A Randomized Controlled Trial of an Automated Exercise Coach for Older Adults

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OBJECTIVES: To compare the efficacy of a computer-based physical activity program (Embodied Conversational Agent—ECA) with that of a pedometer control condition in sedentary older adults.

DESIGN: Single-blind block-randomized controlled trial stratified according to clinic site and health literacy status.

SETTING: Three urban ambulatory care practices at Boston Medical Center between April 2009 and September 2011.

PARTICIPANTS: Older adults (N = 263; mean age 71.3; 61% female; 63% African American; 51% high school diploma or less).

INTERVENTION: ECA participants were provided with portable tablet computers with touch screens to use for 2 months and were directed to connect their pedometers to the computer using a data cable and interact with a computer-animated virtual exercise coach daily to discuss walking and to set walking goals. Intervention participants were then given the opportunity to interact with the ECA in a kiosk in their clinic waiting room for the following 10 months. Control participants were given a control pedometer intervention that only tracked step counts for an equivalent period of time. Intervention participants were also provided with pedometers.

MEASUREMENTS: The primary outcome was average daily step count for the 30 days before the 12-month interview. Secondary outcomes were average daily step count for the 30 days before the 2-month interview. Outcomes were also stratified according to health literacy level.

RESULTS: ECA participants walked significantly more steps than control participants at 2 months (adjusted mean 4,041 vs 3,499 steps/day, $P = .01$), but this effect waned by 12 months (3,861 vs 3,383, $P = .09$). For participants with adequate health literacy, those in the ECA group walked significantly more than controls at both 2 months ($P = .03$) and 12 months ($P = .02$), while those with inadequate health literacy failed to show significant differences between treatment groups at either time point. Intervention participants were highly satisfied with the program.

CONCLUSION: An automated exercise promotion system deployed from outpatient clinics increased walking among older adults over the short-term. Effective methods for long-term maintenance of behavior change are needed. **J Am Geriatr Soc 61:1676–1683, 2013.**

Key words: walking; conversational agent; computer; health literacy

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There is clear evidence of an inverse, linear, dose-response relationship between physical activity and all-cause mortality for older men and women.[1–3] Epidemiological studies have found lower risk of cardiovascular disease, type 2 diabetes mellitus, osteoporosis, stroke, breast cancer, colon cancer, and disability in more physically active or fit individuals.[4,5] Physical activity has a beneficial influence on psychological function and decreases the incidence of depression in older adults.[6] Late-life exercise improves strength, aerobic capacity, flexibility, and physical function.[7] Regular walking has been associated with significantly better postural stability, greater ankle plantar flexor and knee extensor strength, and significantly fewer falls in older adults than in those who do not walk regularly.[8]

Older adults who are sedentary can begin an exercise program and still reap the benefits in later life. Healthy older adults adapt to moderate- to high-intensity cardiovascular training similarly to younger adults, and most health outcomes appear to be achievable with moderate levels of exercise.[9] Low- to moderate-intensity aerobic activities such as walking and stationary cycling at 60% of

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maximal predicted heart rate have been associated with modest improvements in cardiovascular efficiency and mobility tasks.[10] Moreover, a change from a sedentary to a more-active lifestyle in midlife or beyond is associated with lower mortality.[11,12]

Despite these benefits, only approximately 25% of men and 20% of women aged 65 and older meet the national guidelines for regular physical activity.[13] The demographic groups at highest risk of inactivity are minorities and those with low income or educational backgrounds,[14] and it is clear that this is a driver of health disparities.[15,16] Although there have been many physical intervention studies conducted in older adults,[17,18] these interventions are not typically designed to meet the needs of individuals with limited educational attainment and low health literacy, so interventions designed for populations with low educational backgrounds and health literacy are needed.

This study investigated the use of a new technology for health behavior change specifically targeting older adults with low levels of health literacy. The primary aim was to test the efficacy of an embodied conversational agent (ECA)-based physical activity intervention designed specifically for older adults that could be deployed from outpatient clinics, targeting individuals who are in need of greater mobility. The intervention had two phases: a 2-month intensive intervention phase delivered on take-home tablet computers, followed by a 12-month maintenance phase delivered on outpatient waiting room kiosk computers. The intervention was compared with a control pedometer intervention that only tracked step counts for an equivalent period of time. It was hypothesized that intervention participants would have significantly greater physical activity levels (measured according to pedometer steps) than controls at the end of the 2 and 12 months.

