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The ACTIVE Study: Study Overview and Major Findings

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In response to data indicating that persons over age 65 account for almost half of all days of care in short stay hospitals (Graves & Kozak, 1999), constitute the majority of residents of nursing homes (Strahan, 1997), and account for over 75% of required formal home-based care supports (Levit et al., 1997; Office, 1996), the National Institute on Aging and the National Institute for Nursing Research funded an initiative to test the effectiveness of cognitive interventions in maintaining cognitive health and functional independence in older adults. This initiative was based on evidence that the cognitive performance of older adults can be improved through systematic training focused on cognitive skills (Baltes, Kuhl, Gutzmann, & Sowarka, 1995; Caprio-Prevette & Fry, 1996; Hayslip, Maloy, & Kohl, 1995; Kramer, Larish, & Strayer, 2002; Mohs et al., 1998; Neely & Backman, 1995; Noice, Noice, & Staines, 2004; Oswald, Rupprecht, Gunzelmann, & Tritt, 1996) paired with evidence of the importance of cognitive functioning for performing activities of daily living (Allaire & Marsiske, 1999; Backman & Hill, 1996; Burdick et al., 2005; Cahn-Weiner, Malloy, Boyle, Marran, & Salloway, 2000; Owsley, Sloane, McGwin, & Ball, 2002) and maintaining health related quality of life among older adults (Hultsch, Hammer, & Small, 1993; Swan, Carmelli, & LaRue, 1995; Wolinsky & Johnson, 1991). At that time, essentially no research had been conducted demonstrating training transfer to real-world functional outcomes in later adulthood. The Advanced Cognitive Training for Independent and Vital Elderly (ACTIVE) trial addressed this gap.

The goal of ACTIVE was to test the effectiveness of three cognitive interventions (memory, reasoning, and visual speed of processing) in maintaining cognitive health and functional independence in older adults. The targeted abilities-- memory, reasoning, and speed of processing—were selected based on evidence that they exhibit relatively early age-related decline, beginning on average in the mid-sixties (Schaie, 1996), that interventions have been shown to be effective in training these abilities (K Ball, 1997; K. Ball & Owsley, 2000; Kliegl, Smith, & Baltes, 1990; Lachman, Weaver, Bandura, Elliott, & Lewkowicz, 1992; McDougal, 1999; Mohs et al., 1998; Oswald et al., 1996; Rasmusson, Rebok, Bylsma, & Brandt, 1999; Rebok & Balcerak, 1989; S. Willis, 1990; S. Willis, Cornelius, Blow, & Baltes, 1983; S. Willis & Nesselroade, 1990; S. Willis & Schaie, 1986, 1994), and that performance on these abilities is associated with performance of cognitively demanding instrumental activities of daily living, critical for independent living (K. Ball & Owsley, 2000; K. Ball, Owsley, Sloane, Roenker, & Bruni, 1993; Diehl, Willis, & Schaie, 1995; S. L. Willis, 1996; S. L. Willis, Jay, Diehl, & Marsiske, 1992).

ACTIVE began in September, 1996 at six field centers: the University of Alabama at Birmingham, the Boston Hebrew Rehabilitation Center for Aged (now Hebrew Senior Life), the Indiana University School of Medicine, the Johns Hopkins University, the Pennsylvania

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State University, and Wayne State University, with a data coordinating center at the New England Research Institutes.

The conceptual model that informed the design of ACTIVE (Figure 1) was based on prior evidence showing that cognitive training would be domain specific. That is, each intervention was expected to result in specific improvement on measures of the trained ability relative to the other interventions and control group. For example, training in memory was expected to improve memory function (the proximal outcome) but was not expected to improve reasoning or speed of processing skills. On the other hand, intervention effects were expected to show some level of general transfer to daily function (the primary outcome) based on the critical assumption that declines in cognitive function lead to declines in activities in daily living. In other words, improvement in cognitive ability should result in maintenance of functional independence. In turn, maintained functional independence could result in a positive cascade of effects including improvements in quality of life, mobility, and health service utilization.

