

Randomized Controlled Clinical Trial of “Virtual House Calls” for Parkinson Disease

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Importance: The burden of neurological disorders is increasing, but access to care is limited. Providing specialty care to patients via telemedicine could help alleviate this growing problem.

Objective: To evaluate the feasibility, effectiveness, and economic benefits of using web-based videoconferencing (telemedicine) to provide specialty care to patients with Parkinson disease in their homes.

Design: A 7-month, 2-center, randomized controlled clinical trial.

Setting: Patients' homes and outpatient clinics at 2 academic medical centers.

Participants: Twenty patients with Parkinson disease with Internet access at home.

Intervention: Care from a specialist delivered remotely at home or in person in the clinic.

Main Outcome Measures: The primary outcome variable was feasibility, as measured by the percentage of telemedicine visits completed as scheduled. Secondary outcome measures included clinical benefit, as measured by the 39-item Parkinson Disease Question-

naire, and economic value, as measured by time and travel.

Results: Twenty participants enrolled in the study and were randomly assigned to telemedicine (n=9) or in-person care (n=11). Of the 27 scheduled telemedicine visits, 25 (93%) were completed, and of the 33 scheduled in-person visits, 30 (91%) were completed (P=.99). In this small study, the change in quality of life did not differ for those randomly assigned to telemedicine compared with those randomly assigned to in-person care (4.0-point improvement vs 6.4-point improvement; P=.61). Compared with in-person visits, each telemedicine visit saved participants, on average, 100 miles of travel and 3 hours of time.

Conclusion and Relevance: Using web-based videoconferencing to provide specialty care at home is feasible, provides value to patients, and may offer similar clinical benefit to that of in-person care. Larger studies are needed to determine whether the clinical benefits are indeed comparable to those of in-person care and whether the results observed are generalizable.

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PARKINSON DISEASE (PD) IS A chronic neurodegenerative disease whose burden is increasing rapidly in the United States and around the world.

However, access to care is limited by distance, disability, and the distribution of doctors.¹ Among US Medicare beneficiaries with PD, more than 40% have not seen a neurologist.²

Access to neurological care is associated with improved outcomes. Medicare beneficiaries with PD who do not see a neurologist are 14% more likely to fracture a hip, 21% more likely to be placed in a skilled nursing facility, and 22% more likely to die.² In addition, specialist involvement in PD is associated with improved adherence to quality indicators,³ and patients who see a PD

specialist are 3 times more likely to be satisfied with their care than those seeing a general neurologist.⁴

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Use of the latest technology, including the use of simple web-based video assessments akin to Skype, can help overcome geographical barriers to care in PD.⁵⁻⁷ Web-based clinical assessments have been shown to be reliable for patients with PD.^{8,9} A previous randomized controlled trial demonstrated the feasibility of using telemedicine to provide care for PD in a controlled environment, such as a nursing

home.^{10,11} Several telemedicine models have demonstrated value or promise in neurology.¹²⁻¹⁵ However, the feasibility and potential benefits of providing care directly in people's homes ("virtual house calls") have not been assessed systematically. Therefore, we conducted a small, 2-center, randomized controlled clinical trial to evaluate the feasibility, clinical effects, and economic value of providing specialty care directly in the homes of people with PD.

METHODS

STUDY DESIGN

We conducted a randomized controlled clinical trial of the feasibility, effectiveness, and economic benefits of using web-based videoconferencing to provide specialty care to patients with PD in their homes compared with receiving in-person care from a specialist. The institutional review boards at the University of Rochester Medical Center in Rochester, New York, and Johns Hopkins Medicine in Baltimore, Maryland, approved the research protocol and consent forms. Our study was funded by Google and Excellus Blue Cross Blue Shield, which had no role in the design, analysis, or reporting of the study.

