The Lifestyle Interventions and Independence for Elders Pilot (LIFE-P): 2-Year Follow-up

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Background. It is well recognized that physical activity (PA) is important for older adults; yet, clinicians remain pessimistic about the ability of older adults with compromised function to adhere to long-term treatment and to maintain behavior change once treatment has been terminated.

Methods. We examined the functional status of older adults at a field center (Wake Forest University) 2 years after completing 12 months of treatment in the Lifestyle Interventions and Independence for Elders Pilot study. At baseline, participants were randomized to either a PA or a successful aging (SA) control group. Outcome measures included an interview assessment of PA, the Short Physical Performance Battery (SPPB), and performance on a 400-m self-paced walking test.

Results. Two years after the formal intervention had ended, participants who were originally in the PA group continued to engage in more minutes of moderate PA and tended to have better SPPB and walking speed than those in the SA group (effect sizes [ES]: SPPB = 0.40, walking speed = 0.37). Seven (12.7%) participants in the PA group failed the 400-m walk at the 36-month follow-up assessment, whereas this number was 11 (21.6%) in the SA group.

Conclusion. Older adults who have compromised physical function are able to sustain some of the benefits derived from participating in structured PA 2 years after supervised treatment has been terminated.

Key Words: Aging—Disability—Mobility—SPPB—400-m walk.

OLDER adults in the age group 70+ years represent one of the fastest growing segments of the U.S. population (1). Clearly, an important public health goal in this population is maintaining the capacity of these individuals to live independently and to function well (2). The Lifestyle Interventions and Independence for Elders Pilot (LIFE-P) study was designed to examine whether a physical activity (PA) program, compared with a successful aging (SA) education control condition, could prevent mobility disability in at-risk, functionally compromised older adults aged 70–89 years. As reported in the main outcomes paper (3), at the 1-year assessment, participants in the PA group experienced greater improvement on the Short Physical Performance Battery (SPPB) and in 400-m walking speed than those in the SA group. There was also a trend for those in the PA group to have a lower incidence of major mobility disability defined as the incapacity to complete a 400-m walk. In the current article, we examine the functional status of these older adults at 36 months from baseline testing, that is, 2 years after the participants had completed the original 12-month assessment in the LIFE-P study. These are important data in that studies with this age group have not examined the outcomes of PA trials following the termination of treatment. Many clinicians remain pessimistic about the ability of older adults to adhere to long-term treatment and to per-

sist with an active lifestyle once formal interventions have been terminated.

METHODS

Participants

The LIFE-P study was conducted at four field centers: the University of Pittsburgh, the Cooper Aerobics Center, the Stanford University, and the Wake Forest University (WFU). At the time of randomization, 213 participants were assigned to the PA group and 211 to the SA group, with 68.9% of the sample consisting of women. In addition, 30% had a high school education or less, 39.4% were married, 18.2% were African American, and the average body mass index (BMI) was 30.2. Complete descriptive information on the cohort can be found in the primary outcome paper for the LIFE-P (3). The current study involved a 2-year follow-up of participants who were randomized into and had completed the 12-month LIFE-P study at WFU (N = 106). The CONSORT diagram for this sample is shown in Figure 1.

