

# Lifestyle Interventions and Independence for Elders Study: Recruitment and Baseline Characteristics

Anthony P. Marsh,<sup>1</sup> Laura C. Lovato,<sup>2</sup> Nancy W. Glynn,<sup>3</sup> Kimberly Kennedy,<sup>4</sup> Cynthia Castro,<sup>5</sup> Kathryn Domanchuk,<sup>6</sup> Erica McDavitt,<sup>7</sup> Ruben Rodate,<sup>8</sup> Michael Marsiske,<sup>9</sup> Joanne McGloin,<sup>10</sup> Erik J. Groessl,<sup>11</sup> Marco Pahor,<sup>9</sup> and Jack M. Guralnik;<sup>12</sup> for the LIFE Study Research Group

<sup>1</sup>Department of Health and Exercise Science, Wake Forest University, Winston-Salem, North Carolina.

<sup>2</sup>Division of Public Health Sciences, Department of Biostatistical Sciences, Wake Forest School of Medicine, Winston-Salem, North Carolina.

<sup>3</sup>Department of Epidemiology and Medicine, University of Pittsburgh Graduate School of Public Health, Pittsburgh, Pennsylvania.

<sup>4</sup>Section on Gerontology and Geriatric Medicine, Department of Medicine, Sticht Center on Aging, Wake Forest University School of Medicine, Winston-Salem, North Carolina.

<sup>5</sup>Stanford Prevention Research Center, Department of Medicine, Stanford University School of Medicine, California.

<sup>6</sup>Department of Medicine, Feinberg School of Medicine, Northwestern University, Chicago, Illinois.

<sup>7</sup>Nutrition, Exercise, Physiology, and Sarcopenia Laboratory, Jean Mayer USDA Human Nutrition Research Center on Aging at Tufts University, Boston, Massachusetts.

<sup>8</sup>Pennington Biomedical Research Center, Louisiana State University System, Baton Rouge.

<sup>9</sup>Department of Aging and Geriatric Research, Institute on Aging, College of Medicine, University of Florida, Gainesville.

<sup>10</sup>Department of Medicine, Yale School of Medicine, New Haven, Connecticut.

<sup>11</sup>Department of Family and Preventive Medicine, University of California at San Diego.

<sup>12</sup>Department of Epidemiology and Public Health, Division of Gerontology, University of Maryland School of Medicine, Baltimore.

Clinicaltrials.gov identifier: NCT01072500

Address correspondence to Anthony P. Marsh, PhD, Department of Health and Exercise Science, Wake Forest University, Winston-Salem, NC 27109-7868. Email: [marshap@wfu.edu](mailto:marshap@wfu.edu)

**Background.** Recruitment of older adults into long-term clinical trials involving behavioral interventions is a significant challenge. The Lifestyle Interventions and Independence for Elders (LIFE) Study is a Phase 3 multicenter randomized controlled multisite trial, designed to compare the effects of a moderate-intensity physical activity program with a successful aging health education program on the incidence of major mobility disability (the inability to walk 400 m) in sedentary adults aged 70–89 years, who were at high risk for mobility disability (scoring  $\leq 9$  on the Short Physical Performance Battery) at baseline.

**Methods.** Recruitment methods, yields, efficiency, and costs are described together with a summary of participant baseline characteristics. Yields were examined across levels of sex, race and ethnicity, and Short Physical Performance Battery, as well as by site.

**Results.** The 21-month recruiting period resulted in 14,812 telephone screens; 1,635 participants were randomized (67.2% women, 21.0% minorities, 44.7% with Short Physical Performance Battery scores  $\leq 7$ ). Of the telephone-screened participants, 37.6% were excluded primarily because of regular participation in physical activity, health exclusions, or self-reported mobility disability. Direct mailing was the most productive recruitment strategy (59.5% of randomized participants). Recruitment costs were \$840 per randomized participant. Yields differed by sex and Short Physical Performance Battery. We accrued 11% more participant follow-up time than expected during the recruitment period as a result of the accelerated recruitment rate.

**Conclusions.** The LIFE Study achieved all recruitment benchmarks. Bulk mailing is an efficient method for recruiting high-risk community-dwelling older persons (including minorities), from diverse geographic areas for this long-term behavioral trial.

**Key Words:** Mobile disability—Older adults—Physical activity—Minority recruitment—Randomized controlled trial.

Received March 21, 2013; Accepted March 26, 2013

Decision Editor: Dr. James Goodwin

THE growth in the population aged 65 years and older has focused attention on the importance of prevention of age-associated physical function decline and disabilities

(1,2). Older adults who lose the ability to move without assistance are less likely to remain in the community; have higher rates of morbidity, mortality, health care utilization,

and cost; and experience a poorer quality of life (3–5). To address this critical public health issue, the LIFE Study, a phase 3 multicenter randomized controlled trial, was designed to compare a long-term physical activity (PA) program with a successful aging (SA) health education program on the incidence of major mobility disability (the inability to walk 400 m) in sedentary older persons (6).

A significant challenge in the conduct of all clinical trials of older persons, particularly long-term trials involving behavioral interventions like PA, is the identification and recruitment of participants who reflect the sex, race, and functional capacities of the target population and who might stand the most to gain from interventions designed specifically to enhance physical and cognitive function (7–14).

