Project Title: Using Technology to Deliver Multidisciplinary Care to Individuals With Parkinson Disease in Their Homes

Principal Investigator: E. Ray Dorsey, MD, MBA

Authors: Meredith A. Achey, BM[1]; Ryan E. Korn, BA[1]; Abigail Arky[1]; E. Ray Dorsey, MD, MBA[1,2]; Christopher A. Beck, PhD [3]; Kevin M. Biglan, MD, MPH[2,4]; E. Anna Stevenson, MS[1]; William Zhu, BA[1]; Jennifer R. Mammen, PhD [5]; Molly J. Elson, BA [1]

Affiliations:

1. CHET, University of Rochester, Rochester, New York
2. Department of Neurology, University of Rochester Medical Center, Rochester, New York
3. Department of Biostatistics and Computational Biology, University of Rochester, Rochester, New York
4. Movement and Inherited Neurological Disorders Unit, University of Rochester, Rochester, New York
5. University of Rochester School of Nursing, Rochester, New York

Table of Contents

Connect.Parkinson: A National Randomized Controlled Trial of Virtual House Calls for People With Parkinson Disease

Abstract

Background: Access to care for individuals affected by chronic conditions is limited by distance, disability, the distribution of doctors, and other socioeconomic factors. National large-scale studies of virtual house calls are lacking for Parkinson disease and other chronic conditions.

Objective: To assess whether the use of virtual house calls to provide care in the homes of patients with Parkinson disease is feasible, improves quality of life, enhances quality of care, and provides additional value to patients and care partners by saving time, reducing travel, decreasing care partner burden, and reducing utilization of health care services.

Methods: We conducted a 12-month national, randomized, controlled trial of virtual house calls for individuals with Parkinson disease comparing usual care with usual care augmented by 4 virtual house calls from a remote specialist in patients' homes. Interested participants were identified by completing an online interest form on our 1-page Web site or by calling the National Parkinson Foundation's helpline. The University of Rochester coordinating site screened all participants and collected baseline information including demographics, health history, details related to usual care, travel time to visit a specialist, and technology access. After an initial evaluation by an independent rater who remained blind to treatment assignment, we randomized the participants to 1 of 2 arms using R version 3.0.2. Randomization was concealed from sites, stratified by enrolling site, and contained a block size of 4. Individuals in the control arm continued with their usual care in their community, received educational materials about Parkinson disease, and were offered a 1-time virtual house call with a Parkinson disease specialist after their final evaluation. Participants in the intervention arm received care from a Parkinson disease specialist via videoconferencing in their home for up to 4 virtual house calls over 12 months, in addition to their usual care and educational materials. Specialists provided recommendations and sent a consultation note to patients and their physicians. Participants completed a survey after each virtual house call. We conducted all study activities, including recruitment, enrollment, and study visits, remotely. We also asked participants' primary care partners (family members or friends who assisted the participant on a regular basis and were not paid caregivers) to enroll into the study and complete remote assessments of their experiences as care partners. Primary outcomes included (1) feasibility, as defined as the percentage of participants who completed at least 1 virtual house call and the overall

percentage of virtual house calls completed as scheduled, and (2) efficacy, as measured by the 12-month change in the patient-reported Parkinson's Disease Questionnaire 39. All secondary outcomes, which included quality of care, caregiver burden, and time and travel savings, were patient-reported and unblinded (except for the 12-month blindly rated change by an independent rater in the Movement Disorder Society-Unified Parkinson's Disease Rating Scale).[1]

Results: We randomized 159 individuals with Parkinson disease, and 111 of their care partners participated. Most study participants were white (96%) and college educated (73%), and on average were 66 years old. Those randomized to the treatment and control group were comparable except for in their previous use of participating in a video chat: Those in the control group had more previous experience (62% versus 435; $p = 0.012$). Of the 97 individuals randomized to the treatment group, 95 (98%) completed at least 1 virtual house call, and 84 (87%) completed all 4 recommended virtual house calls. Quality of life did not improve in those receiving virtual house calls (0.3 points worse on a 100-point scale; 95% CI –2.0 to +2.7 points; $p = 0.78$), nor did the change in quality of care or caregiver burden. Each virtual house call saved patients a median of 80 minutes (95% CI 70 – 120; $p < 0.0001$) and 38 miles per visit (95% CI 36-56; $p < 0.0001$). Participants were highly satisfied with the care, convenience, and comfort of virtual house calls. Parkinson disease–related quality of life did not change appreciably over the course of the study in either group. The Patient Global Impression of Change did improve over 12 months in those randomized to virtual house calls (50% versus 32% randomized to the control group reported feeling at least "a little better"; $p = 0.002$).

Conclusions: Virtual house calls offer the opportunity to provide comfortable, convenient specialty care to individuals with Parkinson disease in their homes. Barriers to large-scale implementation of this method include inconsistent reimbursement for providers, state-based licensure laws, and variability in Internet access and connectivity. Despite these barriers, virtual house calls have the potential to offer anyone, anywhere, access to specialists.

Trial registration: Clinicaltrials.gov, NCT02038959

Background

Access to care for individuals affected by chronic conditions is limited by distance, disability, the distribution of doctors, and other socioeconomic factors. Parkinson disease, which affects approximately 1 million Americans,[2] represents a prototypical chronic condition for which to evaluate methods of improving care delivery. In the United States, more than 40% of individuals with Parkinson disease older than age 65 do not received care from a neurologist within 4 years of diagnosis, and those that do not are more likely to suffer injuries and even death.[2-4] Disparities in access to care remain a pressing challenge for these patients and those with other neurological conditions such as Alzheimer disease. In particular, the burden of time and travel to a multidisciplinary center of excellence or even to a general neurologist in many areas of the country remains an obstacle for individuals with increasingly limited mobility and progressive physical and cognitive disability.

The development of secure, high-speed Internet and home videoconferencing technology holds great promise to alleviate the burdens of time, travel, and expense that individuals with Parkinson disease face when attempting to access quality care.[5-12] However, while many studies have evaluated telemedicine for chronic conditions, few have examined videoconferencing,[13] and even fewer have examined videoconferencing in the home. Further, most of these studies evaluated remote, generally asynchronous (e.g., text messages) monitoring or telephone support. Additionally, with the exception of 1 multicenter spinal cord injury study,[14] most studies have been single center, short, and small.[13] National, large-scale studies of virtual house calls for Parkinson disease and other chronic conditions may help support the development of this care delivery model at scale.

We therefore conducted a national, randomized, controlled trial to determine whether providing virtual house calls from Parkinson disease specialists is feasible, improves quality of life, enhances quality of care, and provides additional value to patients and care partners by saving time, reducing travel, decreasing care partner burden, and reducing other utilization of health care services. The research's long-term objective is to provide evidence for a scalable care model that overcomes barriers present in the current health care system to provide patient-centered care to individuals with chronic conditions regardless of where they live. We envision a future in which anyone, anywhere, can receive the care that they need.

Stakeholder Engagement

Patients, family members, and caregivers, and organizations that represent them, have been instrumental in every aspect of the Connect.Parkinson study. The National Parkinson Foundation (NPF), the largest Parkinson disease patient organization in the country, has been an invaluable partner. NPF was involved with design and implementation of the study, and provided feedback and assistance along every step of the way. NPF created a landing page for the Connect.Parkinson Web site and its helpline assisted individuals interested in enrollment. In addition, NPF negotiated agreements with each of the participating sites and cohosted the kick-off meeting.

Our patient advisory board and steering committee (including 2 individuals from NPF and a patient) were engaged in design of the protocol, recruitment, and training study teams with patients in mind. We designed the trial to ensure that all procedures and assessments could be completed by participants in the comfort of their own homes, with support from study personnel if needed. Richard Simone, a member of the patient advisory board, served as a test patient to train site investigators and coordinators. Simone joined the Connect.Parkinson steering committee as a permanent member and has provided valuable insights into the patient perspective.

Our partners at NPF and patient advisory board members were essential in recruitment and other efforts. NFP provided outreach to communities to build awareness of the study through centers of excellence. Sara Riggare, a member of our patient advisory board, created an information video, “Connect.Parkinson: Connecting Anyone Anywhere to Care,” to increase awareness of the study. Dr. Steven DeMello, a member of the patient advisory board, advised on recruitment and institution review board (IRB) questions. PatientsLikeMe conducted a clinical trial awareness campaign, a successful engagement effort that resulted in nearly 200 interested individuals in eligible states.

The Connect.Parkinson steering committee includes academicians involved in clinical practice and research relating to individuals with Parkinson disease, movement disorders, and/or multiple chronic conditions. Committee members are well versed in clinical trials and have published in leading medical journals. Members of our steering committee and patient and dissemination boards contributed to drafting, editing, and critiquing our clinical trials and baseline manuscripts published in *Trials* and *Telemedicine and eHealth*. In addition, we invited site investigators and coordinators to review and critique our primary manuscript, soon to be published in *Neurology*.

Bimonthly steering committee calls engaged key stakeholders throughout the course of the study. This kept everyone involved in both high-level discussions and the week-to-week accomplishments and challenges (e.g., recruitment and IRB site approvals). Periodic meetings with dissemination and patient advisory boards provided important guidance and feedback on barriers we faced regarding recruitment and IRB approval process for a multisite study involving novel technologies. The end-of-study meeting at the World Parkinson Congress in Portland, Oregon, provided an opportunity to meet face to face with investigators, coordinators, and members of our advisory boards. At this meeting, we discussed results and limitations of the study, proposed efforts to disseminate and implement the results, and discussed future initiatives to build on the results.

Methods

The Connect.Parkinson study was a national, multicenter, randomized, controlled trial comparing 1 year of usual care for Parkinson disease in the community to 1 year of usual care augmented by 4 virtual house calls from a remote Parkinson disease specialist. The protocol details have been previously published.[15] We designed the study to enroll 200 individuals with Parkinson disease and their care partners and had 4 specific aims: (1) to demonstrate the feasibility of using virtual house calls to deliver specialty care in the homes of individuals with Parkinson disease who have limited access to care; (2) to demonstrate that such an approach can improve participants' quality of life; (3) to establish that virtual house calls can enhance the quality of care received by participants; and (4) to demonstrate that this remote approach to care can save time, reduce travel, and decrease caregiver burden.

To conduct the study, we partnered with the largest Parkinson disease patient organization in the country, the National Parkinson Foundation, and formed a patient advisory board with patients and patient advocates who contributed to the design of the trial and were involved throughout the project as advisors. We also assembled a dissemination and implementation advisory board to assist in disseminating the results of the research and drive broader adoption. The members of the National Parkinson Foundation and the Dissemination and Implementation advisory boards are identified in the **Ancillary Information** section of this report.

The study received approval from the institutional review boards of the University of Rochester (coordinating center protocol in January 2014 and enrolling site protocol in March 2014) and of the participating sites (**Appendix Table 1**). Study activities concluded in July 2016. We completed the primary data analysis July 28, 2016.

Participants

We designed the eligibility criteria to permit broad participation in the study. Participants self-reported access to specialist care upon screening, and individuals were able to enroll if they met the following criteria: (1) physically located in a state where a participating site investigator was licensed to practice medicine when visits were conducted; (2) clinically diagnosed with idiopathic Parkinson disease; (3) access to a nonpublic, Internet-enabled device with the capacity for videoconferencing; and (4) willing and able to provide informed consent. Participants were required to have a local health care provider (e.g., primary care physician, nurse practitioner) who the study team could contact to provide recommendations from the site investigators, and to live at home, in a senior housing complex, or in an assisted living facility. Individuals who were presently hospitalized, enrolled in another telemedicine study, or had a condition (e.g., prominent psychosis) that precluded study participation were excluded from study participation.