DESIGN

ACTIVE is a randomized, controlled, single-masked trial utilizing a four-group design (Figure 2) with three intervention arms and a no-contact control group. Details of the study design are provided in(Jobe et al., 2001). Eligibility criteria were established to ensure that the study population would be in good physical and cognitive health at the time of enrollment, yet at risk for cognitive and functional decline. Prior longitudinal studies have demonstrated that significant age-related decline occurs in the mid-sixties for cognitive abilities, the targets of training (Schaie, 2005). In contrast, significant age-related decline on daily function has been shown to occur later than for the targeted mental abilities, occurring for IADLs in the mid seventies to early eighties. Thus, intervention on the cognitive abilities was timed to occur at the normative onset of age-related decline in these abilities, but prior to expected normative decline in the functional outcomes.

Participants

Recruitment occurred from March 1998 through October 1999 in six metropolitan areas using a variety of sampling strategies. Community-dwelling adults aged 65 years and older were eligible. Persons were excluded if they had significant cognitive dysfunction (score < 23 on the Mini-mental State Examination, MMSE (Folstein, Folstein, & McHugh, 1975)); functional impairment (dependency or regular assistance in ADL on Minimum Data Set Home Care (J. N. Morris et al., 1997)); self-reported diagnoses of Alzheimer disease, stroke within the last 12 months, or certain cancers; current chemotherapy or radiation therapy; or poor vision, hearing, or communicative ability that would have interfered with the interventions or outcome assessments. Enrollment resulted in a sample of 2,802 individuals (average age 74 years, average education 13 years, 74% white and 26% African American, and 76% women).

The ACTIVE sample was not intended to be representative of the US population. As shown in Table 1, ACTIVE participants were slightly younger than the U.S. population over age 65 and were more likely to be female and not married. As a result of the targeted efforts to recruit African Americans, they were over-represented in this sample. ACTIVE participants have slightly less health care utilization and slightly better perceived health compared to the general population of older adults in the U.S.; however, the prevalence of selected health conditions, especially those associated with lower cognitive functioning such as hypertension and diabetes (Carmelli et al., 1998), indicate that they were at risk for cognitive decline.

Study Procedures

Eligibility and demographic data (age, gender, race, education, and marital status) were gathered in a telephone screening. Health history (self-report of diabetes, myocardial infarction, angina, heart failure, stroke, hypertension, high cholesterol, and current alcohol use), physical status (MOS Short-form 36 (Ware & Sherbourne, 1992)), functional status (MDS, see below), mental status (MMSE (Folstein et al., 1975)) and cognitive and function measures (see below) were gathered via in-person examinations in individual and small-group formats at baseline. Eligible participants were randomly assigned to one of three intervention arms or the no-contact control group. Screening and baseline assessment took place before randomization. Due to logistical considerations related to testing and training a large sample, recruitment and all subsequent field work were conducted in six replicates of approximately eight weeks duration. Outcome assessments were conducted immediately following and 1, 2, 3, and 5 years after the intervention (Figure 2). A 10-year follow-up was recently completed.

Site staff who conducted the training interventions (trainers) and completed assessments (assessors) were trained centrally, followed by performance-based certification. Trainers for an intervention were not allowed to be cross-trained in the other interventions. Assessors were masked to participant assignments. Annual recertification was required. Annual monitoring visits were conducted by the Data Coordinating Center which included data audits and observations of trainers and assessors to check for drift.

Study procedures were approved by the institutional review boards at the collaborating institutions, and all subjects gave informed consent to participate.

Interventions

Interventions were conducted in small groups in ten 60–75 minute sessions over 5 to 6 weeks. Memory training focused on improving verbal episodic memory through instruction and practice in strategy use. Reasoning training focused on improving the ability to solve problems that contained a serial pattern. Speed training focused on visual search and the ability to process increasingly more information presented in successively shorter inspection times. In all three interventions, sessions 1–5 focused on strategy instruction and exercises to practice the strategy while sessions 6–10 provided additional practice exercises. Content for each of the 10 sessions was scripted in a trainer's manual. Booster training (four 75-minute sessions) was provided at 11 and 35 months after training to a randomly selected subset of participants in each intervention arm who completed initial training (defined as 8 of 10 sessions).