In this report, we describe the successes and lessons learned from the LIFE recruitment effort and report recruitment yields overall and by sex, race, and baseline lower extremity functional status. We also describe the baseline characteristics of the participants. These data will provide helpful information for investigators seeking to recruit older adults on the brink of losing their independence into clinical trials aimed at improving physical function with behavioral and/or pharmacological interventions.

## METHODS

### *Study Design*

The LIFE Study is being conducted at eight field centers: University of Florida, Gainesville, Florida; Northwestern University, Chicago, Illinois; Pennington Biomedical Research Center, Baton Rouge, Louisiana; University of Pittsburgh, Pittsburgh, Pennsylvania; Stanford University, Stanford, California; Tufts University, Boston, Massachusetts; Wake Forest University, Winston-Salem, North Carolina; and Yale University, New Haven, Connecticut. The Administrative Coordinating Center (ACC) is at the University of Florida and the Data Management, Analysis and Quality Control Center is located at Wake Forest School of Medicine. The LIFE Study was approved by the Institutional Review Boards of all participating centers.

The rationale, design, and methods of the LIFE Study have been presented in detail (6). In terms of sample size and duration, the LIFE Study is the largest and longest randomized controlled trial of PA conducted to date as evidenced by reviewing randomized controlled trials of PA in older adults with functional assessments as the primary outcomes (Supplementary Figure 1). Participants will be in the LIFE study from 1.9 to 3.7 years, depending on the time of randomization during the 21-month recruitment period. Sedentary older adults at high risk for mobility disability were randomized to either a PA intervention that encompassed both structured exercise and PA focused on walking, which also included strength, flexibility, and balance

training, or a successful aging (SA) health information and education program. The details of these interventions can be found in the study by Fielding and colleagues (6). The primary outcome of major mobility disability was evaluated every 6 months and at study closeout. Secondary and tertiary endpoints were evaluated every 6, 12, or 24 months during the trial.

### *Study Recruitment Goals*

The recruitment goals over the 21-month recruitment phase of the LIFE Study were to randomize 1,600 sedentary older adults (200/site), aged 70–89 years, without major mobility disability but at high risk for developing it (Short Physical Performance Battery [SPPB] score  $\leq 9$ ), with at least 45% of the sample having a SPPB score less than or equal to 7, and with minorities comprising more than or equal to 22.5% of the sample. In the LIFE Pilot (LIFE-P) study (8), 7.4 participants were screened for each person randomized. We used more stringent criteria for PA screening in LIFE, and therefore predicted that 20% more individuals would be excluded than in LIFE-P, leading to an anticipated need to screen 9.3 individuals for every randomized participant.

The Data Management, Analysis and Quality Control Center monitored recruitment activities and provided the study Recruitment Committee and each field center with a range of on-line real-time reports to track recruitment progress on critical study benchmarks. Sites also generated local tracking reports to monitor site-specific features of recruitment. Reports included graphs and tables summarizing recruitment yields and progress toward the recruitment goal of 11–13 randomized participants per month for each site and the desired subgroup distributions according to SPPB score, sex, and race and ethnicity.

### *Eligibility Criteria*

The LIFE Study eligibility criteria were designed to identify older persons who are (a) sedentary, defined as less than 20 min/wk of regular PA in the past month and reporting less than or equal to 125 min/wk of moderate/vigorous PA based on 18 items from the Community Healthy Activities Model Program for Seniors (CHAMPS) physical activity questionnaire (15); (b) at high risk for mobility disability based on objectively assessed lower extremity functional limitations assessed by the SPPB (score  $\leq 9$ ) (3); (c) able to walk 400 m in less than or equal to 15 minute without sitting, leaning against the wall, the assistance of another person, or a walking aid other than a straight cane; and (d) are able to safely participate in the intervention (see Table 1 in ref. [6]). This represents a large segment of the older population in which successful prevention of mobility disability through a lifestyle intervention would have a major public health impact (16).

Table 1. LIFE Study Recruitment Source Overall and by Site

Clinical Site	Rand	Media											Multiple Sources					Do Not Know		Refused	Missing
		Event	Flyer	FU Call	Letter	Referral	Magazine	Newspaper Ad		Radio Ad	Television Ad	Brochure and Letter	Brochure and News Ad	Letter and News Ad	Other Combinations	Other	Do Not Know	Refused			
								3,981	149										167		
All clinics, all telephone screens	14,812	3,981	149	167	21	4,274	441	33	2,078	477	521	385	52	48	178	1,710	283	3	11		
All clinics, randomizations	1,635	512	13	22	7	397	59	3	240	49	50	41	10	8	31	175	17	0	1		
Northwestern University	203	11	0	1	0	0	7	0	64	32	0	0	0	0	0	84	3	0	1		
Pennington Biomedical Research Center	208	26	2	1	0	36	2	0	80	0	23	1	1	0	7	28	1	0	0		
Stanford University	200	52	7	1	0	50	5	0	30	9	0	25	2	3	7	6	3	0	0		
Tufts University	202	131	0	6	3	10	16	2	7	7	2	2	1	0	0	11	4	0	0		
University of Florida	201	145	1	0	0	13	2	1	11	0	0	9	0	0	2	15	2	0	0		
University of Pittsburgh	216	18	0	6	0	171	8	0	2	0	1	1	0	0	1	5	3	0	0		
Wake Forest University	205	108	0	1	4	0	19	0	24	0	24	0	5	0	12	8	0	0	0		
Yale University	200	21	3	6	0	117	0	0	22	1	0	3	1	5	2	18	1	0	0		

