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Exercise: An Active Route to Healthy Aging

Effects of a Physical Activity Intervention on Measures of Physical Performance: Results of the Lifestyle Interventions and Independence for Elders Pilot (LIFE-P) Study

The LIFE Study Investigators*
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Background. The Short Physical Performance Battery (SPPB), which includes walking, balance, and chair stands tests, independently predicts mobility disability and activities of daily living disability. To date, however, there is no definitive evidence from randomized controlled trials that SPPB scores can be improved. Our objective was to assess the effect of a comprehensive physical activity (PA) intervention on the SPPB and other physical performance measures.

Methods. A total of 424 sedentary persons at risk for disability (ages 70–89 years) were randomized to a moderate-intensity PA intervention or a successful aging (SA) health education intervention and were followed for an average of 1.2 years.

Results. The mean baseline SPPB score on a scale of 0–12, with 12 corresponding to highest performance, was 7.5. At 6 and 12 months, the PA versus SA group adjusted SPPB (± standard error) scores were 8.7 ± 0.1 versus 8.0 ± 0.1, and 8.5 ± 0.1 versus 7.9 ± 0.2, respectively ($p < .001$). The 400-meter walking speed was also significantly improved in the PA group. The PA group had a lower incidence of major mobility disability defined as incapacity to complete a 400-meter walk (hazard ratio = 0.71, 95% confidence interval = 0.44–1.20).

Conclusions. A structured PA intervention improved the SPPB score and other measures of physical performance. An intervention that improves the SPPB performance may also offer benefit on more distal health outcomes, such as mobility disability.

As the life expectancy in the United States continues to rise, the maintenance of independence of older Americans has emerged as a major clinical and public health priority (1,2). Physical performance measures have been used to assess the risk of disability and to test the efficacy of preventive strategies (3,4). The Short Physical Performance Battery (SPPB) is a standardized measure of lower extremity physical performance that includes walking, balance, and strength tasks, and has been used in a broad range of epidemiological studies of aging (5–11). A low SPPB score is a strong risk factor for institutionalization, morbidity, mortality, and disability in initially nondisabled older persons. The association of low SPPB scores with clinically relevant outcomes is independent of other health conditions and socioeconomic factors, a finding that has been consistently confirmed in diverse settings and populations (5–10,12).

Randomized controlled trials in older persons have shown that structured physical activity (PA) interventions, including resistance and endurance exercises, improve a variety of physical performance measures, such as walking speed, stair-climb speed, balance, and chair stands (13–24). Additional intervention studies have shown that PA can result in improved changes in the SPPB score (25,26). The latter studies have been limited by relatively small sample size and short duration of follow-up. To our knowledge, conclusive evidence from large, multicenter, randomized controlled trials that a structured PA intervention can improve the SPPB score is still lacking. To address this gap in knowledge, we report the main results of the Lifestyle Interventions and Independence for Elders pilot (LIFE-P) study. An intervention that improves performance on the SPPB score may also offer benefit on more distal health outcomes, such as major mobility disability (7).

Methods

Study Design

LIFE-P was a single-blind, multicenter, randomized controlled trial of a PA intervention compared to a successful aging (SA) intervention in sedentary older adults (27). The study was implemented to refine key trial design benchmarks, including the primary outcome of major mobility disability, sample size calculations, methods for recruitment, participant retention, adherence to and safety of the interventions, and organizational infrastructure, and to provide internal validity concerning the efficacy of the PA intervention by assessing its effects on the SPPB score and on 400-meter walk speed.