Proximal Outcomes - Measures of Cognitive Abilities

Multiple measures of basic mental ability for memory (Hopkins Verbal Learning Test total of the 3 learning trials (Brandt, 1991), Rey Auditory-Verbal Learning Test total of the 5 learning trials (Rey, 1941), and Rivermead Behavioral Memory Test immediate recall (Wilson, Cockburn, & Baddeley, 1985)), reasoning (Letter Series total correct (Thurstone & Thurstone, 1949), Letter Sets total correct (Ekstrom, French, Harman, & Derman, 1976), and Word Series total correct (Gonda & Schaie, 1985)), speed of processing (Useful Field of View (Owsley et al., 1998)), and vocabulary (Ekstrom et al., 1976) formed the proximal outcomes. Individual scales were normalized to the same metric with a z-score transformation using the control group's baseline mean and standard deviation (each participant's test score subtracted from the control group mean score at baseline and the difference divided by the control group standard deviation at baseline resulting in z-score with mean of 0 and standard deviation of 1), and subsequently combined into domain-specific composites (average of the component z-scores).

Primary Outcomes - Measures of Daily Function

Daily functional was measured with an instrument based on the Minimum Data Set for Home Care (MDS) (J. N. Morris et al., 1997) which taps instrumental and basic activities of daily living (ADL). The instrumental activities covered by the MDS include 19 daily tasks spanning meal preparation, housework, finances, health care, telephone, shopping, and travel over the past seven days. The basic activities covered by the MDS include need for assistance in dressing, personal hygiene, and bathing. The Performance subscale assesses the degree of independent completion of tasks. The Difficulty subscale assesses the perceived degree of difficulty in completing these subtasks. The MDS has high correlations with Barthel measure of basic ADL (r = .74) and the Lawton measure of instrumental ADL (r = .81) (Landi et al., 2000). Outcome measures based on the MDS scores have been shown to be valid(J.N. Morris, Carpenter, Berg, & Jones, 2000) and have demonstrated utility for quality monitoring in home care settings (Hirdes et al., 2004).

Performance-based measures of daily functioning included: Everyday Problems Test (EPT) (ability to utilize information from 14 daily tasks (S. L. Willis et al., 1998); Observed Tasks of Daily Living (OTDL) (Diehl et al., 2005) (ability to perform daily actions like searching medication label for side effects, making change, using a telephone); Complex Reaction Time (CRT, a computer-administered test of reaction time to traffic signs (Roenker, Cissell, Ball, Wadley, & Edwards, 2003); and Timed IADL (TIADL, measures time to complete five daily tasks like finding a number in telephone book, finding items on a simulated grocery shelf) (Owsley, McGwin, Sloane, Stalvey, & Wells, 2001). The EPT and OTDL were combined to form an Everyday Problem Solving Composite. The CRT and TIADL were combined to form an Everyday Speed Composite.

Secondary Outcomes

If the cognitive interventions transferred to daily function, it was hypothesized that training would have farther reaching effects on health-related quality of life, everyday mobility, and health service utilization. Health-related quality of life was measured with the MOS SF-36 (Ware & Sherbourne, 1992). Everyday mobility included self-reported falls, a measure of life space and abstracted archival driving record information on crashes (Fitti & Kovar, 1987; Myers, Juster, & Suzman, 1997; Stalvey, Owsley, Sloane, & Ball, 1999; Ware & Sherbourne, 1992). Utilization of health, nursing home and home health services was captured by self-report and Medicare claims data.

SUMMARY OF MAJOR FINDINGS-TO-DATE

ACTIVE data through five years are archived at National Archive of Computerized Data on Aging (NACDA, http://www.icpsr.umich.edu/icpsrweb/NACDA/).