Potential participants identified their care partners—individuals who assisted them on a regular basis and who were not paid caregivers—and we invited these partners to enroll. Care partners were required to be adults who were willing and able to provide informed consent.

Recruitment

Based on our objective to reach those with limited access to care, we prioritized enrollment of individuals not currently seeing a neurologist (i.e., those not having seen a neurologist for 12 months) or coming from an underserved region, as identified by their ZIP code. We designed recruitment methods to reach the large number of patients with Parkinson disease who do not currently see a neurologist. To address disparities in access to care, we identified and targeted underserved areas nationally, in which a majority of Medicare beneficiaries diagnosed with Parkinson disease had not seen a neurologist.[16] Remote recruitment efforts included e-mails from NPF, sent to individuals who had previously requested to be informed about research in which NPF was participating; Google AdWords advertisements, which were targeted to ZIP codes previously identified as having a higher proportion of underserved individuals with Parkinson disease (i.e., individuals with a diagnosis of Parkinson disease who were not cared for by neurologists)[4]; postings on Fox Trial Finder (Michael J. Fox Foundation), a clinical trial announcement created and distributed in conjunction with the patient social networking site PatientsLikeMe; and posting on clinicaltrials.gov. The study team also asked participating sites to identify support groups that may include a large proportion of underserved patients with Parkinson

disease, and then distributed study flyers to these groups. Additionally, study team members identified primary care providers who might see a large proportion of Parkinson disease patients and sent study materials via fax to those practices in eligible states (ie, states in which participating providers were licensed to practice). The study team then followed up select faxes with phone calls.

We directed all individuals expressing interest in the study to the study Web site at http://Connect.Parkinson.org, which includes an explanatory video (https://youtu.be/naQQ53hT6zc) created by the study team using videoconferencing software and featuring patient advisory board member Sara Riggare and Principal Investigator Ray Dorsey. The Web site then featured a link to a brief enrollment interest survey, which asked individuals to submit their names, contact information, and state of residence, as a preliminary eligibility screening. We saved this contact information in a database that allowed the study team to contact individuals interested in the study when the sites where they might be eligible were able to enroll them.

We recruited and enrolled individuals with Parkinson disease at 18 of 20 IRB-approved sites and sent them educational materials about Parkinson disease created by NPF. We identified and selected 20 sites in 14 states (**Appendix Table 1**) through outreach to interested clinicians at NPF Centers of Excellence. Individuals who expressed interest in the study through the study Web site were subsequently screened by the University of Rochester coordinating site. Recruitment for the study began in February 2014.

Enrollment

Enrollment was completed in 2 parts: First, a study coordinator at the central site—the University of Rochester—contacted interested individuals to verify their eligibility and complete a more in-depth screening form. Once enrollment site staff determined that individuals were eligible and willing to enroll, the staff contacted the potential participants to obtain consent. Participants provided consent with a written signature on a printed consent form. We completed all study activities remotely, using e-mail, phone, fax, mail, and videoconferencing modalities to enable individuals to participate from home. We collected and managed study data using Research Electronic Data Capture (REDCap) tools hosted at the University of Rochester.[17] REDCap is a secure, Web-based application designed to support data capture for research studies, providing an interface for validated data entry; audit trails for tracking data manipulation and export procedures, automated export procedures for seamless data downloads to common statistical packages; and procedures for importing data from external sources if needed.

REDCap supports the use of electronic patient surveys and automated e-mail invitations, which we used in this study to allow participant-completed assessments to be completed securely from home, with the aid of a family member if needed.

We e-mailed to participants who enrolled a link to download secure Health Insurance Portability and Accountability Act–compliant virtual house call software from SBR Health (Cambridge, MA, USA). The software embeds videoconferencing software from Vidyo (Hackensack, NJ, USA) that is hosted by ID Solutions (Indianapolis, IN, USA), which uses 2-way encrypted video transmission to ensure privacy. SBR Health also created a virtual waiting room that allowed patients to "check in" for appointments. If participants did not have access to a Webcam, we mailed a Creative Labs (Jurong East, Singapore) Live! Cam Chat HD camera to them prior to their baseline assessment virtual house call. We created de-identified usernames for patients and e-mailed these to them in advance of their appointments along with the link to download the software. A study coordinator at the University of Rochester performed a test connection with the participants, providing technical support by phone if needed. No in-person technical support was sent to participants' homes.

We evaluated participants via videoconferencing and electronically administered surveys at baseline and at 12 months. At baseline, the survey tools included a baseline survey, which assessed the participants' demographics, usual care (including care partner assistance with activities of daily living and instrumental activities of daily living), travel time for Parkinson disease appointments, health history, usual computer and Internet use, and virtual house call technology access. The participants then completed a set of assessments of health, quality of life, and care that was repeated at the end of the study. They included an assessment of the participants' satisfaction with their current care, a 1-year health care resource utilization estimate,[18] an assessment of recommendations the participant had received for Parkinson disease treatment, the Parkinson's Disease Questionnaire 39 (PDQ-39),[19] the Patient Assessment of Chronic Illness Care (PACIC),[20] and the Geriatric Depression Scale 15 (GDS-15).[21-26] Independent raters blinded to treatment assignment completed remote baseline and end-of-study (12-month) assessments of Parkinson disease using the Movement Disorder Society Unified Parkinson Disease Rating Scale (MDS-UPDRS)[1] modified for remote assessment (e.g., excluding assessment of tone and balance).[28] Individuals who an independent rater believed not to have idiopathic Parkinson disease were withdrawn prior to randomization. A study team member also completed a remote Montreal Cognitive Assessment (MoCA)[29,30] at this visit, as well as recorded the participants' responses to a paper-based European Quality of Life Five Dimension Five Level Scale (EQ-5D-5L).[31]

Appendix Table 2 details additional baseline assessments completed by the participant/care partner and study staff. We electronically surveyed care partners at baseline and at the end of the study about the time and travel required to help the participant with his or her Parkinson disease appointments, and the perceived burden of caring for the participant, identified using the Multidimensional Caregiver Strain Index (MCSI).[32] All participant-completed study assessments were completed via secure survey links sent to their e-mail addresses using REDCap, while study teams entered data from each visit directly into the study database electronically.

Randomization

We randomized individuals 1:1 either to continue with their usual care or to continue their usual care plus receive virtual house calls from a specialist at 1 of 18 sites. The study's biostatistician (C.A.B.) generated the randomization allocation sequence using R version 3.0.2. Randomization was concealed from sites, was stratified by enrolling site, contained a block size of 4, and occurred after a baseline visit with a blinded rater. Because recruitment occurred primarily online rather than at the sites, sites (and their investigators) had limited opportunity to bias selection to favor 1 of the arms. We conducted randomization in the study's REDCap database after we completed the baseline assessments and confirmed the diagnosis of idiopathic Parkinson disease. We generated the randomization plan using validated software by a professional statistician. The process underwent strict quality control measures to ensure the treatment assignments were truly randomized. Programs were developed at the University of Rochester and have been used to generate randomization plans for dozens of clinical trials over the past decade.

Interventions

Control Group—Usual Care

The care the usual care (control) group received was variable but was a reflection of the status quo for Parkinson disease care in the United States. This group was free to seek out in-person specialty care over the course of the study. The content of these in-person visits were at the discretion of the patient and his or her in-person physician. We offered participants the opportunity to have a 1-time virtual house call with the Parkinson disease specialist at their site after their final study assessment.

Intervention Group—Virtual House Calls

Participants randomized to the intervention group were scheduled for virtual house calls from Parkinson disease specialists licensed in their state (site coinvestigators). The investigator set the visit schedule in consultation with the patient, with a suggested minimum of 4 visits in 12 months. We based this minimum on the preferred visit schedules of Parkinson disease specialists. Investigators completed the movement assessment portion of the MDS-UPDRS during the first and fourth virtual house calls and were surveyed about their satisfaction with the experience of performing the assessment virtually during these visits. During the first visit, the investigators performed a complete history as well as a complete Parkinson disease–specific examination. Time was always left for the participant to ask questions. Otherwise, visits were similar to regular in-person clinical visits for Parkinson disease; investigators assessed and made recommendations to patients as they would in their clinics.

Assessments were similar to those in the first visit but may have been shorter. Due to differences in state laws regarding the ability of physicians to prescribe medications on the basis of virtual house calls, the study protocol asked investigators not to make any changes to patients' care plans directly. Instead, the protocol asked investigators to provide a clinical note summarizing the visit and any recommendations for treatment to the patients and their local health care providers at the conclusion of each visit, allowing the participants' regular physicians to decide whether to act on these recommendations. The study team did not measure follow-through on these recommendations by participants' regular physicians.

Outcome Measures

Primary outcomes included (1) feasibility, defined as the percentage of virtual house call participants who complete at least 1 virtual house call as well as the overall percentage of completed virtual house calls, and (2) quality of life, measured by the change in the validated PDQ-39 from baseline to 12 months.

The study also included a variety of validated secondary outcome measures designed to evaluate many dimensions of the impact of virtual house calls on individuals with Parkinson disease and their care partners. Participant-reported outcomes included quality of care, measured by change in the PACIC,[20] time and travel savings from remote appointments, and change in caregiver burden as measured by the MCSI.[32]The study also evaluated participants for changes in depression, a common comorbidity with Parkinson disease,[33-35] using the GDS-15.[21-26] The Patient Global Impression of Change

scale[36] and the EQ-5D-5L [31] provided additional insights into changes in participant-reported quality of life. We also compared utilization of health care services such as hospitalizations, emergency room visits, and visits to primary care doctors[18] between the control and intervention arms to evaluate the impact of virtual house calls on health care needs. In addition, we also surveyed participants about aspects of their Parkinson disease care, including recommendations for the care of their Parkinson disease they had received over the past 12 months.

The study also included several investigator-reported secondary outcomes, selected to determine the impact of the virtual house calls on Parkinson disease–specific outcomes as assessed by the investigators and by the independent raters. We assessed the change in Parkinson disease signs and symptoms using change in the MDS-UPDRS[27] from baseline to 12 months as administered by the independent raters, and we evaluated cognitive changes using the MoCA.[29,30]

Sample Size

We selected the sample size of 200 Parkinson disease patients to ensure adequate power (80% to 90%) to detect a moderate effect size on the PDQ-39 (Cohen's d of 0.5—equivalent to a difference in means of half a standard deviation) using a 2-sided *t*-test at a significance level of 5%, allowing for the anticipated dropout rate of up to 20%. For the PDQ-39, an estimate of the standard deviation of change over 1 year is 12.2 units (based on 3300 participants in a quality initiative study). Therefore, for the PDQ-39 a Cohen's d of 0.5 translates to a difference in mean change over 1 year of 6.1 units.

Statistical Analyses

The aims of the study were to evaluate the feasibility, quality of life, clinical benefit, quality of care, and value of using virtual house calls to deliver specialty care to patients in their home. We summarize primary measures of feasibility using descriptive statistics. We considered virtual house calls to be feasible if 80% of participants in the virtual house calls arm completed at least 1 virtual house call and at least 80% of all virtual house calls were completed as scheduled. We performed the analyses according to the intention-to-treat principle and included all randomized participants.

We present baseline characteristics using summary statistics and compare them between treatment groups using Fisher's exact test for nominal data and the exact Wilcoxon rank-sum test for ordinal and continuous data (**Tables 1** and **2**).