Recruitment Strategies

As in the LIFE-P Study (8,17,18), the Recruitment Committee had representation from all sites, coordinated all recruiting activities, and developed materials for study-wide use, all facilitated by monthly conference calls. In consultation with the Recruitment Committee, field centers were encouraged to implement recruiting plans to best suit local needs. The recruitment strategies used in LIFE-P proved very successful, so the LIFE Study sites used updated versions of the LIFE-P advertising materials, brochure, and press release, tailored to suit their local mailing and media market (see Supplementary Material for an example of a study letter and trifold bulk mail brochure). In addition, several sites (University of Florida, Wake Forest University, Pennington, Tufts, Northwestern University) made use of their existing participant research registries. To kick off the recruitment phase, the Administrative Coordinating Center issued a national press release (in conjunction with National Institute on Aging), and each site issued a site-specific press release describing the study and providing contact numbers for enrollment information. Centers employed a variety of recruitment strategies (Table 1).

Advertising materials targeted older adults with preexisting lower extremity functional limitations focused on the theme, “Do you have trouble getting in and out of the car; walking outside your home; climbing stairs?” We made significant efforts to recruit racial and/or ethnic minorities, and each site produced culturally appropriate recruitment materials. Transportation and/or monetary incentives were used to offset the burden of travel to assessment visits.

Screening and Randomization

Respondents were screened by telephone or, rarely, face to face. The screening instrument was scripted and designed to identify eligible participants efficiently by focusing on major criteria that could be self-reported (age, functional limitations, amount of PA, and medical history). Individuals who participated in LIFE-P were not eligible because of concerns about contamination and dropout if they were unsatisfied with their group allocation. Demographic information and the recruitment source were also collected. Participants provided verbal informed consent for the telephone screening.

Those who remained eligible were invited to attend a prescreening visit where an overview of the study was provided in a group or one-on-one format. Following a question and answer session, attendees were invited to review and sign a prescreening consent form for the SPPB and CHAMPS. This was implemented to avoid administration of the much longer full-study consent form only to determine that a person was ineligible on SPPB, which we knew from LIFE-P would excluded a large number of individuals (8). Those still eligible after administration of the SPPB and the CHAMPS-18 were invited to attend a first screening

visit (SV1) or, in the case of a one-on-one prescreen, simply continued with SV1.

At SV1 and SV2, medical and functional exclusions were assessed (see Tables 1 and 2 in ref. [6]). Briefly, SV1 included the completion of the main study consent form; the collection of height, weight, pulse, and blood pressure; completion of a medical history questionnaire and a battery of cognitive function assessments; and an electrocardiogram. Following a physical examination and medical history review by a physician, advanced nurse practitioner, or physician assistant, participants with no potential exclusions or safety concerns were asked to complete self-reported disability assessments and the 400-m walk. The study clinician cleared all participants for the study before the administration of the 400-m walk. If the participant remained eligible, they were given an accelerometer and instructions on how to use it. A prerandomization “study expectations contract” was discussed at the end of SV1 or beginning of SV2, with the goal of augmenting the informed consent process, reinforcing study expectations, and providing additional time to consider their commitment to the study in an effort to reduce dropout (see [Supplementary Material](#) for an example of the prerandomization study expectations contract).

At SV2, if necessary, participants completed any measures not completed at SV1. SV2 was done in the fasted state. A snack was provided after the collection of blood and urine and then the following measures were collected: computerized cognitive testing battery, process measures, claudication and ankle brachial index, sleep quality questionnaires, spirometry and pulmonary function questionnaire, grip strength, and Quality of Well-being and Health Care Utilization questionnaires. A senior staff member reviewed the “study expectations contract” with the participant. If the participant reaffirmed their commitment to the study, they were randomly assigned (1:1 ratio) using a web-based system to either the PA or SA intervention. The Neighborhood Environment Walkability Survey was administered postrandomization.

*Tracking Costs*

Direct recruitment costs were tracked and broken out from other costs that included the item description, quantity of item used, and the cost of items used. Research staff completed the tracking forms quarterly. Total recruitment costs were aggregated across all sites. To estimate personnel costs, staff effort was obtained because actual personnel costs varied significantly across sites.

*Staff Training*

A training meeting was held for all investigators and staff in January 2010 at the University of Florida. All study staff reviewed the protocol and the chapters of the Manual of Procedures pertaining to their role in the project. Assessment

Table 2. LIFE Study Screening Yields Studywide and for Each Site

Clinical Site	Telephone Screens			SPPB and/or CHAMPS			Screening Visit 1			Screening Visit 2			Randomizations				
	Total	Inelig	Elig	Total	Inelig	Elig	Total	Inelig	Elig	Total	Inelig	Elig	Total	Inelig	Elig	Total	
				% of Elig TS*			% of Elig SPPB and CHAMPS*			% of Elig SV1*			% of SV2				
All clinics	14,812	5,576	9,236	68	6,308	2,875	3,311	88	2,901	1,191	1,710	98	1,669	18	1,651	99	1,635
Northwestern University	2,175	938	1,237	61	753	303	447	79	354	138	216	98	211	7	204	100	203
Pennington Biomedical Research Center	1,568	517	1,051	79	826	374	411	95	392	183	209	100	209		209	100	208
Stanford University	1,969	751	1,218	70	854	455	392	88	346	129	217	95	206	3	203	99	200
Tufts University	1,441	310	1,131	65	737	354	377	82	311	102	209	99	207	1	206	98	202
University of Florida	1,503	316	1,187	76	902	468	399	79	317	112	205	100	204	1	203	99	201
University of Pittsburgh	1,818	552	1,266	69	870	350	518	94	489	263	226	99	224	3	221	98	216
Wake Forest University	1,062	318	744	69	512	170	327	98	319	110	209	99	206	1	205	100	205
Yale University	3,276	1,874	1,402	61	854	401	440	85	373	154	219	92	202	2	200	100	200