METHODS

A two-arm, single-blind, randomized controlled trial was conducted to compare the ECA intervention with a control pedometer intervention. All participants were assessed in person at baseline, at the end of the active phase of the intervention (2 months), and at the conclusion of the intervention (12 months).

Participants

Participants were 263 older adults recruited from three outpatient clinics at Boston Medical Center between April 2009 and September 2011. The institutional review board at Boston University Medical Campus approved the study. Community-dwelling adults who attended the geriatrics or internal medicine ambulatory care clinics at Boston Medical Center and were aged 65 and older, English speaking, inactive (not engaged in regular moderate-intensity or greater physical activity ≥3 d/wk for at least 20 min/d over the previous 6 months),[13] free of any medical condition that would limit participation in a walking program, and stable on all medications for at least 3 months were eligible. Individuals were excluded if they had cognitive impairment (Mini-Cog score <2),[19] significant depressive symptoms (Patient Health Questionnaire (PHQ-9) score ≥16),[20] were at high risk of falls, or had a timed maximal walking velocity of less than 0.5 m/s (0.2 m/s is considered frail).[21]

Data Collection

Trained research assistants who administered structured research protocols collected data in face-to-face sessions in a private room. Potential participants who agreed to be in the study and passed final screening procedures completed the baseline assessment, which included sociodemographic information, depressive symptoms (PHQ-9),[20] cognitive status (Mini-Cog),[19] fitness and mobility (timed maximal walking velocity),[22] and health literacy. Health literacy was assessed using the Test of Functional Health Literacy in Adults (TOFHLA),[23] and participants were split into adequate and inadequate health literacy groups, using a TOFHLA cutoff of 23.[24] All participants returned for assessments at 2 and 12 months, at which a different research assistant blinded to group assignment and findings from earlier data collection points collected data.

Steps were measured using a digital pedometer (HJ-720ITC, Omron Healthcare, Inc., Bannockburn, IL) to track daily steps throughout the walking program. This device provides valid and reliable step counts under a range of walking conditions in normal-weight and overweight adults.[25] All participants were instructed to wear the pedometer at the waist or in a pants pocket daily, to record their steps daily on paper log sheets, and to return the log sheets to the researchers monthly (by mail or in person). Research staff also electronically downloaded pedometer steps from the pedometer at the 2- and 12-month in-person interviews. Intervention participants also downloaded pedometer steps on the ECA computer (at home or in a waiting room kiosk) through a data cable each time they interacted with the ECA.

Step count analyses were based on electronically recorded pedometer readings, excluding daily step values below the 5th percentile (233 steps) and above 20,000 steps. A low-value cutoff of this kind is typically assigned in pedometer research because days with extremely low step counts probably represent minimal use of the device.[26,27] A high-value cutoff is typically assigned in pedometer research because of the rare occurrence of high-value pedometer errors.[28] Participants must have had at least 7 days of valid data to be included in analyses.[29] Pedometer steps per day were averaged for the first 2 weeks of the intervention as a baseline and 30 days before the 2-month interview and 30 days before the 12-month interview as outcomes.

Adherence to Intervention

Intervention participant use of the system was determined according to analysis of log files on the tablet and kiosk computers.

Primary Outcome

The primary outcome measure was average daily step count for the 30 days before the end of the intervention at 12 months.

Secondary Outcomes

Average daily step count for the 30 days before the end of the active intervention phase at 2 months was also assessed, as were 2-month and 12-month step counts stratified according to health literacy level.

Supplementary Intervention Group Findings

Satisfaction with the intervention was assessed through a single question and semistructured interviews with participants.

Adverse Events

An independent data safety monitoring board monitored the study for safety (but not efficacy), reviewing all adverse event reports for determination of whether they were attributable to study participation.

Randomization

At study entry and at the end of baseline data collection, participants were randomized in blocks of six or eight, selected randomly, and stratified according to clinic site and health literacy status (inadequate vs adequate).