The PDQ-39 was the primary efficacy outcome measure of this study. For this outcome, we fit an analysis of covariance (ANCOVA) model with the change in PDQ-39 from baseline to 1 year as the response, treatment group as the factor of interest, participating physician (site) as a stratification factor, and baseline PDQ-39 as a covariate. We performed a *t*-test to compare the adjusted treatment group means. Also, we investigated the interaction between treatment group and baseline PDQ-39 by including the appropriate term in the ANCOVA model and testing for its significance. We thoroughly checked the underlying assumptions of the ANCOVA models. We assessed the robustness of the analyses to these assumptions by repeating the primary analysis after excluding outliers identified by the model (based on standardized residuals larger than 3 units in absolute magnitude). In all cases, the removal of a small number of outliers resulted in models that satisfied the linearity, normality, and homoscedasticity assumptions.

The primary efficacy analysis included only those participants who completed all items of the PDQ-39 at both baseline and end of study. We also performed secondary analyses to evaluate the sensitivity of this approach by imputing missing data according to a standard multiple imputation algorithm. Specifically, we used Multivariate Imputation by Chained Equations[37,38] (MICE) to impute missing individual items on the PDQ-39 based on the available (nonmissing) items at both baseline and end of study. We used predictive mean matching to preserve the ordinal scale of the individual PDQ items. We generated each imputed data set using 25 cycles (burn-in iterations), and repeated this 50 times to produce 50 multiply imputed data sets.

We similarly analyzed secondary measures of quality of life, clinical benefit, quality of care, value to patients and care partners, and time and travel savings. For travel savings, we asked participants in both the control and treatment groups how much time the visit took (in minutes) from the time they left home until the time they returned home. We performed all statistical tests at the 2-sided significance level of 5%, and made no corrections for multiple testing.

Qualitative Analyses

We collected qualitative data at the end of each virtual house call (including the 1-time virtual house calls offered to control participants). We asked the participants 3 questions, which they were prompted to answer in free-text response form:

1. Please let us know what you liked about your virtual house call.
2. Please let us know what you did NOT like about your virtual house call.

3. Please provide any feedback about the visit.

We also asked the investigators to provide any feedback about performing the motor assessment remotely, and to provide any general comments.

We analyzed data from 149 participants and all investigators using case-based qualitative content analysis and quantitative sentiment analysis techniques. We coded data for sentiment (positive, negative, neutral) and concepts associated with each sentiment, and then pattern coded them to identify common themes within the data. For the quantitative sentiment analysis, we assigned comments a binary score (–1 for negative sentiment and +1 for positive sentiment) and calculated summary statistics.

PCORI Methodology Standards

This study adhered to the PCORI Methodology Standards for research questions and patient centeredness by involving patients, patient advocates, and other stakeholders in the planning, design, and ongoing conduct of the study through the patient advisory board and the involvement of investigators from the National Parkinson Foundation. All parts of the design and implementation process involved representatives of Parkinson disease patient communities, including patients and patient advocates, as well as physicians and experts from related but different specialties, such as geriatrics. This engagement ensured that the study evaluated outcomes relevant to patients and families, as well as to the medical research team.

This study met PCORI Methodology Standards for data integrity and rigorous analysis in several ways. First, we preplanned the data analysis and included this in the study protocol, and we performed the primary analysis reported here as planned. We chose a number of previously validated scales and indices to evaluate research questions, and also wrote new questions with the help of patient and patient advocate stakeholders. To address study aims, we selected previously validated measures such as the PDQ-39,[19] MDS-UPDRS,[27] PACIC,[20] GDS-15,[22-26,34] MoCA,[29,30] EQ-5D-5L,[31] MCSI,[32] and the Patient Global Impression of Change (PGIC) scale, all of which are widely used in clinical trials.

To comply with the methodology standards for missing data, we designed the study to allow for easy completion of study assessments and forms through electronic data collection in REDCap. Coordinators at the University of Rochester monitored data, and the study's biostatistician, under the direction of the Primary Investigator, reviewed data regularly. We designed assessments to allow

participants to skip questions they did not wish to answer, but acknowledged this could result in unintentionally incomplete responses to assessments. When participants were missing a response, coordinators reviewed the assessments with the participants over the phone or during video calls prior to randomization or end-of-study evaluation. We performed secondary analyses to evaluate the sensitivity of this approach by imputing missing data according to a standard multiple imputation algorithm (as described above). We were not able to collect some missing data, and the analyses have accounted for these missing values as described.

The study followed PCORI's standards for heterogeneity of treatment effect; we conducted analyses according to the prespecified analysis plan, which included tests of treatment interaction with baseline scores. The analysis also evaluated the impact of assumptions on outcomes. We summarized primary measures of feasibility using descriptive statistics. We thoroughly checked the underlying assumptions of the ANCOVA models, and when we detected serious violations, we assessed the robustness of the analyses to these assumptions by performing supportive analyses after taking remedial measures (eg, transformations, deletion of outliers). The purpose of the heterogeneity of treatment effect analyses was to demonstrate consistency of the treatment effect across subgroups. We used the supportive analyses to examine the sensitivity of the results to missing data and deviations from the underlying model assumptions. For the former, we used MICE to impute missing data and compared the results with analyses excluding missing data. For the latter, we used standard residual diagnostics to identify and exclude outliers, as well as influential and high-leverage data points, and we compared the results with analyses including all data. We observed no meaningful differences across all these analyses, so we present only the primary (prespecified) analyses.

Methodology standards for causal inference are applicable to our study, which addressed these standards in the following ways. First, we asked investigators to report visits as soon as they occurred, which triggered the participants they had seen to receive their virtual house call evaluations. This helped ensure that participants' experiences with their virtual house calls were easily recalled. We addressed participant withdrawals and losses to follow-up in the statistical analysis (by imputing missing data in a sensitivity analysis for anyone with at least a baseline assessment) to ensure that the participants who remained in the study did not have systematic differences from those who did not. Had there been a systematic difference, this would have suggested a bias in our results. We selected the study duration to allow sufficient time for changes in quality of life and care to occur. We chose randomization to minimize the effects of potentially confounding variables. By allowing individuals assigned to the control

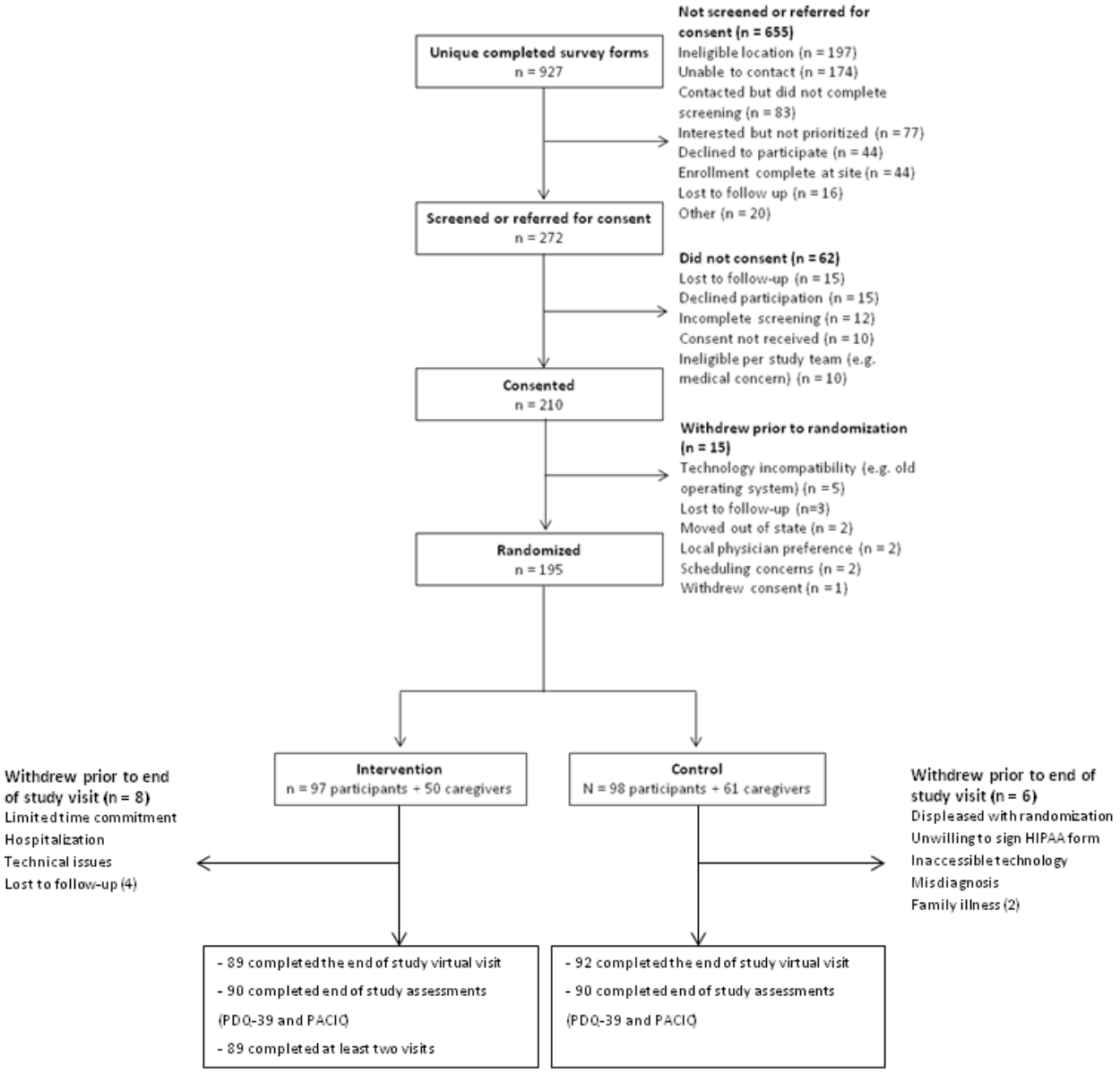
group to continue their care as usual without restriction, this group was meant to be an accurate representation of the care many patients with Parkinson disease currently receive.

Results

Enrollment

We previously published baseline enrollment data and participant characteristics in *Telemedicine Journal and e-Health*.[39] As described previously, 11 734 individuals from 50 states and 80 counties visited the 1-page study Web site from February 1, 2014, to August 25, 2015. Of the individuals who viewed the Web site, 1704 (15%) clicked through to the study interest form, and 927 (8%) completed it. Most (79%) forms came from individuals in eligible states (ie, states in which investigators were licensed to practice), potentially because individuals in states that were not eligible were shown a message indicating as much and offering them the opportunity to submit their contact information for future contact in the event that a site became available. Initial interest was high, and given the study's emphasis on prioritizing the underserved, we initially prioritized individuals who were not seeing a Parkinson disease to the exclusion of 77 others. We eventually excluded another 44 individuals because enrollment was complete in their state's site. Ultimately, 272 individuals were referred to 18 sites to be consented. Of these individuals with Parkinson disease, 210 enrolled in the study, and 195 were eventually randomized. Initially, 111 care partners also enrolled in the study. Eventually, 181 individuals with Parkinson disease and 70 care partners completed the study (**Figure 1**).