The study was conducted at four field centers (Cooper Institute, Stanford University, University of Pittsburgh, and

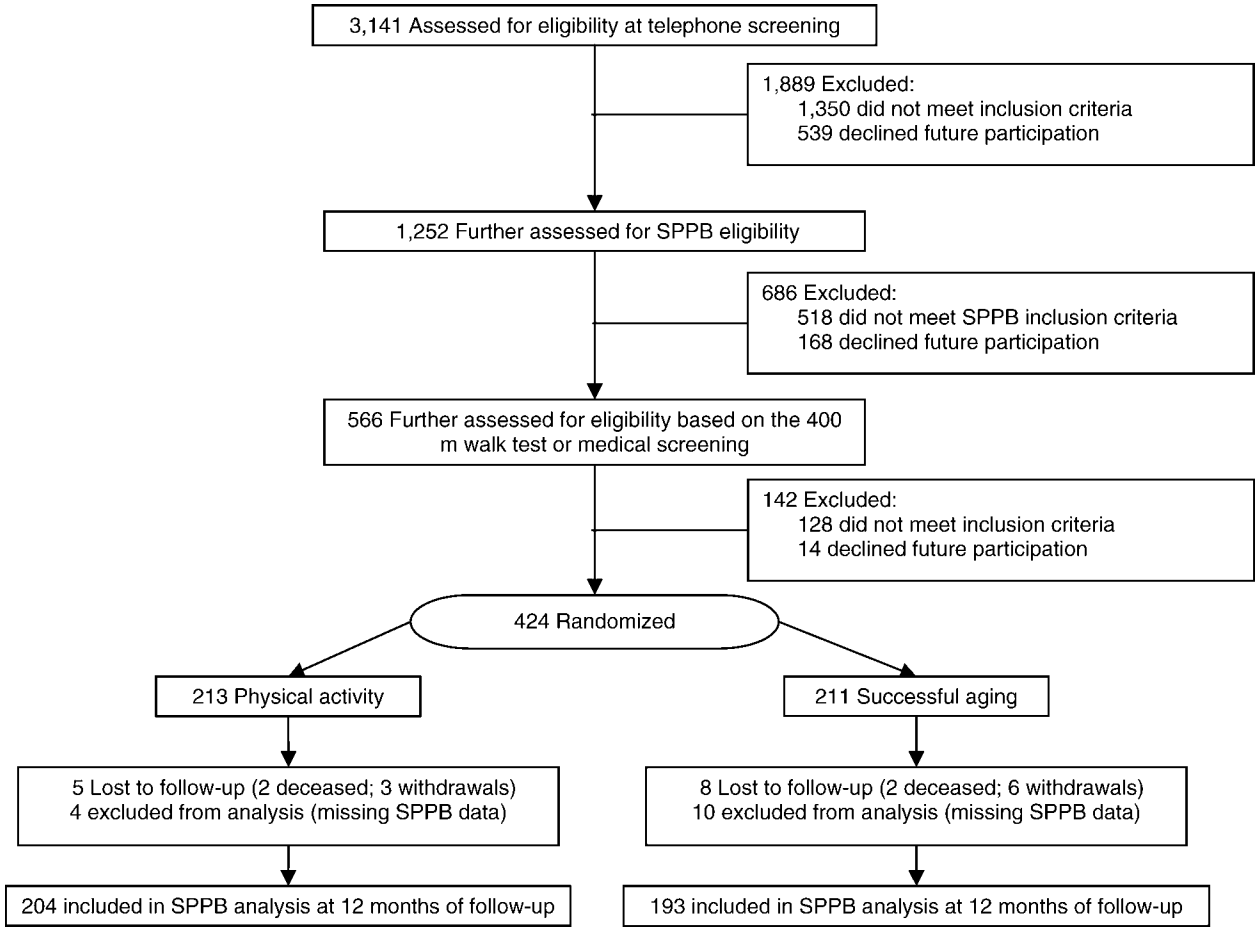

Figure 1. Flow diagram. SPPB = Short Physical Performance Battery.

Wake Forest University [WFU]). Data management and statistical analyses were performed at WFU, and the Administrative Coordinating Center was first at WFU, and later moved to the University of Florida. The study was approved by the local institutional review boards. A data safety monitoring board monitored safety and the conduct of the trial; participants gave written informed consent. The protocol is consistent with the principles of the Declaration of Helsinki and is registered at www.ClinicalTrials.gov (registration # NCT00116194).

