HHS Public Access

Author manuscript

Public Health. Author manuscript; available in PMC 2018 November 12.

Published in final edited form as:

Public Health. 2016 April ; 133: 116–123. doi:10.1016/j.puhe.2016.01.004.

Clinically Meaningful Changes in Functional Performance Resulting from Self-directed Interventions in Individuals with Arthritis

Meghan Baruth, PhD[a,1], **Sara Wilcox, PhD**[a], **Bruce McClenaghan, PhD**[a], **Katie Becofsky, PhD**[a], and **Danielle E. Schoffman, BA**[a]

[a]University of South Carolina, 921 Assembly Street, Columbia, SC 29208 USA

Abstract

Objectives: To examine the clinically meaningfulness of changes observed in functional performance from two self-directed interventions targeting adults with arthritis.

Study design: Randomized controlled trial.

Methods: Participants (n=312) were randomized to a 12-week self-directed exercise or nutrition intervention. Objective measures of functional performance (6-minute walk, seated reach, grip strength, 30-second chair stand, gait speed, balance) were obtained at baseline, 12 weeks, and 9 months. Minimally (≥0.20 standard deviation) and substantially (≥0.50) meaningful changes in functional performance were examined. Changes in the percent 'impaired' and at risk for losing independence using established standards, and associations between physical activity and impairment/risk status were also examined. Group x Time interactions were not significant; therefore groups were combined in all analyses.

Results: Minimally (31–71%) and substantially (13–54%) meaningful changes in function were shown. There was a significant decrease in the percentage of participants 'impaired' on the 30-second chair stand (both time points) and gait speed (9 months). The percentage of participants at risk for losing independence significantly decreased for the 30-second chair stand (both time points) and the 6-minute walk (9 months). Those engaging in ≥2 hours of leisure-time physical activity were significantly less likely to be impaired on the 6-minute walk, 30-second chair stand, and gait speed at 12 weeks, and the 6-minute walk at 9 months.

Conclusions: Interventions that can slow functional declines, and ideally result in clinically meaningful improvements in functional performance among adults with arthritis are needed.

Correspondence to: Meghan Baruth.

[1]Present address: Saginaw Valley State University, 7400 Bay Road, University Center, MI 48710

This work was done at the University of South Carolina, in Columbia, SC

Ethical approval: The study was approved by the University of South Carolina's Institutional Review Board. All participants completed an informed consent form prior to participation.

Disclosure: All authors have approved the final article.

- MB, SW, and BM contributed to the conception and design of the study, acquisition of data, data analysis and/or interpretation of the data, and drafting the article.
- KB contributed to the acquisition of data, data analysis and/or interpretation, and drafting the article
- DS contributed to data analysis and/or interpretation and drafting the article

Competing Interests: None declared

Meaningful improvements in various indicators of functional performance can result from self-directed exercise and nutrition programs. These types of programs have the potential for wide-spread dissemination, and thus broad reach.

Keywords

arthritis; physical function; physical activity; nutrition; public health

Introduction

Arthritis is one of the most common chronic health conditions, affecting nearly 50 million adults in the United States in 2007–2009.[1] The high prevalence of arthritis-associated disability,[1] in addition to the billions of dollars attributed to arthritis,[2] make it a major public health concern. Unfortunately, arthritis and its subsequent limitations are expected to continue to grow over the next 40 years due to the aging population.[3] Among the many consequences of arthritis are decreased range of motion and reduced physical functioning,[4] likely leading to activity limitations. Limitations in activity due to arthritis are highly prevalent[1] and are also expected to grow by 2030.[3] Although functional limitations can vary significantly in how they are defined, studies have consistently shown a decline in function over time among individuals with arthritis.[5, 6]

The high and growing prevalence[1] and disabling effects of arthritis[7] have prompted a number of governmental agencies to formulate plans and strategies aimed at combating the condition and its negative consequences.[4, 8, 9] For example, one objective of Healthy People 2020[9] is to reduce the proportion of adults with doctor-diagnosed arthritis who find it “very difficult” to perform specific joint-related activities including walking a quarter of a mile; walking up 10 steps without resting; stooping, bending, or kneeling; and using fingers to grasp or handle small objectives.

Physical activity may be one means for slowing the progression and/or preventing functional declines among adults with arthritis. While a number of physical activity intervention studies have administered objective functional tests and examined change in function over time, [10–15] the meaningfulness of the changes has not been explored. Although examining whether a significant change in functional performance occurred is important, examining what that change means, and whether the change is meaningful, may be more valuable from a clinical standpoint.

