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Research paper

Transportation innovation to aid Parkinson disease trial recruitment

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ABSTRACT

Among the barriers to participation in clinical trials, transportation to and from study sites may be a prominent issue. Patients with Parkinson's disease have unique circumstances that add to the barriers including dementia, loss of driving ability, timing of medications, impact of reduced mobility, and bowel and bladder concerns. We sought to alleviate some of the burden of transportation by setting up pre-arranged rides through a third-party ride sharing service. This pilot project was established to assess feasibility and to explore the possibility that reducing the transportation burden may enhance participation in studies. One out of three academic sites was successful in setting up this service, and surveyed participants on the impact of this service. In general, study participants who opted into the ride-sharing service felt it made the process easier and less stressful. Most participants agreed that they are more likely to participate in another study if transportation was provided. This short-term pilot intervention suggests that participants were satisfied with a ride sharing service to help with their medical transportation needs, but larger studies that include data collection about retention are needed.

1. Introduction

Clinical studies hinge on the participation of eligible patients and controls who have a vested personal interest in the outcome of research [1]. The rate of clinical trial participation needs improvement [2]. The majority of clinical trials fail to recruit on time, delaying the study of interventions and increasing costs to sponsors.

There are many barriers to participation in clinical trials, including economic, provider bias, patient/family preferences, age policies or accessibility of trials. In addition to barriers that participants face, some reasons for delays in initiating clinical trials may be outside of the control of the staff designing and implementing the clinical trial. For example, regulatory requirements or approvals from the Food and Drug Administration may lead to delays. Ethics board approval (including informed consent document development), contracts, budget and other necessary internal processes also must be in place prior to starting research.

While there are many barriers to consider when starting or conducting research, this intervention focused on transportation-specific barriers, including the difficulty for some patients in arranging for transportation to a tertiary care center for study visits. Currently, transportation options for research participants include self-determined options such as driving, study partner driving, public transportation and biking or study-provided options such as a car service. In addition to barriers that all research participants face such as traffic, parking and the difficulty of driving in a city, people with Parkinson's disease (PD) may have additional unique circumstances, including dementia, loss of driving ability, timing of medications, impact of reduced mobility, and bowel and bladder concerns [3]. It is common for people with PD to require the assistance of another person to help with transportation for routine clinical visits and transportation issues may be more common in those with PD than the general population. Individuals with PD are commonly at or beyond retirement age, but 10% are 45 years old or younger, making balancing of work and family another aspect to consider when scheduling a research visit. The more senior population may be less independent and might benefit from aid with transportation to attend visits and maintain independence.

Fox Trial Finder is a clinical trial matching tool that helps patients and their loved ones get involved in speeding a cure for Parkinson's disease (https://foxtrialfinder.michaeljfox.org/). Through Fox Trial Finder, The Michael J. Fox Foundation for Parkinson's Research (MJFF) completed a transportation due diligence project in anticipation of this

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study [4]. Briefly, MJFF conducted qualitative interviews with 11 PD clinical trial sites to compare similarities and differences across: geography, infrastructure, institution, and source of funding/type of research. The conclusions based on those interviews were that larger cities had more transportation issues, parking availability and entrance proximity mitigated some transportation issues and there was a heavy reliance on private cars for transportation. Based on these findings, a survey was distributed to 843 investigators/coordinators in the Fox Trial Finder database. Forty-nine responses were received (6% response rate; 100% completion rate from respondents). Findings from the survey, although limited, suggest a belief by sites that transportation infrastructure would facilitate participation in a study or trial. Eighty-four percent of sites reported that if they were to participate in a transportation initiative a partnership with a taxi or livery service would provide the greatest benefit for recruitment and retention efforts. Based on that survey and the need to improve clinical trial recruitment for PD, this study explored the possibility that barriers to participation relating to transportation could be reduced by providing study subjects with the option for a pre-arranged ride sharing service for transportation to and from study visits.

2. Methods

This pilot intervention was conducted at three sites that were specifically chosen by the staff at MJFF based on geographic diversity, large research portfolios and commitment to implement recruitment interventions. All sites had the intention of implementing a transportation initiative, based on the transportation survey data that suggested larger cities like Boston would have a greater need for this transportation service. Study participants who opted into this transportation initiative were recruited from July 2017 through July 2018.

The transportation initiative was intended to help with recruitment with ongoing or anticipated clinical studies. At each site, there was also a second recruitment initiative implemented, including engaging general practitioners and community neurologists, assessing attitudes toward research participation of underrepresented populations and educating and engaging patients on genetics research. Each site developed individualized protocols for this project and the protocols were approved by individual site IRBs. A survey for clinical trial participants was developed to assess their satisfaction with using a pre-arranged ride sharing service to transport them to the study visit. Sites were also provided with standardized data collection templates.

The purpose of this effort was to generate pilot data regarding the feasibility and impact of a ride sharing service for study subjects. The ride-sharing service selected was the only one at the time that offered a concierge-style service that was set up for medical appointments. The rides were ordered in advance by the site coordinator and research participants were not involved in the online ordering. The location of pickup and name listed for pickup were determined after discussion between the coordinator and research participant. The online concierge portal allowed rides to be scheduled up to seven days in advance. Payments were processed through the concierge portal with no cost limitations. The site coordinator obtained verbal consent to use the participant's first name and address to schedule the rides. Additionally, the portal service required the participant's phone number to provide updates on the transportation vehicle, driver, and expected time of arrival. Notifications were also sent in cases of cancelations and unexpected time delays. Dispatched drivers were not informed of the purpose of the service, so their treatment of participants was standard. The ride sharing service allowed coordinators to schedule rides and the bill went directly to the research center (i.e. participants did not have to wait for reimbursement). The portal service enabled coordinators to connect with study participants and arrange rides even for those who did not have access to a smartphone.