Eligibility

Major inclusion criteria were as follows: men and women of age 70–89 years, SPPB summary score less than 10 (4),
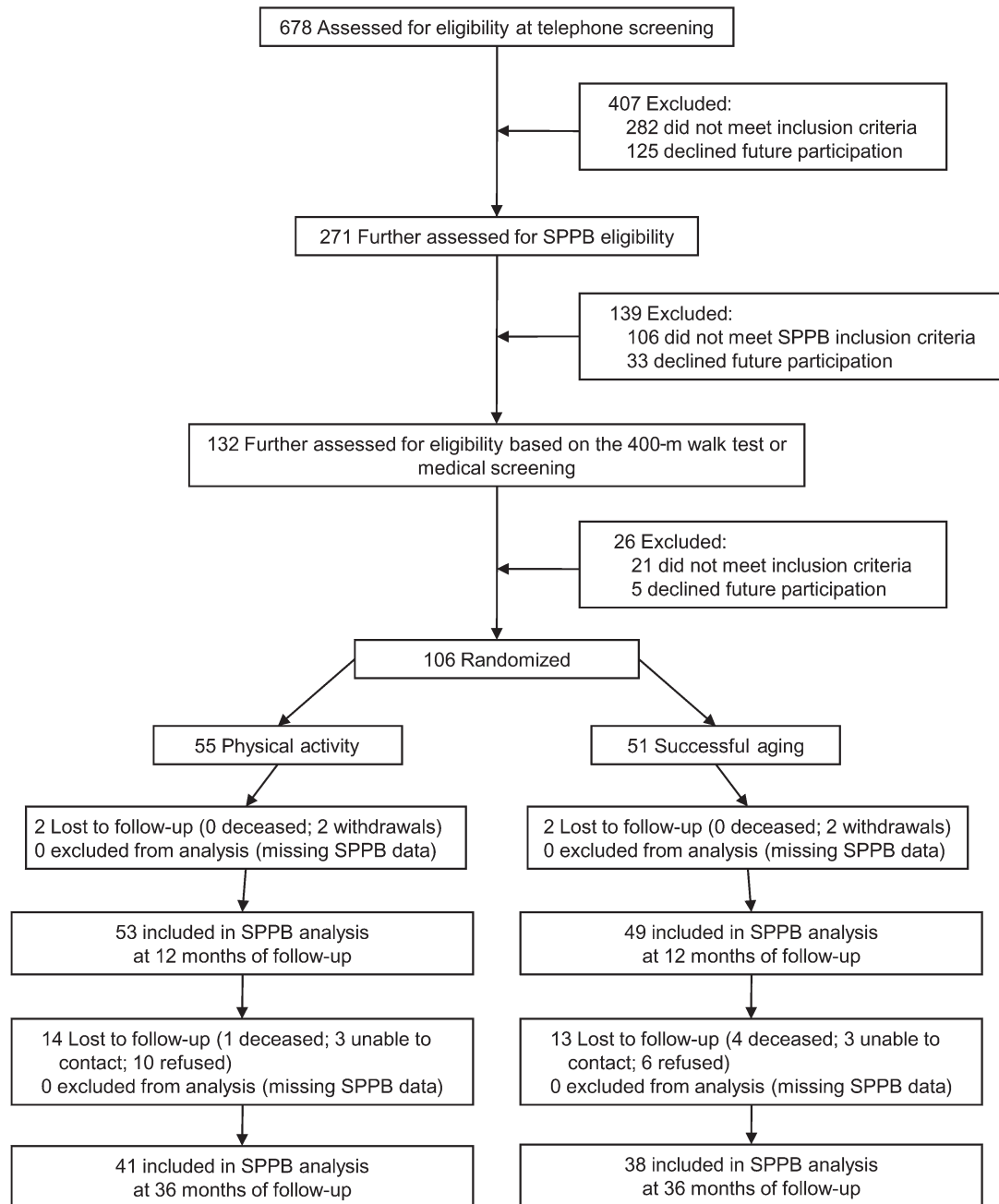
Figure 1. CONSORT diagram.

able to complete the 400-m walk in 15 minutes at baseline (5), and sedentary (<20 minutes of exercise each week for the past month). Individuals were excluded if they had a major medical or psychiatric condition that might pose a risk for either safety or intervention compliance or if they had a Mini Mental State Exam score less than 21 (6). Complete details can be found in the design paper for the LIFE-P (7). For the 36-month assessment, participants were initially contacted by phone to determine their willingness to participate in additional testing; if willing, they were then scheduled for a clinic visit. As shown in Figure 1, of the

total sample, 5% had died, 6% had relocated to another residence and could not be reached, and 15% refused to participate in this follow-up visit.

Measures

400-m walk.—The major outcome in the LIFE-P was a self-paced 400-m walk test (5). Individuals walked 10 laps at a comfortable, self-directed pace in a corridor between two cones spaced 20-m apart. Participants were ineligible for the LIFE-P study if they either could not complete the test or took

more than 15 minutes to complete the course. Time to complete the 400-m walk was recorded in minutes and seconds.

Short Physical Performance Battery.—The SPPB involves timed measures of lower extremity performance: balance, chair stands, and 4-m self-paced walking speed (8). Performance in each of these three areas is assigned a categorical score ranging from 0 to 4, with 4 indicating the highest level of performance and 0 an inability to complete the test. A summary score ranging from 0 (worst performers) to 12 (best performers) is calculated by adding walking speed, chair stands, and balance scores.