Eligible participants provided written consent. At baseline, participants traveled to either the University of Rochester or Johns Hopkins and were randomly assigned using a random number table in a 1:1 allocation to the 2 treatment arms stratified by site. Patients who were randomly assigned to telemedicine were provided e-mail links to download secure, Health Insurance Portability and Accountability Act-compliant videoconferencing software from Vidyo and hosted by IDSolutions. The technical requirements for using Vidyo are less than those for Skype.^{16,17} A technology assistant (M.J.G., M.T.B., or V.V.) helped participants or their family members or friends by telephone with downloading the software and connecting to the physician.

For all participants, baseline assessments were conducted in person at their clinic and included assessments of quality of life as measured by the 39-item Parkinson Disease Questionnaire (PDQ-39),¹⁸ of PD as measured by the Unified Parkinson Disease Rating Scale (UPDRS) parts I to III,¹⁹ and of cognition as measured by the Montreal Cognitive Assessment.²⁰ In addition, participants at one site (Johns Hopkins Medicine) evaluated the quality of their chronic illness care as measured by the Patient Assessment of Care for Chronic Conditions (PACIC).²¹ All participants completed a survey of general computer and Internet usage derived from the Pew Internet survey,²² of economic outcomes that assessed time and travel (if applicable) devoted to the visit, and of interest in and willingness to pay for future telemedicine visits.

Following the baseline visit, the participants who were randomly assigned to telemedicine received 3 visits over 7 months (months 1, 4, and 7) with a specialist using web-based videoconferencing. The participants who were randomly assigned to in-person care received 3 in-person clinic visits over 7 months. The assessments conducted remotely were the same as those conducted in person, with the exception of the motor examination section (part III) of the UPDRS. Because rigidity (question 22) and postural stability (question 30) cannot be assessed visually, we excluded these 2 items in our calculation of the "modified" UPDRS. Previous research has demonstrated that remote assessments of the UPDRS are valid and reliable when compared with in-person assessments.^{10,11,23}

STUDY PARTICIPANTS

Study participants were recruited and enrolled at 2 academic clinical sites (University of Rochester and Johns Hopkins) in the United States. Participants were men and women older than 30 years of age who received a clinical diagnosis of a parkinsonian disorder (eg, PD, multiple systems atrophy, or progressive supranuclear palsy) and were receiving care from 1 of 2 investigators (E.R.D. or K.M.B.). Participation was solicited by the investigators from their existing clinical practice. Because of state licensure laws generally restricting the practice of medicine across state lines, participants had to reside in either New York or Maryland. Individuals had to have access to a computer with Internet access. If they did not have a web camera, one was provided for them. Exclusion criteria included conditions (eg, prominent psychosis) that, in the investigator's judgment, would preclude participation in a telemedicine visit.

OUTCOME MEASURES

For the randomized controlled clinical trial, the primary outcome was feasibility, which was measured by the percentage of visits completed as scheduled, the proportion of visits completed via telemedicine vs in person, the total number of individuals randomly assigned to telemedicine who required in-person visits, and the total number of in-person visits required by individuals randomly assigned to the telemedicine arm.

The secondary outcome measure was clinical benefit, which was measured by change from baseline to the month 7 score in the PDQ-39 and the modified motor UPDRS score, which excludes rigidity and balance. We also calculated the change from baseline in quality of care as measured by the PACIC. The tertiary outcome measure was economic benefit, which included measures of time spent (including connection or travel time) for the last study visit (telemedicine or in person), the amount of the total time that was spent with the physician, the distance traveled, whether anyone accompanied the patient to their visit, their willingness to pay for telemedicine visits above what their insurance covers, and their comfort and interest in future telemedicine visits. Individuals at one site (Johns Hopkins Medicine) were also asked to provide their 3 favorite and 3 least favorite aspects of telemedicine, which were coded (by V.V.) using interpretive phenomenological approaches.²⁴

STATISTICAL ANALYSIS

The primary outcome measure in our study was feasibility as measured descriptively by the proportion of telemedicine visits that were completed as scheduled. We prespecified a feasibility threshold of completion of 80% of telemedicine visits. As a secondary analysis, the proportion of completed visits was compared between treatment groups using the Fisher exact test. The sample size for this proof-of-concept study was chosen to provide evidence that providing medical care from a physician to individuals with a chronic neurological condition in their home is feasible and potentially valuable.

