previously been shown to increase levels of 1,5-AG, however our study findings indicate a counterintuitive alignment between 1,5-AG and cortisol [50]. So, while the full AFL intervention might lead to improvements in pain, it is possible that participants experienced psychological stress due to intervention burden. Interestingly, increasing cortisol trends appeared to be offset by GYYB that has been linked to control of pain, improvements in stress and fatigue, and metabolic alterations [19,55-57]. For example, yogic practices reduced salivary cortisol levels among recovering breast cancer patients who had completed radiotherapy [58], while yogic breathing led to acute changes in salivary biomolecules associated with immune response (including tumor suppressors) as measured by proteomic analysis [59]. To our knowledge, there have been no previous studies conducted that correlated the levels of 1,5-AG and yoga practice in older adults. Future studies in a larger number of older participants will be helpful to determine the possible interaction effects of the multimodal intervention on physical, functional, and physiological outcomes, as our conclusions are currently limited by the small sample size of the study.

Strengths: A strength of the present study is the inclusion of comprehensive, validated instruments to assess self-reported health measures in a real-life setting of community dwelling older adults. The combination of self-reported data collected through both the mHealth application and PROMIS questionnaires administered by the study coordinator may have helped to circumvent reporting bias by one or both parties. The addition of biometric measurements contributed another level of validation to reports of pain and discomfort.

Limitations: As this was a small pilot study, it was not powered appropriately. Preliminary changes in health-related outcomes related to the AFL intervention were not considered clinically relevant due to the small sample size of the pilot study. This prevented determination of significance needed for robust hypothesis testing and for generalizability of study findings. Another unforeseen issue that affected participation, engagement, and post-intervention data collection was the housing instability of our participants that forced some to move or resulted in significant distress during the study period. Unfortunately, we were not able to address those issues as they were beyond the control of the research team. Finally, while trends from this study suggest that the combined AFL intervention produces benefits related to pain, mobility, and stress in lower-income older adults, we still lack a complete understanding of how interactions between the three components influence health-related behaviors and adherence to the prescribed changes [60]. Future modifications to this program may focus on developing an abbreviated version of this intervention (with regards to both time and participant effort) in consideration of the challenges faced by older adults living in low-income communities. While our study was to assess feasibility, future studies should extend the follow-up period to at least 16 weeks to determine overall intervention effects.

Conclusion

Older adults with lower incomes experience significant disparities with respect to their health status (in particular, incidence of chronic disease) as well as access to programs that would support healthy behaviors for managing pain and fatigue. Modified, non-pharmacological interventions that incorporate mHealth options are needed for older community-dwelling individuals that 1) are cost effective, 2) reduce the need for travel, and 3) combat stress-related behaviors (e.g., social isolation) that would impede adoption of healthy activities). While the benefits of OG are well established, data from this pilot study suggest the addition of BA can help to further improve health outcomes. Future studies should validate the efficacy of OG / BA with or without GYYB in larger groups of older adults to power for significance and explore additional intervention modifications that would help address unique barriers experienced by a lower-income, older population.

