

Long-Term Effect on Mortality of a Home Intervention that Reduces Functional Difficulties in Older Adults: Results from a Randomized Trial

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OBJECTIVES: To evaluate the long-term mortality effect of a home-based intervention previously shown to reduce functional difficulties and whether survivorship benefits differ according to initial mortality risk level.

DESIGN: Two-group randomized trial with survivorship followed up to 4 years from study entry.

SETTING: Homes of urban community-living elderly people.

PARTICIPANTS: Three hundred nineteen adults aged 70 and older with difficulties performing daily activities.

INTERVENTION: Occupational and physical therapy sessions to instruct participants in compensatory strategies, home modifications, home safety, fall recovery techniques, and balance and muscle strength exercises.

MEASUREMENTS: Survival time was number of days between baseline interview and date of death, as determined using data from the National Death Index or December 31, 2005. Participants were stratified according to baseline mortality risk (low, moderate, high) using a prognostic indicator.

RESULTS: At 2 years, intervention participants (n = 160) had a 5.6% mortality rate (n = 9 deaths) and controls (n = 159) a 13.2% rate (n = 21 deaths; $P = .02$). Mortality rates remained lower for intervention participants up to 3.5 years from study entry. At 2 years, intervention participants with moderate mortality risk had a 16.7% mortality rate (n = 16 deaths/96), compared with 28.2% for equivalent control group participants (n = 24 deaths/85; $P = .02$). By 3 years, mortality rates were not statistically significantly different between the experimental and control groups.

CONCLUSIONS: The intervention extended survivorship up to 3.5 years and maintained statistically significant differences for 2 years. Subjects at moderate mortality risk derived the most intervention benefit. Findings suggest that

the intervention could be a low-cost clinical tool to delay functional decline and mortality. *J Am Geriatr Soc* 57:476–481, 2009.

Key words: home care; frailty; survivorship; occupational therapy; physical therapy

Functional disability due to age-related chronic or debilitating conditions is common in older adults, and its prevalence is expected to increase as the population ages, particularly in the oldest old.¹ As a marker of frailty, functional difficulties have significant negative consequences, including social disengagement, fall risk, depression, reliance on personal assistance, relocation, and high service utilization and healthcare costs.^{2,3} Moreover, functional disability is predictive of mortality.⁴

Numerous interventions to address disability have been evaluated, with most studies showing small to no treatment effects.^{5,6} Studies examining mortality effects of interventions designed to reduce disability have been conducted mostly in countries other than the United States, focused on specific diseases or clinical populations, or reported inconsistent results.^{7–9} Thus, the best treatment for minimizing disability, and whether this reduces mortality, is unclear.

It was previously reported that a home-based occupational (OT) and physical therapy (PT) intervention (Advancing Better Living for Elders (ABLE) program), tested in a randomized controlled trial, reduced functional difficulties, fear of falling, and home hazards and enhanced self-efficacy and use of control-oriented strategies (e.g., assistive devices, home modifications, energy conservation techniques).^{10,11} It was also found that, by 12 months, ABLE participants had a 1% mortality rate, compared with a 10% mortality rate in control group participants, with subjects who were hospitalized before study enrollment having a greater survivorship advantage (0% mortality rate for ABLE participants vs 21% mortality rate for control group

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participants).¹² These statistically significant differences in mortality rates at 12 months suggested the possibility of a survivorship effect beyond this initial study period and the importance of evaluating how long the intervention benefit lasted.

This follow-up study examined National Death Index (NDI) records to determine length of time ABLE participants sustained a survivorship benefit and whether survivorship benefits differed according to level of risk for mortality at time of study enrollment.¹³ As an exploratory study, there was no prediction concerning length of time of survivorship, but based on the initial findings concerning the benefits conferred for participants hospitalized before study enrollment, it was expected that the ABLE program would have the strongest effect on those entering the study with a moderate mortality risk level. Alternately, less intervention benefit was expected for those at high risk who, it was reasoned, would require medical intervention beyond the scope of ABLE. It was also anticipated that subjects at low mortality risk would enter the study with a survivorship advantage such that ABLE would have minimal effect on survivorship.

METHODS

Study Sample and Procedures

All study procedures including Consolidated Standards of Reporting Trials flow chart, recruitment, and randomization are reported elsewhere.¹⁰ Briefly, participants were recruited from the community, ambulatory, aged 70 and older, English-speaking, and cognitively intact (Mini-Mental State Examination (MMSE) score >23)¹⁴ and reported one or more functional difficulties. Participants were randomized to treatment (the ABLE program) or to a usual care control group. Baseline interviews were conducted from September 14, 2000, to July 14, 2003. NDI records were obtained for deaths up to December 31, 2005. Thus, follow-up ranged from 2.5 to 5.25 years from study entry.