Notes: TS = telephone screens; SV1 = screening visit 1; SV2 = screening visit 2; SPPB = short physical performance battery; CHAMPS = Community Healthy Activities Model Program for Seniors. \*Note that because different clinical sites manage recruitment flow differently, we have adjusted some interim totals to make clinics comparable.



staff also reviewed web-based tutorials and/or CD training modules for several study outcomes. The lead assessors and interventionists received certification related to their role in the study. We used a “train-the-trainer” model to train and certify additional staff at each field center. Recertification is required annually (quarterly for the SPPB), prompted via emails from the Administrative Coordinating Center, in order to minimize assessment drift and enhance standardization across all field centers. Webinars are conducted as needed for continuing education of assessment staff.

### Statistical Analyses

Descriptive statistics were used to provide mean characteristics of study participants and randomization rates among those completing a baseline visit. Chi square tests were used to compare randomization rates across recruitment sources, sex, race and ethnicity, level of baseline function assessed by SPPB, and site where we compared sites based in the large metropolitan areas (Chicago, Boston, Pittsburgh) to the other sites. For the baseline characteristics, between-group differences were examined using independent-samples *t* tests for the continuous variables and chi square tests for the categorical variables.

The recruitment efficiency factor (*R*-factor), the ratio of the number of person-years actually accrued divided by the number of person-years expected during the planned recruitment period, was used to assess the efficiency of the recruitment process (19,20). The LIFE Study power estimates assume a constant rate of recruitment over the recruitment period that is consistent with most clinical trials. Calculating the area under the curve of the recruitment line identifies the proportion of expected person-years during recruitment (21). An *R*-factor of 1 indicates 100% efficiency.

## RESULTS

In total, 1,635 participants were randomized over the 21-month recruitment period, with the target of 1,600 reached in late November 2011 (Supplementary Figure 2a). The first randomization occurred on March 12, 2010, and the final randomization on December 27, 2011. Sites with participants in the recruitment pipeline completed screening and testing visits and randomized these individuals; hence, the total number of participants randomized ( $N = 1,635$ ) exceeded the target of 1,600.

The *R*-factor for the study was 1.11, indicating that we accrued 11% more person follow-up than planned during the recruitment period. The recruitment rates for participants with SPPB less than or equal to 7 (Supplementary Figure 2b) and racial minority (Supplementary Figure 2c) also tracked on or above the recruitment goals. The recruitment of Hispanic participants lagged initially but accelerated when a second intervention location was opened in San

Jose by the Stanford site in Summer 2010 (Supplementary Figure 2d). There were site variations in recruiting particular cells, and sites dynamically changed recruitment emphasis to stay on track with study goals. The consistency of the flow of randomized participants into the trial during the recruitment phase both studywide and at each field center was remarkable (Supplementary Figures 2a and 3).

The recruitment flow from telephone screening to randomization is depicted in Figure 1. In total, 14,812 telephone screening interviews were completed, and 1,635 participants (11.0%) were ultimately randomized to PA ( $n = 818$ ) or SA ( $n = 817$ ). We screened 9.06 individuals for every randomized participant. A common reason for declining further screening was the realization by the participant of the commitment required for participation in the study. The SPPB excluded a much higher percentage of participants compared with the CHAMPS because it was typically completed first at the prescreening visit. The 75 participants who successfully completed all screening steps but were not randomized were not willing to sign the expectations contract or were unwilling to accept randomization to either group.

### Recruitment Strategy, Yield, and Costs

The number of screened and randomized participants according to recruitment strategy were comparable across sites (Table 1). Directly mailing a study brochure or personalized letter to households with age-eligible residents (obtained from commercial databases and voter registration lists) was the most commonly employed strategy, leading to 59.4% of study contacts and 59.5% of randomizations. Newspaper advertisements were the next most commonly employed strategy, accounting for 14.0% of contacts and 14.7% of randomizations. Although the field centers employed similar strategies, the emphasis across sites differed. For example, Pittsburgh and Yale focused on personalized letters, whereas Tufts, University of Florida, and Wake Forest University expended more resources on the study brochure and Northwestern University focused on newspaper and radio advertisements.

