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Randomized, controlled trial of "virtual housecalls" for Parkinson disease

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Abstract

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—Seven-month, two-center, randomized controlled clinical trial.

Setting—Patients' homes and outpatient clinics at two academic medical centers

Participants—20 patients with Parkinson disease with internet access at home.

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Author contributions

Drs. E. Ray Dorsey and Kevin M. Biglan take full responsibility for the content of this article. Both had full access to all of the study data and take full responsibility of the data and the accuracy of the data. All authors were involved in the decision to submit the manuscript for publication

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^{*}Full trial protocol can be accessed by request

Intervention—Care from a specialist delivered remotely at home or in-person in 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 Parkinson Disease Questionnaire-39 (PDQ-39) and economic value as measured by time and travel.

Results—Twenty participants enrolled in the study and were randomized to telemedicine (n=9) or in-person care (n=11). Ninety-three percent (n=25) of 27 scheduled telemedicine visits were completed compared to 91% (n=30) of 33 scheduled in-person visits (p=1.0). In this small study, the change in quality of life did not differ for those randomized to telemedicine compared to inperson care (4.0 point improvement v. 6.4 point improvement; p = 0.61). Compared to in-person visits, each telemedicine visit saved participants on average 100 miles of travel and three hours of time.

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

Clinical Trial Registry—"Providing Specialty Care to Individuals with Parkinsonism Directly in Their Homes Via Web-based Video Conferencing — A Comparative Effectiveness Study (TELEMED-PD)": clinicaltrials.gov Identifier: NCT01476306

INTRODUCTION

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. Among U.S. Medicare beneficiaries with Parkinson disease, more than 40% have not seen a neurologist.

Access to neurological care is associated with improved outcomes. Medicare beneficiaries with Parkinson disease 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 Parkinson disease is associated with improved adherence to quality indicators³, and patients who see a PD specialist are three times more likely to be satisfied with their care than those seeing a general neurologist.⁴

Technology, including simple web-based video assessments akin to Skype[™] (Luxembourg), can help overcome geographical barriers to care in Parkinson disease.^{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 environments, 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 into people's homes ("virtual house calls") has not been assessed systematically. We, therefore, conducted a small, two-center, randomized controlled trial to evaluate the feasibility, clinical effects, and economic value of providing specialty care directly into the homes of people with Parkinson disease.

METHODS

Study design

We conducted a randomized, controlled study of the feasibility, effectiveness, and economic benefits of using web-based videoconferencing to provide specialty care to patients with Parkinson disease in their homes compared to receiving in-person care from a specialist. The

institutional review boards at the University of Rochester Medical Center and Johns Hopkins Medicine approved the research protocol and consent forms. This study was funded by Google and Excellus BlueCross BlueShield, 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 randomized using a random number table in a 1:1 allocation to the two treatment arms stratified by site. Patients who were randomized to telemedicine were provided by e-mail links to download secure, Health Insurance Portability and Accountability Act-compliant videoconferencing software from Vidyo® (Hackensack, NJ) and hosted by ID Solutions (Indianapolis, IN). The technical requirements for using Vidyo are less than those for SkypeTM.16, 17 A technology assistant (M.G., M.B., V.V.) helped participants or their family members or friends by phone 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 Parkinson Disease Questionnaire (PDQ-39)¹⁸, Parkinson disease as measured by the Unified Parkinson's Disease Rating Scale (UPDRS) parts I–III,¹⁹ and cognition as measured by the Montreal Cognitive Assessment²⁰. In addition, participants at one site (Johns Hopkins) 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 economic outcomes that assessed time and travel (if applicable) devoted to the visit, and interest in and willingness to pay for future telemedicine visits.

Following the baseline visit, participants randomized to telemedicine received three visits over seven months (months one, four, and seven) with a specialist using web-based video conferencing. Participants randomized to in-person care received three in-person clinic visits over seven 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 two items in our calculation of the "modified" UPDRS. Previous research has demonstrated that remote assessments of the UPDRS are valid and reliable when compared to in-person assessments. ^{10, 11, 23}

Study participants

Study participants were recruited and enrolled at two academic clinical sites (University of Rochester, Rochester, NY, and Johns Hopkins, Baltimore, MD) in the United States. Participants were men and women over 30 with a clinical diagnosis of a parkinsonian disorder (e.g., Parkinson disease, multiple systems atrophy, progressive supranuclear palsy) that were receiving care from one of two investigators (E.R.D., K.M.B.). Participation was solicited by the investigators from their existing clinical practice. Due to 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 (e.g., prominent psychosis) that in the investigator's judgment would preclude participation in a telemedicine visit.

Outcome measures

For the randomized, controlled study, the primary outcome was feasibility, which was measured by the percentage of visits completed as scheduled, the proportion of visits

completed via telemedicine versus in person, the total number of individuals randomized to telemedicine who required in-person visits, and the total number of in-person visits required by individuals randomized to the telemedicine arm.