Figure 1. *Participant Flow Through the Study*



The study team also evaluated referral sources into the study to determine the effectiveness of the various online recruitment efforts. Most participants learned about the study from the National Parkinson Foundation's Web site (339), PatientsLikeMe (204), and Fox Trial Finder (132). The least effective referral sources were those not directly provided by the study team, such as "Other social networking site" (9), where the study Web site or other online listings may have been reposted, "Primary care provider" (3), and Twitter (2).[39]

Baseline Characteristics of the Study Population

Table 1 reports the baseline characteristics of all randomized study participants, which we also reported previously.[39] Of the participants, 15 withdrew or were lost to follow-up prior to their baseline assessment and randomization visit, most commonly due to technological incompatibilities (eg, old operating systems or unsupported devices, or very slow Internet connections). The characteristics of those who withdrew were similar to those who were randomized. **Table 1** shows the baseline characteristics of the study participants with Parkinson disease by group, while **Table 2** shows the baseline characteristics of their participating care partners. The control group differs significantly ($p < 0.05$) from the treatment group in 2 ways: the percentage of individuals who have used a computer to participate in a video chat (63% of control participants had done so, while 44% of treatment arm participants had done so), and in the percentage of individuals who had seen a Parkinson disease specialist in the previous 12 months (81% of control participants had done so, while 66% of treatment arm participants had done so). These differences may have impacted our results, as more control participants than treatment group participants had seen a Parkinson disease specialist in the 12 months prior to enrollment.

Table 1. Baseline Characteristics of the Study Population

	All Randomized Participants (*n* = 195)	**Virtual House Calls (*n* = 97)**	**Usual Care (*n* = 98)**	**Difference (*p*-value)**
Demographics				
Age as of screening (mean ([SD])	66.4 (8.1)	65.9 (7.8)	66.9 (8.5)	0.25
Women (*n* [%])	91 (46.7)	49 (50.5)	42 (42.8)	0.32
Race (*n* [%])				0.43

White	187 (95.9)	92 (94.9)	95 (96.9)	
Other	3 (1.5)	3 (3.1)	0 (0)	
Did not answer/unknown	5 (2.6)	2 (2.1)	3 (3.1)	
Ethnicity (*n* [%])				1.0
Hispanic/Latino	3 (1.5)	1 (1.0)	2 (2.0)	
Not Hispanic/Latino	183 (93.9)	92 (94.9)	91 (92.9)	
Prefer not to answer/unknown	9 (4.6)	4 (4.1)	5 (5.1)	
Bachelor's degree or higher education (*n* [%])	143 (73.3)	71 (73.2)	72 (73.5)	0.083
Presently married	151 (77.4)	75 (77.3)	76 (77.6)	0.98
Participants with care partners, relationship to participant (*n* [%])				0.71
Spouse/partner	132 (67.7)	63 (65.0)	69 (70.4)	
No response/no care partner	54 (27.7)	29 (29.9)	35 (35.5)	
Child/grandchild	7 (3.6)	3 (3.1)	4 (4.1)	
Other	2 (1.0)	2(2.1)	0 (0)	
Internet Use and Familiarity				
Participants who use the Internet or e-mail at home (*n* [%])	187 (95.9)	95 (97.9)	92 (93.9)	1.0
Participants who have ever used the Internet to look for health or medical information online (*n* [%])	189 (96.9)	96 (99.0)	93 (94.9)	0.37
Participants who have ever used their desktop or laptop computer to participate in a video call or video chat (*n* [%])	105 (53.8)	43 (44.3)	62 (63.3)	0.012*
Clinical Characteristics				
Parkinson disease duration – year (*n* = 185) (mean [SD])	8.0 (5.6)	8.3 (6.15)	7.6 (4.9)	0.73
Movement Disorder Society Unified Parkinson's Disease Rating Scale, Part 1A (0–24)[a]	4.6 (3.8)	4.3 (3.5)	4.8 (4.1)	0.56

Movement Disorder Society Unified Parkinson's Disease Rating Scale, Part 1B (0–28)[b]	10.3 (4.4)	10.7 (4.5)	10.0 (4.4)	0.22
Movement Disorder Society Unified Parkinson's Disease Rating Scale, Part 2 (*n* = 194) (0–52)[b]	14.7 (7.6)	15.4 (8.5)	14.1 (6.7)	0.51
Modified Movement Disorder Society Unified Parkinson's Disease Rating Scale, Part 3 (0–108)[a,b]	28.9 (10.0)	29.5 (10.2)	28.3 (9.9)	0.40
Movement Disorder Society Unified Parkinson's Disease Rating Scale, Part 4 (*n* = 194) (0–24)[a]	4.5 (4.8)	4.7 (4.9)	4.2 (4.7)	0.59
Montreal Cognitive Assessment score (0–30)[c]	26.2 (2.8)	26.1 (2.7)	26.4 (2.9)	0.22
Parkinson's Disease Questionnaire 39 total score (*n* = 177) (0–100)[a]	25.4 (13.9)	26.3 (15.2)	24.6 (12.6)	0.57
EQ-5D-5L (–1)[c]	0.8 (0.1)	0.8 (0.1)	0.8 (0.1)	0.098
Geriatric Depression Scale 15 (*n* = 190) (0–15)[a]	4.1 (3.2)	4.1 (3.2)	4.1 (3.2)	0.77
Patient Assessment of Chronic Illness Care composite score (*n* = 182) (1–5)[c]	2.4 (0.9)	2.4 (0.9)	2.4 (0.9)	0.97
Parkinson Disease Care				
Participants who have seen a general neurologist for Parkinson disease in past 12 months (*n* [%])	85 (43.6)	48 (49.5)	37 (37.7)	0.15
Participants who have seen a Parkinson disease specialist in the past 12 months (*n* [%])	143 (73.3)	64 (66.0)	79 (80.6)	0.022*
Participants who are satisfied or very satisfied with their current Parkinson disease care (*n* [%])	143 (73.3)	67 (69)	76 (77.5)	0.55
Number of emergency room visits in the past 12 months (*n* = 194) (mean [SD])	0.66 (1.95)	0.84 (2.47)	0.48 (1.23)	0.12
Number of times admitted to the hospital overnight in the past 12 months (mean [SD])	0.23 (0.62)	0.24 (0.67)	0.21 (0.56)	0.75

Note: All values are mean (standard deviation) unless otherwise noted.
The number of responses is 195 unless otherwise noted.
[a] Higher scores indicate greater disability
[b] Excludes "rigidity" and "postural stability" assessments, which cannot be performed remotely
[c] Lower scores indicate greater disability/dissatisfaction
[*] Statistically significant $p < 0.05$

Table 2. Baseline Characteristics of the Participating Care Partners of Randomized Participants

	Care Partners of Randomized Participants (*n* = 111)	**Treatment (*n* = 50)**	**Control (*n* = 61)**	**Difference (*p*-value)**
Women (*n* [%])	67 (60.4)	29 (58.0)	38 (62.3)	0.70
Age	64.6 (9.2)	64.4 (8.7)	64.8 (9.7)	
Bachelor's degree or higher education (*n* [%])	61 (56.0)	26 (52.0)	35 (57.4)	0.20
Ethnicity (*n* [%])				1
Hispanic/Latino	1 (0.9)	0 (0)	1 (1.64)	
Not Hispanic/Latino	92 (82.9)	42 (84.0)	50 (82.0)	
Prefer not to answer/unknown	18 (16.2)	8 (16.0)	10 (16.4)	
Race (*n* [%])				0.53
White	88 (79.3)	38 (76.0)	50 (82.0)	
Other	7 (6.3)	5 (10.0)	2 (3.3)	
Prefer not to answer/unknown	16 (14.4)	7 (14.0)	9 (14.8)	
Multidimensional Caregiver Strain Index score (*n* = 80) (0–72)[a]	11.6 (9.5)	11.2 (8.5)	12 (10.4)	0.90

Note: Values are mean (standard deviation) unless otherwise noted.

[a] Higher scores indicate higher amounts of strain for caregiver

Indeed, at the 5% significance level one should expect to see 5% of the baseline characteristics statistically significant (by definition of significance level). The 2 "large" differences referenced are in fact the only 2 significant baseline differences we found (*p*-values of 0.02 and 0.01). Given that we tested more than 50 baseline characteristics, finding only 2 *p*-values less than 5% is not surprising. These 2 *p*-values would not survive any sort of correction for multiplicity. The demographics of the study population reveal a group of mostly white (96%), college-educated (73%) men (53%), who are a mean of 66 years old and have an average Parkinson disease duration of 8 years. Despite the efforts to enroll individuals with limited access to specialty care for Parkinson disease, nearly half of study participants' usual care involved a neurologist and for almost 75% a Parkinson disease specialist. Only 3% of participants had seen neither a general neurologist nor a movement disorders specialist in the 12 months prior to the study, but 55% were from counties in which less than half of Medicare beneficiaries with Parkinson disease receive care from neurologists.

The mean baseline PDQ-39 score of 25.4 out of 100 indicates mild perceived impairment, though the standard deviation of 13.9 points indicates a broad spread. Participants rated their current chronic illness care as average, with a mean PACIC score of 2.4 out of 5 at baseline. We used the ZIP codes of participants' home addresses and those of their Parkinson disease provider's office to compute probable driving distances for participants to see their Parkinson disease providers, and we found that participants travel a median of 38 miles round trip (interquartile range 17 to 133 miles) for each Parkinson disease care visit. Care partners' demographics closely mirror those of the participants: They are 79% white and 54% college educated.[39]

It should be noted that scored assessments included on electronic, patient-completed assessment forms (including the PDQ-39, the MDS-UPDRS patient-completed portions, the PACIC, and the GDS-15) were prone to incomplete data collection. This was because we did not create all survey answers to be "required" in order to complete the form. We used electronic assessment forms to enable patients and care partners to participate entirely remotely and to improve convenience for participants and care partners, but this may have influenced respondents' ability to verify the completeness of their data. Research assistants who were not blinded to treatment assignment made an effort to recover the missing data in baseline assessment appointments (prior to randomization) and via telephone at end-of-study assessments by asking participants whether they would be willing to answer missing questions. This resulted in inconsistent completion of these indexes and missing data for both participants with

Parkinson disease and care partners. We completed the statistical analysis using a dataset excluding those individuals with incomplete questions, as well as using multiple imputation methods to include anyone with missing data. The sensitivity analyses that imputed missing data or excluded outliers revealed negligible differences from our main analyses, mainly due to the low fraction of missing information and the few number of outliers.

Primary Outcomes

We measured feasibility of virtual house calls by the percentage of individuals who completed at least 1 virtual house call and by the percentage of virtual house calls completed as scheduled. Of the 97 individuals randomized to the intervention group, 95 (98%) completed at least 1 virtual house call, and 92 (95%) of the 97 completed at least 3 virtual house calls. Finally, 84 individuals (87%) of those randomized to the treatment group completed all 4 virtual house calls (76, or 78%, completed all 4 as scheduled). Overall, 92% of virtual house calls in the study were completed as scheduled. The most common reasons for not completing visits as scheduled were last-minute schedule conflicts, software incompatibility, deleted software, and compromised Internet connection. Of the 98 individuals randomized to the control group, 90 (92%) individuals successfully completed both the baseline and end-of-study virtual house calls, and 48 (49%) individuals took advantage of the optional 1-time virtual house call after study completion. Excluding 1 outlier (277 visits) in the intervention group, the number of visits to the local clinician was similar between the 2 groups (2.5 in-person visits in the virtual house call group and 3.0 in-person visits in the usual care group; $p = 0.14$).

The primary efficacy outcome was patient-reported change in Parkinson disease–specific quality of life, as measured by the PDQ-39. As shown in **Table 4**, quality in life as measured by the PDQ-39 did not differ but increased in both groups. However, the change did not differ between treatment groups (both groups scored 0.3 points lower on a 100-point scale (lower score corresponds to better quality of life); 95% CI –2.0 – 2.7 points; $p = 0.78$).

Secondary Outcomes

Patient assessment of quality of care improved from baseline similarly in both groups: by 0.3 points (95% CI 0.1 – 0.5; $p = 0.01$) in those randomized to virtual house calls and 0.3 points (95% CI 0.1 – 0.4; $p = 0.02$) in those randomized to usual care.