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References

1. Stolz E, Mayerl H, Waxenegger A, Freidl W (2017) Explaining the impact of poverty on old-age frailty in Europe: material, psychosocial and behavioural factors. Eur J Public Health 27: 1003-1009.
2. National Center for Health Statistics (2021) Percent of U.S. Adults 55 and Over with Chronic Conditions [Internet]. Centers for Disease Control and Prevention.
3. National Center for Chronic Disease Prevention and Health Promotion (2020) Promoting Health for Older Adults [Internet]. Centers for Disease Control and Prevention.
4. Cubanski J, Wyatt K, Damico A, Neuman T (2018) How Many Seniors Live in Poverty? Henry J. Kaiser Family Foundation.
5. Li Z, Dalaker J (2021) Poverty among americans aged 65 and older [Internet]. Congressional Research Service.
6. Maresova P, Javanmardi E, Barakovic S, Barakovic Husic J, Tomsone S, et al. (2019) Consequences of chronic diseases and other limitations associated with old age – a scoping review. BMC Public Health 19: 1431.
7. Nakai Y, Makizako H, Kiyama R, Tomioka K, Taniguchi Y, et al. (2019) Association between Chronic Pain and Physical Frailty in Community-Dwelling Older Adults. Int J Environ Res Public Health 16: 1-9.
8. Dahlhamer J, Lucas J, Zelaya C, Nahin R, Mackey S, et al. (2018) Prevalence of Chronic Pain and High-Impact Chronic Pain Among Adults -United States, 2016. Centers Dis Control Prev Morb Mortal Wkly Rep 67: 1001-1006.
9. Meng H, Hale L, Friedberg F (2010) Prevalence and predictors of fatigue in middle-aged and older adults: evidence from the health and retirement study. J Am Geriatr Soc 58: 2033-2034.
10. Hardy SE, Studenski SA (2010) Qualities of fatigue and associated chronic conditions among older adults. J Pain Symptom Manage 39: 1033-1042.
11. Miaskowski C, Blyth F, Nicosia F, Haan M, Keefe F, et al. (2020) A Biopsychosocial Model of Chronic Pain for Older Adults. Pain Med 21: 1793-1805.
12. Butera KA, Roff SR, Buford TW, Cruz-Almeida Y (2019) The impact of multisite pain on functional outcomes in older adults: biopsychosocial considerations. J Pain Res 12: 1115-1125.
13. Cai Y, Leveille SG, Shi L, Chen P, You T (2020) Chronic Pain and Risk of Injurious Falls in Community-Dwelling Older Adults. J Gerontol A Biol Sci Med Sci 76: e179-e186.
14. Crowe M, Jordan J, Gillon D, McCall C, Frampton C, et al. (2017) The prevalence of pain and its relationship to falls, fatigue, and depression in a cohort of older people living in the community. J Adv Nurs 73: 2642-2651.
15. Domenichiello AF, Ramsden CE (2019) The silent epidemic of chronic pain in older adults. Prog Neuropsychopharmacol Biol Psychiatry 93: 284-290.
16. Kechichian A, Lafrance S, Matifat E, Dubé F, Lussier D, et al. (2020) Multimodal Interventions Including Rehabilitation Exercise for Older Adults With Chronic Musculoskeletal Pain: A Systematic Review and Meta-analyses of Randomized Controlled Trials. J Geriatr Phys Ther 45: 34-49.
17. Arkkukangas M, Söderlund A, Eriksson S, Johansson A-C (2019) Fall Preventive Exercise With or Without Behavior Change Support for Community-Dwelling Older Adults: A Randomized Controlled Trial With Short-Term Follow-up. J Geriatr Phys Ther 42: 9-17.
18. Faber MJ, Bosscher RJ, Chin A Paw MJ, van Wieringen PC (2006) Effects of exercise programs on falls and mobility in frail and pre-frail older adults: A multicenter randomized controlled trial. Arch Phys Med Rehabil 87: 885-896.
19. Ho LYW, Ng SSM (2020) Non-pharmacological interventions for fatigue in older adults: a systematic review and meta-analysis. Age Ageing 49: 341-351.
20. Patel NK, Newstead AH, Ferrer RL (2012) The effects of yoga on physical functioning and health related quality of life in older adults: a systematic review and meta-analysis. J Altern Complement Med 18: 902-917.
21. Saoji AA, Raghavendra BR, Manjunath NK (2019) Effects of yogic breath regulation: A narrative review of scientific evidence. J Ayurveda Integr Med 10: 50-58.
22. Polenick CA, Flora SR (2013) Behavioral activation for depression in older adults: theoretical and practical considerations. Behav Anal 36: 35-55.
23. Osborn R, Doty MM, Moulds D, Sarnak DO, Shah A (2017) Older Americans Were Sicker And Faced More Financial Barriers To Health Care Than Counterparts In Other Countries. Health Aff (Millwood) 36: 2123-2132.
24. Bradway M, Carrion C, Vallespin B, Saadatfard O, Puigdomènech E, et al. (2017) mHealth Assessment: Conceptualization of a Global Framework. JMIR mHealth uHealth 5: e60.
25. Pew Research Center (2021) Mobile Fact Sheet - Who Owns Smartphones and Cellphones [Internet]. Pew Research Center: Information and Technology.
26. Haase KR, Cosco T, Kervin L, Riadi I, O'Connell ME (2021) Older Adults' Experiences With Using Technology for Socialization During the COVID-19 Pandemic: Cross-sectional Survey Study. JMIR aging 4: e28010.
27. Aslam A, van Luenen S, Aslam S, van Bodegom D, Chavannes NH (2020) A systematic review on the use of mHealth to increase physical activity in older people. Clin eHealth 3: 31-39.
28. Changizi M, Kaveh MH (2017) Effectiveness of the mHealth technology in improvement of healthy behaviors in an elderly population-a systematic review. MHealth 3: 51.
29. Mansson L, Lundin-Olsson L, Skelton DA, Janols R, Lindgren H, et al. (2020) Older adults' preferences for, adherence to and experiences of two self-management falls prevention home exercise programmes: a comparison between a digital programme and a paper booklet. BMC Geriatr 20: 209.
30. Stevens JA, Burns E (2015) A CDC Compendium of Effective Fall Interventions: What Works for Community-Dwelling Older Adults (3rd Edn) [Internet]. Centers for Disease Control and Prevention.3rd edn 885-896.
31. Satchidananda SS (2002) Integral Yoga Hatha. Buckingham, VA: Integral Yoga Publications1-189.
32. Sundaravadivel Balasubramanian. Gentle Yoga & Yogic Breathing for Scleroderma Symptom Management [Video] [Internet].

