Willingness of Parkinson's Disease Patients to Participate in Research Using Internet-Based Technology

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Abstract

Background: Motor impairment and travel time have been shown to be important barriers to recruitment for Parkinson's disease (PD) clinical trials. This study determined whether use of Internet-based video communication for study visits would improve likelihood of participating in PD clinical trials. **Subjects and Methods:** University of Utah PD clinic patients were invited to complete a survey asking if they would be willing to participate in a hypothetical research study under four different scenarios. McNemar's test was used to test the hypothesis that remote assessments would improve willingness to participate. **Results:** Willingness to participate was 101/113 (87%) in the standard scenario. Willingness to participate was highest (93%; $p=0.046$) with most visits occurring via telemedicine at a local clinic, followed by some visits occurring via telemedicine at a local clinic (91%; $p=0.157$). Willingness to participate was lower with some (80%; $p=0.008$) or most (82%; $p=0.071$) visits occurring by home telemonitoring. **Conclusions:** Use of telemedicine may be an acceptable means to improve participation in clinical trials. This would need to be confirmed with the use of a larger-scale inquiry involving rural populations. Future research should assess subject or caregiver comfort and trainability with respect to computer-based technology in the home and systems barriers for wider implementation of telemedicine in neurology.

Key words: Parkinson's disease, clinical trials, telemedicine, telemonitoring, neurodegenerative disease

Introduction

Motor and cognitive disability imposed by Parkinson's disease (PD) pose a significant barrier to participation in research. Undue travel burden may further discourage clinical research participation. Accommodations to ease travel burden might improve recruitment for clinical trials. In a survey of Alzheimer's disease caregivers, investigator travel to subjects' homes for study visits would have improved the proportion willing to participate in a clinical trial from 24% to 47%.¹ Home study visits, however, may not be practical for monitoring large numbers of subjects over a broad catchment area. Another accommodation with potential to improve participation would be telemonitoring, the electronic recording and transmission of information for clinical assessments utilizing a personal computer and/or Internet connection from the subject's home.²⁻⁵ Telemonitoring does not allow drawing of blood for safety monitoring laboratory studies and may not be practical for important elements of PD motor assessment (such as postural instability or tone). These limitations could be addressed through the use of telemedicine, where a patient is presented to a remote clinician by a trained healthcare professional.⁶ We designed a survey study to evaluate whether availability of telemedicine or telemonitoring would improve the likelihood of participation in a hypothetical PD clinical trial.

Subjects and Methods

STUDY POPULATION

From November 2009 to March 2011, staff at the University of Utah movement disorders specialty clinic were instructed to invite all patients checking out with a diagnosis of PD (defined by 332.0 ICD-9 code) to complete an anonymous survey and return in a business reply envelope. In addition, the principal investigator (D.S.) personally invited all of his patients to complete the survey. Using a billing records inquiry (made 12 months after first surveys were returned) we ascertained the number of unique patients seen with a diagnosis of PD by University of Utah movement disorders center clinicians. We obtained approval of this study and used an informed consent process from the local Institutional Review Board.

SURVEY CONTENT

Demographic information (age, gender, race, ethnicity, driving status, number of motor vehicle accidents in past year, dependence for activities of daily living, travel time in minutes from the movement disorders clinic and from nearest medical clinic) was requested.

The Neuroprotective Exploratory Trials for PD Long-term Simple study (NET-PD LS-1) is closed to enrollment and was chosen for hypothetical scenarios because it involves several study visits over an extended period of time. The description concluded with the following information, "In the proposed study, about 1,700 individuals with PD will be randomly assigned to receive either creatine or a placebo (inactive substance). Participation in this study lasts a minimum of 5 years and includes at least 9 follow-up clinic visits and at least 3 telephone calls." Remaining questions asked about willingness to participate in the study as described (standard scenario) or in four different scenarios: with all but the first and final visits performed at a local clinic "at a clinic near your home using a videoconference with the University of Utah" (almost all visits by telemedicine); with at least three visits by telemedicine (most visits by telemedicine); with at least three visits performed "in your home using a personal computer and Web camera" (most visits by telemonitoring); or with all but the first and last visits by telemonitoring (almost all visits by telemonitoring) (see Supplementary Data available online at www.liebertonline.com/tmj for the survey document).