Participants

The design of the trial has been described in detail elsewhere (27). Briefly, inclusion criteria were having an age of 70 to 89 years, having a sedentary lifestyle (<20 min per week spent in structured PA during the past month), being able to walk 400 meters within 15 minutes without sitting and without use of any assistive device, having a SPPB score ≤9 (on a scale of 0 to 12, as described below), having completed a behavioral run-in related to logging health behavior, given informed consent, living in the study area, and not planning to move for at least 9 months. Participants were ineligible if they had severe heart failure, uncontrolled angina, severe pulmonary disease, chest pain or severe shortness of breath during the 400-meter walk test, severe arthritis, cancer requiring treatment in the past 3 years, Parkinson's disease, other severe illness that may interfere with physical activity, illness with life expectancy of less than 12 months, or a Mini-Mental State Examination score <21 (28). Temporary exclusion criteria were acute myocardial infarction, deep venous thrombosis, pulmonary embolism, major arrhythmias, or stroke within 6 months, recent major surgery, uncontrolled hypertension, uncontrolled diabetes, and ongoing lower extremity physical therapy.

Recruitment relied primarily on mass mailing, community outreach, and media advertising. Participants who were eligible after an initial phone screening were invited for clinic visits, during which they signed the informed consent form and completed a personal interview, the SPPB, a physical exam, an electrocardiogram, and a 400-meter walk test. Eligible participants received detailed instructions for a 1-week to 2-week behavioral run-in, during which they were asked to self-monitor specific behaviors and to complete forms related to these behaviors. Participants who successfully completed the behavioral run-in received additional baseline assessments and were randomized to the study interventions via a web-based system. Of the 3141 persons who were initially screened by phone, a total of 424 (13.5%) were ultimately randomized (Figure 1). The

recruitment goal was 400 participants (70% women, 25% minorities, and 40% with SPPB score ≤7).

Physical Activity Intervention

The PA intervention consisted of a combination of aerobic, strength, balance, and flexibility exercises. The intervention was divided into three phases: adoption (weeks 1–8), transition (weeks 9–24), and maintenance (week 25 to the end of the trial). Each participant in the PA group received a 45-minute individualized, introductory session to describe the intervention and to provide individual counseling to optimize safety and participation. For the first 2 months (adoption), three center-based exercise sessions (40–60 min) per week were conducted in a supervised setting. During the next 4 months (transition), the number of center-based sessions were reduced (2/week) and home-based endurance/strengthening/flexibility exercises (≥3/week) were started. The subsequent maintenance phase consisted of the home-based intervention, optional once-to-twice-per-week center-based sessions, and monthly telephone contacts. The PA intervention included group-based behavioral counseling sessions (1/week for the first 10 weeks) that focused on PA participation and disability prevention, and on encouraging participants to increase all forms of PA. The PA intervention focused on walking as the primary mode of exercise. The goal was walking for at least 150 minutes over the course of the week (29). Each session was preceded by a brief warm-up and followed by a brief cool-down period. To complement the walking program, participants completed lower extremity strengthening exercises, followed by lower extremity stretching exercises. Balance training was introduced during the adoption phase. The intensity of training was gradually increased over the first 2–3 weeks. Perceived exertion assessed by the Borg scale (30) was used to regulate the intensity of exercise; moderate intensity exercise was promoted (31,32). Participants were asked to walk at a target intensity of 13 (somewhat hard), and they were discouraged from exercising at levels ≥15 (hard) or ≤11 (fairly light). Strengthening exercises were performed at a perceived exertion of 15–16.

Successful Aging Intervention

An SA health education intervention was used as the active control and was designed to provide attention and health education. Participants met in small groups weekly for the first 26 weeks and then monthly. Sessions included health topics relevant to older adults such as nutrition, medications, foot care, and recommended preventive services at different ages. Basic educational information related to physical activity was provided. At the end of each session, a short instructor-led intervention (5–10 min) of gentle upper extremity stretching exercises was delivered. Telephone calls were made after each missed session to encourage regular participation, and participants received a monthly newsletter.

Measurements

Participants were enrolled between April 2004 and February 2005. Follow-up was planned for 12 to18 months, depending on the date of randomization, and included semiannual clinic visits for data collection. The 18-month visit was performed only in participants who were recruited early in the study, primarily to assess the persistence of major mobility disability (data are not reported here). To ensure blinding, participants were instructed not to discuss their intervention during the assessments, and the assessments were conducted by blinded staff members at locations other than the intervention sites.

