



PD COMM Trial COVID-19 Guidance for sites 27-MAR-2020

Due to the rapidly changing situation regarding COVID-19, we anticipate difficulties with participants attending protocol-defined visits due to closure of clinics, restricted travel for staff and participants, and redeployment of research staff to NHS frontline roles. We are working under these unprecedented circumstances to ensure participant safety, maintain the integrity of the trial, and collect primary outcome data.

As part of our response to the COVID-19 pandemic, it has been necessary to implement a pause on the recruitment of new patients into PD COMM from 27th March 2020 until further notice.

Follow up visits of participants who have already been recruited to PD COMM should continue, where possible please use the flexibility of the visit windows to facilitate this. We do recognise however that this may not be possible.

For now, please retain any hard-copy documentation that you would usually post to the PD COMM Trial Office. If your capacity permits then you can upload these documents in an encrypted manner to BEAR DataShare:

<https://intranet.birmingham.ac.uk/it/teams/infrastructure/research/bear/BEARDataShare>).

Please contact the PD COMM Trial Office if this is something that you would like to utilise and do not already have access.

Please refer to the following guidance:

- Where possible, alternative proportionate mechanisms of participant contact may be introduced (such as telephone calls, video calls, home visits etc.) to enable follow-up that aligns with the schedule of assessments. Since it may not be possible to accurately capture all data during a remote consultation, please just capture what is possible, focussing on the outcome measure, particularly the primary outcome measure.
- Where speech therapy has already been initiated, every effort should be made to ensure that the intervention is delivered as per the timeline outlined in the trial protocol, with treatment completed prior to 3 months post randomisation. However, we understand that this may not always be feasible particularly in the case of LSVT where intensive periods of intervention are required.
- Where patients have been randomised but speech therapy has not yet been started, the intervention can be deferred until the capacity to deliver has been restored. In such a case please notify the trial team of your decision to defer.

- Where 12 month clinical follow up appointments become due, please make every effort to complete it within the 1 month window outlined in the trial protocol. If non-urgent outpatient appointments have been cancelled during this period, remote follow up sessions should be conducted where possible.
- Expedited SAEs should continue to be reported to the PD COMM Trial Office within 24 hours of an investigator site becoming aware of an SAE. This should be via email to the PD COMM trial inbox copying in trial manager. The PD COMM SAE Form can be found at: <https://www.birmingham.ac.uk/research/bctu/trials/pd/PD-COMM/investigators/documentation.aspx>
- All participant contact should be documented in the participant's medical record.
- Please document all protocol deviations locally and complete a file note for each patient. These include out-of-window visits, missed assessments and missed visits. The PD COMM Trial Office will provide guidance on how these should be reported when the COVID-19 crisis is over.

Trial Team Contacts

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All the latest updates can also be found via our website:

<https://www.birmingham.ac.uk/research/bctu/trials/pd/PD-COMM/investigators/documentation.aspx>

Twitter [@PDCOMM_trial](https://twitter.com/PDCOMM_trial)

Guidance documents

HRA:

<https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/covid-19-guidance-sponsors-sites-and-researchers/>

MHRA:

<https://mhrainspectorate.blog.gov.uk/2020/03/12/advice-for-management-of-clinical-trials-in-relation-to-coronavirus/>

NIHR:

<https://www.nihr.ac.uk/news/dhsc-issues-guidance-on-the-impact-on-covid-19-on-research-funded-or-supported-by-nihr/24469>

Please Note: This document is correct as of 27th March 2020, and further changes may follow in the coming days. We will try to offer as much practical advice as we can to help you with the running of the PD COMM trial under the current circumstances.

Thank you

PD COMM Trial Management Group