



RANDOMISATION CHECKLIST

1) Check:

- i. Consent forms have been signed and correctly dated by participant/carer and person taking informed consent (and witness if required)
- ii. Randomisation Form, Entry Form and Baseline Participant/carer Questionnaires have been fully completed and accurate
- iii. Therapist is able to start Standard NHS SLT within 4 weeks or LSVT within 7 weeks

2) Randomise:

- i. Log on to www.trials.bham.ac.uk/PDCOMMTrial
- ii. Follow the onscreen instruction and enter all information required
- iii. Write down the trial number allocated on all baseline documents

A confirmation email will be sent out to the randomiser confirming the allocated treatment.

(If the website is not accessible, call 0800 953 0274 between 9am – 5pm Monday to Friday. The BCTU team will check eligibility criteria (all on randomisation form), randomise participant, and send a fax or email confirmation of participant treatment allocation and trial number.)

3) Inform:

- i. Participant of their allocation
- ii. Therapist, if randomised to one of the therapy arms, to allow the therapy to start
- iii. GP using the standard letter, if participant gave specific consent

4) File in the Site File:

- i. Original of signed Consent Form and Randomisation Form
- ii. A copy of Entry Form and Participant/carer Questionnaires

5) Post to the PD COMM Trial Office in 2 freepost envelopes:

Envelope 1 - Original of Entry Form and Participant/carer Questionnaires

Envelope 2 - A copy of signed Consent Form

Address: PD COMM Trial, Birmingham Clinical Trials Unit, Public Health Building,
University of Birmingham, Edgbaston, B15 2TT

(Do not send a copy of the Randomisation Form to the PD COMM Trial Office.)

If you have any difficulties please call the PD COMM trial office on 0121 415 9126 or email PDCOMM@trials.bham.ac.uk.