Baseline assessments included a personal interview, anthropometric measures, physical exam, electrocardiogram, and a physician evaluation. The Mini-Mental State Examination test was used for cognitive screening (28). Prevalence of clinical conditions was determined using self-reported physician-diagnosed disease information. The Community Healthy Activities Model Program for Seniors (CHAMPS) questionnaire was used to assess self-reported physical activity (33).

Outcomes

The SPPB score is based on timed measures of standing balance, walking speed, and ability to rise from a chair (7,9). For the balance test, participants were asked to maintain their feet in side-by-side, semitandem (heel of one foot beside the big toe of the other foot), and tandem (heel of one foot in front and touching the other foot) positions for 10 seconds each. Walking speed was assessed by asking participants to walk at their usual pace over a 4-meter course. Two walk times were recorded, and the faster of the two was used to compute the walking test score. For the chair test, participants were asked to stand up from a sitting position with their arms folded across the chest. If participants were able to perform this task, they were asked to stand up and sit down five times as quickly as possible, and the time to perform the test was recorded.

Each of the three performance measures was assigned a score ranging from 0 to 4, with 4 indicating the highest level of performance and 0 the inability to complete the test. A summary score (range 0–12) was subsequently calculated by adding the three scores. For the test of balance, participants were assigned the following scores: 1 if they could only hold a side-by-side standing position for 10 seconds; 2 if they could hold a semitandem position for 10 seconds, but were unable to hold a full-tandem position for more than 2 seconds; 3 if they could stand in a full-tandem position for 3 to 9 seconds; and 4 if they could stand in a full-tandem position for 10 seconds.

Four categories were computed for walking speed and chair stands, according to cut-points based on quartiles of the time to perform each task established by the Established Populations for Epidemiologic Studies of the Elderly (EPESE) (6). Gait speed was scored as follows: <0.41 m/s = 1; 0.41–0.57 m/s = 2; 0.58–0.75 m/s = 3; >0.75 m/s = 4. The time required to perform five chair stands was scored as follows: >16.6 s = 1; 13.7–16.6 s = 2; 11.2–13.6 s = 3; <11.2 s = 4.

For the 400-meter walk, participants were asked to walk 10 laps of a 20-meter course at their usual pace. Participants were allowed to stop and rest if necessary, but without sitting. Major mobility disability was defined as the inability to complete the 400-meter walk test within 15 minutes. If the 400-meter walk test could not be assessed, the outcome

Table 1. Baseline Characteristics of Study Participants According to Randomized Groups

Characteristics	Physical Activity ($N = 213$) N (%) or Mean ± *SD*	Successful Aging ($N = 211$) N (%) or Mean ± *SD*
Age		
<80 years	160 (75.1%)	149 (70.6%)
≥80 years	53 (24.9%)	62 (29.4%)
Gender, female	146 (68.5%)	146 (69.2%)
Race		
White	160 (75.1%)	155 (73.5%)
African American/Black	37 (17.4%)	40 (19.0%)
Other	16 (7.5%)	16 (7.6)
Education		
No formal education	0 (0.0%)	0 (0.0%)
Elementary school	5 (2.3%)	6 (2.8%)
High school or equivalency	58 (27.2%)	58 (27.5%)
College	106 (50.0%)	88 (41.7%)
Post graduate	36 (17.0%)	54 (25.6%)
Other	8 (3.8%)	5 (2.4%)
Smoking habits		
Never	174 (81.7%)	176 (83.4%)
Former	32 (15.0%)	28 (13.3%)
Current	7 (3.3%)	7 (3.3%)
Body Mass Index (weight • height^{-2})	30.7 ± 6.2	29.7 ± 5.8
MMSE Score	27.1 ± 2.4	27.4 ± 2.1
Prevalent diseases		
Hypertension	148 (69.5%)	145 (68.7%)
Diabetes	58 (27.2%)	34 (16.1%)
Cancer	38 (17.8%)	36 (17.1%)
Myocardial infarction	24 (11.3%)	15 (7.1%)
Congestive heart failure	11 (5.2%)	13 (6.2%)
Stroke	8 (3.8%)	12 (5.7%)
Atrial fibrillation/flutter	6 (2.8%)	10 (4.7%)
Pacemaker	5 (2.4%)	3 (1.4%)
SPPB score	7.6 ± 1.5	7.5 ± 1.4
400 m walk speed m/s	0.86 ± 0.18	0.85 ± 0.18