ABLE Intervention

As described elsewhere,^{10–12} the ABLE program compensated for declining abilities by introducing modifications to home environments and task performance. The active phase consisted of five OT contacts (four 90-minute visits and one brief telephone contact) and one 90-minute PT visit during the first 6 months. Occupational therapists worked with participants to identify and prioritize problem areas. For each identified targeted area, occupational therapists observed and evaluated performance for safety, efficiency, difficulty level, environmental barriers and supports. Occupational therapists problem-solved with participants to refine personal goals, and identify behavioral and environmental contributors to performance difficulties. They then instructed subjects in strategies customized to needs, preferences, and environmental contingencies. Strategies included cognitive (e.g., reframing), behavioral (e.g., pace self), and environmental (e.g., grab bars) modifications. Physical therapists provided balance and muscle strengthening exercises to support participation in targeted areas, fall recovery techniques to reduce fear of falling, and referrals for additional therapy if necessary.

The maintenance phase (from 6–12 months), consisted of three brief OT telephone calls to reinforce strategy use and help generalize use to newly identified problems. In a final home visit, occupational therapists reviewed and reinforced strategies and obtained closure.

Control group participants did not receive intervention contact but, at study completion (12 months), received a home safety education booklet.

Measures

Background characteristics included age, sex, education ($<$ high school, high school, $>$ high school), living arrangement (alone, with others), race (white, African American, other), and financial difficulty (0–4, higher scores representing greater difficulty).

Risk Groups

To categorize participants according to mortality risk level, 11 of a 12-item validated prognostic indicator was used and its scoring approach followed.¹⁵ One prognostic item, body mass (point = 1 for high body mass), derived from weight and height information, was not included because these data were not collected in the trial. The 11 items and assigned risk points were age (70–74 = 3 points; 75–79 = 4 points; 80–84 = 5 points; ≥ 85 = 5 points), sex (male = 2), comorbidities and health behavior (diabetes mellitus = 1; cancer = 2; lung disease = 2; heart failure = 2; current smoker = 2), and functional difficulties (bathing = 2; managing finances = 2; walking several blocks = 2; pushing/pulling heavy objects = 1). Higher scores indicated greater mortality risk.

A risk score (range 1–15) was calculated for each participant by adding points for each risk factor and then categorizing overall risk scores into three groups: low risk (Group I) (1–5), moderate risk (Group II) (6–9), and high risk (Group III) (≥ 10), based on the previous study.¹⁵ Whereas the previous study had a fourth risk group (> 14), only two individuals had these scores, and thus they were included in risk Group III. Average mortality risk scores were 4.1 for the low-risk group, 7.8 for the moderate-risk group, 11.3 for the high-risk group, and 8.1 for the entire sample. Similar to the original 12-item index, it was found that the 11-item version differentiated between risk groups. Although the mortality risk scores from the current study were slightly higher for each risk group than those of the previous study, this was expected given that the sample in the current study was older.

The three risk groups were compared on each risk factor and demographic characteristics using chi-square (χ^2) procedures. As in the previous study, statistically significant differences emerged between risk groups in the expected direction for each health and functional risk item except for smoking. The high-risk group had greater functional difficulties in all areas and a higher proportion of health conditions than the moderate- and low-risk groups ($P = .001$ – $.003$ for each item). Risk groups also differed in terms of education ($\chi^2 = 16.1$, $P = .003$) and income ($\chi^2 = 10.2$, $P = .04$), with greater risk for those with less than a high school education and annual income less than \$20,000.

As expected and similar to the previous study, risk groups differed in terms of mortality rate. At 2 years, the mortality rate for low-risk participants was 5.9% ($n = 3/51$

deaths), compared with 8.3% ($n = 15/181$ deaths) for moderate-risk participants, and 13.8% ($n = 12/87$ deaths) for those at highest mortality risk.

Data Analysis

The dependent variable, survival time, was defined as number of days between baseline interview (randomization date) and date of death or censoring. The only censoring was administrative; all participants' follow-up was administratively censored at December 31, 2005, corresponding to the last date for which NDI information was available. The main effects of treatment and risk level were analyzed using standard statistical methods for censored data, with graphs of survival plotted using the Kaplan-Meier method. Statistical significance of treatment and risk level was determined using log rank tests. Survival rates were estimated for treatment condition at 2, 3, and 4 years from date of study entry and risk level at 2 years from study entry. There was no censoring before 2 years of follow-up. Rates reported for time periods longer than 2 years were based on the Kaplan-Meier analyses. SPSS version 15.0 (SPSS Inc., Chicago, IL) was used with significance level set at .05.