The secondary outcome measures included metrics of clinical benefit and economic value. Our study was not adequately powered to detect meaningful differences in clinical benefit as measured by the PDQ-39. With a sample size of 20 participants, we had 80% power at a 5% significance level to detect a 15-point difference in the PDQ-39 between the 2 groups, which is greater than the 10-point difference that has been regarded as the minimally clinically important difference.²⁵ We used analysis of covariance models to analyze the change from baseline to 7 months in the PDQ-39, the UPDRS part III, and the PACIC. Each model included treatment group (telemedicine or in-

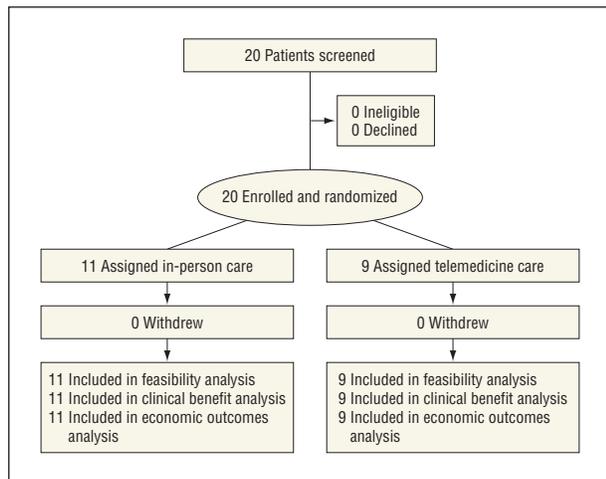


Figure. Flowchart of the screening and enrollment of 20 study participants with Parkinson disease who were randomly assigned to telemedicine or in-person care.

person care) as the factor of interest, with investigator and corresponding baseline outcome as covariates. These models were used to compute 95% CIs for the mean change from baseline in each outcome for each treatment group, as well as the difference in mean changes from baseline between treatments. The focus in these analyses was on the 95% CIs, not solely to determine what effect sizes were supported by the data but also to rule out any treatment differences that the data exclude (ie, outside the 95% CI). This approach allowed for the simultaneous assessment of whether the treatments differed and by what margins of difference they could be considered equivalent. The underlying model assumptions (normality, linearity, and homogeneity of variances) were thoroughly checked, and no significant departures were detected. Economic outcomes were compared using the Wilcoxon rank sum test for median values and the Fisher exact test for proportions. We did not adjust our results for multiple comparisons.

RESULTS

STUDY PARTICIPANTS

From September 30, 2011, through January 24, 2012, 20 potential participants were identified and evaluated; none were excluded. Of these, 20 participants were eligible and were enrolled and randomly assigned to either continue their usual in-person care with a specialist (n=11) or receive care with their specialist via telemedicine in their homes (n=9) (**Figure**). All 20 participants received a clinical diagnosis of PD. The demographic and clinical characteristics were similar between groups at baseline, except for a lower quality of life for patients seen in person (**Table 1**).