Note: *SD* = standard deviation; MMSE = Mini-Mental State Examination; SPPB = short physical performance battery.

was adjudicated by a committee of masked investigators who used information from self-reports and proxy reports, the result of the 4-meter walk test, and medical records. Deaths were verified from proxies, death certificates, and medical records.

Statistical Analysis and Sample Size Considerations

For comparing the SPPB scores at the 6-month or 12-month visits, the study had 80% power to detect a mean difference between intervention groups of 0.52 and 90% power to detect a mean difference of 0.60, assuming a two-sided 0.05 significance level and testing hypotheses as contrasts using repeated measures analysis of covariance. A 0.5 difference in SPPB score is considered a meaningful change (34).

All comparisons between intervention groups were performed with participants grouped according to randomization assignment. Comparisons of discrete baseline characteristics (e.g., gender, race) were performed using chi-square tests and comparisons of continuous variables were performed using Wilcoxon's rank–sum test. The numbers of participants experiencing serious and nonserious adverse events, as reported during assessment visits, were compared between groups using chi-square tests. Mean differences in SPPB scores and 400-meter walk speed between intervention groups were estimated using repeated measures analysis of covariance, with the baseline value, gender (stratifying variable for randomization), intervention assignment, follow-up visit, and an intervention by visit interaction included in the model. Hypothesis tests for intervention effects at the 6-month and 12-month follow-up visits were performed using contrasts of the 6-month and 12-month intervention means. Overall comparison between groups for the SPPB score and 400-meter walk time were obtained using a contrast to compare average effects across both follow-up visits. The distribution of times until failure to complete the 400-meter walk (or death) was described using Kaplan–Meier plots. Hazard ratios and 95% confidence intervals were estimated using proportional hazards regression.

Table 2. Frequency of Moderate Physical Activity per Week and Estimate of Calories Spent in Moderate PA per Week (CHAMPS Questionnaire) According to Randomized Groups

Group	Baseline	6 Months	12 Months
Frequency of moderate physical activity per week			
Successful aging	2.8 ± 3.8	3.6 ± 4.3	3.5 ± 4.0
Physical activity	2.7 ± 3.9	6.4 ± 5.2	5.1 ± 5.2
	$p = .60$	$p < .001$	$p < .002$
Calories spent in moderate PA per week			
Successful aging	596 ± 903	772 ± 1189	710 ± 978
Physical activity	655 ± 1033	1284 ± 1343	1001 ± 1084
	$p = .98$	$p < .001$	$p = .002$

Note: PA = physical activity; CHAMPS = Community Healthy Activities Model Program for Seniors.

Results

The mean age of the 424 participants was 76.8 years (standard deviation [*SD*] = 4.2 years); 68.9% were women, 25.5% were racial/ethnic minorities, and 41.7% had an SPPB score ≤7. The two randomized groups had similar baseline characteristics, except for a higher prevalence of diabetes in the PA group (Table 1).

The attendance rate of the follow-up assessments was excellent, with attendance rates for the clinic visits being 94.8% at 6 months and 94.0% at 12 months. In the PA group, attendance rates to the adoption and transition phases were 70.7% and 60.9%; during the maintenance phase, participants who returned their activity logs engaged in an average of 3.7 walking sessions per week and walked an average of 138 minutes per week (*SD* = 149, 25th percentile = 63, 75th percentile = 185). Attendance rates to SA were 70% for weeks 1 to 26 and 73% for weeks 27 to 52. The number of bouts of moderate PA and estimated calories expended in such activities were similar in the two groups at baseline and significantly higher in the PA group during follow-up (Table 2).