33. Twal WO, Wahlquist AE, Balasubramanian S (2016) Yogic breathing when compared to attention control reduces the levels of pro-inflammatory biomarkers in saliva: a pilot randomized controlled trial. BMC Complement 16: 294.

34. Dimidjian S, Hollon SD, Dobson KS, Schmaling KB, Kohlenberg RJ, et al. (2006) Randomized trial of behavioral activation, cognitive therapy, and antidepressant medication in the acute treatment of adults with major depression 74 :658-670.

35. Ader DN (2007) Developing the Patient-Reported Outcomes Measurement Information System (PROMIS) 45: S1-S2.

36. Cella D, Riley W, Stone A, Rothrock N, Reeve B, et al. (2010) The Patient-Reported Outcomes Measurement Information System (PROMIS) developed and tested its first wave of adult self-reported health outcome item banks. 63: 1179-1194.

37. Schneider S, Choi SW, Junghaenel DU, Schwartz JE, Stone AA (2013) Psychometric characteristics of daily diaries for the Patient-Reported Outcomes Measurement Information System (PROMIS®): a preliminary investigation. Qual Life Res 22: 1859-1869.

38. Lai JS, Cella D, Choi S, Junghaenel DU, Christodoulou C, et al. (2011) How item banks and their application can influence measurement practice in rehabilitation medicine: a PROMIS fatigue item bank example Arch Phys Med Rehabil 92: S20-S27.

39. Askew RL, Cook KF, Revicki DA, Cella D, Amtmann D (2016) Evidence from diverse clinical populations supported clinical validity of PROMIS pain interference and pain behavior. J Clin Epidemiol 73: 103-111.

40. Cook KF, Jensen SE, Schalet BD, Beaumont JL, Amtmann D, et al. (2016) PROMIS measures of pain, fatigue, negative affect, physical function, and social function demonstrated clinical validity across a range of chronic conditions. J Clin Epidemiol 73: 89-102

41. Rose M, Bjorner JB, Gandek B, Bruce B, Fries JF, et al. (2014) The PROMIS Physical Function item bank was calibrated to a standardized metric and shown to improve measurement efficiency. J Clin Epidemiol 67: 516-526.

