



National Institutes of Health

EMBARGOED FOR RELEASE:

Wednesday, June 4, 2014

2:00 p.m. Eastern time

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NIH, PCORI announce major award to prevent falls injuries in older people

Large, multi-site, multi-intervention trial will test new patient-centered strategies

Each year, 1 out of 3 adults aged 65 and over falls. A third of those falls result in moderate to severe injuries that can lead to further declines in health and loss of independence. Thousands of older adults die each year from such falls as well. To find effective, evidence-based strategies to address the personal and public health burden of these falls, the National Institutes of Health (NIH) and the Patient-Centered Outcomes Research Institute (PCORI) have joined to support a clinical trial to test individually tailored interventions to prevent fall-related injuries. The award, made by the National Institute on Aging (NIA) of the NIH and funded by PCORI as part of the Falls Injuries Prevention Partnership of the two organizations, is expected to total some \$30 million over the five-year project.

The trial will be led by Shalender Bhasin, M.D., Brigham and Women's Hospital, Harvard Medical School, Boston; Thomas Gill, M.D., Yale School of Medicine, New Haven, Connecticut; and David Reuben, M.D., David Geffen School of Medicine at the University of California, Los Angeles. The team will include more than 100 researchers, stakeholders, patients and their representatives at 10 clinical health system sites across the country. First-year funding of \$7.6 million was awarded on June 1, 2014.

The study's approach differs from others in that it will integrate proven falls reduction strategies into a cohesive intervention that can be adopted by many health care systems. "This collaboration with PCORI exemplifies our efforts to go beyond the norms to solve the nation's health issues," said NIH Director Francis S. Collins, M.D., Ph.D. "The problems we face are complex and therefore require thoughtful and complex solutions. I am hopeful this initiative will greatly improve the lives of those most at risk for falls."

Previous studies have analyzed risk factors for falls and falls injuries, along with interventions to prevent them. But the best evidence about how to reduce falls has not been broadly applied. Attempts to change physician behavior about falls through conventional medical education

channels and other methods have not been very effective. Patients and other stakeholders generally have not been partners in the research process and, as a result, not fully engaged.

“With this trial, we will be able to evaluate interventions on a comprehensive and very large scale,” said NIA Director Richard J. Hodes, M.D. “This study will focus on people at increased risk for injuries from falls, the specific care plans that should be implemented, including interventions tailored to individual patients, and how physicians and others in health care and in the community can be involved.”

Each person in the trial will be assessed for his or her risk of falling, and receive either the current standard of care—primarily information about preventing falls—or the experimental study intervention in which individualized care plans will be developed and administered. The plans will be presented to the participant’s primary care physician for review, modification, and approval and will include proven fall risk reduction interventions that can be implemented by the research team, physicians and other health care providers, caregivers and community-based organizations. The intervention centers on the concept of a falls care manager working with each participant’s primary care provider to develop the plans and monitor success.

The research team plans to enroll 6,000 adults age 75 and older, living in the community, with one or more modifiable risk factors for falls. The first year of the study is a pilot phase, during which many aspects of the intervention will be tested with small numbers of people across 10 clinical sites. If the go-ahead is given by NIA and PCORI to proceed with the study after that, enrollment for the full trial will start in year two and take place over 18 months. The participants will be followed for up to three years.

The primary trial outcome is reduction in serious fall injuries, including nonspinal fractures, joint dislocation, head injuries, lacerations, internal injuries, and hypothermia. Secondary outcomes include reduction in all falls that cause injuries; all falls regardless of injury; indicators of well-being, physical function and disability, and anxiety and depression.

“PCORI’s goal is to develop evidence and provide that information to help patients, their health care providers, and health care policymakers make better informed decisions,” said PCORI Executive Director Joe Selby, M.D., M.P.H. “With active input from patients and other stakeholders from the very beginning of this study, we think we can have a major impact, changing practice to make a real difference in the lives of older people.”

Patients and other stakeholders will partner with the investigators in national and local councils throughout the study development process and will continue to be engaged during the trial at national and site levels. These contributors have advised the research team on several important study features. For example, one recommendation focused on the need for someone to follow up on referrals to determine whether and how participants follow through on them. Another honed in on occupational therapy as a component of interventions for improving quality of life for patients with sensory impairments such as low vision. Community organizations also helped inform the design of the community-based exercise program and the use of referral forms.

Ten trial sites across the country were chosen to address geographic, rural/urban, academic/nonacademic, and racial/ethnic diversity, and to include a range of health care systems and models of care. The 14 NIA-funded [Claude D. Pepper Older Americans Independence Centers](#), which include the nation's premier research programs in complex geriatric syndromes, helped to develop the trial protocol and will participate in the study. Some centers will be involved as trial sites, while others will be involved in data analysis and dissemination of the study findings.

“We have an interdisciplinary dream team of investigators, clinicians, and stakeholders from the participating Pepper Centers and trial sites,” said principal investigator Bhasin. “With this team, we can put all the different pieces of the falls prevention puzzle together. The trial will focus on clinical practice redesign, while also using interventions tailored to individuals. The goal is to recognize and overcome challenges in implementing fall-injury prevention strategies in diverse health systems.”

The 10 trial sites and regions they serve are:

- Essentia Health, Duluth, Minnesota (Midwest)
- HealthCare Partners, Torrance, California (Southern California)
- Johns Hopkins Medicine, Baltimore (Mid-Atlantic)
- Mount Sinai Health System, New York City (Northeast)
- Partners HealthCare, Waltham, Massachusetts (Northeast)
- Reliant Medical Group, Worcester, Massachusetts (Northeast)
- University of Iowa Health Alliance, Iowa City (Midwest)
- University of Pittsburgh Medical Center (Mid-Atlantic)
- University of Texas Medical Branch, Galveston Health (Southwest)
- University of Michigan, Ann Arbor (Midwest)

Data management and analysis will be coordinated by the Yale School of Public Health.

Details of this study will be shared at a 1-hour public briefing via webinar/teleconference, 1 to 2 p.m. Eastern time, Wednesday, June 4. Register at <https://events.meetingbridge.com/Register/Default.aspx?EventCode=06123451326>.

The NIH award for a “Randomized Trial of a Multifactorial Fall Injury Prevention Strategy” was supported by the Patient-Centered Outcomes Research Institute (PCORI) through a research partnership with NIH. NIH, the nation's medical research agency, includes 27 Institutes and Centers and is a component of the U.S. Department of Health and Human Services. NIH is the primary federal agency conducting and supporting basic, clinical, and translational medical research, and is investigating the causes, treatments, and cures for both common and rare diseases. For more information about NIH and its programs, visit www.nih.gov. PCORI is an independent, non-profit research funder authorized by Congress to help people make informed healthcare decisions, and improve healthcare delivery and outcomes. It does this by producing high-quality, useful information that comes from clinical effectiveness research guided by patients, caregivers, and the broader healthcare community. For more information about PCORI, visit www.pcori.org.

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