CHAMPS PA questionnaire.—We used the CHAMPS PA questionnaire, conducted in interview format, to assess changes in PA over time as a manipulation check for the interventions. The CHAMPS measure was developed specifically for older adults; investigators can derive average minutes and frequency of both moderate and overall PA performed across an average week in the past month. The measure has good psychometric properties and is sensitive to change (9).

Procedures

The PA intervention included aerobic walking exercise, along with strength, balance, and flexibility training; walking was the primary component, given its widespread popularity among older persons (10,11) and the focus of the LIFE-P, which was mobility disability. In line with the Surgeon General's recommendations, the walking component had a general weekly goal of 150 minutes performed 5 or more days of the week, attained in a progressive and individualized manner across the first 3 months of the trial (12,13). In addition, one time per week for the first 10 weeks, participants engaged in group-mediated behavioral counseling sessions that focused on self-regulatory skills central to promoting PA and on the role of PA in disability prevention. Details of the intervention can be found in the main outcomes paper for the LIFE-P study (3).

Successful Aging Arm

An active control intervention was used in the LIFE-P as a comparison group to the PA intervention and was framed in the context of health education for SA. Participants met in small groups weekly for the first 26 weeks and then monthly. This program involved workshops on a variety of health topics relevant to older adults (eg, healthful nutrition, how to effectively negotiate the health care system, how to travel safely) and also involved a short instructor-led program (5–10 minutes) of upper extremity stretching exercises.

Statistical Methods

Baseline characteristics were compared between randomized groups, and all tests of group differences were based on

Table 1. Descriptive Statistics for the Two WFU Groups at Baseline

Variable	Physical Activity Group (N = 55)	Successful Aging Group (N = 51)
Age in y, n (%)		
<80	45 (81.8)	36 (70.6)
≥80	10 (18.2)	15 (29.4)
Gender, n (%)		
Female	37 (67.3)	36 (70.6)
Male	18 (32.7)	15 (29.4)
Race/ethnicity, n (%)		
African American/Black	13 (23.6)	14 (27.5)
Caucasian/White	42 (76.4)	36 (70.6)
Latino, Hispanic, or Spanish	0 (0.0)	1 (2.0)
Education, n (%)		
Elementary school	1 (1.8)	3 (5.9)
High school or equivalency	18 (32.7)	17 (33.3)
College	31 (56.4)	21 (41.2)
Postgraduate	4 (7.3)	10 (19.6)
Other	1 (1.8)	0 (0.0)
Smoking status, n (%)		
Never	35 (63.6)	33 (64.7)
Former	18 (32.7)	14 (27.5)
Current	2 (3.6)	4 (7.8)
Body mass index[1]	30.1 ± 6.7	28.6 ± 6.3
Mini Mental State Exam score[1]	26.8 ± 2.7	27.1 ± 1.9
Myocardial infarction, n (%)	6 (10.9)	6 (11.8)
Hypertension, n (%)	40 (72.7)	35 (68.6)
Stroke, n (%)	2 (3.6)	1 (2.0)
Diabetes, n (%)	12 (21.8)	6 (11.8)
Congestive heart failure, n (%)	1 (1.8)	4 (7.8)
Cancer, n (%)	12 (21.8)	7 (13.7)
Falls[1]	1.2 ± 2.1	1.3 ± 2.3
CHAMPS caloric expenditure of moderate activities[1]	684.8 ± 982.0	569.5 ±1031

Notes: WFU = Wake Forest University.
[1] mean ± SD.

the principle of intent to treat. Mixed effects analysis of covariance models were used to obtain adjusted mean changes for each outcome at 6, 12, and 36 months. Terms entered into these models included the baseline level of the outcome, sex, an indicator of visit for the repeated outcome measures, and intervention assignment. This mixed effects maximum likelihood analysis of repeated outcomes was carried out in Proc Mixed of SAS, Version 8, using a 0.05 alpha level and an unstructured covariance matrix to account for correlation between repeated outcomes.