We assessed value to patients and care partners using various measures of time, travel, and caregiver strain. At baseline, participants reported spending a median of 120 minutes from leaving the house to returning for their most recent Parkinson disease appointment, with 30 (25%) of those minutes spent with a provider. By contrast, at the end of the study, participants in the treatment group reported spending a median of 40 minutes on their last Parkinson disease appointment, 30 minutes (75%) of which were spent with the provider, while control group participants still spent a median of 120 minutes on their last Parkinson disease appointment, 30 minutes (25%) of which were spent with a provider (**Table 3**). **Table 4** reports the end-of-study, patient-reported time and travel requirements for Parkinson disease–related appointments and differences in overall health care resource utilization at the end of the study. Compared with usual in-person care, virtual house calls saved patients time (median of 80 minutes per visit [95% CI 70-120; $p < 0.0001$]) and travel (median of 38 miles round trip per visit [95% CI 36-56; $p < 0.0001$]). Although the treatment group experienced significantly less total visit time and a significantly higher proportion of time spent with the provider, no difference existed between the groups in number of hospitalizations or ER visits (both were quite low). Treatment group participants reported more frequent visits to their primary care provider during the year-long study than the control group (3 visits as opposed to 2.33; $p = 0.0364$). We observed no significant change in caregiver strain from baseline to the end of the study (**Table 4**).

Table 3. Time and Travel to Most Recent Appointment—Baseline and End of Study

		All Randomized Participants	**Treatment**	**Control**	***p*-Value**
Total minutes spent on appointment (median [interquartile range])	**Baseline**	120 (90 to 240) (*n* = 194)	120 (90 to 240) (*n* = 97)	120 (90 to 240) (*n* = 97)	0.52
	End of study	60 (35 to 135) (*n* = 157)	40 (29 to 45) (*n* = 69)	120 (89.5 to 225) (*n* = 88)	**< 0.0001**
Minutes spent with Parkinson disease provider (median [interquartile range])	**Baseline**	30 (20 to 45) (*n* = 195)	30 (20 to 45) (*n* = 97)	30 (20 to 45) (*n* = 98)	0.85
	End of study	30 (20 to 45) (*n* = 180)	40 (20 to 45) (*n* = 92)	30 (20 to 45) (*n* = 88)	0.43

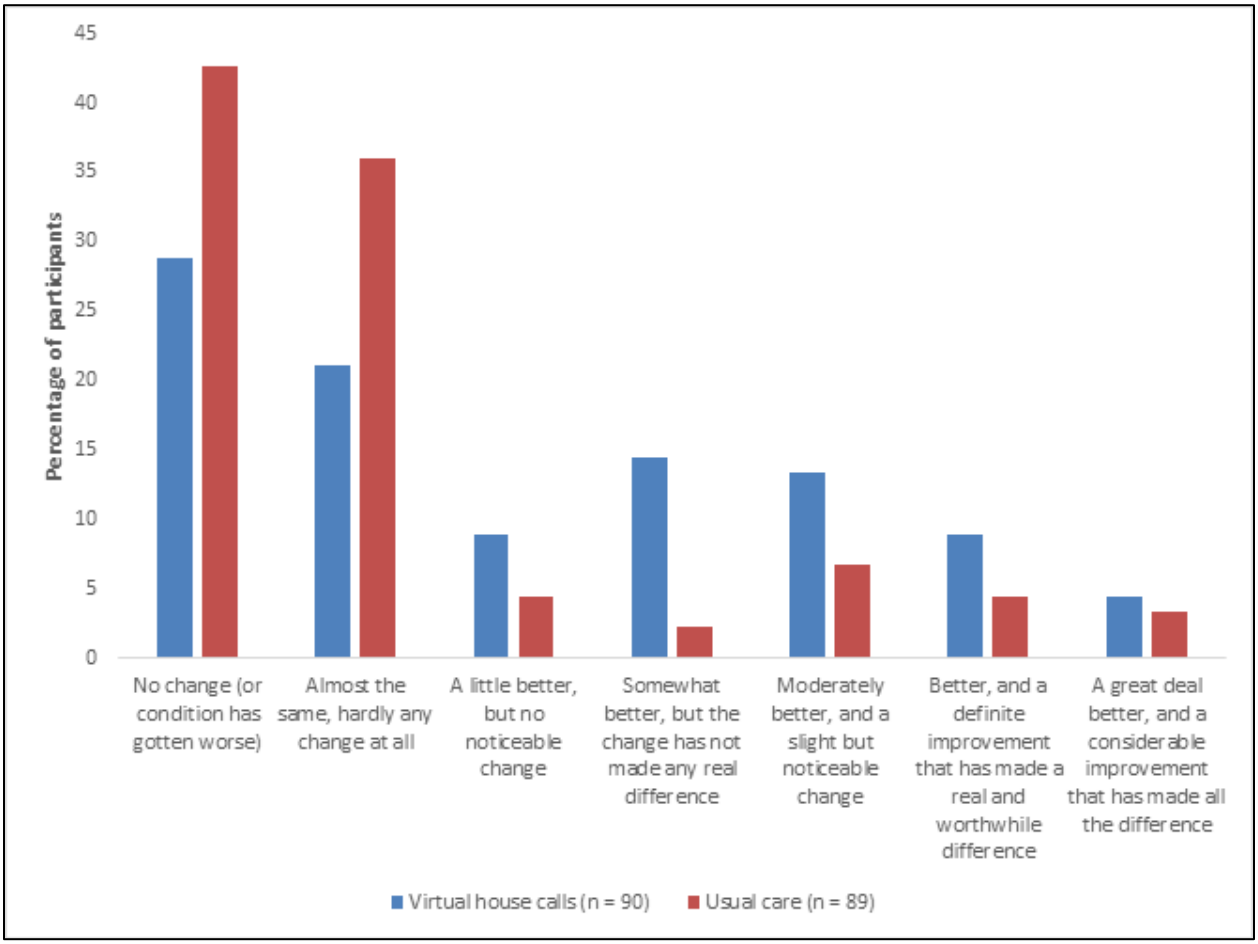
Table 4. Primary and Secondary Outcomes

Measure	Mean Change in Virtual House Call Group (95% CI), *n* = 97	Mean Change in Usual Care Group (95% CI), *n* = 98	Mean Difference Between Groups (95% CI)	*p*-Value
Primary Outcome Measure				
Parkinson's Disease Questionnaire 39 (*n* = 160)	–0.4 (–2.4 to 1.6)	–0.8 (–2.6 to 1.1)	0.3 (–2.0 to 2.7)	0.78
Participants who completed at least 1 virtual house call (*n* [%])	95 (98)	NA	NA	
Virtual house calls completed as scheduled per patient (mean [SD])	3.66 (0.80)	NA	NA	
Secondary Outcome Measures				
Patient Assessment of Chronic Illness Care (*n* = 167)	0.3 (0.1 to 0.5)	0.3 (0.1 to 0.4)	0.0 (–0.2 to 0.3)	0.79
Caregiver Strain Index (*n* = 51)	0.3 (–3.0 to 3.6)	0.5 (–2.2 to 3.3)	–0.2 (–4.4 to 3.9)	0.90
Movement Disorder Society-Unified Parkinson Disease Rating Scale, Part 1A (*n* = 181)	–0.8 (–1.4 to –0.2)	–1.0 (–1.6 to –0.4)	0.2 (–0.6 to 0.9)	0.68
Movement Disorder Society-Unified Parkinson Disease Rating Scale, Part 1B (*n* = 177)	0.1 (–0.6 to 0.9)	0.4 (1.1 to 0.3)	–0.3 (–1.2 to 0.7)	0.57
Movement Disorder Society-Unified Parkinson Disease Rating Scale, Part 2 (*n* = 176)	0.1 (–0.8 to 1.1)	–0.3 (–1.3 to 0.7)	0.5 (–0.8 to 1.7)	0.46
Modified Movement Disorder Society-Unified Parkinson Disease Rating Scale, Part 3 (*n* = 177)	–5.7 (–7.7 to –3.7)	–4.9 (–6.8 to –3.0)	–0.8 (–3.3 to 1.6)	0.51
Modified Movement Disorder Society-Unified Parkinson Disease Rating Scale, Part 4 (*n* = 180)	–0.2 (–1.0 to 0.7)	–0.2 (–1.0 to 0.6)	0.0 (–1.0 to 1.1)	0.96
Geriatric Depression Scale (*n* = 175)	0.2 (–0.4 to 0.7)	–0.0 (–0.5 to 0.5)	0.2 (–0.5 to 0.8)	0.62
Montreal Cognitive Assessment (*n* = 180)	0.6 (0.1 to 1.2)	0.2 (–0.3 to 0.7)	0.4 (–0.2 to 1.1)	0.16
EQ-5D-5L (*n* = 180)	0.0 (–0.1 to 0.0)	0.0 (–0.1 to 0.0)	0.0 (0.0 to 0.0)	0.32
Number of emergency room visits in the past 12 months (*n* = 181)	0.5 (0.4 to 0.7)	0.7 (0.3 to 1.0)	0.1 (–0.3 to 0.5)	0.38

Number of times admitted to the hospital overnight (*n* = 181)	0.2 (0.1 to 0.3)	0.3 (0.2 to 0.4)	0.1 (–0.1 to 0.2)	0.32

Overall quality of life, as measured by the EQ-5D-5L index value and visual analogue scale, declined slightly in both groups, but the analysis did not reveal a treatment effect (**Table 4**). Additional secondary outcomes evaluated the impact of specialist care on the quality of participants' care. No significant difference existed in ER visits or overnight admissions to the hospital in the past year between control and treatment group participants at the end of the study (**Table 4**). Most clinical outcomes did not show significant treatment effects. However, the patients' global impression of change (**Figure 2**) was significantly favorable for those receiving virtual house calls (50% versus 32% randomized to the control group reported feeling at least "a little better"; $p = 0.002$). Participants randomized to virtual house calls reported that since the beginning of the study, their "activity, limitations, symptoms, emotions, and overall quality of life" were significantly better than controls. With encouragement from study investigators and PCORI's support, we performed a qualitative analysis of free-text responses to identify underlying themes related to satisfaction of patients and providers.

Figure 2. *Participant-Rated Patient Global Impression of Change (n = 179): "Since beginning treatment, how would you describe the change (if any) in activity limitations, symptoms, emotions, and overall quality of life, related to your painful condition?"*



Another important aspect of the study's evaluation of value to patients and care partners concerned patient satisfaction with and attitudes toward virtual house calls. **Figure 3A** illustrates participants' satisfaction with various aspects of virtual house calls throughout the study. Treatment group participants completed a survey at the conclusion of their final virtual house call to compare virtual house calls with their usual in-person visits; **Figure 4** displays these results. To further evaluate the feasibility and acceptability of this method of providing care, we also surveyed participating investigators about their experiences with each virtual house call (**Figure 3B**). Overall, Parkinson disease patient and provider satisfaction with virtual house calls was very high. Provider satisfaction with virtual house calls was slightly lower than that of patients.