Table 1

	Ride Sharing	Self Transportation
Age, mean ± SD	57.1 ± 13.6 years	57.9 ± 14.4
Time to coordinate, mean ± SD	10.1 ± 5.6	n/a
Mean cost per ride, each direction	$53.00	n/a
Total miles traveled, mean ± SD	56.1 ± 56.2	data not available

3. Results

Two sites had contractual issues with the ride sharing service due to a concurrent effort to initiate institutional-wide contracting. In addition, despite the HIPAA compliant policies in place, privacy and liability concerns interfered with the contracting process as well. Due to the scope of the issue at two of the institutions, the study staff were unable to accelerate the process, intervene or set up a contract for this study. There were additional delays in setting up the contract due to staff turnover at the ride-sharing service.

One site (Beth Israel Deaconess Medical Center) was able to successfully obtain IRB approval and implement a ride sharing service for research participants for two active PD studies. Of the 21 participants in studies at the site and had the opportunity to utilize a ride-sharing service, 10 opted to use the service while the remaining study participants declined and instead either took public transportation or drove themselves to the visits. See Table 1 for characteristics of the ride sharing service users and of those who provided self transportation, including data on the cost and mean distance for the trips.

Of those who used the ride-sharing transportation service, all agreed or strongly agreed with the statements:

- The car service that was provided made it easier for me to attend my appointment(s)
- Having the study team make travel arrangements for me made it easier for me to participate
- I would have participated in the study regardless of whether or not transportation was provided
- I would be more likely to participate in another study or trial if transportation were provided

9/10 agreed or strongly agreed with the statement “I experienced less stress about my appointment(s) knowing that a car service was provided.” One participant was neutral about the statement.

4. Discussion

Based on a due diligence survey of research sites, we identified transportation considerations as a major barrier to participation and retention in clinical trials. Initial survey results suggested that geography played a role in that there were more transportation issues in larger cities. Most of the US continues to primarily rely on private methods of transport, specifically, individual vehicles with few passengers. Few cities offer easy-to-navigate public transportation modes for patients with altered mobility and balance. In some regions of the US, a few health care facilities may have some transportation infrastructure that includes proximity to public transportation, partnerships with local taxi services, parking vouchers, and/or hotel accommodations. Funding is not consistently available across sites for provision of transportation services.

While we attempted to implement the use of a ride sharing service to increase recruitment at three centers for research purposes, logistical issues were too great at two of the academic sites. One site was able to offer a means to reduce transportation barriers through the use of a pre-arranged ride-sharing service into a congested area of Boston. About half of the participants who were offered a ride sharing service opted into that program. For those who did, there was great enthusiasm and

appreciation as noted in the survey results. In addition, anecdotal comments such as being able to make the visits in a practical “off” state (no medications after midnight the day prior to and on the day of a study visit) without the need to drive were notable. Clinical evaluations or participation in clinical trials while in the “off” state is common and can be a challenge due to lack of mobility and flexibility in addition to cognitive challenges. When patients are able to avoid potential anxiety and stress about transportation, it may be of great overall benefit. The impact on retention also should be studied in the future.

The cost of some transportation is commonly included in the budget for clinical trials, whether it is reimbursement of miles, flights or hotel stays. The mean cost per ride in this study shifted some of the burden of transportation away from participants, but overall, this cost was low in comparison to other means of recruitment and retention in studies. Even the cost of a relatively long ride was feasible and may possibly improve satisfaction in research participation with door-to-door service. Such costs likely will be offset by costs savings that result from more rapid recruitment of participants and potentially improved retention. Similar to other recruitment tools, there is an administrative process that includes the IRB, coordinator time to arrange rides and contracting with external entities. An additional advantage of incorporating transportation services through a ride-sharing service is avoiding delayed participant reimbursement. There is also an increased level of customer service by incorporating a concierge experience.

Providing financial assistance alone seems to be inadequate to implement the use of a ride-sharing service since study subjects had the option to use and not worry about the cost of the service. Emerging frameworks of regulatory and bureaucratic parameters are now being established that may enhance success of future transportation initiatives.

Overall, participants in research may have more control over their time and lives with the use of a ride-sharing service and this may improve research satisfaction, serving as another possible mechanism for long-term engagement and participation in studies (i.e. retention). Since the participation rate in this study was low, recruitment was difficult to quantify. Although not explicitly studied, this mechanism could also serve to engage lower socioeconomic groups with limited access to transportation. A limitation of the intervention studied is the restricted environment these interventions were tested, including tertiary care referral centers in mid- to large cities. In the future, as part of other interventional studies, randomization schemes may be needed to study whether recruitment enhancement techniques are effective.

While this short-term pilot intervention suggested that participants who opt to use a ride sharing service to help with their transportation needs to get to clinical study visits are satisfied, larger and longer term investments are needed in clinical trial outreach efforts to test various recruitment strategies to reduce barriers, including the effectiveness of providing transportation.

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