Re-Enrolling Study Participants Eight Years after Original Study Ended: Issues and Solutions Found in the Ocular Hypertension Treatment Study (OHTS)

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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 to 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) allowing participants to complete quality of life questionnaires through the mail, and 8) collection of data from non-study clinics by non-certified clinicians and technicians.

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, benefitting 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.

OHTS Phase 2 (2002 – 2008):

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
- Hiring Battelle Memorial Institute to provide tracings of participants
- Provide 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

SAMPLE RECRUITMENT TOOLS

THE OHTS STUDY
Monthly Enrollment Status Report

Report Due to Coordinating Center 4/28/2017

Clinic Name: Washington University
Clinic PI: Theodore Geisel, MD
Coordinator: Cindy Lou Who, CCRP

OHTS Deadlines

10/31/2017	Scheduling participants completed
12/31/2017	Core level visits completed
4/30/2018	All visits completed
5/31/2018	All data entry complete
6/30/2018	Clinical Center funding ends

Monthly Recruitment Goal	**3**
OHTS 3 Presumed Survivors	25
Declines	2
OHTS 3 Completed Core Visits	9
Target Recruitment of Core Visits 16	

Notes/Suggestions for making contact/scheduling:

Telephone QOL:	Please try to complete a Core visit
	Please collect interim data (VF, OCT, Medical History)
Declines:	Please record if participant stated "never contact me again"
	Please ask participant if they will reconsider to participate at a later date
	Please ask participant if they will consent to release interim data
	If for health reasons, will participant agree to use of LAR
Unable to Contact:	Please attempt contacts at different times of day/week
	Ask PI to contact participant
	Send letter/certified letter
Unable to Locate:	Let Coordinating Center know so Battelle can do a retracing
Deceased Pts.	Confirm Death Form complete in REDCap & note in Comment Section

Instructions: List dates of successful contact and/or scheduling for the following participants and return to Ellen Fischbach at ellen@wustl.edu by 4/28/2017.

OHTS ID	Core Visits Scheduled (Enter Date of Visit)	Telephone QOL Scheduled (Enter Date of Call)	Interim Data Requested (VF, OCT, Medical History)	Comments	Coordinating Center Responses
12345		4/5/2017		collecting old data	
23456		5/1/2017			
34567				Declined	5/2/17-leave on list-pt did not state "do not contact again"
45678		12/8/2016		collecting old data	
56789				Declined	5/2/17-leave on list-pt did not state "do not contact again"
67890		11/23/2016		collecting old data	
78901				mailed info/no other contact info	5/2/17-Let us know if you want a Battelle retrace
89012		4/13/2017		collecting old data	
90123		4/6/2017		collecting old data	
	0	6	0		

Completed by: _____

Date Completed: _____

Battelle Memorial Institute Tracing Result

OHTS STUDY **DATE:** 8/8/2017

Patient ID 12345	**Clinic Site** X1	**Trace#** T-2
Patient Name Wylie Coyote		

Email Address(es)

New Address(es)

New Phone Number(s)

Patient Related Comment
No new information on participant

Alternative contacts
Name & Relationship
Update on Daughter
Road Runner

Address
Road Runner
(possible work address)
123 NW 108th Ave
Anytown, US 12345

Phone Number
Road Runner
(123) 555-5555
Acme Explosive Corp
(123) 456-7890 - work

Alternative Contact Related Comment
Update on daughter

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