ABSTRACT

Purpose
Long-term studies are critical for understanding the impact of chronic conditions on functional impairment in older adults. The Ocular Hypertension Treatment Study (OHTS) tested the efficacy of eye drops to lower intraocular pressure to prevent glaucoma, a leading cause of blindness. OHTS originally ran from 1994 through 2008 and had two phases. During these phases, the OHTS recruited 1,636 participants and provided follow-up for a minimum of 10 years at 32 clinical centers. In 2015, the NIH awarded funds to conduct a third phase of OHTS, during which clinical centers would invite participants back for a 20-year follow-up visit.

To determine feasibility of a 20-year follow-up, clinical centers conducted a survey in 2013 to all surviving participants about their interest in participating in a 20-year follow-up visit. The survey contacted 80% of the surviving participants of whom 85% said they would return for the visit.

This abstract details some of the issues and solutions in re-recruiting an aging population to a study designed to document clinical status and severity of self-reported functional limitations.

Methods
When re-recruitment of OHTS Phase 3 began in January 2016, the median age of participants was 75. We set an enrollment goal of 80% of the presumed surviving participants (n=1,381). Within the first 12 months of recruitment, we found that many of the presumed surviving participants could not be located, had died or had developed a physical cognitive impairment that prevented an in-office visit.

The Coordinating Center, located at Washington University, began employing many tools to assist the coordinators with recruitment. Some of the methods include 1) employing Battelle Memorial Institute to provide tracing services for 400 participants considered lost follow-up, 2) site visits to clinical centers with low recruitment, 3) meeting of coordinators to discuss problems and solutions, 4) use of a monthly enrollment status report to assist coordinators with tracking efforts and setting priorities for recruitment, 5) providing funds to offer transportation to participants, 6) allowing use of a legally acceptable representative to assist participants with quality of life questionnaires, 7) providing funds to offer transportation to participants, which resulted in the use of the tracing service, the monthly enrollment status report, and the coordinator meeting;

Results
The methods utilized by the Coordinating Center and clinical centers have been very helpful with improving recruitment and collection of usable data. This is especially true of the use of the tracing service, the monthly enrollment status report, and the coordinator meeting;

Conclusions
Having a clear path of communication between the Coordinating Center and clinical sites, along with flexibility of methods for how data are obtained has improved recruitment; therefore, benefiting the study as a whole.

HISTORY of the OCULAR HYPERTENSION TREATMENT STUDY (OHTS)

OHTS Phase 1 (1994 – 2002):
In the first phase of OHTS, one half of the participants were followed by close observation and the other half was prescribed topical ocular medications. We followed all participants for five years.

At the end of Phase 1 we were able to definitively demonstrate that topical ocular medications were safe and effective in preventing glaucoma.

In the second Phase of OHTS, participants in the medication group continued medication and participants in the observation group began topical ocular medications. All participants were followed for an additional 5 years.

At the end of Phase 2 we were able to determine that delaying treatment did not increase the risk of developing glaucoma except in patients

OHTS Phase 3 (2015 – 2020):
In the third phase of OHTS, we are developing tools to aid eye doctors and patients with assessing the risk of developing glaucoma, as well as to determine which patients are likely or unlikely to experience vision loss.

RECRUITMENT ISSUES

• Age of participants, which resulted in -Cognitive impairment
• Loss of mobility
• Inability to drive to clinic
• Residence in an assisted living facility
• New PI and/or coordinator at clinic, with no established relationship to participant
• Unable to locate participant
• Participant no longer willing to participate

RECRUITMENT SOLUTIONS

• Use of legally acceptable representative (LAR) for cognitively impaired participants
• Collection of interim data (Eye exams and tests completed since last study visit)
• Collection of Quality of Life questionnaires over the phone or through the mail
• Allowing participants to complete measures over several days and receive the stipend for each day they visit the clinic
• Hired Battelle Memorial Institute to provide tracings of participants
• Provided transportation (cab, airfare, hotel) to clinic
• Site visits to underperforming clinics – target of visits was to assist PI and Coordinator with additional recruiting methods
• Instituted a Monthly Enrollment Tracking Report that requires each clinic coordinator to provide an accounting of communication attempts. This document allows the Coordinating Center at Washington University the opportunity to suggest help or request a re-tracing from Battelle
• Allow clinics to schedule participants at satellite clinics, even if technicians are not certified

Support
Supported by grants from National Eye Institute & National Center on Minority Health & Health Disparities, National Institutes of Health (EY025183, EY025182, EY025181, EY025180 & Core Grant 062687), Merck, White House Station, Pfizer & unspecified grants from RPB.

Clinical Trial Registration: http://www.clinicaltrials.gov/ct/show/NCT00000125