ECA Intervention

The intervention used an ECA (Figure 1) on a take-home touch-screen tablet computer as the primary communication medium to motivate participants to do more walking during the first 2 months of the intervention. ECAs are animated computer characters that simulate face-to-face conversation using voice, hand gesture, gaze cues, and other nonverbal behavior to make the computer interface as acceptable and intuitive as possible for individuals who may have no prior experience with computers. Simulating face-to-face conversation is particularly important for individuals with low health literacy, because a face-to-face encounter with a health provider remains one of the best methods for communicating health information to individuals with low health literacy levels,[30–32] and prior studies have indicated that this medium works well for individuals of all levels of health and computer literacy.[33] ECAs have also been successfully used in several prior interventions promoting lifestyle health behavior change with younger adults, including physical activity promotion, in which several mechanisms were used to maintain long-term engagement in addition to behavior change counseling.[34–38] In the simulated conversations, the ECA talks using synthetic speech and animated nonverbal behavior, and participants "talk" by selecting what they want to say from a multiple-choice list of options on the touch screen.

At their baseline visit, participants in the ECA group were instructed on how to use the ECA system, were sent home with touch-screen tablet computers, and were instructed to conduct daily conversations with the ECA for 2 months. At the 2-month interview, ECA participants returned their tablet computers (100% returned) and were provided instruction on how to use a kiosk computer in the clinic waiting room whenever they were at the clinic for regularly scheduled appointments.

Daily conversations with the ECA consisted of dialogue and other media designed to promote health behavior change.[38] A daily 5-minute conversation typically consisted of a greeting, social chat, and well-being check-in to determine whether the participant needed to stop his or her walking program and to provide empathic opportunities. The participant was instructed to connect his or her pedometer into the system to upload steps. Next, the virtual coach reviewed the participant's progress relative to her or his short- and long-term goals, provided positive reinforcement if warranted, identified barriers to walking and engaged the participant in a problem-solving discussion for any barriers identified, and then negotiated a new short-term goal, if needed.[39] The session ended with an exercise tip of the day. Each day's dialogue was varied in content and structure and augmented with additional media to help maintain participant engagement and retention.[33] The dialogue and animated character display were augmented with media consisting of various images, such as characters demonstrat-

Figure 1. Embodied conversational agent virtual exercise coach interface.

ing stretching exercises and the proper use of the pedometer and dynamically generated self-monitoring charts showing the participant's step counts relative to goals over time. ECA conversations on the in-home tablet computer and in-clinic kiosks were identical.

Control Group Intervention

The control participants received pedometers, which they were encouraged to wear every day, and monthly logs to track their step counts.

Statistical Analysis

The study was designed to have 80% power (two-sided alpha = .05) to detect effect sizes of 0.4 at 2 months and 0.5 at 12 months between the treatment and control groups based on pilot data[40] and the literature.[41] The necessary baseline sample size was 66 per study group. Because the study was stratified and randomized according to health literacy level, the total sample size required was 264, with outcomes according to literacy level performed as a secondary analysis.

Statistical analysis was performed on an intention-to-treat basis, in accordance with CONSORT guidelines.[42] Separate linear regression analyses were performed for physical activity outcomes at 2 and 12 months using the log of average steps per day in the 30 days before the 2-month interview and the 30 days before the 12-month interview. Models were controlled for age, factors used in the stratified randomization (health literacy and clinic site), and sex, the one characteristic that appeared to differ according to randomization group. Baseline steps, which was defined as the average steps per day in the first 2 weeks of the study from paper logs, were controlled for.

A sensitivity analysis was conducted replacing missing or invalid electronic values with paper log values when available and then replacing excluded values as described above to test the effect of missing data on results.

All analyses were conducted using SAS version 9.2 (SAS Institute, Inc., Cary, NC).

RESULTS

Baseline Characteristics

There were no significant differences before the treatment between groups in participant demographic characteristics other than sex (Table 1). Of the 263 participants who completed the study, 63% self-identified as African American, 61% were female, and 51% had an educational attainment of a high school diploma or less. Participants had a mean age ± SD at enrollment of 71.3 ± 5.4, and 39.9% had low health literacy.

Participant Study Adherence

Of the 263 participants who enrolled in the study, 250 (95%) completed the 2-month assessment, and 226 (86%) completed the 12-month assessment (Figure 2). There were no significant differences in rates of attrition between the groups, but there was a higher rate of pedometer data capture in the control group at 12 months (52.5% vs 39.6%).