STEPS to Health was a randomized, controlled trial that evaluated the effects of a 12-week, self-directed exercise program (First Step to Active Health®) for people with arthritis. The primary outcomes paper [16] examined and reported changes in functional performance at 12 weeks and 9 months. In general, results showed significant improvements in functional performance in both the intervention (exercise) and attention control (nutrition) groups at both follow-up time points. The purpose of this sub study was to further explore if the changes observed in functional performance were (1) clinically meaningful, (2) impacted the percentage of study participants classified as impaired , and (3) changed the percentage of participants at risk of losing functional independence.

Methods

Participant recruitment

A number of recruitment strategies were used, with the most common and most successful being emails to worksite listservs and newspaper advertisements. Because this study evaluated the effects of a public health intervention, a public health definition of arthritis, consistent with what is used in the National Health Interview Survey and the Behavioral Risk Factor Surveillance System,[17] was used. Participants responding yes to the question, "have you ever been told by a doctor or other health care professional that you have some form of arthritis, rheumatoid arthritis, gout, lupus, or fibromyalgia?" were eligible to take part in this study. Interested participants contacted the study office and completed a phone screen to assess eligibility status (Table 1).

Procedure

Participants deemed eligible following the telephone screening were scheduled to take part in a measurement session at the University of South Carolina. Prior to the scheduled measurement session, participants were mailed a survey and an informed consent form.

At the baseline measurement session, participants completed the informed consent form that was approved by the Institutional Review Board at the University of South Carolina, turned in their survey, and completed physical, functional, and anthropometric measurements. At then end of the session, each participant selected and opened a sealed envelope with his/her randomization assignment (prepared prior to the session by a biostatistician). Participants were randomized to a self-directed exercise program (First Step to Active Health®) or to an attention control self-directed nutrition program (Steps to Healthy Eating). Study staff met with participants to orient them to their self-directed program.

Prior to the 12-week and 9-month visits, participants received a reminder email (if provided) and telephone call. The same survey and measurement procedures were followed at both follow-up visits. Participants received a small cash incentive for taking part in each measurement session and for returning self-monitoring logs.

Interventions

First Step to Active Health® is a self-directed multi-component progressive exercise program. Each participant received a First Step to Active Health® kit and a folder containing weekly self-monitoring logs, postage-paid return envelopes (for the logs), a one-page handout that provided exercise tips and safety guidelines for adults with arthritis, and a calendar that described weekly study expectations.

The First Step to Active Health® kit contained (1) a program manual that included tools that helped participants set goals, customize their program, enhance motivation, and ensure safety, (2) a Thera-Band, and (3) four 'Steps' with illustrated fold-outs that demonstrated how to perform each exercise. Step 1 focused on cardiovascular activities; Step 2 on flexibility; Step 3 on strength; and Step 4 on balance. Once participants were comfortable with Step 1, they were instructed to add Step 2 into their routine (while continuing on with

Step 1), and so on. Although progression through the program was self-paced, participants were encouraged to incorporate all four steps by the end of 12 weeks.

Participants randomized to the attention control group received the Steps to Healthy Eating program, which was based on the USDA MyPyramid approach (which has since been replaced with MyPlate www.choosemyplate.gov), and developed for this study. Although MyPyramid and MyPlate have five food groups, only four were included to be consistent with the number of steps in the exercise program (dairy not included). This program had the same instructions, look, and feel as the exercise program. Participants received a folder with weekly logs, postage paid return envelopes (for the logs), and a study expectations calendar. They also received a kit with four nutrition 'Steps' that they were instructed to progress through during the 12 week study: (1) fruits, (2) vegetables, (3) grains, and (4) meat and beans.

Measures

Demographic and health-related.—Participants reported their age, gender, race, marital status, education, and number of years with arthritis. Height to the nearest 0.25 inch and weight to the nearest 0.1 pound were obtained via trained measurement staff, and BMI (kg/m^2) was calculated.

Physical activity.—The Community Health Activities Model Program for Seniors (CHAMPS) questionnaire measured total hours/week of leisure-time MVPA (≥ 3.0 METs; excluded household activities).[18] This measure has been shown to be valid [19], have acceptable test-retest reliability [19], and be sensitive to change [18, 20–23]. Participants were classified as engaging in ≥2.0 hours or <2.0 hours of leisure-time MVPA.

