

## **Executive Summary**

### **Lifestyle Interventions and Independence For Elders (LIFE) Study**

As life expectancy in the United States continues to rise, the maintenance of physical independence among older Americans has emerged as a major clinical and public health priority. Efficient and reliable locomotion, or the ability to move without assistance, is a fundamental feature of human functioning. Older people who lose mobility are less likely to remain in the community, have higher rates of morbidity, mortality, and hospitalizations and experience a poorer quality of life. Several studies have shown that regular physical activity improves physical performance, but definitive evidence showing that mobility disability can be prevented is lacking. A Phase 3 randomized controlled trial is needed to fill this evidence gap.

The LIFE Study is a Phase 3, multicenter randomized controlled trial (RCT) designed to compare a moderate-intensity physical activity program to a successful aging health education program in 1,600 sedentary older persons who are followed for an average of 2.7 years. The primary outcome is major mobility disability, defined as inability to walk 400 m. Secondary outcomes include cognitive function based on the Digit Symbol Substitution Test (DSST) and the Hopkins Verbal Learning Test (HVL); serious fall injuries; persistent mobility disability; the combined outcome of major mobility disability or death; disability in activities of daily living; and cost-effectiveness. Tertiary outcomes include the combined outcome of mild cognitive impairment or dementia, a composite measure of the cognitive assessment battery, physical performance within pre-specified subgroups defined on the basis of race, gender and baseline physical performance, sleep-wake disturbances, dyspnea, ventilatory capacity, pulmonary events, and cardiovascular events.

The physical activity intervention consists primarily of walking at moderate intensity, lower extremity resistance exercises, balance exercises, stretching and behavioral counseling. The successful aging intervention consists of health education seminars regarding health-related matters and upper extremity stretching exercises.

This trial will provide definitive evidence regarding whether physical activity is effective and practical for preventing major mobility disability. These results will have crucial implications for public health prevention in a rapidly aging society, and will fill an important gap in knowledge for practicing evidence-based geriatric medicine. The study will also yield valuable information concerning the efficacy and effectiveness of physical activity across a broad spectrum of important health outcomes. The study will impact both clinical practice and public health policy, and will, therefore, benefit individuals and society.

The Coordinating Center is at the University of Florida and the Data Management Analysis and Quality Control Center (DMAQC) is at Wake Forest University School of Medicine. The 8 field sites participating in the LIFE Study are University of Florida, Gainesville, FL; Northwestern University, Chicago, IL; Pennington Biomedical Research Center, Baton Rouge, LA; University of Pittsburgh, Pittsburgh, PA; Stanford University, Palo Alto, CA; Tufts University, Boston, MA; Wake Forest University, Winston Salem, NC; and Yale University, New Haven, CT.