RESULTS

Table 1 provides descriptive statistics on the WFU LIFE-P study participants. With the exception of participants in the PA group having a slightly higher prevalence of diabetes than those in the SA group, 21.8% versus 11.8%, at baseline, the two groups were similar on demographic, medical, and biometric characteristics. The most common comorbidities were hypertension (69.1%), arthritis (22.0%), diabetes (21.7%), and obesity (66.0%). We compared baseline

Table 2. Estimated Least Squares Means (Standard Errors) for Minutes of Moderate Physical Activity From Repeated Measures ANCOVA[*]

		Time of Assessment		
	Baseline	6-Month FU	12-Month FU	36-Month FU
Successful aging	119.7	163.8 (34.0)	103.1 (25.5)	99.3 (23.1)
	$n = 51$	$n = 49$	$n = 48$	$n = 38$
Physical activity	119.7	248.7 (33.3)	233.5 (24.5)	165.476 (22.2)
	$n = 55$	$n = 50$	$n = 52$	$n = 41$
p Values		.077	<.001	.042

Notes: ANCOVA = analysis of covariance; FU = follow-up.

[*]Results are adjusted for gender and baseline moderate minutes of physical activity. The p value for the test of equality of average group effects across all FU visits is <.001.

data for those who dropped out (DO) of the study with those who remained active at the 36-month testing visit (RA). There were no significant differences between the two groups on any demographic variable, BMI, cognitive function, comorbidities, or level of PA. There were differences in gait speed ($p = .04$) and SPPB scores ($p = .01$); however, the DO group had better physical function at baseline than the RA group (gait speed for DO vs RA = 0.94 vs 0.85 m/s and SPPB = 8.11 vs 7.38).

The self-reported minutes of moderate PA data reported for each follow-up time point in Table 2 illustrate that at 36 months, 2 years after the formal intervention had ended, participants who had been randomly assigned to the PA group continued to engage in more minutes of moderate exercise than those in the SA group.

Status of SPPB and 400-m Walking Speed at 36-Month Follow-up

Tables 3 and 4 present the follow-up data for the SPPB and 400-m walk, respectively. At the 36-month follow-up, there were trends for the PA group to have improved SPPB scores ($p = .052$) and faster 400-m walk speed ($p = .125$) than the SA group. The ES for these variables were 0.40 for SPPB and 0.37 for 400-m walk.

Failure to Complete 400-m Walk at Various Points in the Study

To inform the design of longer term trials of interventions to prevent mobility disability, we evaluated trends for failure to complete the 400-m walk on this subset of the LIFE-P

participants. Table 5 presents frequencies for the status of participants on the 400-m walk at either the 6- or 12-month follow-up crossed with frequencies at 36 months for each treatment arm. There was one death in the PA group at 36 months and four in the SA group. A total of seven (12.7%) participants in the PA group failed the 400-m walk at 36 months, whereas this number was 11 (21.6%) in the SA group. On-trial mobility disability persisted in only one of three PA participants available for evaluation, compared with four of five SA participants.

Discussion

Although short-term randomized clinical trials in older persons have shown that structured PA programs improve performance on various measures of physical function (3,14,15), data are needed on long-term follow-up, and there has been a call for more research with populations that have compromised function (16). The current article examines data collected 2 years after older adults with compromised physical functioning had terminated the 12-month structured PA intervention of the LIFE-P. We were able to recruit 75% of the original randomized participants in both the PA and the SA treatment arms of the WFU field center for 36-month testing (Figure 1). There were no significant baseline differences between those in the original sample who either did or did not participate when examining comorbidities, demographic characteristics, or level of PA. Although these groups did differ on baseline gait speed and SPPB scores, it was those who did not participate that had slightly higher functioning at baseline. Mindful of the

Table 3. Estimated Least Squares Means (Standard Errors) for SPPB From Repeated Measures ANCOVA[*]

		Time of Assessment		
	Baseline	6-Month FU	12-Month FU	36-Month FU
Successful aging	7.6	7.6 (0.3)	7.4 (0.3)	7.3 (0.3)
	$n = 51$	$n = 49$	$n = 49$	$n = 38$
Physical activity	7.6	8.8 (0.3)	8.3 (0.3)	8.3 (0.3)
	$n = 55$	$n = 50$	$n = 53$	$n = 41$
p values		.001	.023	.052

Notes: ANCOVA = analysis of covariance; FU = follow-up; SPPB = Short Physical Performance Battery.

[*]Results are adjusted for gender and baseline walking speed. The p value for the test of equality of average group effects across all FU visits is .006.

Table 4. Estimated Least Squares Means (Standard Errors) for Walking Speed (m/s) From Repeated Measures ANCOVA[*]

	Time of Assessment			
	Baseline	6-Month FU	12-Month FU	36-Month FU
Successful aging	0.89	0.86 (0.02)	0.85 (0.02)	0.85 (0.02)
	$n = 51$	$n = 46$	$n = 47$	$n = 27$
Physical activity	0.89	0.90 (0.02)	0.89 (0.02)	0.90 (0.02)
	$n = 55$	$n = 50$	$n = 51$	$n = 34$
p values		.023	.121	.125

Notes: ANCOVA = analysis of covariance; FU = follow-up.