Functional performance.—The 6-minute walk test measured functional exercise capacity.[24, 25] Participants walked as quickly as possible for 6 minutes on a 38 meter walking course on a carpeted hallway. The score was the total distance walked in 6 minutes. This test has been shown to be valid and reliable [24, 25].

The seated reach test measured lower body flexibility.[26] With shoes removed, participants slowly bent forward, reaching as far forward as possible toward their toes, pushing a marker on a sit and reach box forward. The total distance reached to the nearest 0.5 cm was recorded. This measure has shown acceptable validity (for hamstring flexibility) in a sample of middle-aged to older adults [26].

A calibrated dynamometer set in a standardized position (Jamar®, Lafayette Instruments, Lafayette, IN) measured upper body strength (grip strength) (Jamar®, Lafayette Instruments, Lafayette, IN)[27, 28] in the dominant hand. This measure has been shown to be reliable [27] and valid [28].

The 30-second chair stand test measured lower body strength.[29] From a chair with their hands on the opposite shoulder, participants rose to a full stand and returned to a fully seated position, without using their arms. The total number of unassisted stands was recorded. This

measure has been show be valid and have good test-retest reliability in a sample of older adults[30].

The GAITRite® (CIR Systems, Havertown, PA), a portable walking mat with software, measured gait speed in meters/second.[31, 32] Participants walked on an instrumented walkway without shoes at their normal walking pace. Participants were allowed to use assistive devices. This measure has been shown to be a valid measure of gait [31], and have high test-retest reliability [32].

An AMTI (Advanced Mechanical Technology, Inc. Watertown, MA.) force platform (AccuSway^{PLUS}) measured postural sway (i.e., total displacement of the center of pressure, COP) during a 30-second trial.[33] Participants stood without shoes using a standardized foot position with their arms to the side, and their eyes focused on a target located at eye level and placed 5 feet away. This measure has been shown to have high test-retest reliability [33].

Statistical Analyses

Analyses for each outcome were limited to participants with data at baseline, and at least one follow-up period. Because Group x Time interactions revealed no significant differences in change over time between treatment groups, the groups were combined in all subsequent analyses.

The percentage of participants with a meaningful improvement in each functional measure at each time point was calculated. A minimally meaningful change was defined as an unadjusted pretest-posttest improvement ≥0.20 of the baseline standard deviation; a substantial change was a ≥0.50 improvement.[34]

Using Rikli and Jones' age- and gender-specific normative data,[35] participants' 6-minute walk test and 30-second chair stand test scores were classified as impaired (<25th percentile) or within normal limits (≥25th percentile) at each time point. Norms have only been developed for persons aged 60–94 years, therefore the 60–64 year norms were applied to participants <60. Age- and gender-specific data from two meta-analyses were used to classify participants' gait speed[36] and grip strength[37] as impaired (<25th percentile) or within normal limits (≥25th percentile) at each time point. A repeated measures analysis of covariance (SAS PROC GLIMMIX) examined changes in the percentage classified as impaired for each functional measure. All models controlled for age, gender, education (high school graduate or less vs. at least some college), marital status (married vs. not), and treatment condition. Norms for the seated reach and balance do not exist.

Using Rikli and Jones' age and gender-specific criterion-referenced fitness standards for maintaining physical independence in later life[38], participants' 6-minute walk test and 30-second chair stand test scores were also classified as being 'at risk' or 'not at risk' for losing independence. A repeated measures analysis of covariance (SAS PROC GLIMMIX) controlling for the same variables was conducted to examine changes over time in the percentage classified as at risk for losing independence. Criterion standards are not available for the other functional measures.

Finally, analysis of covariance models (SAS PROC GLIMMIX) examined whether engaging in ≥2.0 hours of leisure-time MVPA was associated with impairment status and risk for losing independence at each follow-up time. All models controlled for the same variables, plus functional status (dichotomous) and physical activity (dichotomous) at baseline.

Results

A more detailed description of the study flow has been previously reported[16] Of the 401 participants randomized, 312 (78%) had 12-week and/or 9-month follow-up data for at least one outcome. Those retained at either time point were more likely to have at least some college education than those lost at both follow-ups (p=.046). Demographic and health-related characteristics of the entire sample are shown in Table 2.