Training Effects on Cognitive Abilities

Each intervention produced an immediate improvement in the cognitive ability trained (K. Ball et al., 2002) that was durable through five years of follow-up (S. L. Willis et al., 2006). Training produced ability-specific effects. For example, Reasoning training did not result in improvement in memory or speed of processing indicating that training effects were not explained by social contact. The largest improvements were seen for Speed of Processing intervention followed by the Reasoning and Memory. Each type of training produced its largest effect immediately after the intervention and with some dissipation over time; however, training gains remained statistically and practically significant at the 5 year follow-up (S. L. Willis et al., 2006). Booster training for Reasoning and Speed training groups produced significantly better performance (above the basic or initial training effect) on their targeted cognitive abilities (S. L. Willis et al., 2006).

A subgroup analysis using an algorithm-based definition of mild cognitive impairment (MCI) was done (Unverzagt et al., 2007). At 2 years, a total of 193 subjects were defined as MCI using this criterion and results indicated that MCI participants failed to benefit from Memory training but did show significant training response to Reasoning and Speed interventions; thus, MCI status mediates response to ACTIVE.

Training Effects on Daily Functioning

At five years, subjects in all three intervention groups reported significantly less difficulty than did participants in the control group in performing instrumental activities of daily living. Since functional decline has been shown to occur first for instrumental tasks, the hypothesis that training benefits would first be detected for these more cognitively challenging everyday tasks was supported. For the total sample in each treatment group, the performance-based measures of Everyday Problem Solving or Everyday Speed did not show this general benefit of training.

The performance-based functional measures, however, did show the hypothesized targeted transfer of training effects at five years for participants receiving booster training. Improved performance on the Everyday Problem Solving composite was found for the boosted Reasoning training group. Likewise, improved performance on the Everyday Speed composite was shown for the boosted Speed training group. Early effects of booster training on performance-based functional measures was also found at the initial booster at 1 year. The boosted Speed training group at 1 year showed an effect for Everyday Speed and the boosted Reasoning group showed an effect for IADL Difficulty.

Training effects on Quality of Life and Driving

The impact of ACTIVE training on health-related quality of life (QOL) was investigated using the SF-36 (Wolinsky et al., 2006). Clinically relevant QOL decline was defined as a drop of 0.5 standard deviations or more from baseline on 3 or more SF-36 scales. At five years, 47.3% of the sample had experienced clinically relevant drops on 3 or more SF-36 scales and logistic regression indicated that participants in each of the interventions were significantly less likely than controls to have QOL decline.

Older drivers who completed cognitive speed of processing training were 40% less likely to cease driving over the subsequent three years ($p = .048$) (Edwards, Delahunt, & Mahncke, 2009). Speed-of-processing and Reasoning training resulted in a 50% lower rate (per person-mile) of at-fault motor vehicle collisions lower rates than for controls over the subsequent approximately 6-year period (K. Ball, Edwards, Ross, & McGwin, 2010). There was no significant difference observed for the Memory group.

PAPERS IN THIS SUPPLEMENT

In this Supplement, we report both baseline and longitudinal data from the ACTIVE Study. Cognitive training has been shown to improve both cognitive and everyday abilities in older adults, however, little is known concerning the amount of training needed, or the characteristics of those who benefit. These analyses examined the longitudinal impact of dosage (number of training sessions) on the improvement and maintenance of cognitive and everyday function. Three papers address this issue for each of the cognitive training interventions. Using latent growth models, each analysis focuses on participants in the respective training groups to examine the impact of initial and booster training on the maintenance of cognitive and everyday function. As reported previously (S. L. Willis et al., 2006), effects of each training intervention were maintained through five years. However, for memory training, Rebok and co-authors report that neither booster training nor adherence to training significantly influenced this effect. In contrast, Ball and her co-authors al report that the effects of initial speed of processing training effects were amplified by booster sessions. This analysis showed that a single booster session counteracted about five months of age-related processing speed decline. Willis and Caskie report similar findings for the Reasoning intervention, including positive effects for the third annual booster and adherence to training.