Table 1. Baseline Measures

Variable	All, N = 263	Control, n = 131	Intervention, n = 132
Female, n (%)	161 (61.2)	72 (55.0)	89 (67.4)
Age at enrollment, mean ± SD	71.3 ± 5.4	70.8 ± 5.2	71.7 ± 5.6
Race, n (%)			
Black	165 (62.7)	86 (65.6)	79 (59.8)
White	75 (28.5)	35 (26.7)	40 (30.3)
Other	23 (8.7)	10 (7.6)	13 (9.8)
Hispanic, n (%)	20 (7.6)	10 (7.6)	10 (7.6)
Education			
<High school	56 (21.3)	30 (22.9)	26 (19.7)
High school	79 (30.0)	34 (26.0)	45 (34.1)
>High school	128 (48.7)	67 (51.1)	61 (46.2)
Married, n (%)	87 (33.1)	43 (32.8)	44 (33.3)
Finances sufficient to support needs, n (%)	172 (65)	83 (63)	89 (67)
Body mass index, kg/m^2, mean	29.5	29.4	29.6
Medical Outcomes Study 12-item Short-Form Survey score, mean ± SD			
Physical Component Subscale	45.6 ± 9.3	45.8 ± 9.6	45.4 ± 9.0
Mental Component Subscale	56.3 ± 7.7	56.3 ± 7.7	56.3 ± 7.7
Smoker, n (%)	23 (8.7)	9 (6.9)	14 (10.6)
Mini-Cog score, mean ± SD	4.1 ± 0.9	4.1 ± 0.9	4.1 ± 0.9
Patient Health Questionnaire score, mean ± SD	2.5 ± 2.9	2.5 ± 2.9	2.6 ± 3.0
Fastest 5-m walk time, seconds, mean ± SD	3.9 ± 0.9	3.9 ± 0.9	3.9 ± 0.9
Inadequate Test of Functional Health Literacy in Adults score (<23), n (%)	105 (39.9)	52 (39.7)	53 (40.2)

The only significant difference between groups was in sex (chi-square test, $P < .05$).
SD = standard deviation.

Participants in the ECA intervention group interacted with the take-home virtual coach an average of 35.8 ± 19.7 times during the 60-day in-home intervention phase, with usage decreasing markedly after the first week (from an average of 4.7 to 4.0 sessions/wk) and then gradually declining (to 3.3 sessions/wk). Participants accessed the ECA on the waiting room kiosks an average of 1.0 ± 2.9 times during the 10-month period between returning the tablet computer at the 2-month interview and the end of the intervention at 12 months.

Outcomes

For the 200 participants with adequate pedometer data for analysis, the adjusted average number of daily steps for the 30 days before the 2-month interview was 3,499 for the control group and 4,041 for the intervention group (Figure 3, Table 2). For the 30 days before the 12-month interview, the adjusted average number of daily steps for