The percentage of participants with at least a minimally meaningful change (improvement ≥0.20 of the baseline standard deviation) and a substantial change (≥0.50 improvement), from baseline to 12 weeks and baseline to 9 months in each of the functional fitness tests is shown in detail in Table 3. At least minimally meaningful improvements were seen in 31% (grip strength) to 60% (chair stands) of participants at 12 weeks and 35% (grip strength) to 71% (chair stands) at 9 months. Substantial improvements were seen in 13% (grip strength) to 42% (chair stands) of participants at 12 weeks and 18% (6-minute walk) to 54% (chair stands) at 9 months.

The percentage of participants classified as impaired is shown in Table 4. There was a significant decrease in the percentage of participants classified as impaired on the 30-second chair stand test at 12 weeks (p<.0001) and 9 months (p<.0001), and a significant decrease in the percentage impaired on gait speed at 9 months (p=.01) but not 12 weeks (p=.45). There were no significant findings for the 6-minute walk test or grip strength.

The percentage of participants classified as at risk for losing independence in later life is shown in Table 5. There was a significant decrease in the percentage classified as at risk for losing independence on the 30-second chair stand test at 12 weeks (p=.0004) and 9 months (p<.0001). There was also a significant decrease in the percentage classified as at risk for losing independence on the 6-minute walk test at 9 months (p=.01), but not 12 weeks (p=.24).

The odds ratios, 95% confidence interval, and p-value examining the association between functional status and physical activity at 12 weeks and 9 months are shown in Table 6. At 12 weeks, participants who engaged in ≥2.0 hours of leisure-time MVPA were significantly less likely to be classified as impaired on the 6-minute walk test (OR 2.54, p=.02), 30-second chair stand test (OR 2.10, p=.02), and gait speed (OR 2.18, p=.03), but not grip strength. At 9 months, participants who engaged in ≥2.0 hours of leisure-time MVPA were significantly less likely to be classified as impaired on the 6-minute walk test (OR 2.39, p=.03), but not on any of the other functional measures. There was no relationship between the risk for losing independence and physical activity at either time point.

Discussion

The highly prevalent and debilitating nature of arthritis makes this condition an important target of public health interventions. Although management strategies differ across various types of arthritis, being physically active is appropriate for all types of arthritis, and may be very beneficial in preventing disability and loss of independence.[17] This study responds to a substantial gap in the literature by examining if the changes observed in functional performance (1) were clinically meaningful, (2) impacted the percentage classified as impaired, and (3) changed the percentage at risk of losing functional independence.

This study found no difference in change over time between the intervention (exercise) and attention control (nutrition) groups in any of the functional performance outcomes examined. Although leisure-time MVPA increased significantly more in the exercise group, unexpectedly, the nutrition group also showed increases, particularly at 9 months.[16] Participants enrolled in the study were likely motivated to make some changes to their lifestyle, and research suggests that health behavior change may serve a gateway to making other healthy lifestyle changes.[39] Therefore, participants making changes to their diet may have also made changes to their physical activity level. Furthermore, there is evidence that dietary intake is associated with functional performance.[40–43] The lack of differences suggests that self-directed nutrition and exercise interventions may both have positive effects on functional performance among adults with arthritis.

The level of change observed in functional measures at both 12 weeks and 9 months among a significant percentage of participants suggests that clinically meaningful improvements in various indicators of functional performance including cardiovascular fitness, strength, flexibility, and balance can result from self-directed exercise and nutrition programs in individuals with arthritis. Furthermore, our findings suggest that these types of public health programs may assist in decreasing one's risk for impairment and for losing independence. Although these findings are promising and appear to have clinical value, overall, the percentage of participants classified as impaired or at risk for losing their independence in this study was very high, and very concerning. Perhaps even more concerning is the fact that these estimates are likely quite conservative for the 6-minute walk and chair stand tests. Rikli and Jones' normative[44] (impaired status) and criterion[38] (risk for losing independence) standards only apply to those 60+ years old; therefore we applied the 60–64 year old standards to those <60 years of age. It is likely that participants <60 years of age who were impaired or at risk were not impaired or at risk *'enough'* to be captured using the 60–64 year old standards we applied. Regardless, these findings support the need for public health strategies/interventions that can result in changes in functional performance meaningful enough to reduce the risk for loss of independence and impairment status.