FEASIBILITY

Table 2 summarizes the feasibility and clinical effects observed in our study. Of 27 scheduled telemedicine visits, 25 (93%) were completed, and of 33 scheduled in-person visits, 30 (91%) were completed ($P = .99$). The 2 missed telemedicine visits were due to technical difficulties (inadequate Internet signal) associated with a spe-

Table 1. Baseline Characteristics of Study Participants With PD

Characteristic	Type of Care	
	In Person (n = 11)	Telemedicine (n = 9)
Demographics		
Age, mean (SE), y	64.5 (3.4)	66.6 (4.0)
Female, %	27.3	22.2
White, %	90.9	100.0
Education, % completing \geq high school	100.0	100.0
Distance from clinic, mean (SE), miles	56.7 (16.2)	51.3 (17.9)
Internet use, at least occasionally, %	100.0	100.0
Use of e-mail, at least occasionally, %	100.0	100.0
PD characteristics		
PD, %	100.0	100.0
UPDRS score, mean (SE)		
Total (range, 0-176)	46.1 (4.2)	45.2 (4.2)
Modified motor ^a	27.7 (2.5)	27.1 (3.0)
Hoehn-Yahr score (range, 1-5), mean (SE)	2.5 (0.3)	2.3 (0.2)
PDQ-39 score (range, 0-100), mean (SE)	42.8 (8.8)	27.3 (5.9)
MCA score (range, 0-30), mean (SE)	25.1 (1.0)	25.4 (0.6)
PACIC score ^b (range, 0-100), mean (SE)	74.2 (7.6)	63.0 (7.3)

Abbreviations: MCA, Montreal Cognitive Assessment; PACIC, Patient Assessment of Care for Chronic Conditions; PD, Parkinson disease; PDQ-39, 39-item Parkinson Disease Questionnaire; UPDRS, Unified Parkinson Disease Rating Scale.

^aExcluding motor assessment of rigidity and postural stability.

^bFor 1 site only (6 patients randomly assigned in-person care and 4 patients randomly assigned telemedicine).

cialist using a new site. One additional visit had poor audio quality such that a telephone had to be used for voice communication. The 3 missed in-person visits were due to a work conflict, a desire to minimize travel, and a car accident on the way to a visit, respectively. None of the individuals randomly assigned to telemedicine required an in-person visit during the course of the study. No harmful or unintended effects were reported.

CLINICAL EFFECTS AND QUALITY OF CARE

The change in quality of life, as measured by the PDQ-39, did not differ between those randomly assigned to telemedicine (4.0-point improvement) and those randomly assigned to in-person care (6.4-point improvement; $P = .61$). The change in UPDRS modified motor score (part III score, except for motor assessments of rigidity and postural stability) for those randomly assigned to telemedicine did not differ from those randomly assigned to in-person care (3.9-point improvement vs 1.2-point improvement; $P = .36$). The change in the PACIC (1.5-point improvement for telemedicine vs 3.8-point worsening for in-person care; $P = .47$) also did not differ between the 2 groups.

ECONOMIC VALUE

As shown in **Table 3**, the average time that a participant devoted to a telemedicine visit from logging onto the videoconferencing software to completing the appointment ("computer on-to-computer off" time) was 53 minutes. By contrast, the average time that a person devoted to an in-person visit from leaving their home to returning ("door-to-door" time) was 255 minutes

Table 2. Feasibility, Clinical, and Quality Outcomes for Patients Randomly Assigned to Telemedicine or In-Person Care

Outcome	Point Improvement (95% CI)		P Value	95% CI of Difference
	In-Person Care (n = 11)	Telemedicine (n = 9)		
Visits completed as scheduled, %	90.9	92.6	.99	-12 to 16
Change from baseline in PDQ-39	6.4 (-12.2 to -0.5)	4.0 (-10.5 to 2.5)	.61	-11.5 to 6.7
Change from baseline in UPDRS modified motor score ^a	1.2 (-5.1 to 2.7)	3.9 (-8.2 to 0.3)	.36	-3.1 to 8.5
Change from baseline in PACIC ^b	3.8 ^c (-12.6 to 5.0)	1.5 (-9.5 to 12.4)	.47	-19.7 to 9.2

Abbreviations: PACIC, Patient Assessment of Care for Chronic Conditions; PDQ-39, 39-item Parkinson Disease Questionnaire; UPDRS, Unified Parkinson Disease Rating Scale.