The secondary outcome measure was clinical benefit, which was measured by change from baseline to the month seven 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 (J.H.U) were also asked to provide their three favorite and least favorite aspects of telemedicine, which were coded (by V.V.), using interpretive phenomenological approaches.²⁴

Statistical analysis

The primary outcome measure in this study was feasibility as measured descriptively by the proportion of telemedicine visits that were completed as scheduled. We pre-specified 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 Fisher's 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. The 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 two groups, which is greater than the ten point difference that has been regarded as the minimally clinically important difference²⁵. We used analysis of covariance models to analyze the change from baseline to seven months in PDQ-39, UPDRS part III, and the PACIC. Each model included treatment group (telemedicine or in-person care) as the factor of interest, with investigator and corresponding baseline outcome as covariates. These models were used to compute 95% confidence intervals 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 confidence intervals, not solely to determine what effect sizes were supported by the data, but also to rule out any treatment differences that the data exclude (i.e. outside the confidence interval). 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, homogeneity of variances) were thoroughly checked, and no significant departures were detected. Economic outcomes were compared using Wilcoxon rank-sum test for medians and Fisher's 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 was excluded. Of these, 20 were eligible and were enrolled and randomized to either continue their usual in-person care with a specialist (n=11) or to

receive care with their specialist via telemedicine in their homes (n=9 as shown in Figure 1). All twenty individuals had a clinical diagnosis of Parkinson disease. 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 the study. Ninety-three percent (n=25) of 27 scheduled telemedicine visits were completed compared to 91% (n=30) of 33 scheduled in-person visits (p=1.00). The two missed telemedicine visits were due to technical difficulties (inadequate internet signal) associated with a specialist using a new site. One additional visit had poor audio quality such that a telephone had to be used for voice communication. The three missed in-person visits were due to a work conflict, desire to minimize travel, and a car accident on the way to a visit. None of the individuals randomized to telemedicine required an in-person visit during the course of the study. No harms 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 randomized to telemedicine (4.0 point improvement) versus those randomized to in-person care (6.4 point improvement; p=0.61). The change in UPDRS modified motor score (part III score except for motor assessments of rigidity and postural stability) for those randomized to telemedicine did not differ from those randomized to in-person care (3.9 point improvement v. 1.2 point improvement; p=0.36). The change in the PACIC (1.5 point improvement for telemedicine v. 3.8 point worsening for in-person care; p=0.47) also did not differ between the two 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 completion of 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 (p < 0.001). The duration of time spent with the physician did not differ for telemedicine and in-person visits (35 minutes v. 48 minutes; p=0.71), but the amount of visit time spent without the physician was much lower for telemedicine visits versus in-person visits (18 minutes v. 207 minutes; p < 0.001). 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, "Telemedicine 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 physician (n=8), the physician not obtaining all 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, ninety percent of participants 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 trial, using web-based video conferencing to provide specialty care to patients with Parkinson disease directly into their homes is feasible, saves patients substantial time and travel, and may offer comparable clinical benefits to inperson 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 two groups. Larger scale studies, involving multiple centers, will be needed to determine whether the clinical benefit provided by telemedicine is truly comparable or non-inferior to that provided by in-person care and whether the results observed are generalizable to broader populations.

Telemedicine is a growing market ²⁶ 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 of the benefits of alternative care delivery model for Parkinson disease, this study addresses priorities identified by the Institute of Medicine in its recent report on comparative effectiveness research.³³ Among the priorities identified include comparing the effectiveness of remote patient monitoring and management technologies and usual care in managing chronic disease.

While the results of this study demonstrate the feasibility and potential value of this model of care, barriers, especially in the U.S., to using telemedicine to deliver care to patients with chronic conditions in their home remain. 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 (e.g., live in states with few specialists, have limited mobility, have limited resources) and have the most to potentially gain from telemedicine cannot do so. Proposed federal legislation seeks to address this barrier.³⁵ Outside the U.S., 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. Telemedicine is increasingly available in prisons 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. However, access to such care in the broader population in the U.S. remains limited. States are trying to address this disparate treatment, the paying for the service remains problematic. Outside the U.S., reimbursement barriers may differ or be absent. Again in Canada, government funded agencies reimburse physicians above traditional face to face assessments and have helped establish telemedicine networks.

In this 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 and a caregiver's time and Internal Revenue Service standard mileage rates,⁴² 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 Parkinson disease.³⁷ Despite this conservative estimate for savings to the patient, participants in this 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 Parkinson disease, who cost Medicare about \$25,000 more than beneficiaries without Parkinson disease, ⁴³ could motivate insurance coverage of this care model.

This study is limited by its size, design, and patient population. While 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} The study also lacked blinding. While 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 Parkinson disease studies (e.g., deep brain stimulation, ⁴⁵ group patient visits ⁴⁶) where blinding is not feasible. The patient population in this study also was not representative of the broader Parkinson disease population. The patients were largely well educated white men with familiarity with the internet 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 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 Parkinson disease specialist will be important to determining its broader value and potential for dissemination.