Table 3. Adverse Events According to Randomized Groups

	Physical Activity $N = 213$ No. of Persons (%)	Successful Aging $N = 211$ No. of Persons (%)	p
A—Nonserious adverse events			
Outpatient surgical procedure	82 (38.5%)	62 (29.4%)	.06
Sought advice from a physician or medical professional for any of the following:			
Back injury	30 (14.1%)	36 (17.1%)	.42
Fainting/passing out	12 (5.6%)	8 (3.8%)	.49
Shortness of breath/asthma	34 (16.0%)	40 (19.0%)	.44
Abnormal heart rhythm	43 (20.2%)	24 (11.4%)	.016
Joint sprain	21 (9.9%)	20 (9.5%)	>.99
Other problem affecting walking	98 (46.0%)	83 (39.3%)	.23
Experienced any of the following:			
Muscle strain, stiffness or soreness	178 (83.6%)	168 (79.6%)	.52
Foot pain	112 (52.6%)	104 (49.3%)	.62
Fatigue	169 (79.3%)	165 (78.2%)	>.99
Dizziness	91 (42.7%)	87 (41.2%)	.92
Other illness restricting activity	75 (35.2%)	68 (32.2%)	.60
Total	208 (97.7%)	207 (98.1%)	.21
B—Serious adverse events			
Death	2 (0.9%)	2 (0.9%)	>.99
Life-threatening event	3 (1.4%)	3 (1.4%)	>.99
Inpatient hospitalization	44 (20.7%)	44 (20.9%)	>.99
Clinically significant abnormal laboratory or diagnostic test	6 (2.8%)	8 (3.8%)	.60
Total	48 (22.5%)	50 (23.7%)	.82

The two groups had similar rates of nonserious adverse events (Table 3). Among individual events, outpatient surgical procedures (primarily elective cataract surgery) were more frequent in the PA group ($p = .06$). A significantly higher number of participants in the PA group sought advice from a physician or medical professional for an abnormal heart rhythm ($p = .016$). Both groups had similar rates of serious adverse events, with the most common being acute hospital admissions.

Over 1 year of follow-up, the SPPB score was significantly improved in the PA group compared with the SA group (Figure 2). The adjusted difference in SPPB score between the two groups was 0.7 at 6 months and 0.6 at 12 months. At each time point, significant differences were observed for improvement and decline in SPPB scores; a higher number of participants in the PA group improved by $\geq$1 point and a higher number of participants in the SA group declined by $\geq$1 point (Figure 3). The 400-meter walk speed declined in the SA group and remained approximately stable in the PA group ($p < .001$) (Figure 2). The beneficial effects of PA on the SPPB score and on the 400-meter walk speed were fairly uniform across subgroups defined by age, gender, race, baseline physical performance, and comorbidity (Figure 4).

Over an average follow-up duration of 1.2 years, 12.2% (26/213) of participants in the PA group and 15.6% (33/211) of participants in the SA group experienced the outcome of

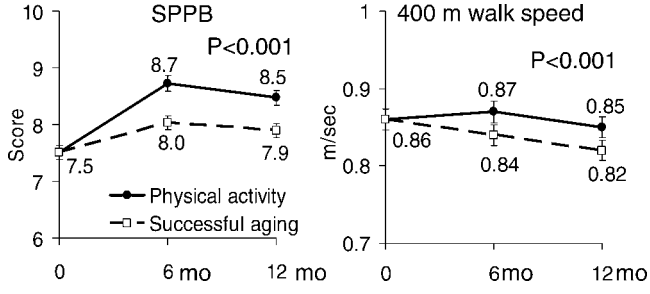

Figure 2. Short Physical Performance Battery (SPPB) score and 400 m walk speed according to randomized groups at baseline and during follow-up. Means estimated from repeated measures analysis of covariance adjusted for gender, field center and baseline values.