Our findings suggest that physical activity did in fact play at least some role in functional improvements. Participants who engaged in ≥2.0 hours of leisure-time MVPA were less likely to be classified as impaired on the 6-minute walk test, 30-second chair stand test, and gait speed at 12 weeks and the 6-minute walk test at 9 months. Although not statistically significant, engaging in ≥2.0 hours of leisure-time MVPA was associated with a lower odds of being at risk for losing independence at 12 weeks (ps=0.09). Increasing physical activity

levels may be one approach for producing meaningful improvements in functional performance among adults with arthritis.

Although other studies among adults with arthritis have examined change in functional performance using objective measures,[10–14] no studies to date have looked beyond this, examining the extent of meaningful change, change in impairment status, or change in risk for loss of independence. Additional studies are needed to better understand the clinical effects of both exercise and nutrition interventions on functional performance among adults with arthritis, as it appears that both types of interventions may produce meaningful changes. The findings of this study are very promising, particularly from a public health standpoint. Both programs are self-directed programs and have the potential for widespread dissemination. Neither program requires equipment, facilities, or face-to-face instructions with a trained facilitator. Although First Step to Active Health® was put on the CDC's Arthritis Programs 'watch list' [45] and is being further evaluated for its effectiveness as a public health intervention,[16] we believe that Steps to Healthy Eating also warrants further exploration.

The results of this study should be interpreted with limitations in mind including the self-reported nature of the physical activity measure. Despite being validated, there are inherent biases in using self-report tools. Second, our sample was largely well-educated females with low to moderate symptom severity and low levels of disability which may reduce the generalizability of our findings. Despite this, a number of participants were functionally impaired and/or at risk for losing independence at baseline.

Declines in functioning are often a consequence of arthritis. Interventions that can, at minimum, slow functional declines, and ideally, result in clinically meaningful improvements in functional performance are needed. Because arthritis and disability attributed to arthritis are so prevalent, public health approaches/interventions are a necessity. First Step to Active Health® and Steps to Healthy Eating are two self-directed, public health interventions that have the potential for wide spread dissemination, and thus broad reach. The results from this study are promising, showing clinically meaningful improvements in functional performance and reductions in impairment status and risk for loss of independence. Improvements of this magnitude across the entire population with arthritis could have a major impact on public health.

Acknowledgements

This study is registered with ClinicalTrials.gov: NCT01172327. This research is supported by the Centers for Disease Control and Prevention's National Center for Chronic Disease Prevention and Health Promotion by Cooperative Agreement Number U48-DP-001936, Special Interest Project (SIP) 09–028. The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention or the Department of Health and Human Services. We wish to thank the study participants and the research staff and students for their important contributions.

Role of Funding Source: None declared

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Table 1.

Eligibility Criteria for Steps to Health

Participants were eligible for the study if they:
• Were told by a health care professional that they have some form of arthritis
• Reported at least one symptom of arthritis (joint pain, stiffness, tenderness, decreased range of motion, redness and warmth, deformity, crackling or grating, fatigue)
• Were ≥18 years of age
• Were the only one in their household participating in the study
• Were not planning to move out of the area in the next nine months
• Were able to read and write in English
• Were not participating in another research study (unless it was an observational study without and intervention or medication)
Participants were ineligible for the study if they:
• Endorsed an item on the PA Readiness Questionnaire (PAR-Q) [46] :
○ Note: participants were not excluded if they took medication for hypertension and their blood pressure was controlled
• Had a fall in the past year that required medical assistance
• Were pregnant, breastfeeding, or planning to become pregnant in the next year (women)
• Were diabetic and taking insulin
• Could not walk longer than 3 minutes without a rest
• Could not stand without assistance for more than 2 minutes
• Could not sit in chair without arms for more than 5 minutes
• Were already physically active (aerobic activities ≥3 days/week for ≥30 minutes/day or strength training ≥2 days/week for ≥20 minutes/day)

Table 2.

Baseline demographic and health-related characteristics of participants

	N	Mean (SD) or %
Age, years	312	56.6 (10.4)
Body mass index, kg/m^2	312	33.0 (8.3)
Arthritis duration, years	312	10.3 (9.4)
Gender, % female	273	87.5
Race, % White	200	64.3
Education, % at least some college	277	88.8
Marital Status, % married or partnered	192	61.5
Presence of health conditions	310	1.2 (1.0)
Hypertension	152	48.7
High cholesterol	130	41.8
Osteoporosis	41	13.2
Cancer	35	11.3
Stroke	4	1.3

Table 3.