Figure 3A. *Patient Satisfaction with Virtual House Calls (n = 320)*

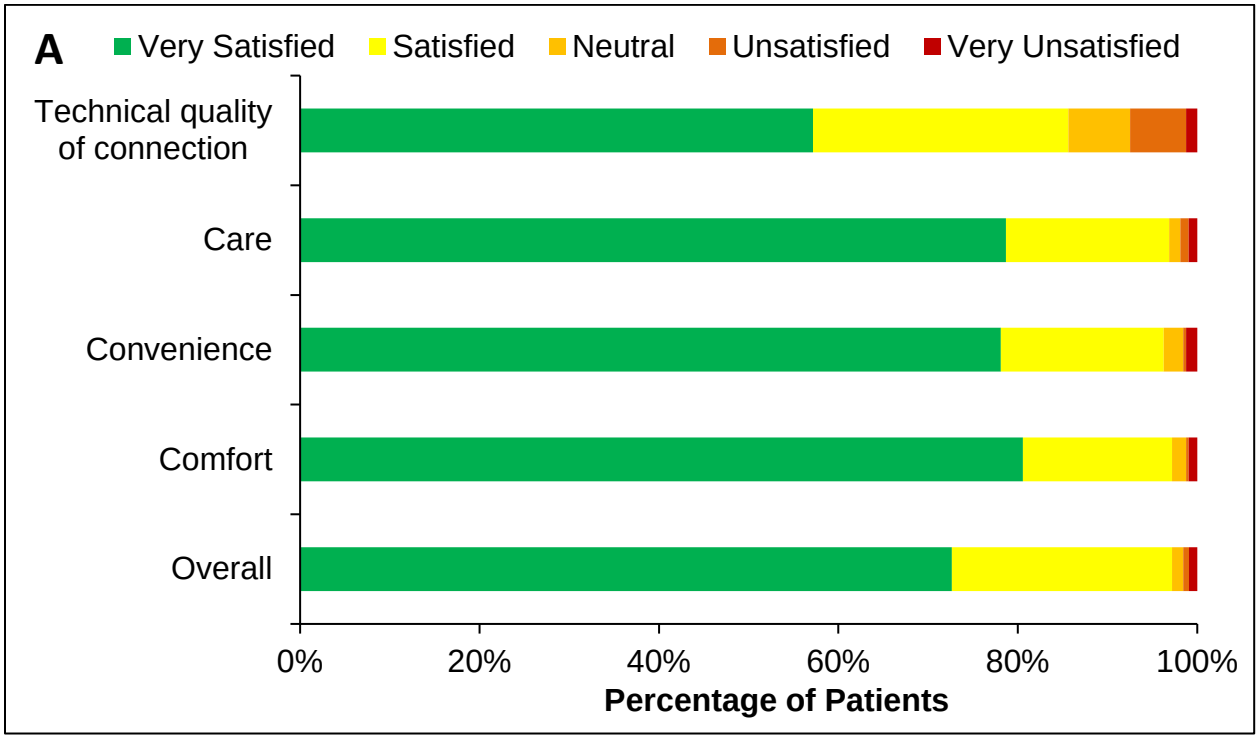


Figure 3B. *Physician Satisfaction with Virtual House Calls (n = 361)*

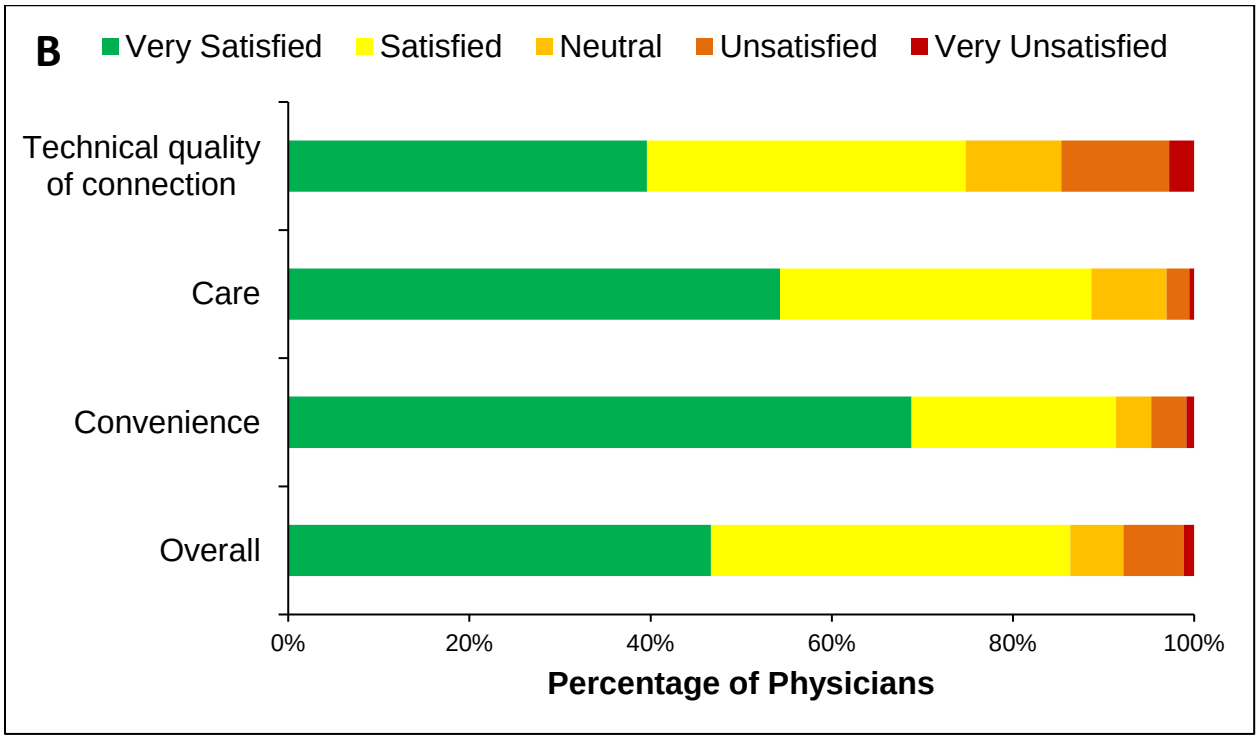
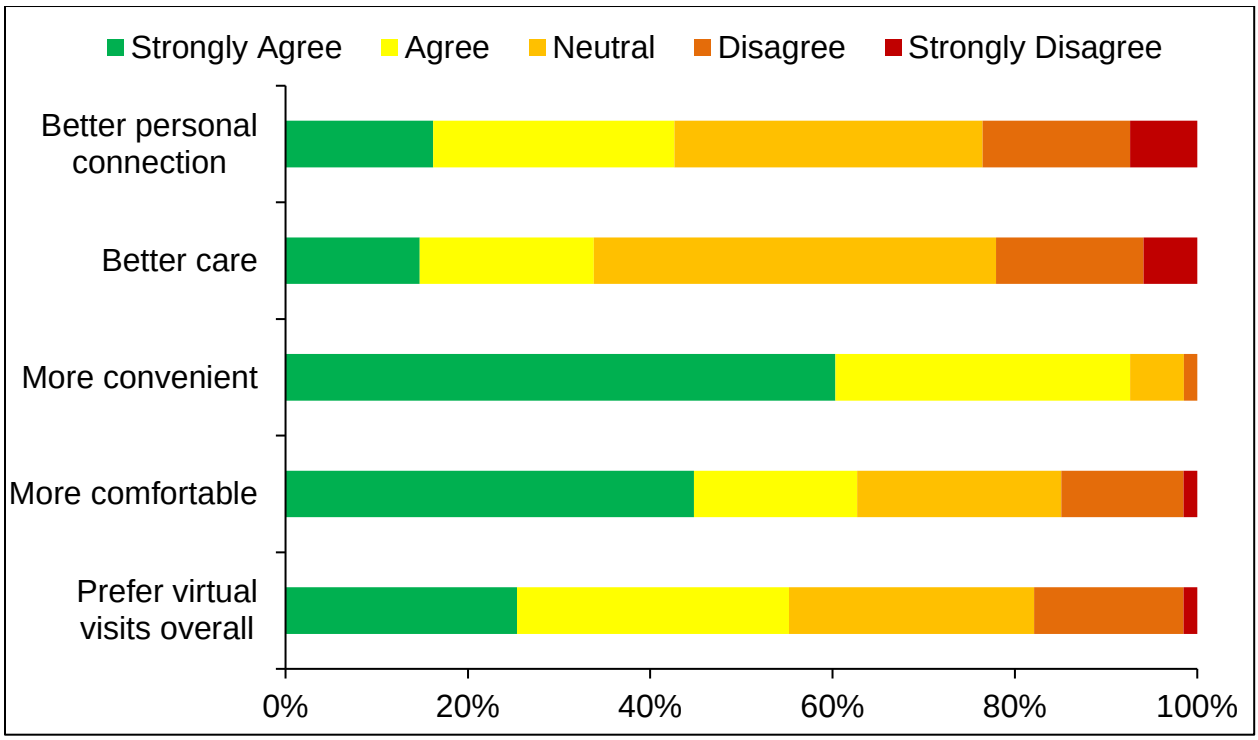


Figure 4. *Participants' Relative Preference of Virtual House Calls with Remote Specialist Versus In-person Visit With Usual Parkinson Disease Provider Across Different Dimensions (n = 68)*



Qualitative Results

Three common themes drove positive and negative perceptions of virtual house calls: (1) personal benefits of the virtual house call, (2) perceived quality of care, and (3) perceived quality of interpersonal engagement. In general, participants who identified greater personal benefit, high quality of care, and good interpersonal engagement perceived visits positively. Technical problems with the software were commonly mentioned. The sentiment analysis for patients was strongly favorable (+2.5) and moderately favorable for physicians (+0.8). Physician scores were lowest (–0.3) for the ability to perform a detailed motor examination remotely.

Discussion

In a national, randomized controlled trial, the Connect.Parkinson study demonstrated that specialty care can be delivered remotely in the homes of individuals with Parkinson disease using increasingly ubiquitous videoconferencing technology to conduct virtual house calls with patients and their care partners. Connect.Parkinson demonstrated that virtual house calls using patients' own

computers, tablets, and smartphones were feasible, highly satisfactory to patients, and valuable in terms of time and travel savings for patients and their care partners. The study did not find significant differences in Parkinson disease–related quality of life over the course of the study in either the treatment or control groups as measured by the PDQ-39 questionnaire. However, the patients' global impression of change was significantly favorable for those randomized to receive virtual house calls.

The study met the prespecified criteria for feasibility, as we determined the method would be feasible if at least 80% of treatment group participants completed at least 1 virtual house call, and 98% of those randomized to the treatment group completed at least 1. In addition, 84% of those randomized to the treatment group completed all 4-virtual house calls as scheduled.

The primary efficacy outcome in this study was change in Parkinson disease–related quality of life, as measured using the PDQ-39. The final analysis did not find a significant treatment effect on PDQ-39. Given that 81% of individuals in the control group had seen a Parkinson disease specialist at baseline compared with 66% of the treatment group, the lack of improvement may be due to the high access to specialty care at baseline. In addition, the greater access to specialty care in the control arm may have biased the results toward finding no benefit from the addition of the virtual house calls. Future studies should examine the effect solely on populations that have more limited access to specialty care to determine whether there might be a more significant impact. In addition, due to differences in state laws regarding the ability of physicians to prescribe medications, the study protocol asked investigators not to make any changes to patients' care plans directly. Greater benefit may have been possible if the specialists providing care had been able to prescribe medication or other care rather than having to rely on local clinicians to implement changes.

