

A Multi-Centre Parkinson's Disease Study

VCTC Case Study



Overview

 Multi-centre clinical study evaluating the correlation between oculometric measures and clinical assessment in Parkinson's Disease.

 100 Parkinson's Disease participants were required in a rapid 6-month period from Sep-23 to Feb-24.

 VCTC was contracted by a medical device technology company to provide clinical study site services for a global observational trial to compare their novel software-based platform with current validated Parkinson's Disease clinical tools.

 Data collected in this study will directly support the sponsor in the development of a medical device to help detect and diagnose neurological conditions more easily.



Challenges

Specialised Clinical Assessments

In addition to the assessment conducted using the sponsors software, each participant also had to undergo validated Parkinson's Disease clinical assessments, which were performed by specialist healthcare professionals with Parkinson's Disease expertise.

Operating Requirements

The current iteration of the study software runs on computer screens attached to a very heavy cart. The software is complex calibrate and highly sensitive to changes in surroundings. Therefore, once the cart was positioned it could not be moved and required a consistent, fixed light source and no interference from outside personnel.

Participants not known to VCTC

100 participants needed to be recruited from external sources as VCTC did not have any Parkison's Disease patients on our database.

Limited Budget

As the Sponsor was a small start-up company the study needed to be run in a streamlined way to limit the spend on the study.

No direct benefit to participants

This study provided no direct benefit to participants and was to collect data for the advancement of algorithms needed to develop a medical device.



Outcomes

- Streamlined, efficient processes and high-touch communication model built around participants, whilst keeping Investigator (site) fees benchmarked against NHS equivalents and the UK NiHR costing model.
- Happy participants who completed the study and would be willing to take part in future research.
- Highly positive feedback was received from participants regarding the clinic spaces, the knowledge and support of the study team and the respect shown by staff to participants.

- High conversion rate of interested -> enrolled participants.
- 100 participants identified and recruited in under 12-weeks, 3-months ahead of schedule.
- Rapid approvals achieved within 9-weeks of being contracted to the study.
- Flexible and agile ways of working ensured high compliance with study assessments and consistently positive participant satisfaction at each visit.



Tactics

How VCTC overcame these challenges and achieved a successful outcome

NHS PICs to complement recruitment

 28 NHS organisation that were interested in acting as Participant Identification Centres (PICs) for the study, were identified through the NiHr. VCTC contracted with each PIC site, which were mostly GP centres, to do a full review of their databases and identify potential participants for the study. Participants were contacted to see if they were interested in joining the study, and VCTC contact information was provided for them to get in touch with us.





Specialist Parkinson's Disease nurse

We engaged an experienced specialist Parkinson's Disease nurse to conduct the clinical assessments. Their experience in this area, allowed them to easily communicate with the participants, put them at ease, and conduct assessments thoroughly.





High touch engagement

Due to the nature of the study, high touch and proactive communication was key to keeping participants engaged.

The study team were available 24/7 to speak to people about any aspect of the study, to book and confirm appointments, and book taxi's for those that preferred not to drive.

We found that for people with Parkinson's Disease, anxiety can be a real concern, and so having a friendly voice on the end of the phone was reassuring for them.





Community driven recruitment plan

A 360o recruitment strategy was built around community engagement and low-cost recruitment activities, including:

PD-UK and Cure Parkinson's

We worked with these two advocacy groups to distribute information directly to their members via email, and also to place adverts on their websites and social media pages.

PD-UK groups

Many of our early participants were recruited from PD-UK community groups that our Participant Engagement Co-ordinator attended in person to deliver information about the study.

Paid advertising

Adverts were placed in local advertising catalogues and magazines that are delivered to all homes in the immediate area around each clinic.

Paper Advertising

Hardcopy flyers and posters were delivered to places where people with Parkinson's might go, including GPs, community groups, retirement villages, garden centres, and even a Parkinson's specific dance group!

Social media

Adverts distributed via VCTC social media pages.



Realistic recruitment area

Although the VCTC has geographical coverage across the UK, the cart could not be moved easily.

During study set up we worked with the Parkinson's community and specialists to decide on the locations for our clinics.

The aim was to reduce the burden of travelling to participate in a trial by conveniently situating the clinics in areas with higher populations of Parkinson's Disease patients.



Welcoming clinic spaces

We opted to open the study at 2 VCTC clinic sites that were conveniently situated and in picturesque locations. These clinics provided a welcoming and comfortable space that is different from the hospital clinics that are typically used for research.





Patient engagement

Prior to starting the study we engaged with Parkinson's Disease patients and their carer's to really understand their unique needs.

This led to us creating highly tailored study information that met their needs, including a 1-page information sheet to support the consent process and appropriate supportive seating.

We also facilitated transport arrangements where required.











Dedicated study team

From initial approval through to participant recruitment, our study team worked tirelessly to ensure that all study goals were met.