The paper by Jones and colleagues aimed to better understand the effects of the ACTIVE training interventions. In particular, they addressed an interesting observation by Salthouse (Salthouse, 2006) that trained subjects had an accelerated rate of decline in cognitive change over time compared to non-trained subjects. They used growth curve models to decompose this change and found that the appearance of accelerated change in cognition reported by Salthouse is the result of age-related decline coupled with loss of training gains. For example, Speed training resulted in very large gains in processing speed. However, these gains were lost quickly and therefore appeared to be greater age-related decline, suggesting that the intervention did more harm than good. However, all trained subjects performed better than non-trained subjects at five years, with performance differences equivalent to about 2, 5, and 7 years of aging for Memory, Reasoning and Speed training, respectively. Reasoning training was the one intervention to attenuate the pace of normal cognitive decline.

To date, most investigations of the cognitive interventions had focused on the effects of training on the composite measures in each cognitive domain. Sisco and colleagues extend this work by investigating how Memory training improved specific aspects of memory function as well as the durability of that effect. The Memory intervention included mnemonic and structure strategy training, the latter shown to result in improved memory of everyday life information. Their work extended prior analyses of training effects by examining the effects of structure strategy training on prose recall. Their results show that training improved verbatim recall but not the hypothesized paraphrase recall, possibly related to emphasis on mnemonic strategies in the initial sessions. However, durability of this effect was limited to post-initial and booster training only, indicating that intermittent training is necessary to maintain effect on memory performance and potential transfer to daily function.

In addition to the effects of the cognitive training interventions, the ACTIVE study offers broad-based opportunities to investigate cognitive and daily function in a large and diverse population of older adults. The proportion of African-America participants (26%) is considerable, and the size of the control group (n=698) constitutes a large natural longitudinal sample in its own right. While the sample is positively selected (because of study inclusion criteria), it produces a kind of “natural experiment” that permits comparison of race-group trajectories in cognition when African American and White groups are demographically similar. The papers by Marsiske and colleagues and by Yam and Marsiske illustrate such an opportunity. In the first of these papers, Marsiske and colleagues use the control sample to explore 5-year change across multiple cognitive abilities. They report a small effect of race, specifically being African American, on level of cognitive performance after controlling age, gender, education, and health. An important finding is that race was not associated with rates of change in cogntiove performance over 5 years. Similar to findings regarding those with low education, African Americans seem to enter late life at a cognitive disadvantage, but they do not experience heightened rates of decline.

Yam and Marsiske use baseline data for the no-contact control group to identify predictors of IADL performance over 5 years. They distinguish between basic mental abilities (memory, reasoning, processing speed) and `everyday' cognitive skills, defined as the application of these basic abilities in real world contexts. Results of the multilevel analyses across 5 years show that, in addition to physical function, this higher order of cognitive skills appears to be a more proximal predictor of everyday IADL function. These findings identify another potential target of interventions to promote daily functions in older age.

The paper by Rexroth and colleagues is another example of the utility of the ACTIVE data beyond intervention effects. They investigated the relationship of demographic factors and health conditions, alone and in combination, on the composite measures of memory, reasoning, and processing speed in these healthy community-dwelling older adults. They hypothesized that each cognitive domain would be affected by age and education and that the effect of demographics on cognition would be attenuated by chronic health conditions and discrete illnesses. They report that younger age, more education and white race are related to better cognitive function in all three domains after adjusting for gender, chronic health conditions, and discrete illnesses. These findings are consistent with and support results of prior studies, particularly in less diverse or younger populations.

Lohman and colleagues considered depressive symptoms in relation to baseline memory ability and responsiveness to Memory training. They report that the more depressive symptoms a subject had, the lower their memory ability at baseline. However, elevated depressive symptoms did not attenuate the effects of Memory training on memory ability. This is an important finding supporting the robustness of the ACTIVE Memory training program.

Two papers report about driving status. O'Connor and colleagues investigated health and physical performance as mediators of the association between driving cessation and mortality. Mortality risk was 1.7 times higher for non-drivers than for drivers, and this risk was mediated by physical performance and social, physical, and general health. Choi and colleagues looked at whether driving cessation as well as the effect of cognitive training on driving cessation differed by gender and race. Driving has long been associated with functional independence, and most prior studies report that older women and ethnic minorities are less likely to drive. Their results were consistent. However, the effects of the cognitive interventions on driving cessation over five years did not differ by gender or race. In conjunction with prior data showing that Speed training delays driving cessation among subjects with pre-existing deficits in processing speed (Edwards et al., 2009) and that both Speed and Reasoning training reduce the number of motor vehicle collisions (K. Ball et al., 2010), these findings support the robustness of these ACTIVE training interventions in maintaining driving and functional mobility.