RESULTS

A detailed description of the study sample has been presented elsewhere.^{10,11} Briefly, at baseline, participants ($N = 319$) were on average 79 years old, primarily female (81.8%), living alone (61.8%), and reporting low income. Thirty-one percent of participants had less than a high school education, 52.7% were white, and 45.5% were African American. At baseline, participants reported some to a lot of difficulty ambulating (mean 2.5 ± 0.8) and performing self-care (1.8 ± 0.6) and instrumental activities (2.1 ± 0.6). Also at baseline, participants reported a mean of seven health conditions, the most common being arthritis (84.3%), hypertension (70.5%), cataracts or macular degeneration (43.0%), cardiovascular problems (39.0%), and diabetes mellitus (23.3%). Furthermore, at baseline, 69.6% of participants rated their health as fair to poor, and 51.9% indicated their health was not as good as 1 year before. As previously reported, there were no large or statistically significant differences between treatment ($n = 160$) and control group ($n = 159$) participants in terms of these background characteristics, health status indices, or primary outcome measures.¹⁰

Long-Term Mortality Effects

Overall, as of the administrative cutoff (December 31, 2005), 76 (24.0%) of 319 participants had died, of whom 42 (55.0%) were control group participants and 34 (45.0%) treatment participants. By 4 years from study entry, 74 or 319 individuals had died (40 control; 34 treatment). Two additional deaths occurred in the control group after 4 years but before the administrative cut off.

Figure 1 presents an estimate of a life table to 4 years from baseline interview for participants according to treatment assignment without stratification according to level of risk. As shown, the survival curves separate and then come together, with an initial survival benefit for the treatment group remaining up to 3.5 years. However, the statistical significance of the comparison depends on the point at

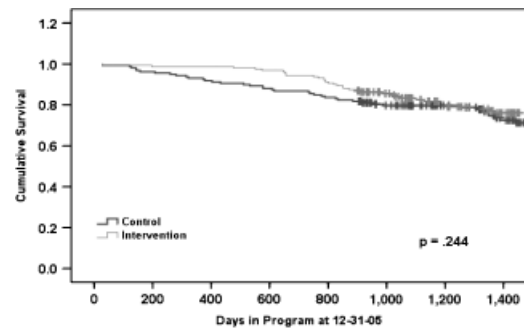


Figure 1. Estimates of survival according to treatment group. *Note:* Vertical lines on the survival curves show dates of censoring. The two vertical lines on the x-axis mark 2 and 3 years of follow-up.

which the data are examined. At 2 years, the treatment condition had a substantial and statistically significant effect (according to log-rank test) on survival ($\chi^2 = 5.4$, $P = .02$) such that only 5.6% ($n = 9/160$) of intervention participants had died, compared with 13.2% ($n = 21/159$) of control participants. At 3 years, intervention participants exhibited a 16.2% Kaplan-Meier mortality rate and controls a 20.2% rate ($P = .25$); at 4 years, intervention participants exhibited a 24.0% Kaplan-Meier mortality rate and controls, a 28.7% rate ($P = .24$).

The curves presented in Figure 1 suggest a postponement of some mortality in the intervention group, with a later catch-up period. To examine this further, conditional 6-month mortality rates for up to 2 years were determined. These are rates of dying in the next 6 months in those alive at the start of that 6-month period. The 6-month mortality rate in the control group remained at approximately 4.0% throughout the first 2 years of follow-up. In the intervention group, the mortality rate was near 0 for 1 year and then began increasing. Before 18 months, the 6-month mortality rate was lower in the intervention group. Beginning at 18 months, the 6-month mortality rate was higher in the intervention group (4.0% in intervention vs 3.0% in control), corresponding to the point in Figure 1 where the curves begin to come together.

Treatment Benefits According to Risk Groups

Given that a statistically significant difference in mortality rates was found at 2 than at 3 or 4 years, this time frame was used to examine whether there was a treatment effect within each risk group. Table 1 shows that the estimated 2-year mortality rate for treatment participants was 0.0% in Group I, 3.0% in Group II, and 15.0% in Group III. This is in comparison with control participants, for whom rates were 11.0% in Group I, 14.0% in Group II, and 13.0% in Group III.