^aExcluding motor assessment of rigidity and postural stability.

^bFor 1 site only.

^cPoint worsening.

Table 3. Economic Outcomes for Patients Randomly Assigned to Telemedicine or In-Person Care

Outcome	Value (95% CI)		P Value
	In-Person Care (n = 11)	Telemedicine (n = 9)	
Total time devoted to each visit, min	255.3 (164.6-346.1)	52.6 (38.1-67.1)	<.001
Time spent with physician per visit, min	47.9 (27.0-68.7)	34.7 (28.5-40.8)	.71
Total visit time not spent with physician, min	207.4 (125.5-289.4)	17.9 (8.8-27.0)	<.001
Visit time spent with physician, %	21.8	71.6	<.001
Amount participants would be willing to pay above insurance coverage for telemedicine visit, ^a \$	17 (-4.0 to 37.3)	31 (-5.5 to 68)	.67
Participants interested in enrolling in telemedicine program instead of conducting visits at clinic, ^a %	83.3	100.0	.99

^aFor 1 site only.

($P < .001$). The duration of time spent with the physician did not differ between telemedicine and in-person visits (35 minutes vs 48 minutes; $P = .71$), but the amount of visit time spent without the physician was much lower for telemedicine visits than for in-person visits (18 minutes vs 207 minutes; $P < .001$). For telemedicine visits, the time spent without the physician was devoted to connecting the patient with a technology assistant and waiting for the physician.

Among participants, the favorite aspects of telemedicine included reduced time and travel ($n = 12$), increased flexibility and convenience ($n = 11$), a more comfortable experience ($n = 8$), and decreased costs ($n = 5$). For example, one participant said “[t]elemedicine for me has become a real convenience, in particular the distance we live from Hopkins. . . I’m relatively young [and have] Parkinson’s; I can’t imagine how it must be for [older patients to get to clinic].” The least favorite aspects of telemedicine included concerns about the difficulty of establishing a personal bond with the physician ($n = 8$), the physician not obtaining all the necessary information ($n = 8$), and technical issues ($n = 6$). One participant said “I found that the visit was not hands-on. It should not replace in-person totally.” At the study’s conclusion, 85% of participants ($n = 17$) expressed interest in enrolling in a telemedicine program rather than conducting visits at their physician’s clinic. Additional economic outcomes are summarized in Table 3.

COMMENT

Based on this small randomized controlled clinical trial, we found that using web-based videoconferencing to provide specialty care to patients with PD directly in their homes is feasible, saves patients substantial time and travel, and may offer comparable clinical benefits to in-person care. However, the effects observed and the study’s small sample size could not exclude the possibility that a potentially meaningful difference in quality of life could be present between the 2 groups. Larger-scale studies, involving multiple centers, will be needed to determine whether the clinical benefit provided by telemedicine is truly comparable or noninferior to that provided by in-person care and whether the results observed are generalizable to broader populations.

Telemedicine is a growing market²⁶ that is viewed as a potential means to increase access to care in a cost-effective way.²⁷ In addition, many organizations currently tout connecting physicians to patients in their homes.²⁸⁻³² However, few, if any, controlled studies have examined the feasibility and benefits of doing so for patients with chronic conditions.

In addition to providing evidence for the benefits of an alternative care delivery model for PD, our study addresses priorities identified by the Institute of Medicine in its recent report on comparative effectiveness re-

search.³³ Among the priorities that it identified in managing chronic disease was the comparison of the effectiveness of remote patient monitoring and management technologies with the effectiveness of usual care.³³

Although the results of our study demonstrate the feasibility and potential value of this model of care, barriers remain, especially in the United States, to using telemedicine to deliver care to patients with chronic conditions. Among them are licensure and reimbursement. Most states require that physicians providing telemedicine services be licensed in the state where the patient is physically located.³⁴ The net result is that patients who often have the least access to care (eg, live in states with few specialists, have limited mobility, or have limited resources) and the most to potentially gain from telemedicine cannot do so. Proposed federal legislation seeks to address this barrier.³⁵ Outside the United States, provincial licensure issues are not a barrier. For example, Canada, which has many remote areas with limited access to care, has some of the largest telemedicine networks in the world.³⁶

