A GROUNDBREAKING OPPORTUNITY TO PROTECT BRAIN HEALTH

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U.S.POINTER
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A landmark Scandinavian study has provided intriguing evidence that lifestyle changes can slow cognitive decline in older people at risk of Alzheimer's disease. The FINGER study (Finnish Geriatric Intervention Study to Prevent Cognitive Impairment and Disability) found that individuals who are at high risk of developing cognitive impairment and dementia showed improvements in memory and other thinking skills after just two years of a lifestyle change that included a healthier diet, increased exercise, more intellectual and social stimulation, and better management of heart and vascular health. The findings provide the most compelling indication to date that we may be able to prevent Alzheimer's and other dementias by adopting healthier lifestyle habits.

"We now can effectively prevent or treat heart disease, cancer and HIV/AIDS with combinations of drugs and lifestyle. The same may also be true for Alzheimer's disease and other dementias in the not too distant future."

— Maria C. Carrillo, Ph.D.
Chief Science Officer
Alzheimer's Association

The Alzheimer's Association® is now leading a new research study to test a similar multi-component non-pharmacological intervention in a larger, more diverse population in the U.S. Though the FINGER results were very encouraging, the study was conducted in a relatively homogenous population. The U.S. Study to Protect Brain Health through Lifestyle Intervention to Reduce Risk (U.S. POINTER) will expand on lessons learned in Finland to evaluate the effectiveness of lifestyle modification in 2,000 Americans from a wide range of racial, ethnic, socioeconomic and geographic backgrounds who are at increased risk for dementia. U.S. POINTER is the first such study to be conducted in a large group of Americans across the United States.

Study volunteers will be assigned randomly into one of two lifestyle intervention programs that include a self-guided program and a structured program. Each program will encourage increased physical exercise, a healthier diet, cognitive and social stimulation and self-management of heart and vascular health.

All participants, regardless of program assignment, will attend regular group meetings to receive information about living a healthy lifestyle and to discuss strategies for maintaining this lifestyle. All participants will also receive physical exams, blood laboratory testing, and health coaching.

Participants assigned to the self-guided program will develop their own plan that best suits their needs and schedules, in collaboration with health professionals, that involves physical activity, a healthier diet, and intellectual and social stimulation. In contrast, participants assigned to the structured program will be asked to carry out a pre-specified plan, with the assistance of health professionals, that is also focused on physical activity, a healthier diet, and intellectual and social stimulation.

The success of the intervention programs to protect or improve cognitive function will be evaluated every six months for all participants. Vascular and metabolic health, physical function, mood and quality of life will also be assessed.

Each participating region of the U.S. will enroll 400 or more study participants into U.S. POINTER. Participants will be assigned to "Teams" of 10-15 participants, and these Teams will progress through the lifestyle intervention programs together. Starting in late 2018 the researchers will identify potential study participants ages 60-79 years using an electronic medical record (EMR) search. They will search within zip codes that have proximity to an Alzheimer's Association chapter and other necessary resources for the interventions (e.g., facilities for group meetings).

The researchers will select individuals with medical conditions that have been linked to an increased risk for cognitive decline in the future, such as mild hypertension and slightly elevated blood sugar levels. They will further screen participants through mailed questionnaires and a telephone interview. U.S. POINTER will be looking for older adults who are not currently experiencing any memory problems but who have a first-degree relative (mother, father, brother, sister) who did have a noticeable memory problem. Eligible participants must also be largely sedentary and have 'room for improvement' with regard to eating a healthy diet.

Diversity is essential to the success of U.S. POINTER. The recruitment process is designed to increase participation by historically underrepresented communities in research, with a priority focus on achieving racial and ethnic diversity and including rural populations. The aim is for at least 23 percent of participants to be from racial/ethnic minority groups (reflecting 2016 U.S. Census demographics), with an equal number of women and men.

Intervention oversight teams in five geographically diverse regions of the U.S. will each include research clinic team members and community partners. The nearest Alzheimer's Association chapter will assist with coordination of intervention delivery. If the POINTER interventions prove effective, this study will lead the way in setting the stage for the development of an accessible and sustainable community-based program for prevention.

U.S. POINTER has begun at three hubs: Western North Carolina, Northern California, and Chicago. Co-Principal Investigators (PIs) Laura Baker, Ph.D., and Mark Espeland, Ph.D. of Wake Forest School of Medicine are leading the U.S. POINTER Coordinating Center in Winston-Salem NC. Dr. Jeff Williamson is the lead site investigator for the North Carolina hub who will be working with the Alzheimer's Association Western Carolina Chapter. Co-PI Rachel Whitmer, Ph.D. of the University of California, Davis School of Medicine is leading the effort in Northern California in partnership with the Alzheimer's Association Northern California and Northern Nevada Chapter. Dr. Martha Clare Morris, Sc.D., is the lead site investigator for the Chicago hub who will be working with the Alzheimer's Association Illinois Chapter. The two remaining U.S. POINTER hubs have yet to be identified.

Additional U.S. POINTER executive leaders include: Maria C. Carrillo, Ph.D., and Heather Snyder, Ph.D., Alzheimer's Association; Rema Raman, Ph.D., and Gustavo Jimenez-Maggiora, Alzheimer's Therapeutic Research Institute, University of Southern California; and co-PI Miia Kivipelto, M.D., Ph.D., Karolinska Institutet, Sweden, National Institute for Health and Welfare, Finland, who is also the PI of FINGER.

"There is a pressing need to test the effectiveness of a multicomponent lifestyle intervention in larger and more diverse populations, such as the United States."

— Laura Baker, Ph.D., Wake Forest School of Medicine, U.S. POINTER Co-Principal Investigator

U.S. POINTER is one of several studies participating in World Wide FINGERS, a consortium of FINGER-like trials taking place in Europe, China, Singapore and Australia, with additional sites in discussion in Canada, Germany, Italy and India. This interdisciplinary network, led by Dr. Carrillo and Dr. Kivipelto, will share experiences, harmonize data and plan joint international initiatives for the prevention of cognitive decline.

The projected timeline for U.S. POINTER, from trial planning through data dissemination, is five years. Final results are projected to be released in late 2022 or early 2023.

Expenses are proposed to total more than $30 million. The entire study will be funded by the Alzheimer's Association and our philanthropic partners.

Leading the Way

The Alzheimer's Association is uniquely positioned to lead U.S. POINTER. With our mission to reduce the risk of dementia through the promotion of brain health; 77 chapters nationwide; partnerships with health care systems and community organizations; international research network; and growing base of philanthropic support — the Alzheimer's Association has both the will and the way to ensure the success of this groundbreaking study.

Positive results would provide evidence for lifestyle changes that could limit the devastating effects of dementia in diverse populations worldwide. This is critical in the absence of effective medications. With more than 5 million Americans living with Alzheimer's dementia today and more than 28 million baby boomers expected to develop Alzheimer's between now and 2050, finding non-pharmacological ways to reduce cognitive decline may be key to mitigating the symptoms of Alzheimer's and other dementias for millions of people.