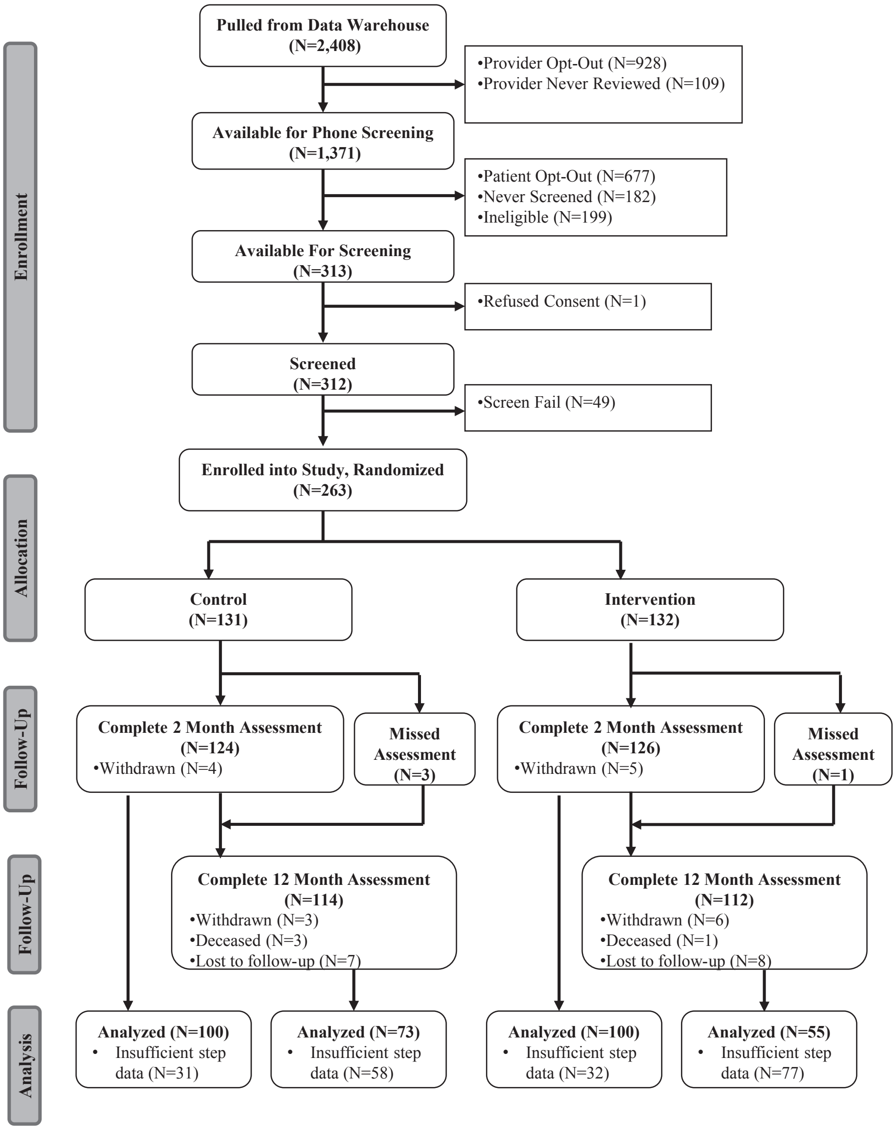

Figure 2. Flow of participants through the trial.

the 128 participants available was 3,383 for the control group and 3,861 for the intervention group. At 2 months, this represents a statistically significant intervention effect (P = .01), but this effect waned and was no longer significant by 12 months (P = .09).

For participants with inadequate health literacy, the adjusted average number of daily steps from the linear regression models for the 30 days before the 2-month interview was 3,116 in the control group and 3,604 in the intervention group (N = 69, P = .24), and for the 30 days before the 12-month interview, the adjusted average number of daily steps was 2,852 in the control group and 3,064 in the intervention group (N = 41, P = .63). For participants with adequate health literacy, the adjusted average number of daily steps for the 30 days before the 2-month interview was 3,762 in the control group and 4,337 in the intervention group (N = 131, P = .03), and for the 30 days before the 12-month interview, the adjusted average number of daily steps was 3,822 in the control group, and 4,681 in the intervention group (N = 87, P = .02).

The sensitivity analysis to test the effect of missing data on results confirmed the general trends above but did not yield significant differences between groups at either time point (P = .08 at 2-month interview, P = .11 at 12-month interview).

Supplementary Intervention Group Findings

Intervention participants expressed a high level of satisfaction with the virtual coach, rating satisfaction an average 6.0 on a scale from 1 (not at all satisfied) to 7 (very satisfied). Data from semistructured interviews also indicated high levels of satisfaction. When asked for their overall impressions of the intervention, 90% of the 125 responses were positive (e.g., "Gives me an incentive to get out there and walk."). When asked whether the virtual coach helped them to walk more, 80% of the 112 responses were affirmative.

Adverse Events

A total of 289 adverse events were identified, of which 10 were mild- to moderate-severity events that were determined to be likely related or probably related to

