Introduction

The Ocular Hypertension Treatment Study (OHTS) was a treatment trial that randomized 1,636 participants with ocular hypertension in 32 clinical centers. Ocular hypertension, which can result in glaucomatous damage and vision loss, primarily affects adults over age 55.

Six years following study close-out, the NIH awarded funds for a 20-year follow-up to determine the clinical and QOL status of participants, now median age 78.

• OHTS study goal is to achieve 80% ascertainment of all randomized patients (n=1636).

• Ascertainments are defined as the sum of the following mutually exclusive categories: core visits, telephone QOL surveys, declines, or confirmed deaths).

• This goal was set to minimize bias due to sampling[1,2] and to protect statistical power[3,4,5].

Despite the ubiquity of site visits in clinical research, little has been documented about their efficacy in participant re-engagement. Here we report the impact of site visits on completed core visits, telephone QOL surveys, and overall ascertainments.

Methods

• Clinics with <50% enrollment at a given date were site visited to increase participant ascertainment rate.

• A time period of five months pre- and post-site visit was selected to avoid bias from our annual coordinators meeting addressing re-engagement.

• Site visit costs were collected from central coordinating center records.

Results

<table>
<thead>
<tr>
<th>Ascertainment</th>
<th>Absolute</th>
<th>Adjusted*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Site Visits</td>
<td>11</td>
<td>-</td>
</tr>
<tr>
<td>Core visits</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Five months Pre-Site visit</td>
<td>33</td>
<td>37.1</td>
</tr>
<tr>
<td>Five months Post-Site visit</td>
<td>24</td>
<td>28.5</td>
</tr>
<tr>
<td>Telephone QOL surveys</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Five months Pre-Site visit</td>
<td>16</td>
<td>16.3</td>
</tr>
<tr>
<td>Five months Post-Site visit</td>
<td>19</td>
<td>20.3</td>
</tr>
<tr>
<td>Ascertainments</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Five months Pre-Site visit</td>
<td>90</td>
<td>110.0</td>
</tr>
<tr>
<td>Five months Post-Site visit</td>
<td>75</td>
<td>168.1</td>
</tr>
</tbody>
</table>

*Adjusted proportionally to account for the decreased participant pool over time; values represent the number of hypothetical outcomes if any given time the participant pool was equal in size to that number at study onset.

➢ The absolute completion rate of core visits, telephone QOL surveys, and total ascertainments peaked shortly after site visits, but waned over the five-month post-site visit period with the exception of telephone QOL surveys.

➢ Proportional adjustment demonstrates a sustained increase in ascertainment and telephone QOL surveys in the five months following site visits; the increase in adjusted core visits was not sustained.

➢ The average cost per site visit was $2106, with a range of $960 to $2588.

Discussion

The OHTS faced the task of re-engaging participants (median age 78) six years after study close-out, and set an ambitious goal of an 80% ascertainment rate to protect study power and reduce bias.

To meet ascertainment goals, 11 underperforming sites were site visited. Our findings demonstrate the following:

• Site visits did not result in an absolute increase in ascerrtamenents, however, they resulted in an absolute increase in telephone QOL of surveys and a proportional increase in ascerrtamenents.

➢ The absolute increase in telephone QOL surveys suggests site visits resulted in coordinators collecting alternative data when they could not secure core visits.

• Our results likely underestimate the effect of site visits as proportional adjustment is unable to account for the increasing difficulties in patient re-engagement over time.

➢ Timely increase in ascertainment status may decrease future spending for alternative retention efforts, and minimizes the probability for costly study extensions.

It is our opinion that site visits potentiate re-engagement efforts by individual sites, however, clinical coordinating centers must weigh the costs and benefits of using site visits as a tool for participant re-engagement.

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References