STATISTICAL ANALYSIS

We used SAS version 9.2 software (SAS Institute, Cary, NC) to generate descriptive statistics for demographic data.

Response rate was calculated 12 months after first surveys were returned by dividing the number of completed surveys by the number of unique patients seen with a diagnosis of PD. McNemar's test with a two-sided alpha of 0.05 was used to test the difference in proportions of patients willing to participate under each of the remote assessment scenarios compared with the regular scenario (all study visits taking place in-person at the tertiary-care center study site).

This analysis was repeated for those in the highest quartile of distance from the center. Univariate logistic regression was used to test for a relationship between willingness to participate in the standard scenario and each of the continuous (patient age, time since PD diagnosis, travel time from the clinic) and categorical (driving status, history of motor vehicle accidents, dependence for activities of daily living, or gender) variables. Responses with missing data

were not counted in the analysis (total with completed responses are indicated in the denominator for each question below).

Results

STATISTICAL ANALYSIS

In total, 116 responses were obtained in 14 months. Response rate, calculated after the first 12 months of the survey, was 108/675 (16%). Respondents were 71% male (82/116) and 98% white and non-Hispanic. Mean age was 67 ($\pm$ SD 10) years, mean duration of PD was 8 ($\pm$ 6) years, mean travel time from the University was 80 ($\pm$ 92) min, and mean travel time from closest medical clinic was 20 ($\pm$ 15) min (Table 1).

WILLINGNESS TO PARTICIPATE

Willingness to participate was 101/113 (87%) in the standard scenario. It improved to 105/113 (93%) ($p=0.046$) with almost all visits performed by telemedicine and to 100/110 (91%) ($p=0.157$) with most visits via telemedicine. It worsened to 87/109 (80%) ($p=0.008$) with most visits via home telemonitoring and to 89/108 (82%) ($p=0.071$) with almost all visits by home telemonitoring (Fig. 1) For those in the highest quartile of travel time (65 or more min) from the primary study center, willingness to participate was 24/26 (92%) in the standard scenario, 24/26 (92%) with most visits performed by telemedicine at a local clinic, 22/24 (92%) with some telemedicine visits, 22/26 (85%) ($p=0.157$) with some home telemonitoring visits, and 22/26 (85%) ($p=0.157$) with most visits by home telemonitoring. There was no significant relationship between likelihood of participation in the standard scenario and patient age ($p=0.973$), time since PD diagnosis ($p=0.212$), travel time from the clinic ($p=0.546$), driving status ($p=0.583$), history of motor vehicle accidents ($p=0.666$), dependence for activities of daily living ($p=0.384$), or gender ($p=0.8$). Therefore, a multivariate analysis was not indicated. Although no opportunity to write in qualitative data

Table 1. Characteristics of Respondents

VARIABLE	MEAN	SD	N ^a	MINIMUM	MAXIMUM
Age (years)	67	9.89	115	34.00	87.00
Years PD	8	6.22	106	0.00	25.00
CtrDist (min)	80	92.33	113	10.00	480.00
TeleDist (min)	20	15.35	113	3.00	120.00

^aNumber (out of 116) responding to the demographic question.

CtrDist, travel time to the center; TeleDist, travel time to the nearest clinic; Years PD, years since diagnosis of Parkinson's disease.

Fig. 1. Willingness to participate in each scenario: Telemedicine (almost all), almost all visits performed by telemedicine; Telemedicine (most), most visits performed by telemedicine; Standard, standard scenario; Telemonitoring (almost all), almost all visits performed by telemonitoring; Telemonitoring (most), most visits performed by telemonitoring.

was provided, 11 respondents still wrote that they did not own a computer and/or Web camera.