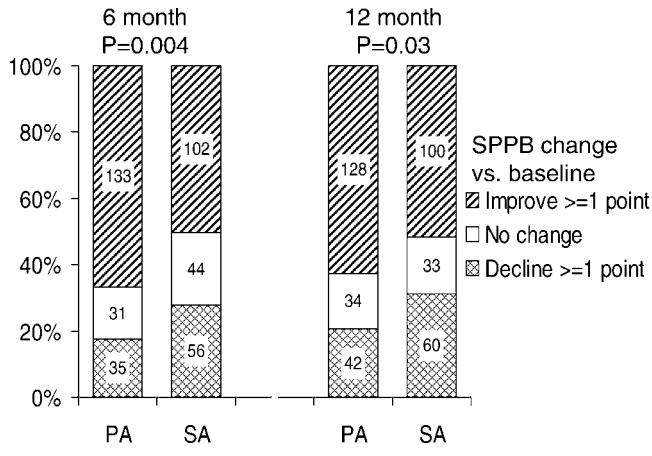

Figure 3. Number of participants who improved by $\geq$1 point, did not change, or declined by $\geq$1 point in the Short Physical Performance Battery (SPPB) score from baseline to 6 and 12 months of follow-up. The number in the bar indicates the number of participants in each category. Accordingly, the number needed to treat (NNT) for improvement was approximately 6 at 6 months and 9 at 12 months, and NNT for preventing decline was approximately 10 at both 6 and 12 months.

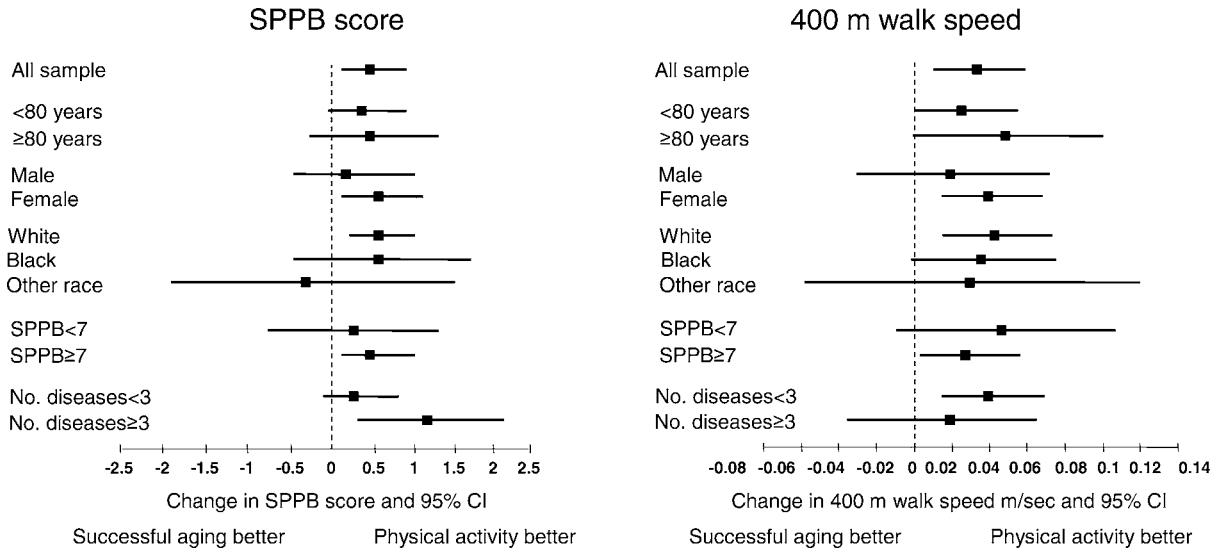

Figure 4. Estimated effects of the intervention on the Short Physical Performance Battery (SPPB) score and 400 m walk speed expressed as mean change in the physical activity group minus mean change in the successful aging group from baseline to 12 months according to selected baseline characteristics. Mean changes and their 95% confidence intervals (CI) are illustrated by the bars.

major mobility disability (Figure 5). The combined outcome of major mobility disability or death was experienced by 12.7% (27/213) and 16.1% (34/211) of participants in the two groups, respectively.

Discussion

Compared with an SA health education intervention, a structured PA intervention significantly improved the SPPB score and 400-meter walk speed, and tended to reduce the risk of major mobility disability. Preserving mobility is central to maintaining a high quality of life and to many activities needed for full independence. Impaired mobility predicts multiple adverse outcomes, such as morbidity, worsening disability, institutionalization, and mortality (5,35,36). To our knowledge, this is the first large, multicenter, randomized controlled trial to conclusively demonstrate that the SPPB score, an established independent risk factor for disability, is modifiable. The study also demonstrates that a simple and practical PA intervention can be safely administered to sedentary older persons who are at high risk of disability.