Virtual house calls save patients and their families a great deal of time and travel burden. Participants in both groups reported spending a median of 30 minutes with the provider at their most recent Parkinson disease–related visit, but the control group reported a median total visit time (including travel, parking, and waiting to see the doctor) of 120 minutes, while the treatment group reported a median of 40 minutes. This means that those receiving virtual house calls spent a greater proportion of their time, when compared with the control group, seeing the doctor rather than traveling or sitting in a waiting room. Participants were highly satisfied with their virtual house calls, and 93% reported that virtual house calls were more convenient than their usual in-person visits. A majority (55%) of participants "agreed" or "strongly agreed" that they prefer virtual house calls to in-person visits. Overall satisfaction with care, convenience, and comfort of virtual house calls on the part of

patients was very high, demonstrating that this model provides great subjective value to patients. Though slightly less enthusiastic, providers also found virtual house calls satisfactory. This could be interpreted as the investigators having a slightly more tempered consideration of the virtual house call process or frustration with the inability to remotely feel for rigidity. Providers particularly felt limited by the difficulties of performing movement and tactile assessments that they would normally perform in person.

This study also demonstrates several problems that should be anticipated with a large-scale implementation of virtual house calls using telemedicine software. Some sites struggled with technical problems when installing or setting up their software due to institutional firewalls and other site-specific network, regulatory, and security challenges. Once these were addressed, the sites would occasionally continue to have difficulty connecting to patients. Participants also confronted multiple technical problems that required study team assistance. In particular, because operating systems and security software are constantly being updated and changed, participants would occasionally be unable to run the telemedicine program. In other instances, participants forgot how to log in, how to call in at their appointment times, or how to run the program on their computer. Others had to replace their devices midstudy, and did not realize that they had not reinstalled the software. This could cause delays and the need to reschedule visits, as participants would sometimes discover at the time of the appointment that they were no longer able to log in to the software, or had deleted it from their devices. Coordinators at the University of Rochester generally provided technical support for study sites and patients when these problems arose, and most did not require assistance from the software developers (SBR Health). However, providing experienced, on-call telephone support for patients and sites to address technical problems proved necessary to the use of virtual house calls and will remain an important component of future multisite telemedicine applications.

Study limitations should guide future research. Like current care[3,40] and many clinical trials,[41] study participation was not equitable. Fueled by online recruitment, the study participants reflected the digital divide—the differential access to the Internet and related technologies due to social and geographic factors.[42] While the study enrolled participants as old as 84 and more than half came from counties with limited access to neurological care, study participants were largely white, well educated, and more familiar with the Internet than the general population.[43] The study results thus may not be generalizable to the broader community of individuals with Parkinson disease. Additional limitations included the target population, intervention, availability of data, and scope of analysis.

First, this study excluded individuals with Parkinson disease who reside in nursing homes, who account for nearly 25% of all Medicare beneficiaries with Parkinson disease,[44] frequently have limited access to neurological care,[6] and could benefit from virtual house calls. Other underserved populations (e.g., rural) who have less access to care may stand more to benefit. Second, we limited the intervention to care from a neurologist, when Parkinson disease, like many chronic conditions, benefits from multidisciplinary care.[45] In addition, while studies have generally demonstrated that remote and in-person motor examinations are comparable,[6] assessing gait remotely can be difficult due to the technology, limited camera view, and absence of trained clinicians. Third, this study had some missing data, which did not appear to affect results, and a lower response rate for some survey questions, which provides the potential for response bias. For example, nonresponders may have rated virtual house calls less favorably than responders, but the latter accounted for 70% of responses. Fourth, this study had limited consideration of costs. Utilization of emergency rooms and hospitalizations was low in both groups before and during the study. One general concern with telehealth is that it will lead to more physician visits,[46] and those in the intervention group had more total physician visits than those in the control group. However, physician visits are inexpensive relative to institutional care, and more frequent visits to a neurologist for Parkinson disease are associated with fewer hospitalizations and lower overall health expenditures.[44,47] Fifth, despite randomization, chance led to some imbalances among the study populations, which could have contributed to the absence of differences found. Sixth, other than the number of visits to their local Parkinson disease clinician, we had only limited information on what constituted usual care during the course of the study. The care (including length and content of visits) or information individuals sought during the course of the study may have been influenced by their participation in the study and could have influenced study results. Future efforts may seek to collect more detailed information on what constitutes "usual care." Seventh, we did not track outcomes of each clinical visit. Prior research suggests that virtual visits result in recommendations to increase exercise and adjusted medications for Parkinson disease in more than three-quarters of cases. Because of variation in state laws regarding the practice of telemedicine, we relied on local clinicians to whom recommendations were sent to implement recommendations. Some of these recommendations (e.g., increasing dose of medication, stopping a medication) may not have been received or implemented (as may be the case in traditional practice). To the extent that these recommendations may have been helpful, such inaction would bias the results toward finding no benefit from the virtual house calls. Changes in state laws, which are occurring, could make such artificial limitations moot in the future.

Conclusion

The Connect.Parkinson study demonstrated that providing care for Parkinson disease patients at home using videoconferencing technology is feasible and may be preferable to patients because of their comfort and convenience. This mode of care also demonstrates value to patients and their care partners by reducing the amount of time needed to attend and participate in physician visits, and reducing travel burdens for those whose mobility is already limited. Virtual house calls did not improve but were comparable to usual care in improving Parkinson disease–related quality of life. Several limitations remain, however. Multidisciplinary care management is needed for individuals with Parkinson disease,[48,49] and we were unable to offer this as part of the study. This may have influenced the ability of the study intervention to significantly improve Parkinson disease–related quality of life. Barriers to widespread implementation of this method also remain, including limited Medicare reimbursement for telehealth applications,[50] state licensure laws, and the digital divide (i.e., the differential access to the Internet and related technologies due to social and geographic factors).[42] Through reduction in these barriers, narrowing of the digital divide, and continued refinement of telehealth applications for chronic care, individuals with Parkinson disease and hopefully other chronic conditions can receive care at home. In this study, virtual house calls were provided in addition to usual care. Future efforts may seek to integrate virtual house calls more closely with current care or may evaluate whether virtual house calls can be a substitute for current care. The answer will likely vary depending on condition, severity, and geography.[51]

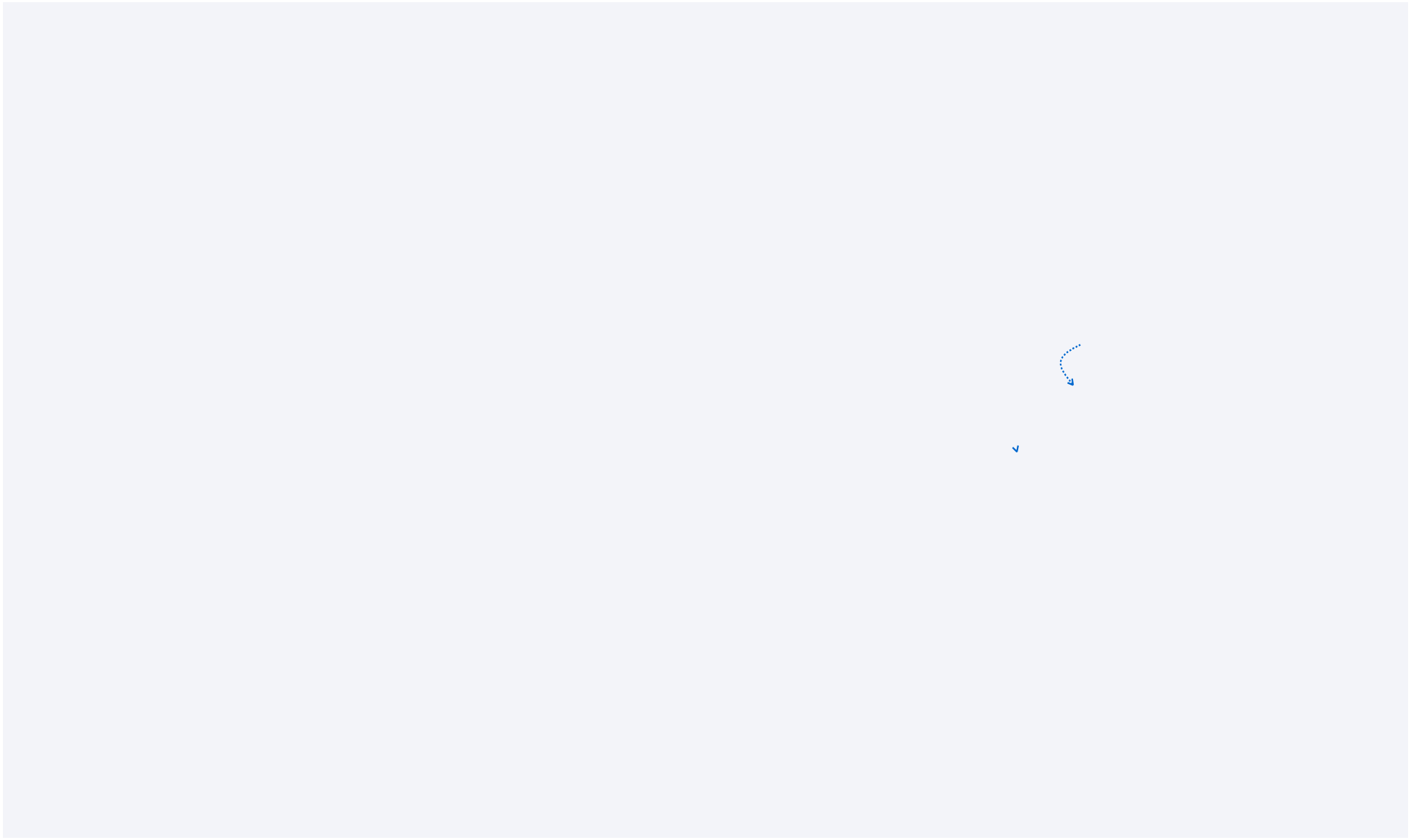
References

1. Goetz CG, Tilley BC, Shaftman SR, et al. Movement Disorder Society-sponsored revision of the Unified Parkinson's Disease Rating Scale (MDS-UPDRS): scale presentation and clinimetric testing results. *Mov Disord.* 2008;23(15):2129-2170.
2. Dorsey ER, Willis AW. Caring for the majority. *Mov Disord.* 2013;28(3):261-262.
3. Willis AW, Schootman M, Evanoff BA, Perlmutter JS, Racette BA. Neurologist care in Parkinson disease: a utilization, outcomes, and survival study. *Neurology.* 2011;77(9):851-857.
4. Dorsey ER, George BP, Leff B, Willis AW. The coming crisis: obtaining care for the growing burden of neurodegenerative conditions. *Neurology.* 2013;80(21):1989-1996.
5. Dorsey ER, Deuel LM, Beck CA, et al. Group patient visits for Parkinson disease: a randomized feasibility trial. *Neurology.* 2011;76(18):1542-1547.
6. Dorsey ER, Deuel LM, Voss TS, et al. Increasing access to specialty care: a pilot, randomized controlled trial of telemedicine for Parkinson's disease. *Mov Disord.* 2010;25(11):1652-1659.
7. Dorsey ER, Venuto C, Venkataraman V, Harris DA, Kieburtz K. Novel methods and technologies for 21st-century clinical trials: a review. *JAMA Neurol.* 2015;72(5):582-588. .
8. Achey M, Aldred JL, Aljehani N, et al. The past, present, and future of telemedicine for Parkinson's disease. *Mov Disord.* 2014;29(7):871-883.
9. Dorsey ER, Venkataraman V, Grana MJ, et al. Randomized controlled clinical trial of "virtual house calls" for Parkinson disease. *JAMA Neurol.* 2013;70(5):565-570.
10. Biglan KM, Voss TS, Deuel LM, et al. Telemedicine for the care of nursing home residents with Parkinson's disease. *Mov Disord.* 2009;24(7):1073-1076.
11. George BP, Scoglio NJ, Reminick JI, et al. Telemedicine in leading US neurology departments. *Neurohospitalist.* 2012;2(4):123-128.
12. Venkataraman V, Donohue SJ, Biglan KM, Wicks P, Dorsey ER. Virtual visits for Parkinson disease: a case series. *Neurol Clin Pract.* 2013;4(2):146-152
13. Achey MA, Beck CA, Beran DB, et al. Erratum to: Virtual house calls for Parkinson disease (Connect.Parkinson): study protocol for a randomized, controlled trial. *Trials.* 2016;17(1):1-5.
14. Dallolio L, Menarini M, China S, et al. Functional and clinical outcomes of telemedicine in patients with spinal cord injury. *Arch Phys Med Rehabil.* 2008;89(12):2332-2341.
15. Achey MA, Beck CA, Beran DB, et al. Virtual house calls for Parkinson disease (Connect.Parkinson): study protocol for a randomized, controlled trial. *Trials.* 2014;15:465.
16. Wright Willis A, Evanoff BA, Lian M, Criswell SR, Racette BA. Geographic and ethnic variation in Parkinson disease: a population-based study of US Medicare beneficiaries. *Neuroepidemiology.* 2010;34(3):143-151.
17. Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research electronic data capture (REDCap)—a metadata-driven methodology and workflow process for providing translational research informatics support. *J Biomed Inform.* 2009;42(2):377-381.
18. Mauldin PD, Guimaraes P, Albin RL, Ray Dorsey E, Bainbridge JL, Siderowf A. Optimal frequency for measuring health care resource utilization in Parkinson's disease using participant recall: the FS-TOO resource utilization substudy. *Clin Thers.* 2008;30(8):1553-1557.
19. Peto V, Jenkinson C, Fitzpatrick R. PDQ-39: a review of the development, validation and application of a Parkinson's disease quality of life questionnaire and its associated measures. *J Neurol.* 1998;245 Suppl 1:S10-S14.
20. Glasgow RE, Wagner EH, Schaefer J, Mahoney LD, Reid RJ, Greene SM. Development and validation of the Patient Assessment of Chronic Illness Care (PACIC). *Med Care.* 2005;43(5):436-444.