Discussion

This study found that extensive use of local telemedicine visits closer to a subject's home could lead to a small (6%), statistically significant, improvement in willingness to participate in the clinical trial NET-PD LS-1. This can be done at a clinic or nursing home using an interactive videoconference with the physician, with assessments of tone and postural stability made by specially trained medical staff.⁷ Telemedicine has been in use as a cost-effective means of providing PD care to large catchment areas by a U.S. Veterans Affairs Hospital.⁸ In a recent pilot study of telemedicine for PD specialty care, 13 of 14 patients opted to continue in the program, and there was a trend for improvements in patient satisfaction and quality of life.⁹ Although patient satisfaction with telemedicine for rural healthcare may extend to research study assessments, significant efforts to establish their validity would be required before incorporating them into new protocols.

Questions remain as to why findings were opposite for telemedicine versus telemonitoring scenarios. One potential explanation is that older individuals are not comfortable with learning to use new technology. Another possibility is that they do not own a computer and/or Web camera and simply did not understand that these would be provided in the hypothetical study scenarios. In order to better understand potential confounders, future surveys of this nature should include questions about educational background, income, and experience with computer technology.

The study results suggest limited comfort with telemonitoring technology (and perhaps a desire for socialization), but this may be changing. In a telephone survey of over 2,500 adults, the proportion 65 years of age and older using social networking sites grew from 4% in 2009 to 13% in 2010.¹⁰ Good reliability between remote and proximate rater have previously been demonstrated,¹¹ and a simpler system involving a wearable device and binary push-button interface (documenting medication compliance) has also been used with success.¹²

There are limitations to this survey study. The reported response rate was low because distribution of the survey was limited by voluntary participation in recruitment efforts by our checkout desk staff. Collaboration with regional or national organizations to ensure larger distribution and participation may be helpful in survey research. However, in our previous experience, use of the Mohammed Ali Parkinson's Disease Registry still led to a modest response rate of 38%.¹³ The anonymous nature of the survey did not allow analysis of reasons for nonresponse or preventing multiple responses from the same individual (although exact duplicates were not found in the data).

The study enrolled only 21 participants living greater than 65 min from the center, so it was limited in its ability to measure impact of travel burden on this segment of the population. Although the study was able to successfully test its primary hypotheses, interpretation in favor of the use of telemedicine to ease travel burden cannot be confirmed. Because they did not want to be obligated to participate in an actual clinical trial, some patients in-

vited by the principal investigator to complete the survey initially refused. They agreed to complete the survey upon clarification that the trial was hypothetical. Therefore, selection bias may exist in favor of individuals already willing to participate in research. The rather high rate of interest in participation in clinical trials raises further concern about selection bias; however, there are other potential reasons. For example, altruism is strongly encouraged in the local community. This may encourage participation in research with limited chance of direct benefit to the patient. As the local academic movement disorders program began just prior to this survey study, most respondents have not yet participated in pharmacological clinical trials. Therefore, respondents could also have overestimated their likelihood to participate. In either case, the finding that individuals with high likelihood of participation in clinical trials are less likely to participate using home-based Internet technology raises important concerns about patient comfort with the technology. This survey did not ask about use of more user-friendly appliances or provision of technical support by telephone (a more familiar modality.) It also did not explain about potential incentives, such as provision of clinical care in tandem with Web-based research assessments. Future surveys of this nature will need to consider these options.

The study results would need to be confirmed in other populations on a larger scale before they could be generalized. Future surveys of this nature may also need to include verbal explanation by study staff, more detailed demographic information, questions about whether study subjects will maintain clinical care at the study center, and patients' prior experience with clinical trials. Finally, it cannot be assumed that willingness to participate would reflect actual rate of participation.

In summary, use of telemedicine may be an acceptable means to improve participation in clinical trials. This would need to be confirmed with the use of a larger-scale inquiry involving rural populations. Use of personal computers to complete self-assessments for a clinical trial may in general decrease willingness of an older PD population to participate. Further information about subject or caregiver comfort and trainability would be necessary before considering use of interactive remote assessments with a home computer for PD clinical trials.

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