A CLINICAL TRIALS 'CHARTER' TO IMPROVE COMMUNICATION ABOUT, RECRUITMENT TO AND RETENTION IN PARKINSON'S CLINICAL TRIALS

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Objective: The objective of the project was to design a durable tool, usable by clinical trial investigators and participants alike, that would improve subject retention in Parkinson's Disease (PD) trials.

Background: Clinical trials fail for many reasons, often unrelated to the trial medication itself. These failures may be avoidable if the reasons are identified and addressed. The present study sought: (a) to identify causes by surveying the stakeholder population, (b) to establish a course of action and (c) to implement this in a multicentre trial.

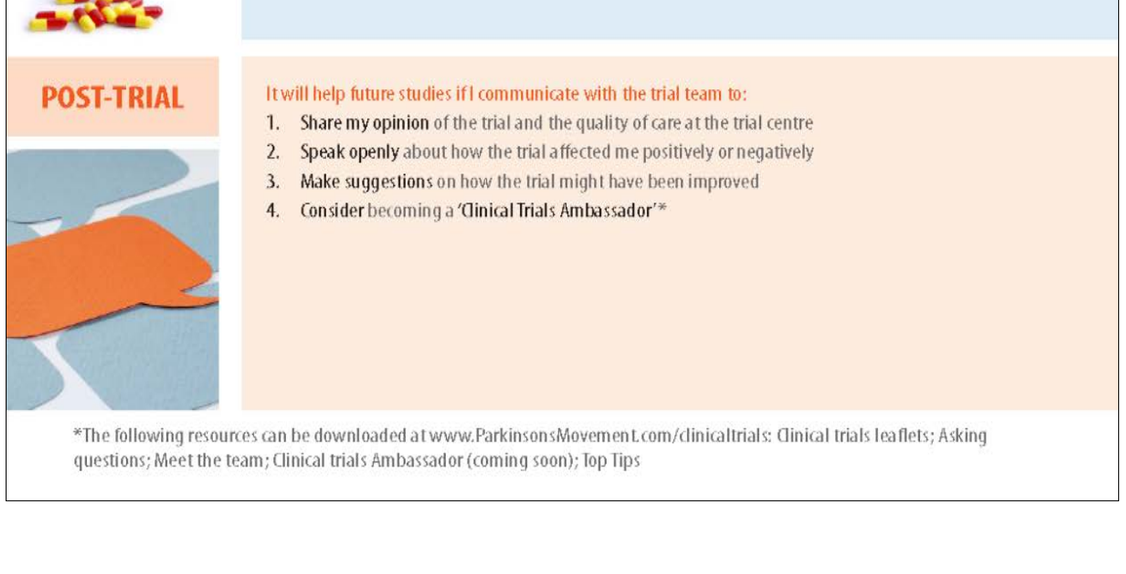
Method: An online survey of people with Parkinson's (PwPs) and clinicians (303 participants) was used to identify barriers to success in clinical trials among the two communities. These were addressed in focus groups and actionable barriers were distilled into best practice recommendations. These recommendations were further distilled into a fact sheet for wider circulation.

Results: The online survey identified the top three barriers to success in clinical trials in PD among clinicians:

- Funding (66%)
- Administrative support (46%)
- Recruitment of patients to trials (44%)

For PWPs, the top reasons were:

- Potential adverse/side effects (58%)
- Disruption of existing medication (53%)
- Risk of placebo (39%)
- General upheaval (38%)
- Lack of info on progress &results of trial (34%)



Charter for Clinical Trials in Parkinson's

Setting standards of practice for those involved in clinical trials for Parkinson's

POTENTIAL PARKINSON'S STUDY PARTICIPANTS

PRE-TRIAL

As a potential volunteer for a clinical trial in Parkinson's, I understand that, at any stage, I have a choice whether to be involved in a trial or not. In making my decision on whether to volunteer for a particular trial, I am prepared to:

1. **Read** all available information about the trial so that I fully understand what will be involved *
2. **Understand** any potential risks and benefits of my involvement in this trial as explained to me by the trial coordinators *
3. **Discuss** the pros and cons of the trial with people whose opinion I value before deciding whether or not to volunteer
4. **Carefully read** through the **'Informed Consent'** form and keep a signed copy.
5. **Choose to participate** only when I am satisfied that the purpose of this study is important to me, and when I have established what it involves and what I might expect
6. **Commit** to taking part in the trial until its completion whilst being aware that I can withdraw if I choose

DURING TRIAL

I should:

1. **Talk to the research team...**
   - if I have questions or concerns
   - if I experience changes to symptoms or side effects
   - if there is an emergency
   - about my appointment or any visits to the trial centre*
2. **Be aware** of what experiences might occur and know to whom and how to report them if they happen

POST-TRIAL

It will help future studies if I communicate with the trial team to:

1. **Share my opinion** of the trial and the quality of care at the trial centre
2. **Speak openly** about how the trial affected me positively or negatively
3. **Make suggestions** on how the trial might have been improved
4. **Consider** becoming a **'Clinical Trials Ambassador'***

*The following resources can be downloaded at www.ParkinsonsMovement.com/clinicaltrials: Clinical trials leaflets; Asking questions; Meet the team; Clinical trials Ambassador (coming soon); Top Tips

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CLINICIANS/RESEARCHERS

PRE-TRIAL

As researchers, we understand we are responsible for designing and delivering ethical studies that are of relevance to patients. We aim to ensure participants' safety and to protect their rights and dignity. We strive to:

1. **Communicate effectively** with all participants and wider stakeholders which will involve:
   - identifying individuals to be responsible for communication*
   - Producing information about the trial which is accessible and easy to understand *
   - Providing ample opportunity to address participants' concerns or questions about the study
   - Involving patient advocates and prospective participants in all aspects of study design and conduct as appropriate
2. **Be transparent and clear** in what we hope to achieve from the study, its potential, the risks and benefits.
3. **Ensure all appropriate approvals and safeguards** are in place prior to the start of the study*

DURING TRIAL

We should:

1. **Listen** carefully to participants' concerns and address unforeseen issues rapidly as they arise
2. **Employ and continuously re-evaluate** the practices used in this trial, to ensure the optimum care of participants
3. **Communicate effectively** and keep trial participants informed, motivated and supported
4. **Use** data collected during the trial to re-assess the design and validity of the study and its potential value in future research

POST-TRIAL

We should:

1. **Create** a project debrief for all participants using a range of media and collect feedback from patients on their trial experience (good and bad)
2. **Disseminate** lessons learnt to the wider Parkinson's community – best practice should evolve
3. **Communicate** the results of the trial to Parkinson's and wider community – if possible publish results as open access
4. **Use information** collected from above to improve future trials

*The following resources can be downloaded at www.ParkinsonsMovement.com/clinicaltrials: Clinical trials leaflets; Asking questions; Meet the team; Clinical trials Ambassador (coming soon); Top Tips

Outcomes: Many of these are communication issues and thus constituted actionable barriers. These were discussed in focus groups drawn from 110 patient conference participants and instigated development of a clinical trials charter for use by those considering participating in, or conducting, PD clinical research

The charter has been developed internationally by PwPs, in consultation with PD advocates, PD clinical trials specialists and key PD patient organisations. It is a simple two-sided document outlining standards of practice and reasonable expectations for participants and researchers. Accompanying resources, including a range of leaflets and informative film, have also been developed.

The charter is currently being evaluated in a randomised clinical trial of simvastatin as a neuroprotective agent in PD, by means of participant surveys, to understand its potential role in supporting recruitment and retention in PD trials.

Conclusions: We have developed a Clinical Trials Charter to assist with participant recruitment and retention in clinical trials. Its effectiveness is currently being evaluated within an ongoing RCT.

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