A higher percentage of initial telephone screens was generated from both newspaper advertisements and direct mail among non-whites compared with whites (16.0% vs 12.5% and 62.3% vs 56.7%, respectively;  $p < .0001$  for both). A lower percentage of initial telephone screens was generated from promotional events (0.58% vs 2.75%;  $p < .0001$ ) among non-whites vs whites. Interestingly, a higher percentage of initial telephone screens was generated from newspaper advertisements for persons with SPPB less than or equal to 7 compared with those with SPPB of 8–9 (16.4% vs 13.6%;  $p = .0043$ ). A lower percentage of initial telephone screens was generated from direct mail for persons with SPPB less than or equal to 7 vs SPPB of 8–9 (59.9% vs 64.7%;  $p < .0001$ ). There was no difference in percentage of contacts generated from promotional events

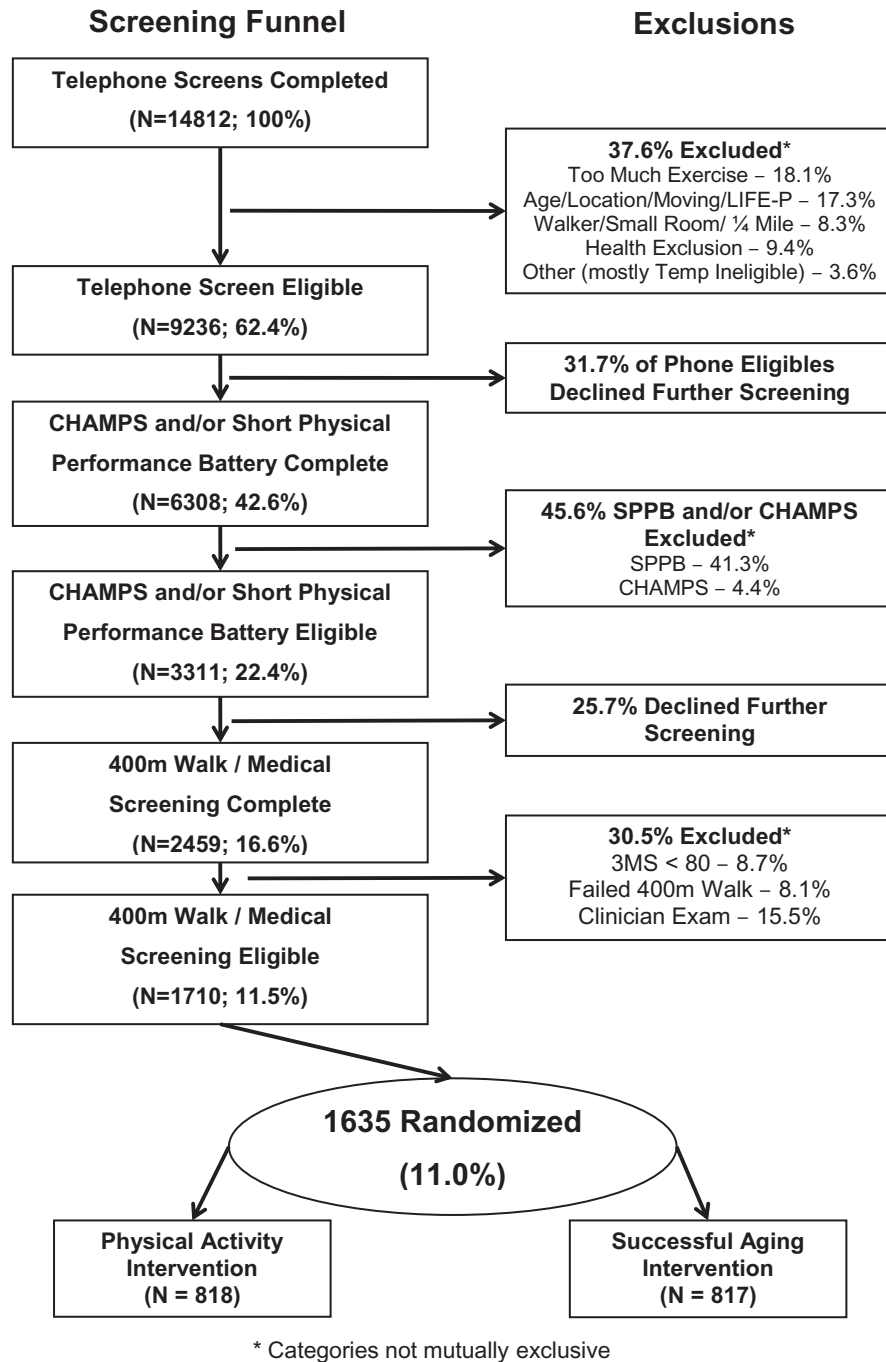


Figure 1. LIFE Study screening funnel. SPPB = short physical performance battery; CHAMPS: Community Healthy Activities Model Program for Seniors; 3MS: Modified Mini Mental State Exam.

when comparing respondents with lower vs higher levels of lower extremity function.

Recruitment yield (randomizations/telephone screens) averaged 11.0%, and ranged from 6.1% at Yale University to 19.3% at Wake Forest University. The screening yields across visits (Table 2) and percentage of participants randomized for the key subgroups of sex and baseline function

(Table 3) showed remarkable consistency across the field centers. The yields for race and ethnicity closely reflected the site-specific goals. Of the 8,853 women initiating a telephone screen, 12.4% were randomized, compared with 9.2% of 5,838 male telephone screenees ( $p < .0001$ ), who tended to be more active and less functionally compromised. There was no difference in yield between white and