DISCUSSION

The ACTIVE study is the first large-scale, randomized trial to test the long-term outcomes of cognitive training effects on prevention of decline in daily function. Results support the effectiveness of cognitive intervention in maintaining cognitive health over the long-term and indicate modest but detectable far transfer to instrumental activities of daily living, health-related quality of life, and driving outcomes. The critical importance of ACTIVE and similar preventive cognitive interventions is that they may preserve the cognitive resources shown to be effective both in maintaining functional competence and in coping with functional impairments. Given the lagged relationship between cognitive decline and functional deficits, however, we expected a delay in the observed effects of cognitive interventions on functional outcomes and planned long-term follow-up of participants. The results at 5 years provide supportive evidence for that decision.

There are many strengths of the including a large, diverse sample that was reasonably cognitively well-functioning at baseline, design of interventions that could be delivered in a multisite format, comprehensive cognitive and functional assessments, rigorous certification and ongoing quality assurance methods for both trainers and assessors, and long follow-up interval. One important limitation relates to the representativeness of the ACTIVE sample. The sample was composed of community volunteers and the final sample was advantaged relative to the general population in terms of age, education, and MMSE; therefore, the results of ACTIVE should be interpreted cautiously as they may apply to the general population. Also, the design of the booster training made it difficult to examine dose effects. We did see significant attrition over the follow-up interval (retention at the 5-year assessment was 67%). Participants who were older, had more health problems and lower cognitive function were more likely to drop out. However, through 5 years, there has not been differential attrition by condition. Therefore, the attrition does not affect the between-group comparisons of intervention effects.

The critical importance of ACTIVE and similar preventive cognitive interventions is that they may preserve the cognitive resources shown to be effective both in maintaining functional competence and in coping with functional impairments. Being the first study to demonstrate the long-term potency of cognitive training and far transfer to daily function, ACTIVE will hopefully stimulate new programs of research on cognitive and behavioral interventions in older adults. Ongoing research with the ACTIVE sample is focused on establishing the limits and determinants of transfer of the ACTIVE cognitive training programs to cognitive, functional, and other outcomes like health care utilization.

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Conceptual Model

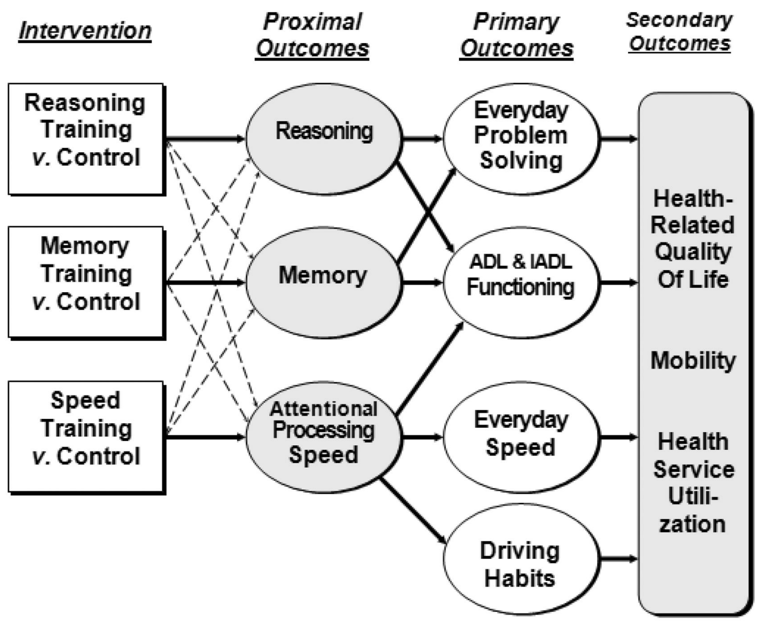

Figure 1.
Hypothesized mode of effects in ACTIVE trial. Influence of intervention on primary and secondary outcomes is mediated through trained abilities. Bold lines represent specific effects of training. Dashed lines represent non-specific effects of training on related abilities, e.g., through social contact or general cognitive arousal.