The second principal barrier is reimbursement. Medicare currently reimburses for telemedicine only under certain circumstances, including that the care be provided in a health professional shortage area (for an eligible medical service), that the site where the patient is located generally be a medical facility, and that a physician provide the service.³⁷ Telemedicine is increasingly available in prisons³⁸ and within the Veterans Affairs system, which recently decided that it will no longer charge beneficiaries a co-pay when receiving in-home care that uses video-conference technology.³⁹ However, access to such care in the broader population in the United States remains limited. States are trying to address this disparate treatment,³⁴ but paying for the service remains problematic. Outside the United States, reimbursement barriers may differ or may be absent. Again, in Canada, government-funded agencies reimburse physicians above traditional face-to-face assessments and have helped establish telemedicine networks.⁴⁰

In our study, the economic value identified largely accrues to the patient and caregiver in time and travel savings. Using federal minimum wage⁴¹ as the value of a patient's and a caregiver's time and Internal Revenue Service standard mileage rates,⁴² we found that each telemedicine visit saves \$52 to \$85 per visit depending on the mileage rate used. By comparison, Medicare reimburses \$100 for a typical follow-up visit for PD.³⁷ Despite this conservative estimate for savings to the patient, participants in our study expressed only limited willingness to pay money above what their insurance would cover for a telemedicine visit. In the future, assessments of whether and how much this model can save insurers for patients with PD, who cost Medicare about \$25 000 more than beneficiaries without PD,⁴³ could motivate insurance coverage of this care model.

Our study is limited by its size, design, and patient population. Although, to our knowledge, it is one of the first studies to examine the use of telemedicine to deliver specialty care into the home, the study size was small and did not have sufficient power to detect potentially meaningful differences between the groups on the clinical

outcome measures used.^{25,44} Our study also lacked blinding. Although less important for objective measures, such as whether a visit occurred, the absence of blinding could have biased the UPDRS results in favor of telemedicine. The PDQ-39 has been used as an outcome measure in other PD studies (eg, deep brain stimulation⁴⁵ and group patient visits⁴⁶) in which blinding is not feasible. The patient population in our study also was not representative of the broader PD population. The patients were largely well-educated white men who were familiar with the Internet and who all had been previously evaluated by a movement disorder specialist and were willing to participate in a telemedicine study. Extending this model to populations of patients who have less access to care either due to race⁴⁷ or location, less familiarity with the Internet, or have not been previously evaluated by a PD specialist will be important to determining its broader value and potential for dissemination. Notwithstanding these limitations, our study demonstrates that using web-based videoconferencing to provide specialty care at home is feasible, provides value to patients, and lays the foundation for larger-scale studies in PD and other chronic conditions.

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Author Contributions: Drs Dorsey and Biglan had full access to all the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis. *Study concept and design:* Dorsey, Boyd, Beck, Seidmann, and Biglan. *Acquisition of data:* Dorsey, Venkataraman, Grana, Bull, and Biglan. *Analysis and interpretation of data:* Dorsey, Venkataraman, Grana, George, Boyd, Beck, Rajan, Seidmann, and Biglan. *Drafting of the manuscript:* Dorsey and Venkataraman. *Critical revision of the manuscript for important intellectual content:* Grana, Bull, George, Boyd, Beck, Rajan, Seidmann, and Biglan. *Statistical analysis:* Venkataraman and Beck. *Obtained funding:* Dorsey, Boyd, Seidmann, and Biglan. *Administrative, technical, and material support:* Venkataraman, Grana, and Bull. *Study supervision:* Dorsey and Biglan.

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