Figures 2A–C present 2-year life table survival estimates for participants at each risk level stratified according to treatment condition. The general trend for all three risk groups was similar to that of Figure 1, with survival curves separating for each level of risk and favoring the intervention group. According to log rank test, treatment assignment had a statistically significant effect on survival for participants who were at moderate risk of mortality ($\chi^2 = 5.3$, $P = .02$). However, no statistically significant

Table 1. Two-Year Mortality Rates According to Risk Group

Risk Group	Risk Index Score*	Usual Care Group	Intervention Group	Overall (N = 319)
		(n = 159)	(n = 160)	
Deaths/Subjects n/N (%)				
I	0-5	3/28 (10.7)	0/23 (0)	3/51 (5.9)
II	6-9	12/85 (14.1)	3/96 (3.1)	15/181 (8.3)
III	10	6/46 (13.0)	6/41 (14.6)	12/87 (13.8)

* Risk score derived from.¹⁵

differences were observed between groups at the lowest and highest levels of risk, although the magnitude of the difference in rates was similar in Group I to that of Group II.

DISCUSSION

This study builds upon previous findings that the ABLE program reduced functional difficulties and conferred a 1-

year survivorship benefit. This study showed that mortality rates were statistically significantly lower for the intervention group than for the control group for up to 2 years, with mortality rates remaining lower for ABLE participants for up to 3.5 years from study entry. The risk of dying within 2 years from study entry was close to 8 times as high in control group participants as in ABLE participants.

The mortality benefit to 2 years was similar in low and moderate mortality risk groups, although this attained statistical significance only in the moderate group (the largest of the three groups in the sample). This may be partially due to the small sample size in the low-risk group. For this moderate-risk group, risk of dying within 2 years from study entry was close to 11 times as high in control group participants as in ABLE participants. The pattern was slightly different in the high-risk group, in which there was an early benefit for ABLE participants, although that benefit did not last to the 2-year point. Although ABLE participants at each level of mortality risk (low, moderate, high) derived some intervention benefit, intervention participants at moderate risk sustained a statistically significant 2-year survival advantage over their control-group counterparts.

These findings suggest that a relatively brief, nonpharmacological intervention that helps older people use cognitive, behavioral, and environmental strategies to reach self-identified functional goals has survivorship benefits that persist. The survivorship advantage extended well beyond ABLE's 6-month active phase of hands-on intensive skills-training.

Reasons for prolonged survivorship are unclear. One explanation may be ABLE's preventive home safety and referral functions. Previous research has shown that health professional visits reduce mortality.^{7,9,16} Nevertheless, medical referrals were not typical in ABLE. Another explanation may be social attention, although it seems unlikely that approximately 10 professional contacts explains survivorship extending 3.5 years from study entry.

A more plausible explanation is that ABLE offered strategies that helped participants achieve personal functional goals. As reported previously, ABLE participants reported greater use of control-oriented strategies than control group participants at 6- and 12-month follow-ups.¹⁰ The Life Span Theory of Control suggests that, as impairments encroach on performance abilities, individuals experience heightened vulnerability to environmental complexities and threats to personal control.¹⁷ Threats to or loss of control have significant negative health consequences; alternatively, enhancing control contributes to well-being and survivorship.¹⁸⁻²⁰

How does enhancing control support survivorship? Control-oriented strategies enable continued engagement in everyday activities, which may have some physiological and psychosocial benefits. Although pathophysiological mechanisms are unclear,²¹ the findings of the current study are consistent with recent evidence on the dynamic interaction between frailty and living environments.²²

There are other competing explanations than the benefits conferred by ABLE. Findings may be a result of attrition bias or selective mortality in the intervention group such that the highest-risk patients died early, leaving a remaining pool of lower risk patients. Mortality rates are higher in the higher-risk group, so the baseline risk