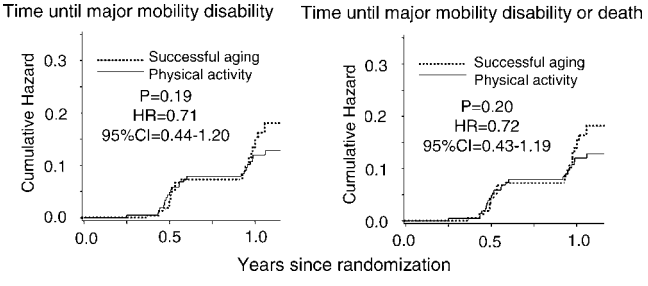

Figure 5. Cumulative hazard of time until major mobility disability and until major mobility disability or death, according to randomized groups. HR = hazard ratio; CI = confidence interval.

There may be potential concern regarding the adherence to and long-term safety of regular structured PA interventions in older persons with functional limitations. In our study, the PA adherence rates were excellent, and comparable to or better than those achieved in other similar PA trials in older persons (19,20,37). The overall rates of nonserious adverse events were similar in the two groups. Among the specific nonserious adverse events, the PA group reported a higher rate of outpatient surgical procedures, which were primarily elective cataract surgery, and more often sought advice from a physician or medical professional for an abnormal heart rhythm. The former is unlikely to be related to the intervention, and the latter might be expected given the increase in heart rate the participants experienced during the PA sessions. Serious adverse events were equally balanced between the two groups.

Longitudinal observational studies suggest that regular PA not only may extend life expectancy, but also may reduce the risk of physical disability in later life (38–45). The benefit of PA on mobility disability may be mediated by ameliorating frequently disabling diseases, such as cardiovascular disease and depression (46), or by a direct effect on impairments such as reduced muscle strength (13,47,48), low cardiorespiratory fitness (49,50), and impaired balance (51–53) .

Physical activity interventions, including resistance and endurance exercises, improve a variety of physical performance measures, such as walking speed, stair-climb speed, balance, and chair stands (13–20,54). Other short-term studies with limited sample size suggest that PA may improve the SPPB score (25,26). Our study provides new and definitive evidence that the SPPB score is significantly improved by a PA intervention, and this was consistently seen within age, gender, race, baseline physical perfor-

mance, and comorbidity subgroups. The adjusted difference in average SPPB score between the two randomized groups (0.7 at 6 months and 0.6 at 12 months) ranks between a small and a substantial meaningful change (SPPB score changes of 0.5 and 1.0 point), according to the recent estimates published by Perera and colleagues (34). During follow-up in the PA group compared to the SA group, there was a significant shift in the distribution of participants that improved or declined by a substantial meaningful change ($\geq$1 SPPB point), with a larger number of participants improving and lower number declining in the PA group (Figure 3). Accordingly, the number needed to treat (NNT) for improvement was approximately 6 at 6 months and 9 at 12 months. NNT for preventing decline was approximately 10 at both 6 and 12 months.

Major strengths of this study include the use of a simple, practical and broadly applicable PA intervention, the large sample size, the duration of follow-up, the excellent retention rate, and the single-blind design. The study was not powered to detect significant effects on major mobility disability, and it remains to be proven whether improvements in performance also translate into benefits on such clinically relevant health outcomes. In this regard, our study provides promising preliminary evidence that PA may prevent major mobility disability. However, a larger and longer-term randomized controlled trial is needed on this important topic [Espeland MA, Gill TM, Guralnik JM, et al. Designing Clinical Trials of Intervention for Mobility Disability: Results from the Lifestyle Interventions and Independence for Elders (LIFE) Pilot Trial. Unpublished observations] (55). Such a study will have crucial implications for prevention and public health in a rapidly aging society, and will fill an important gap in knowledge for practicing evidence-based geriatric medicine.

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