Meaningful change in functional performance at 12 weeks and 9 months

	Minimally Meaningful Change[a]				Substantial Change[b]			
	Baseline to 12 weeks		Baseline to 9 months		Baseline to 12 weeks		Baseline to 9 months	
	N	%	N	%	N	%	N	%
6-minute walk	109	36.8	116	41.7	47	15.9	49	17.6
Yes	187	63.2	162	58.3	249	84.1	229	82.4
No								
30-second chair stands	180	60.4	200	71.4	124	41.6	151	53.9
Yes	118	39.6	80	28.6	174	58.4	129	46.1
No								
Grip strength	93	30.8	98	34.6	40	13.3	55	19.4
Yes	209	69.2	185	65.4	262	86.8	228	80.6
No								
Gait speed	129	43.0	136	48.4	84	28.0	86	30.6
Yes	171	57.0	145	51.6	216	72.0	195	69.4
No								
Seated reach	114	38.1	138	49.1	51	17.1	72	25.6
Yes	185	61.9	143	50.9	248	82.9	209	74.4
No								
Balance	115	38.7	110	39.0	62	20.9	59	20.9
Yes	182	61.3	172	61.0	235	79.1	223	79.1
No								

[a] Minimally meaningful change defined as an improvement of ≥0.20 baseline standard deviation

[b] Substantial change defined as an improvement of ≥0.50 baseline standard deviation

Table 4.

Change in percentage of participants classified as impaired at 12 weeks and 9 months

	N	Baseline[1] (%)	N	12 weeks[1] (%)	N	9 months[1] (%)	p-value[2]
6-minute walk	138		123		115		
Impaired	173	44.4	174	41.4	164	41.2	0.87
Not impaired		55.6		58.6		58.8	
30-second chair stands	218		154		127		
Impaired	94	69.9	144	51.7	153	45.4	<0.0001
Not impaired		30.1		48.3*		54.6*	
Grip strength	168		160		144		
Impaired	129	56.6	131	55.0	126	53.3	0.82
Not impaired		43.4		45.0		46.7	
Gait speed	259		244		211		
Impaired	52	83.3	58	80.8	71	74.8	0.02
Not impaired		16.7		19.2		25.2*	

[1] Unadjusted percentage

[2] Adjusted for group, age, gender, education, marital status

* Significant change from baseline

Table 5.

Change in percentage of participants at risk for losing independence at 12 weeks and 9 months

	N	Baseline (%)[1]	N	12 weeks (%)[1]	N	9 months (%)[1]	p-value[2]
6-minute walk	288		249		218		
At risk	24	92.3	49	83.6	62	77.9	0.04
Not at risk		7.7		16.4		22.1*	
30-second chair stands	255		232		206		
At risk	56	82.0	65	78.1	73	73.8	<.0001
Not at risk		18.0		21.9*		26.2*	

[1] Unadjusted percentage

[2] Adjusted for group, age, gender, education, marital status

* significant change from baseline

Table 6.

Relationship between functional performance and physical activity at 12 weeks and 9 months

	6-Minute Walk		30-second Chair Stands		Grip Strength		Gait Speed	
	N OR (95% CI)	p-value[1]	N OR (95% CI)	p-value[1]	N OR (95% CI)	p-value[1]	N OR (95% CI)	p-value[1]
Impairment Status: Modeling odds of not impaired at 12 weeks and 9 months								
Engaged in ≥2.0 hrs leisure- time MVPA at 12 wks	296 2.54 (1.16, 5.58)	0.02	298 2.10 (1.12, 3.94)	0.02	285 1.48 (0.78, 2.83)	0.23	301 2.18 (1.08, 4.43)	.03
Engaged in ≥2.0 hrs leisure-time MVPA at 9 mos	277 2.39 (1.07, 5.36)	0.03	279 1.35 (0.75, 2.45)	0.32	264 0.53 (0.27, 1.04)	0.07	280 1.31 (0.66, 2.60)	.43
Risk for Losing Independence: Modeling odds of not at risk at 12 weeks and 9 months								
Engaged ≥2.0 in hrs leisure-time MVPA at 12 wks	296 1.93 (0.91, 4.06)	0.09	298 1.92 (0.89, 4.15)	0.09				
Engaged in ≥2.0 hrs leisure-time MVPA at 9 mos	277 1.29 (0.60, 2.76)	0.52	279 1.29 (0.65, 2.56)	0.46				

[1]Adjusted for group, age, gender, education, marital status, baseline physical activity (yes/no), and baseline impairment status (yes/no) or baseline risk for losing independence (yes/no)