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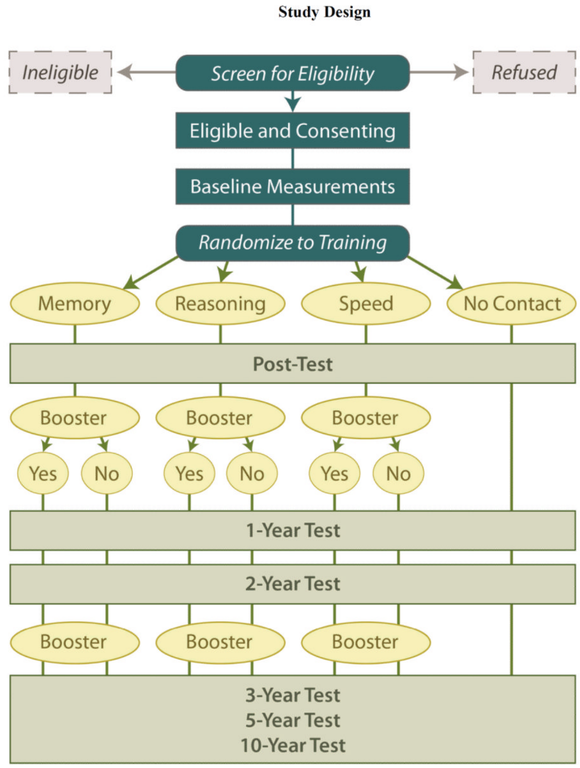

Figure 2.

Table 1

Baseline Characteristics of Participants (n=2,802)

	Sample					General Population			
	N	**%**	**Mean**	**S.D.**	**Range**	**%**	**Mean**	**Ref.**	**p**
Sociodemographics									
Age (years)	2802		73.6	5.9	65–94				
Age 65–74		60.1				57.6		1	n.s.
Age 75–84		35.0				32.5			
Age 85 +		4.9				9.9			
Gender (% female)	2802	75.9				57.9		2	***
Race	2802							2	***
Caucasian		73.3				83.5			
African-American		26.0				8.1			
Other or unknown		0.7							
Education									
High School diploma (%)	2800	88.6				67.0			***
Caucasians	2052	91.4				71.6		3	***
African Americans	728	80.4				43.7			***
Marital Status (married)	2802	35.9				56.6		4	***
SF-36 Physical Function	2802		68.8	24.1	0–100		62.0	5	***
Health Status: Good-Excellent	2753	84.3				72.2		6	***
Caucasians	2019	86.7				74.0			***
African-Americans	714	77.6				58.4			***
Chronic Diseases									
Hypertension	2792	51.1				45.0		7	***
Caucasians	2044	45.1				44.0			n.s.
African Americans	728	67.7				58.7			***
Diabetes Mellitus	2802	12.8				12.0		7	n.s.
Caucasians	2054	9.9				10.9			n.s.
African Americans	728	21.2				20.4			n.s.
TIA/Stroke	2791	7.0				8.9		7	***
Caucasians	2043	7.4				8.6			n.s.
African Americans	728	5.9				12.2			***
Ischemic Heart Disease	2792	11.0				13.9		8	***
Caucasians	2044	11.9				14.7			***
African Americans	728	8.4				8.2			n.s.
Health Service Utilization (prior 12 months)									
Physician visits	2772	96.6	5.2	6.4	0–99	92.1	6.1	9	***
E.D. Visits	2785	22.4	0.3	0.8	0–12	21.9	0.5	10	n.s.
Hospitalizations	2505	16.3	0.2	0.6	0–12	28.3		11	***
Hospital Days (LOS)	405		4.6	5.3	1–42		6.3	11	***

***p<.001

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