Notwithstanding the above limitations, this study demonstrates that using care to provide medical care into patients' homes is feasible, provides value, and lays the foundation for larger scale studies in Parkinson disease and other chronic conditions.

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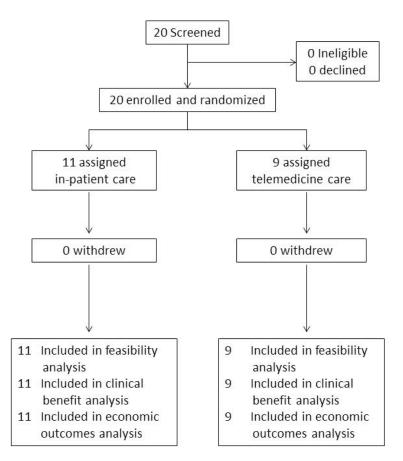


Figure 1. Screening and enrollment of study participants

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Table 1

Baseline characteristics of study participants *

Baseline characteristics	In-person (n=11)	Telemedicine (n=9)
<u>Demographics</u>		
Age	64.5 (± 3.4)	$66.6 (\pm 4.0)$
Women (%)	27.3	22.2
White (%)	6.09	100.0
Education, (% completing high school or more)	100.0	100.0
Distance from clinic in miles	56.7 (± 16.2)	51.3 (± 17.9)
Use internet, at least occasionally (%)	100.0	100.0
Use email, at least occasionally (%)	100.0	100.0
Parkinson disease characteristics		
Percent with Parkinson disease	100.0	100.0
Unified Parkinson's Disease Rating Scale, total score (0–176)	46.1 (± 4.2)	45.2 (± 4.2)
Unified Parkinson's Disease Rating Scale, modified motor score	27.7 (± 2.5)	27.1 (± 3.0)
Hoehn & Yahr (1–5)	2.5 (± 0.3)	$2.3 (\pm 0.2)$
Parkinson Disease Questionnaire 39 (0–100)	42.8 (± 8.8)	27.3 (± 5.9)
Montreal Cognitive Assessment (0–30)	25.1 (± 1.0)	25.4 (± 0.6)
Patient Assessment of Chronic Illness Care (0-100) ***	74.2 (± 7.6) (n=6)	63.0 (± 7.3) (n=4)

» Mean (±Standard Error) reported

** Excluding motor assessment of rigidity and postural stability

*** For one site only Page 11

Table 2

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Feasibility, clinical, and quality outcomes for those randomized to telemedicine versus in-person care

Outcome	In-person care (n=11)	Telemedicine care (n=9)	P-value	P-value 95% CI of Difference
Proportion of visits completed as scheduled	%6.06	92.6%	1.00	1.00 [-12%, 16%]
Change from baseline in Parkinson Disease Questionnaire 39 6.4 point improvement (95% CI: [-12.2, -0.5]) 4.0 point improvement (95% CI: [-10.5, 2.5]) 0.61 [-11.5, 6.7]	6.4 point improvement (95% CI: [-12.2, -0.5])	4.0 point improvement (95% CI: [-10.5, 2.5])	0.61	[-11.5, 6.7]
Change from baseline in the Unified Parkinson's Disease Rating Scale, modified motor score *	1.2 point improvement (95% CI: [-5.1,2.7])	3.9 point improvement (95% CI: [-8.2,0.3]) 0.36		[-3.1,8.5]
Change from baseline in Patient Assessment of Care for Chronic Conditions ***	3.8 point worsening (95% CI: [-12.6,5.0])	1.5 point improvement (95% CI: [-9.5,12.4]) 0.47		[-19.7, 9.2]

CI = Confidence Interval

 $\stackrel{*}{\ast}$ Excluding motor assessment of rigidity and postural stability

** For one site only

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Table 3

Economic outcomes for those randomized to telemedicine versus in-person care

Outcome	In-person care (n=11)	Telemedicine care (n=9)	P-value
Total time devoted to each visit	255.3 minutes (95% CI: [164.6, 346.1]) 52.6 minutes (95% CI: [38.1, 67.1]) $p < 0.001$	52.6 minutes (95% CI: [38.1, 67.1])	p < 0.001
Time spent with physician per visit	47.9 minutes (95% CI: [27.0, 68.7])	34.7 minutes (95% CI: [28.5, 40.8]) 0.71	0.71
Total visit time not spent with the physician	$207.4 \ minutes \ (95\% \ CI: [125.5, 289.4]) \qquad 17.9 \ minutes \ (95\% \ CI: [8.8, 27.0]) \qquad p < 0.001$	17.9 minutes (95% CI: [8.8, 27.0])	p < 0.001
Proportion of visit spent with the physician	21.8%	71.6%	p < 0.001
Amount participants would be willing to pay above insurance coverage for a telemedicine visit st	\$17 (95% CI: [-4.0, 37.3])	\$31 (95% CI: [-5.5, 68])	0.67
Proportion of participants interested in enrolling in a telemedicine program instead of conducting visits at a physician's clinic *	83.3%	100.0%	1.00

CI = Confidence Interval

* For one site only Page 13