Table 3. LIFE Study Subgroup Recruitment Goals and Performance

Clinical Site	Number Randomized	SPPB Score					
		% Racial Minority		% Ethnic Minority		SPPB Score ≤ 7	SPPB Score 8 or 9
		Goal	Actual	Goal	Actual	Actual % (Goal 45%)	Actual % (Goal 55%)
All clinics	1,635	22.5	21.0	4.4	3.7	45	55
Northwestern University	203	28.0	33.5	8.0	2.5	55	45
Pennington Biomedical Research Center	208	21.6	17.8	3.6	0	45	55
Stanford University	200	7.6	10.5	18.0	18.0	45	55
Tufts University	202	22.8	22.3	2.4	3.0	39	61
University of Florida	201	26.4	10.0	0	1.0	44	56
University of Pittsburgh	216	26.0	27.8	0	0.9	43	57
Wake Forest University	205	26.0	24.9	0	0.5	45	55
Yale University	200	21.6	20.5	3.2	4.5	43	58

minority screenees. Screenees who had higher functioning, as assessed by the SPPB, were more likely to be randomized than lower functioning individuals (48.2% among SPPB 8–9 vs 40.8% among SPPB < 8;  $p < .0001$ ). There was no difference in yield at sites based in the large metropolitan areas compared with the other sites.

Table 4 displays the percentage of participants recruited using each recruitment method and the associated recruitment costs. Overall, total direct recruitment cost was \$1,374,214, which does not include indirect or personnel costs. This equates to \$840 per randomized participant. Mass mailings resulted in 57.9% of the total randomized participants and cost \$695 per randomized participant, and newspaper advertisements resulted in 14.9% at a cost of \$1,128. Television and radio advertisements and recruitment events were relatively inefficient recruitment strategies, costing \$3,199 and \$3,981 per randomized participant, respectively.

#### Recruitment Goals and Baseline Characteristics

The descriptive statistics for the randomized study sample are presented in Table 5. The mean age of the total sample was nearly 79 years, and 63.8% reported education beyond high school. Two thirds were female participants, and approximately one quarter reported a race or ethnicity other than white. On average, the sample was classed as obese with a mean body mass index of 30.2 kg/m<sup>2</sup>. High

blood pressure/hypertension was the most prevalent comorbidity (70.4%), followed by diabetes (25.3%) and cancer (22.6%). The mean SPPB score was  $7.4 \pm 1.6$ , with 44.7% of participants having a score less than 8.

As expected, the randomization scheme produced baseline characteristics that were balanced across treatment groups. In particular, the two groups were qualitatively similar in lower extremity physical function and disease burden, two important potential moderators of the key outcomes in the study.

#### Staff Effort

In general, the mean staff effort budgeted for the 21-month recruiting effort was approximately 1.0 full-time equivalents (FTEs) although the sites varied in the manner in which staff effort was allocated within the site infrastructure. For example, the Pittsburgh site employed a recruitment coordinator at 0.1 FTEs for 1 year and two staff recruiters at 0.5 FTEs for 1 year for a total of 1.1 FTEs. Similarly, the recruitment coordinator at the Pittsburgh site averaged 0.6 FTEs over the course of the recruitment period but was supplemented by two telephone screeners at 0.7 FTEs. Pennington Biomedical funded a recruitment coordinator at 1.0 FTE and telephone screener at 0.5 FTE from an existing recruiting core during the recruitment period. In contrast, the recruitment coordinators at the Tufts, Wake Forest, and Stanford sites were recruited exclusively for LIFE but served other duties in addition to recruitment (eg, assessment). Additionally, the Stanford site employed Spanish-speaking staff to recruit Hispanic participants.

Table 4. LIFE Study Recruitment Costs by Recruitment Method

	Cost (\$)	Number of Participants Randomized	Cost Per Randomized Participant
Brochures/letters	658,850	947	695
Community events/outreach	47,780	12	3,981
Print advertisement (newspaper/magazines)	275,335	244	1,128
TV and radio	355,113	111	3,199
Other (flyers, newsletters, Internet)	37,136	245	151
Referral	—	60	0
Don't know/refused	—	16	0
Total	\$1,374,214	1635	\$840.00

#### DISCUSSION

In the LIFE Study, eight field centers recruited 1,635 older adults, aged 70–89 years, at high risk for mobility disability for a PA intervention trial to prevent mobility disability over a 21-month period. The study met its recruitment goals for minority enrollment (22.5%) and SPPB scores (45% ≤ 7). The recruitment yield was 11.0% of the total screened volunteers, and approximately \$840 was spent per randomized participant in direct recruiting