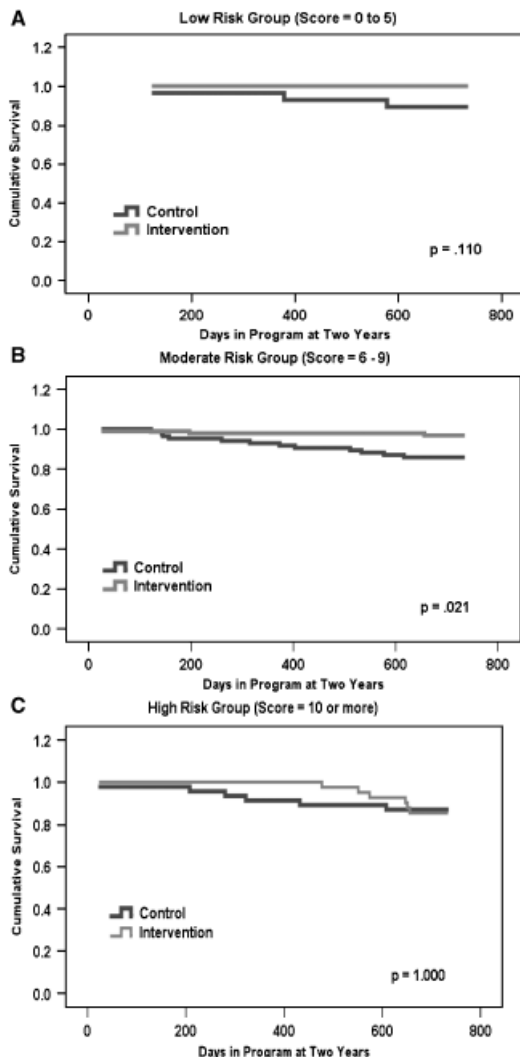


Figure 2. Estimates of survival according to level of risk. (A) Low-risk group (score = 0 to 5). (B) Moderate-risk group (score = 6 to 9). (C) High-risk group (score ≥10).

distribution of those remaining alive slowly moved toward the lower-risk groups, but because there was little mortality in the intervention group early on, this effect was not seen in the intervention group in the early period. However, this does not explain the increase in the 6-month rates in the intervention group. Also, as a randomized study, any attrition effect should be the same in both groups in the absence of an intervention effect. It appears that the intervention delays mortality in a subset but that medical problems eventually take over.

A potential limitation is that the database does not allow for multivariate risk adjustments or control of clinical variables (e.g., comorbidities, health service utilization, hospitalizations). Also, survival analyses were unplanned and post hoc. Nevertheless, these are minor limitations, given that the original study was a randomized trial with no large or statistically significant differences between treatment and control groups on study outcomes or health variables.

Another issue is representativeness. Similar to population-based studies of older adults with similar ages and functional problems, a 10% mortality rate was found at 2 years for the study sample overall.⁴ This suggests that the sample may be representative of the larger population of elderly people living at home with performance difficulties. ABLE participants had a mortality rate of 5.6%, below the rate for the control group (13.2%) and those in representative studies (10%). Although not the main focus, in the current sample, individuals with low income and education were at the highest risk of mortality. This association is consistent with population-based health disparities research, again suggesting the representativeness of the sample.^{23,24}

Several clinical implications can be derived. Interventions addressing disability are not typically part of medical management. Evidence from other studies shows that those most in need (frail, post-hospitalized, vulnerable elderly people) receive inadequate follow-up care.^{25–27} ABLE may be most beneficial for these groups who have been previously identified as most at risk for functional decline.

Nevertheless, older adults with no functional difficulties also report using accommodations to perform activities. Use of accommodations by this independent group has been shown to reflect a subclinical stage predictive of frailty.²⁸ Therefore, older adults with incipient functional difficulties may also benefit from ABLE, as suggested by the slight intervention advantage afforded to the low-mortality-risk group.

Essential to ABLE is its client-centered focus; use of problem-solving; active engagement of older adults in problem-identification and strategy-generating processes; and individualizing of strategies to fit needs, cultural preferences, and environments. These elements resonate with an emerging vision for geriatric care,^{29,30} which emphasizes that patient-centered care and symptom management should be integrated with medical management and become standard practice.

Overall, ABLE demonstrated that teaching elderly people new approaches to performing valued activities resulted in additional years of life. Further research is necessary to substantiate mortality findings using a preplanned, hypothesis-driven randomized trial. Equally important is determining why ABLE lost its benefit; whether different dose,

intensity, or boosters prolong benefit; and how to integrate ABLE into other proven interventions (e.g., physical activity) to extend positive effects. Future research should clarify physiological mechanisms by which survivorship benefits are conferred, effects of ABLE on health utilization, and cost and cost-effectiveness of this promising program.

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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 manuscript.

Author Contributions: L.N. Gitlin: principal investigator, developed study concept and design, developed research questions, oversaw scientific integrity and interpretation of data, primary responsibility for preparation of manuscript. W. Hauck: statistician, oversaw design development, statistical analyses, and integrity of data interpretation; manuscript preparation. M. Dennis: conducted data analysis, constructed manuscript tables, participated in writing of manuscript. L. Winter: co-project director of study, assisted in acquisition of subjects and manuscript preparation. N. Hodgson: interpretation of data and review of the article for clarity and accuracy. S. Schinfeld: co-project director, assisted with subject recruitment, coordinated data from NDI, and reviewed manuscript for accuracy.

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