[*]Results are adjusted for gender and baseline walking speed. The *p* value for the test of equality of average group effects across all FU visits is .039.

limitation in sample size, these patterns do offer support for the external validity of the study results.

It was encouraging to find that at the 36-month follow-up, participants in the PA group continued to self-report more moderate PA and had higher SPPB scores than those who had been randomized to the SA group. Although the results for gait speed in the 400-m walk did not reach conventional levels of statistical significance, the results were in the expected direction, favoring the PA group. Note that between-group differences for the SPPB and the 400-m walk were constant over time, indicating that the change in the size of the *p* values from baseline to 36 months was due to a reduction in statistical power due to decreasing cell sizes. Patterns in participants' major mobility disability status—failure to complete the 400-m walk—also warrant comment. Of those who had successfully completed the 400-m walk at both the 6- and the 12-month assessment, 58.2% of those in the PA group successfully competed the 400-m walk at the 36-month assessment, whereas the percentage was 49.0% in the SA group. Also, whether one examines differential death rates between groups or persistent disability, trends favor the PA group.

In a prospective epidemiological study, the Women's Health and Aging Study (WHAS), Simonsick and colleagues (17) collected SPPB data on walkers versus nonwalkers—defined as walking either more than or less than eight blocks each week, respectively. At the 1-year assessment visit, SPPB scores of walkers declined by approximately 0.1 points compared with nonwalkers who experienced a decline of approximately 0.6 points (*p* = .01). Based on their PA data, participants within the SA group of the current study were more similar to the walkers than to the nonwalkers in WHAS. Specifically, on average, at 36 months, the SA group in the LIFE-P reported 99.3 minutes of moderate PA each week. Even though the PA group was only doing an additional 66.1 minutes of moderate PA per week at 36 months compared with the SA group, it does represent an increase of 66.5%. As noted in recent PA guidelines for older adults (16), it takes less of a stimulus to produce meaningful health benefits in older adults who have compromised function than in the general population.

The data reported by Simonsick and colleagues (17) in combination with the current findings are encouraging. Whereas they suggest that even though low-level, free-living PA among older adults with compromised function is protective against further decline, a more formal intervention such as the LIFE-P can provide added benefit, which can be maintained up to 2 years after treatment has been terminated. This is an area of study that warrants further attention. It is also important to emphasize that the LIFE-P intervention was state of the art and included a 10-week group-meditated behavioral component that has been found to be superior to traditional exercise programming in enhancing long-term rates of adherence (18).

To our knowledge, the current study data are unique. Rarely is information reported on extended posttreatment

Table 5. Failure at 400-m Walk by Treatment Arm, Given as Frequency (%)

	Status at 36-Month Assessment			
	Physical Activity Group			
Status at 6- or 12-Month Assessment	Missing	Success	Failed	Deceased
Missing both 6- and 12-month assessment	5 (9.1)	0 (0.0)	1 (1.8)	0 (0.0)
Success at 6- and 12-month assessment	7 (12.7)	32 (58.2)	5 (9.1)	1 (1.8)
Failed at either 6- or 12-month assessment	1 (1.8)	2 (3.6)	1 (1.8)	0 (0.0)
Status at 6- or 12-Month Assessment	Status at 36-Month Assessment			
	Successful Aging Group			
	Missing	Success	Failed	Deceased
Missing both 6- or 12-month assessment	1 (1.9)	1 (1.9)	2 (3.9)	1 (1.9)
Success at 6- and 12-month assessment	6 (11.8)	25 (49.0)	5 (9.8)	3 (5.9)
Failed at either 6- or 12-month assessment	2 (3.9)	1 (1.9)	4 (7.8)	0 (0.0)

follow-up in PA intervention trials. However, it is important to keep in mind the limited sample size due to having data available from only one of the four clinical sites. This sample size restriction reduced statistical power and impaired our ability to examine potential moderators of treatment effects. The LIFE-P was conducted with the intent of providing guidance on study design for a large multicenter trial. Study funds were not available for posttreatment follow-up; however, this study was supported internally at Wake Forest because we felt that these data could inform the design of future studies.

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