21. Obeid JS, McGraw CA, Minor BL, et al. Procurement of shared data instruments for Research Electronic Data Capture (REDCap). *J Biomed Inform.* 2013;46(2):259-265.
22. Thompson AW, Liu H, Hays RD, et al. Diagnostic accuracy and agreement across three depression assessment measures for Parkinson's disease. *Parkinsonism Relat Disord.* 2011;17(1):40-45.
23. Yesavage JA, Brink TL, Rose TL, et al. Development and validation of a geriatric depression screening scale: a preliminary report. *J Psychiatr Res.* 1982;17(1):37-49.
24. Brink TL, Yesavage JA, Lum O, Heersema P, Adey MB, Rose TL. Screening tests for geriatric depression. *Clin Gerontol.* 1982;1:37-44.
25. Sheikh JI, Yesavage JA. Geriatric Depression Scale (GDS): recent evidence and development of a shorter version. In: *Clinical Gerontology: A Guide to Assessment and Intervention*. New York, NY: The Haworth Press; 1986:165-173.
26. Sheikh JI, Yesavage JA, Brooks JO III, et al. Proposed factor structure of the Geriatric Depression Scale. *Int Psychogeriatr.* 1991;3(1):23-28.
27. Goetz CG, Tilley BC, Shaftman SR, et al. Movement Disorder Society-sponsored revision of the Unified Parkinson's Disease Rating Scale (MDS-UPDRS): Scale presentation and clinimetric testing results. *Movement Disorders.* 2008;23(15):2129-2170.
28. Abdolahi A, Scoglio N, Killoran A, Dorsey ER, Biglan KM. Potential reliability and validity of a modified version of the Unified Parkinson's Disease Rating Scale that could be administered remotely. *Parkinsonism Relat Disord.* 2013;19(2):218-221.
29. Nasreddine ZS, Phillips NA, Bédirian V, et al. The Montreal Cognitive Assessment, MoCA: a brief screening tool for mild cognitive impairment. *J Am Geriatr Soc.* 2005;53(4):695-699.
30. Gill DJ, Freshman A, Blender JA, Ravina B. The montreal cognitive assessment as a screening tool for cognitive impairment in Parkinson's disease. *Mov Disord.* 2008;23(7):1043-1046.
31. Herdman M, Gudex C, Lloyd A, et al. Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). *Qual Life Res.* 2011;20(10):1727-1736.
32. Stull D. The Multidimensional Caregiver Strain Index (MCSI): its measurement and structure. *Journal of Clinical Geropsychology.* 1996;2(3):175-196.
33. Buchanan RJ, Wang S, Huang C, Simpson P, Manyam BV. Analyses of nursing home residents with Parkinson's disease using the minimum data set. *Parkinsonism Relat Disord.* 2002;8(5):369-380.
34. Latoo J, Mistry M, Dunne FJ. Depression in Parkinson's disease: diagnosis and management. *Br J Hosp Med (Lond).* 2012;73(6):331-334.
35. Weerkamp NJ, Tissingh G, Poels PJ, et al. Nonmotor symptoms in nursing home residents with Parkinson's disease: prevalence and effect on quality of life. *J Am Geriatr Soc.* 2013;61(10):1714-1721.
36. Hurst H, Bolton J. Assessing the clinical significance of change scores recorded on subjective outcome measures. *J Manipulative and Physiol Ther.* 2004;27(1):26-35.
37. van Buuren S, Groothuis-Oudshoorn K. Mice: multivariate imputation by chained equations in R. *2011 J Stat Softw.* 2011;45(3).
38. White IR, Royston P, Wood AM. Multiple imputation using chained equations: issues and guidance for practice. *Stat Med.* 2011;30(4):377-399.
39. Dorsey ER, Achey MA, Beck CA, et al. National randomized controlled trial of virtual house calls for people with Parkinson's disease: interest and barriers. *Telemed J E Health.* 2016;22(7):590-598.
40. Dahodwala N, Xie M, Noll E, Siderowf A, Mandell DS. Treatment disparities in Parkinson's disease. *Ann Neurol.* 2009;66(2):142-145.

41. Cummings J, Isaacson S, Mills R, et al. Pimavanserin for patients with Parkinson's disease psychosis: a randomised, placebo-controlled phase 3 trial. *Lancet.* 2014;383(9916):533-540.
42. Norris P. *Digital Divide: Civic Engagement, Information Poverty, and the Internet Worldwide.* Cambridge; New York, NY: Cambridge University Press; 2001.
43. *Pew Research Center. Internet/Broadband Fact Sheet 2014. http://www.pewinternet.org/fact-sheet/internet-broadband/* Accessed Accessed May 1, 2017.
44. Willis AW, Schootman M, Tran R, et al. Neurologist-associated reduction in PD-related hospitalizations and health care expenditures. *Neurology.* 2012;79(17):1774-1780.
45. Post B, van der Eijk M, Munneke M, Bloem BR. Multidisciplinary care for Parkinson's disease: not if, but how! *Pract Neurol.* 2011;11(2):58-61.
46. Housman L, Williams Z, Ellis P. *Congressional Budget Office: Nonpartisan Analysis for the U.S. Congress 2015.* Congressional Budget Office. 2015.
47. Wechsler LR. Advantages and limitations of teleneurology. *JAMA Neurol.* 2015;72(3):349-354.
48. van der Marck MA, Bloem BR, Borm GF, Overeem S, Munneke M, Guttman M. Effectiveness of multidisciplinary care for Parkinson's disease: a randomized, controlled trial. *Mov Disord.* 2013;28(5):605-611.
49. Keus SH, Oude Nijhuis LB, Nijkrake MJ, Bloem BR, Munneke M. Improving community healthcare for patients with Parkinson's disease: the dutch model. *Parkinsons Dis.* 2012;(2012).
50. Centers for Medicare & Medicaid Services. Medicare Benefit Policy Manual. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS012673.html. Accessed May 1, 2017.
51. Ashwood JS, Mehrotra A, Cowling D, Uscher-Pines L. Direct-to-consumer telehealth may increase access to care but does not decrease spending. *Health Aff.* 2017;36(3):485-491.

Figure 5. *Themes Underlying Patient and Physician Perceptions of Virtual House Calls, With Substantiating Coding Schema*



Appendix—Table 1.

Site Name	Date IRB Approved
University of Rochester (coordinating center)	1/6/2014
University of Rochester (enrolling site)	3/21/2014
Oregon Health and Science University	5/27/2014
Northwest Neurological, PLLC	5/29/2014
Northwestern	5/29/2014
Beth Israel Deaconess	6/16/2014
Duke Medical Center	6/17/2014
University of Kansas Medical Center	7/21/2014
University of Pennsylvania	7/21/2014
Georgia Regents University	7/24/2014
Johns Hopkins	8/3/2014
Mayo Clinic	8/25/2014
Massachusetts General Hospital	9/19/2014
Struthers	9/23/2014
University of California San Francisco	9/29/2014
Baylor College of Medicine	10/2/2014
North Shore Long Island Jewish	10/3/2014
Parkinson's Institute	3/31/2015
University of Florida	4/22/2015
University of Miami	3/2/2015
Medical University of South Carolina	2/10/2015

Appendix—Table 2.

Schedule of Activities								
Activity	**Screening Visit (phone)**	**Consent (phone or in person)**	**Baseline Assessment (video call and survey)**	**Virtual House Calls 1 and 4 (months 0 and 12)**	**Virtual House Calls 2 and 3**	**End of Study Assessment (video call and survey)**	**1-time Virtual House Call**	**End of Study**
Study Personnel	*Study Coordinator*	*Site Coordinator*	*Independent Rater*	*Site Investigator*	*Site Investigator*	*Independent Rater*	*Site Investigator*	*Site Investigator*
Study Site	**Rochester**	**Site**	**Rochester**	**Site**	**Site**	**Rochester**	**Site**	**Site**
Participant arm	All	All	All	Virtual house calls	Virtual house calls	All	Control	NA
Screening	X							
Contact local health care provider	X							
Consent		X						
Baseline survey			X					
Randomization			X					
Assessments of health, quality of life, and care*			X			X		
EQ-5D-5L			X			X		
Medication log			X			X		
MoCA			X			X		
MDS-UPDRS			X			X		
PGIC						X		
Time and travel + MCSI**			X			X		
Virtual house call survey***				X	X		X	
Overall virtual house call survey						X	X	
Provider virtual house call survey****								X
MDS-UPDRS, Part 3****				X				
Clinic note sent to participant and local health care provider				X	X			

* Includes Parkinson's Disease Questionnaire 39, Geriatric Depression Scale 15, Patient Assessment of Chronic Illness Care, time and travel, Parkinson disease recommendation survey, and health care resource utilization

Abbreviations: EQ-5D-5L = European Quality of Life Five Level Scare; MoCA = Montreal Cognitive Assessment; MDS-UPDRS = Movement Disorder Society Unified Parkinson Disease Rating Scale; PGIC = Patient Global Impression of Change; MCSI = Multidimensional Caregiver Strain Index

**For participating care partners
*** Participants and investigators

**** For investigators giving care via virtual house calls

Disclaimer:

The [views, statements, opinions] presented in this report are solely the responsibility of the author(s) and do not necessarily represent the views of the Patient-Centered Outcomes Research Institute® (PCORI®), its Board of Governors or Methodology Committee.

Acknowledgement:

Research reported in this report was [partially] funded through a Patient-Centered Outcomes Research Institute® (PCORI®) Award (# AD-12-11-4701) Further information available at: https://www.pcori.org/research-results/2013/do-video-house-calls-specialist-help-get-care-people-parkinsons-disease