

Patient diaries can reveal hidden truths in clinical trials

Patient diaries can add complementary, qualitative data to quantitative clinical trials in ophthalmology and can help explain a trial's statistical results, said Professor Heather Waterman RN PhD, University of Manchester.

Prof Waterman described how a patient's diary was designed for use in the Prism Spectacles Study (Smith 2004), a clinical trial to test the effectiveness of prism spectacles for patients with AMD. Prism spectacles refocus light to direct it to the most sensitive area of the retina.

There were 243 patients participating in the study, with a mean age of 81 years. Two-thirds of the study group were women. A little more than half of the patients lived alone. The patients had AMD for anywhere from one to five years. Their median logMAR visual acuity was 0.88, ranging from 0.62 to 1.18. The mean contrast sensitivity was 1.05 log units, ranging from 0.75 to 1.20 log units.

All participants had standard low vision services provided by Manchester Royal Eye Hospital. They received low vision aids for about six weeks prior to receiving the prism spectacles. They were given diaries to describe this experience.

The patients were divided into three groups - those using custom (optimum prescription) prism spectacles, standard prescription prism spectacles, and a control group using sham (placebo) spectacles. All the patients received standard low vision assessment including the

prescription of conventional low vision aids (LVAs). The researchers had patients recording: the type of aid, the name of activity, time spent using the vision aid and comments on usefulness.

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Diaries provide subjective feedback

The researchers chose to use a diary because it is descriptive, flexible and subjective. It expresses patients' feelings, offers unique insights and can generate hypotheses. This complements the statistical, measured and objective data typically collected in a clinical trial, which is pre-determined, must be universally applicable, and is designed to test hypotheses, she explained.

"We had a lot of quantitative data, so we thought it was appropriate to balance that with qualitative data, and that is why we decided to include a diary as an outcome measure," she said.

The researcher for the trial, Prof Heather Smith, reinforced compliance through oral instructions and regular checks. When patients could not complete the diary alone they were encouraged to enlist help from a friend or family member.

"We were really surprised by the level of participation with the pilot diaries despite the visual impairment, so we decided to include the diary in the full trial," said Prof Waterman.

The results were impressive, she noted, with 224 (93%) patients providing some comments, while 168 (75%) wrote comments on both the test spectacles and low vision aids. In 75% of cases, the patients wrote the comments themselves while the remainder received assistance from others.

Insight into low-vision

Analysis of diary data indicated that prism spectacles offered no benefit to patients. It also revealed the nature of patients' difficulties with the devices. For example, one patient wrote: **"I vary the use of my own specs and prism – no difference."**

Another wrote:

"The glasses are no real use. I can see TV with my own glasses better."

A third patient wrote:

"Makes me feel giddy. Surroundings lop-sided, floor falls away into decline, I feel big relative to my surroundings."

A few participants had a positive experience with the spectacles saying that the spectacles made life easier and reduced their need for magnifying glasses. However, data from the diaries of the control group suggests that these positive comments might be the result of a placebo effect. Several control patients claimed to have had dramatic improvements in their vision, she noted.

"The diaries were really useful in identifying this effect and helped to illustrate why the spectacles were of no benefit. Diaries are complementary to objective data, and our study shows that visually impaired patients will complete diaries," Prof Waterman added.

Prof Waterman presented the study's findings at the 2nd Annual Meeting of ESONT in Paris.

Smith H.J. (2004) A randomised controlled trial to investigate the effectiveness of prism spectacles for patients with age related macular degeneration. Unpublished PhD University of Manchester Funded by the Health Foundation. R. Harper: Principal Investigator

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