42. Schalet BD, Hays RD, Jensen SE, Beaumont JL, Fries JF, et al. (2016) Validity of PROMIS physical function measured in diverse clinical samples. J Clin Epidemiol 73: 112-118.

43. Bohannon RW (2017) Normative reference values for the two-minute walk test derived by meta-analysis. J Phys Ther Sci 29: 2224-2227.

44. Jones CJ, Rikli RE, Beam WC (1999) A 30-s chair-stand test as a measure of lower body strength in community-residing older adults. Res Q Exerc Sport 70: 113-119.

45. Berg KO, Wood-Dauphinee SL, Williams JI, Maki B (1992) Measuring balance in the elderly: validation of an instrument. Can J Public Heal 2: S7-S11.

46. Park SH (2018) Tools for assessing fall risk in the elderly: a systematic review and meta-analysis. Aging Clin Exp Res 30: 1-16.

47. Herman JP, Ostrander MM, Mueller NK, Figueiredo H (2005) Limbic system mechanisms of stress regulation: hypothalamo-pituitary-adrenocortical axis. Prog Neuropsychopharmacol Biol Psychiatry 29: 1201-1213.

48. Gaffey AE, Bergeman CS, Clark LA, Wirth MM (2016) Aging and the HPA axis: Stress and resilience in older adults. Neurosci Biobehav Rev 68: 928-945.

49. Chaleckis R, Murakami I, Takada J, Kondoh H, Yanagida M (2016) Individual variability in human blood metabolites identifies age-related differences. Proc Natl Acad Sci USA 113: 4252-4259.

50. Honda H, Igaki M, Hatanaka Y, Komatsu M, Tanaka SI, et al. (2017) Repeated 3-minute stair climbing-descending exercise after a meal over 2 weeks increases serum 1,5-anhydroglucitol levels in people with type 2 diabetes. J Phys Ther Sci 29: 75-78.

51. Martins AC, Santos C, Silva C, Baltazar D, Moreira J, et al. (2018) Does modified Otago Exercise Program improves balance in older people? A systematic review. Prev Med Rep 11: 231-239.

52. Cederbom S, Arkkukangas M (2019) Impact of the fall prevention Otago Exercise Programme on pain among community-dwelling older adults: a short- and long-term follow-up study. Clin Interv Aging 14: 721-726.

53. Acierno R, Rheingold A, Amstadter A, Kurent J, Amella E, et al. (2012) Behavioral activation and therapeutic exposure for bereavement in older adults. Am J Hosp Palliat Care 29:13-25.

54. Quijano LM, Stanley MA, Petersen NJ, Casado BL, Steinberg EH, et al. (2007) Healthy IDEAS: A Depression Intervention Delivered by Community-Based Case Managers Serving Older Adults. J Appl Gerontol 26:139-156.

55. Vallath N (2010) Perspectives on yoga inputs in the management of chronic pain. Indian J Palliat Care 16: 1-7.

56. Kelley GA, Kelley KS (2020) Yoga, Health-Related Quality of Life and Mental Well-Being: A Re-analysis of a Meta-analysis Using the Quality Effects Model. J Gerontol A Biol Sci Med Sci 75: 1732-1736.

57. Mohammad A, Thakur P, Kumar R, Kaur S, Saini RV, et al. (2019) Biological markers for the effects of yoga as a complementary and alternative medicine. J Complement Integr Med 16: 1-15.

58. Chandwani KD, Perkins G, Nagendra HR, Raghuram NV, Spelman A, et al. (2014) Randomized, controlled trial of yoga in women with breast cancer undergoing radiotherapy. J Clin Oncol 32: 1058-1065.

59. Balasubramanian S, Janech MG, Warren GW (2015) Alterations in Salivary Proteome following Single Twenty-Minute Session of Yogic Breathing. Evid Based Complement Altern Med : 376029.

60. Middleton KR, Anton SD, Perri MG (2013) Long-Term Adherence to Health Behavior Change. Am J Lifestyle Med 7: 395-404.