Table 5. LIFE Study Baseline Characteristics by Randomized Group

	Successful Aging ( <i>N</i> = 817)	Physical Activity ( <i>N</i> = 818)	Overall ( <i>N</i> = 1,635)
Age	79.1 ± 5.2	78.7 ± 5.2	78.9 ± 5.2
Gender			
Female	551 (67.4%)	547 (66.9%)	1,098 (67.2%)
Male	266 (32.6%)	271 (33.1%)	537 (32.8%)
Race/ethnicity			
Caucasian/white	635 (77.7%)	604 (73.8%)	1,239 (75.8%)
African American/black	125 (15.3%)	163 (19.9%)	288 (17.6%)
Latino, Hispanic or Spanish	30 (3.7%)	31 (3.8%)	61 (3.7%)
Asian	8 (1.0%)	7 (0.9%)	15 (0.9%)
Other/mixed	17 (2.1%)	10 (1.2%)	27 (1.6%)
Refused/missing	2 (0.2%)	3 (0.4%)	5 (0.3%)
Education			
No formal education (00)	6 (0.7%)	7 (0.9%)	13 (0.8%)
Elementary school (K-08)	17 (2.1%)	15 (1.8%)	32 (2.0%)
High school/equivalent (09-12)	236 (28.9%)	248 (30.3%)	484 (29.6%)
College (13-17)	320 (39.2%)	321 (39.2%)	641 (39.2%)
Post Graduate	208 (25.5%)	194 (23.7%)	402 (24.6%)
Other	26 (3.2%)	32 (3.9%)	58 (3.5%)
Unknown	4 (0.5%)	1 (0.1%)	5 (0.3%)
Total SPPB Score	7.3 ± 1.6	7.4 ± 1.6	7.4 ± 1.6
3MS score	91.6 ± 5.5	91.5 ± 5.6	91.5 ± 5.5
Digital Symbol Substitution Test Score	46.8 ± 12.5	45.8 ± 12.9	46.3 ± 12.7
CHAMPS 18 total score	18.2 ± 33.8	15.9 ± 32.1	17.0 ± 33.0
HDL cholesterol (mg/dL)	61.1 ± 17.6	61.1 ± 18.0	61.1 ± 17.8
LDL cholesterol (mg/dL)	93.1 ± 33.1	93.6 ± 32.2	93.4 ± 32.6
Triglycerides (mg/dL)	121.8 ± 58.6	123.0 ± 56.6	122.4 ± 57.6
Total cholesterol (mg/dL)	178.5 ± 39.9	179.3 ± 39.6	178.9 ± 39.8
Systolic BP (mean of two measures)	127.0 ± 17.8	127.9 ± 18.1	127.4 ± 18.0
Diastolic BP (mean of two measures)	67.7 ± 10.1	68.7 ± 10.3	68.2 ± 10.2
Weight (kg)	82.0 ± 19.3	81.9 ± 18.4	81.9 ± 18.8
BMI	30.3 ± 6.2	30.1 ± 5.9	30.2 ± 6.1
High blood pressure/hypertension	578 (70.7%)	573 (70.0%)	1,151 (70.4%)
Heart attack/coronary/MI	69 (8.4%)	60 (7.3%)	129 (7.9%)
Heart failure/congestive heart failure	45 (5.5%)	26 (3.2%)	71 (4.3%)
Pacemaker	33 (4.0%)	33 (4.0%)	66 (4.0%)
Stroke/brain hemorrhage	52 (6.4%)	57 (7.0%)	109 (6.7%)
Cancer/malignant tumor	192 (23.5%)	178 (21.8%)	370 (22.6%)
Diabetes/high blood sugar	216 (26.4%)	198 (24.2%)	414 (25.3%)
Pain and/or stiffness in the knees	116 (14.2%)	113 (13.8%)	229 (14.0%)
Pain and/or stiffness in the hips	72 (8.8%)	71 (8.7%)	143 (8.7%)
Pain and/or stiffness in the back/spine	102 (12.5%)	110 (13.4%)	212 (13.0%)
Chronic lung disease	123 (15.1%)	130 (15.9%)	253 (15.5%)
Emotional/nervous/psychiatric problems	129 (15.8%)	162 (19.8%)	291 (17.8%)

Notes: Data are means and standard deviations or *n* (%). SPPB = short physical performance battery; 3MS = Modified Mini Mental State Exam; CHAMPS = Community Healthy Activities Model Program for Seniors; HDL = high-density lipoprotein; LDL = low-density lipoprotein; BP = blood pressure; BMI = body mass index.

costs. Importantly, we accrued 11% more follow-up time as a result of the accelerated recruitment rate throughout the recruitment phase. The primary reasons for exclusion were being too healthy or too active; as such we recruited a sample who were on the cusp of losing independent mobility and who reflected the characteristics of a large number of older adults living in the community.

The success of the recruitment effort in LIFE can be greatly attributed to the lessons learned in the LIFE-P Study (8) and to the high prevalence of the target population in the community. The yields observed in LIFE are similar to those in LIFE-P, which are remarkable when considering the additional

complexity of the recruitment effort due to the additional field centers and their diverse environments. The pilot study prompted several changes to the screening and recruitment strategies used in LIFE. First, in an effort to enhance intervention group differences in PA and prevent dropout or crossover, we modified the CHAMPS physical activity screening criteria to assess 18 items of moderate to vigorous intensity during the screening visits to exclude participants who were regularly active in moderate/vigorous activities. Second, we omitted the behavioral run-in in favor of very direct and repeated explanations of the requirements of the trial. Third, we added and emphasized a “participant expectations



contract” to underscore the significant commitment required of participants in the trial. Given the similarities in yields in LIFE-P and LIFE, and the comparable efficiency of recruitment, it seems unlikely that these modifications played more than a minor role in the success of the recruitment effort. It is important to note that all field centers had considerable experience recruiting older adults and used strategies previously identified as important for successful recruitment of at-risk older adults (22). The ability to connect with potential participants at the individual level and establish a rapport based on trust was emphasized at all sites, and strategies to enhance this were topics of discussion on Recruitment Committee monthly calls. The ability to operate on a flexible schedule for baseline assessments, the provision of transportation or monetary incentives to offset the burden of travel to assessment visits (which was not done in a systematic way across sites in LIFE-P), and the prompt and efficient follow-up calls were cited by the recruitment coordinators at all sites as critical to the success of the recruitment effort once a respondent had contacted study staff. The experiences from LIFE-P also allowed the investigators to refine the flow of participants, albeit minimally, through the screening visits to minimize travel and testing burden. This was critical given the number and variety of assessments collected in this trial.