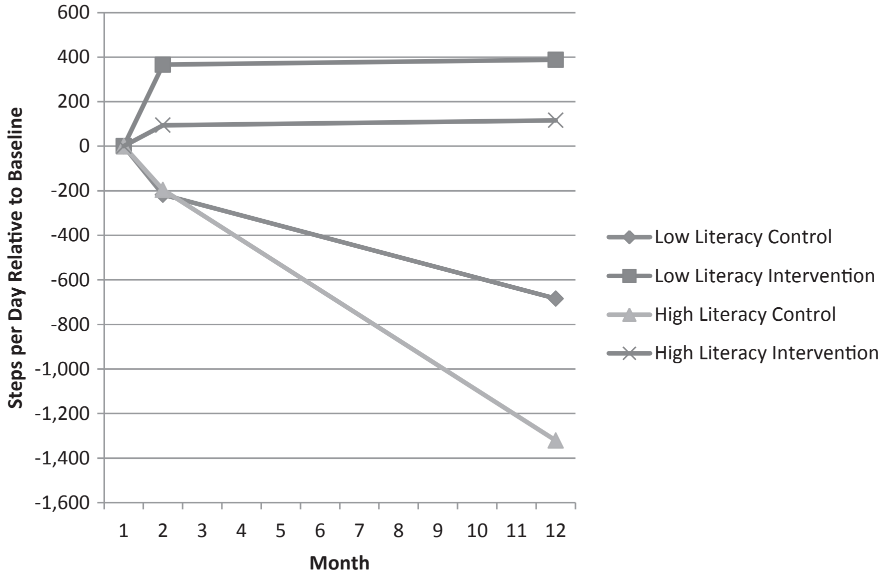

Figure 3. Average daily pedometer steps as differences from baseline (unadjusted). The baseline was computed as average daily steps during the first 2 weeks of the intervention, with outcome measurement points shown for average daily steps 30 days before the 2-month interview and 30 days before the 12-month interview.

participation in the study: eight in the control group and two in the intervention group. The remainder of the adverse events was determined to be unrelated to the study.

DISCUSSION

This study evaluated the efficacy of an exercise-promotion intervention to improve physical activity in sedentary older adults. The intervention featured a novel conversational agent technology designed to increase its reach to persons with low health and computer literacy that could be deployed from primary care clinics. Study results demonstrate that participants were adherent to the initial 2-month intensive phase of the intervention and that it was more effective at increasing physical activity levels than a control group that was only given pedometers, but the subsequent 10-month maintenance phase of the intervention was less successful; intervention participants used the waiting room kiosks once on average over the course of 10 months, and by the end of 12 months of follow-up, there were no significant differences between the groups in number of daily steps. For participants with adequate health literacy, those in the intervention group did significantly better at 2 and 12 months than controls. For patients with inadequate health literacy, there were no significant differences at either time point, although the trends were promising.

As shown in Figure 3, the differences in group means—especially at 12 months—appear to be mostly due to walking declines in the control groups. This could be due to an initial novelty or the Hawthorne effect, causing an initial increase in walking behavior immediately after participants received their pedometers. It could be due to natural declines in mobility over the year in study participants. It could also be due to differential dropout, with control group participants who were doing well with self-monitoring more likely to discontinue use over time.

There are several possible reasons why the second phase of the study was not effective at maintaining behavior change. If the behavior change exhibited in the first 2 months was a simple dose-response function, then it is possible that the frequency of use of the ECA may have been insufficient to maintain physical activity in the latter 10 months. The waiting room kiosks may have been avoided because of concerns about privacy or may have been ignored or simply overlooked because of the time elapsed since last use, competing agendas that commonly arise during clinic visits, or uncertainty about how long the ECA interaction might take (wanting to be ready for the clinician when called from the waiting room). Future interventions should focus on ECA deployments using media that are more accessible than waiting room kiosks, such as web-based or smart phone–based applications that can be accessed daily and indefinitely.

Despite overall low levels of health and computer literacy, most intervention participants had no difficulty using the take-home tablet computer system, satisfaction was generally very high, and all computers were returned at the end of 2 months. The study demonstrated very high retention and a low rate of adverse events, given the age of the participants. It also demonstrated significant increases in walking, even though it used pedometers and log sheets as a control condition. Interventions that use only pedometers and step diaries have been found to be effective for increasing walking in younger adults,[18] so the intervention had a significantly higher bar to overcome than a nonintervention control.

Despite the widespread use of pedometers in society, there is still a great deal of methodology that needs to be developed regarding their use in walking-promotion interventions. Although baseline measures in health behavior–change interventions are typically obtained before the start of the intervention, it was felt that a true preintervention baseline measure of steps per day was not possible,