The recruitment methods, yields, and costs in LIFE were comparable with other trials of behavioral interventions (23). Ory and colleagues reported an average yield of 12.7% for eight very diverse trials and costs ranging from \$103 to \$939/randomized participant. Gill and colleagues (24) reported costs of \$764–868/randomized participant in a clinical trial of physically frail, community-living persons, aged 75 and older. Costs when targeting unique and challenging patient populations can be much higher (\$2000+) (10), especially compared with trials using office visits for low burden interventions (25). The LIFE Study costs of \$840/randomized participant falls in the mid-range, perhaps reflecting the fact that although a large number of older adults would meet our inclusion criteria, they represent a challenging population to attract to intensive behavioral interventions. We employed multiple mailings to the same areas in an effort to attract older adults who may not have been ready to engage with the study when they received the first mailing. We were also cognizant of the fact that maximizing the number of follow-up years by completing recruitment within the 21-month recruitment period would increase the anticipated number of 400-m walk failures and increase the statistical power of the study. All field center recruitment staff identified the robust recruitment budget, which included resources for transportation to assessment visits and incentives, as a critical factor in the success of the LIFE Study recruitment effort. Without these funds, it would have been difficult to accommodate a diverse sample of individuals, particularly those at the lower end of the functional spectrum.

Mass mailing of brochures and letters was an efficient and cost-effective recruitment method by a wide margin.

A critical feature of contemporary mass mailing techniques is the relatively sophisticated targeting of age, sex, race, and zip code that can be achieved. Generally, a nontargeted list generates a 1% response, whereas a targeted list can generate a 2%–6% response (26). All sites had a nonprofit bulk rate permit and a business reply account, obtained at the US Postal Service. The study brochure included a study telephone number and a tear-off postage paid mail-back card. Several sites also used their participant registries that allowed a very efficient use of resources since the registries contain the names and basic demographic information of older adults interested in participating in research. Events and television and radio advertisements were expensive methods that did not ultimately result in a large number of randomized participants. In contrast to LIFE-P, where only 6.8% of randomized participants came from the “Other” source, in the LIFE Study, this was 15% and it was, by far, the cheapest recruitment source.

The Hispanic population represents the second largest ethnic group in the United States (16.7%) but constitutes a relatively small proportion of older adults (4%). We set a goal of recruiting 4.4% ethnic minorities into the LIFE Study. This effort was mainly carried out at the Stanford field center where 18% of randomized participants were Hispanic. Stanford employed Latino bilingual staff, produced culturally appropriate recruitment materials, and provided all study-related forms in Spanish. A critical aspect to the success was the development of a satellite site in a location convenient to the Latino community. With the exception of Northwestern University, other field centers did not have a sufficiently high proportion of Hispanic older adults within their catchment area. Although Stanford’s county of Santa Clara and Chicago’s Cook County have similar Hispanic populations (27.2% and 24.4%, respectively), Northwestern University was not able to achieve its goal of 8% Hispanic enrollment. A potential reason for this was the absence of resources at Northwestern University to employ a bilingual staff to accommodate the Hispanic population. This highlights the importance of utilizing additional resources for recruitment of ethnic minorities into clinical trials.

The baseline characteristics of our sample are indicative of a group of older adults at very high risk for physical decline. By design, all the participants have existing lower extremity functional limitations (SPPB  $\leq 9$ ) although all were able to walk 400 m. However, they are living with significant comorbidity that reflects the situation of a large percentage of the older adult population aged 70 years and older. For example, the prevalence of diabetes in the LIFE Study is very similar to the Centers for Disease Control estimates for the population aged 65 years and older (~27%). Also, virtually all participants are overweight or obese, reflecting the increase in overweight and obesity that has occurred in the older adult population. Therefore, we are dealing with a population at high risk of health outcomes, which is relevant for the trial outcomes.

In conclusion, these data from the LIFE Study demonstrate the feasibility of recruiting a geographically and ethnically diverse population of older community-dwelling adults at high risk for mobility disability for a long-term PA intervention trial. Key strategies for future trials to consider for successful recruitment of at-risk older persons include adequate budget, focus on low-cost direct mailing and targeted newspaper advertisements, staff training and language ability, and resources to provide transportation and incentives for screening visits.

#### SUPPLEMENTARY MATERIAL

Supplementary material can be found at: <http://biomedgerontology.oxfordjournals.org/>

#### FUNDING

A.P.M. is supported by the WFU Claude D. Pepper Center National Institutes for Aging (P30 AG021332). J.M. is supported by the Yale Claude D. Pepper Older Americans Independence Center (P30AG021342). The Lifestyle Interventions and Independence for Elders Study is funded by a National Institutes of Health/National Institute on Aging Cooperative Agreement (UO1 AG22376) and a supplement from the National Heart, Lung and Blood Institute (3U01AG022376-05A2S), in part supported by the University of Florida Claude D. Pepper Older Americans Independence Center (P30AG028740) and sponsored in part by the Intramural Research Program, National Institute on Aging, National Institutes of Health.

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