Table 2. Outcomes

Measure	Overall Control, n = 131	Intervention, n = 132	Low Literacy Control, n = 52	Intervention, n = 53	High Literacy Control, n = 79	Intervention, n = 79
Steps per day						
30 days before 2-month interview						
Unadjusted, mean ± SD	4,303 ± 2,747	4,335 ± 2,498	3,741 ± 2,487	4,204 ± 2,806	4,603 ± 2,847	4,418 ± 2,298
Adjusted, mean[a]	3,499[b]	4,041[b]	3,116	3,604	3,762[b]	4,337[b]
30 days before 12-month interview						
Unadjusted, mean ± SD	4,033 ± 2,573	4,365 ± 2,957	3,275 ± 2,116	4,226 ± 3,331	4,378 ± 2,704	4,440 ± 2,778
Adjusted[a]	3,383	3,861	2,852	3,064	3,822[b]	4,681[b]
Percentage of days with valid step counts, mean ± SD						
30 days before 2-month interview	77.1 ± 34.4	73.4 ± 33.8	64.4 ± 40.5	66.5 ± 35.5	85.5 ± 26.9	77.9 ± 32.1
30 days before 12-month interview	52.5 ± 44.1	39.6 ± 43.3	40.4 ± 44.2	34.1 ± 41.9	60.5 ± 42.4	43.3 ± 44.1
Log-ins at home during first 2 months	N/A	35.1 ± 19.8	N/A	29.1 ± 19.8	N/A	39.1 ± 18.8
Log-ins in clinic during Months 3–12	N/A	0.9 ± 1.8	N/A	0.4 ± 0.8	N/A	1.1 ± 2.1

All data unadjusted except as noted.
[a]Adjusted for sex, literacy category, clinic location, average steps per day during Days 1 to 13 of study.
[b]$P < .05$.
SD = standard deviation; N/A = not applicable.

given the effect that pedometers alone can have on walking. In addition, the clinical significance of daily step counts (or changes in daily step counts) is still lacking evidence and needs to be established, although physical activity in general has been shown to have many physical and mental health benefits. The difference of 542 steps per day observed at 2 months may have limited clinical significance. A recent review of walking studies of older adults identified an association between increases of 2,000 to 3,000 steps per day and increases in immune functioning, decreases in body mass index, and achievement of the Centers for Disease Control and Prevention–recommended 30 minutes per day of moderate or greater physical activity through walking alone,[13] although the dose-response relationships between steps per day and bone density of the hip and spine,[43] markers of inflammation,[44] and health-related quality of life[45] appear to be linear and without threshold.

Although there have been many physical intervention studies conducted with older adults,[21,22] and there have been many health behavior interventions targeted at disadvantaged populations,[46] there are few studies of walking in urban, minority, low-income older adults. This is the first study the authors are aware of that has attempted to reach this population with a walking intervention deployed from outpatient clinics affiliated with a safety net hospital. The results indicated that the study had partial success in reaching this population, although more work is needed to develop effective interventions for those with low health literacy.

There are several limitations to this study. Older adults with significant cognitive impairments and mobility limitations were excluded, 667 of 990 eligible patients declined participation, and the study was conducted in a single metropolitan area (Boston), which may not be representative of all locales in the United States. The effect of seasonality on walking is especially relevant given New England winters, although the permuted block randomization scheme with small block sizes controlled for seasonal effects by enrolling equal numbers of participants in each arm of the study at each time of year.

The lack of significance at 12 months is possibly due in part to low power, because the sample size for the analysis was smaller (128 at 12 months vs 200 at 2 months). Low power was particularly relevant for the subanalyses in participants with low literacy. Overall, the lack of pedometer data (76% of participants available for analysis at 2 months, 49% at 12 months) is somewhat surprising given the high retention rate in the study (95% at 2 months, 86% at 12 months), and the increase in missing pedometer data was especially large in the intervention group. One explanation for this may be that the intervention participants thought the intervention was over once they returned their tablet computers, causing them to stop using their pedometers and resulting in a significant drop in pedometer use in Months 3 to 12. Improving pedometer use adherence is a prerequisite for improving outcomes in pedometer-based walking interventions and should thus be the target of future research efforts.

In spite of these limitations, the study demonstrated that an ECA-based intervention can be successfully deployed from outpatient clinics to the homes of older adults, that the individuals adhered to the intervention and were satisfied with it, and that it can be effective in increasing short-term physical activity. This study is one of the few physical activity interventions involving an urban, largely minority population with a high rate of inadequate health literacy.

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Conflict of Interest: The editor in chief has reviewed the conflict of interest checklist provided by the authors and has determined that the authors have no financial or any other kind of personal conflicts with this paper.

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intervention and the study. Rebecca A. Silliman was Principal Investigator of the project and provided overall direction of the study. Kerrie Nelson and Debbie M. Cheng directed the statistical analysis of the study data. Michael Winter conducted data acquisition and validation and performed statistical data analysis and reporting. Lori Henault was project manager for the study.

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