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Physiotherapy and occupational therapy vs no therapy in mild to moderate Parkinson disease

Clarke, Carl E; Patel, Smitaa; Ives, Natalie; Rick, Caroline E; Dowling, Francis; Woolley, Rebecca; Wheatley, Keith; Walker, Marion F; Sackley, Catherine M; PD REHAB Collaborative Group

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Randomised (N = 762)

Allocated to PT/OT (N=381)†

- Started PT/OT within 3 months of randomisation: n=353 (93%)
- Did not receive PT/OT within 3 months of randomisation: r=25 (6%)^Ω
 - Started PT/OT after 3 months (r=12)
 - Never received PT/OT (n=13)
- Unknown whether patient has received PT/OT as therapy logs not returned: r=3 (1%)

3 months NEADL data available for analysis: n=350 (/381; 92%)

- Form expected, but not returned (n=23)
- Form not expected (n=8)
 - Withdrawn (r=2)
 - Partially Withdrawn* (n=5)
 - Died (r=1): Respiratory

9 months NEADL data available for analysis: n=326 (/373; 87%)

- Form expected, but not returned (r=41)
- Form not expected (n=6)
 - Partially Withdrawn* (n=3)
 - Died (r=3): Cancer, Respiratory, Road traffic

15 months NEADL data available for analysis: n=311 (/367; 85%)

- Form expected, but not returned (r=45)
- Form not expected (n=11)
 - Withdrawn (r=3)
 - Partially Withdrawn* (n=4)
 - Died (n=4): Cancer, Cardiovascular, Respiratory, Falls/Fracture

Allocated to no therapy $(N=381)^{++}$

- Received no therapy within 3 months of randomisation: n=372 (98%)
- Crossed over to PT/OT within 3 months of randomisation: n=9 (2%) !
 - Reasons for cross-over included worsening PD symptoms, falls and balance problems

3 months NEADL data available for analysis: n=349 (/381; 92%)

- Form expected, but not returned (n=27)
- Form not expected (n=5)
 - Withdrawn (n=2)
 - Partially Withdrawn* (r=1)
 - Died (r=2): Cardiovascular, Natural causes

9 months NEADL data available for analysis: n=331 (/376; 88%)

- Form expected, but not returned (n=33)
- Form not expected (r=12)
 - Withdrawn (r=1)
 - Partially Withdrawn* (n=2)
 - Died (n=9): Cancer, Cardiovascular, Respiratory, Infection

15 months NEADL data available for analysis: n=322 (/364; 88%)

- Form expected, but not returned (n=36)
- Form not expected (n=6)
 - Partially Withdrawn* (r=2)
 - Died (n=4): Cancer, Cardiovascular, Respiratory

[†] Eight patients randomised to the PT and OT group were later found to be ineligible as they had received PT and/or OT for PD in the 12 months prior to randomisation (exclusion criteria). One patient did not receive any PT or OT post-randomisation (cross-over, only baseline data available - diagnosed with cancer and died at 5 months post-randomisation). One patient did not receive PT or OT within 3 months, but was referred for PT outside of the trial at 6 months (3, 9 and 15 month data available). The other six patients all received PT and/or OT post-randomisation (baseline and 3 month data available, except for one patient where only baseline data are available).

^{††} Three patients randomised to the no therapy group were subsequently found to be ineligible as they had received PT and/or OT for PD in the 12 months prior to randomisation (exclusion criteria). One patient received PT and/or OT within 3 months of randomisation (cross-over). For all three patients, baseline and 3 month data was available.

Thirteen patients randomised to the PT and OT group are known to have not received any PT or OT. Baseline and 3 month data are available for two of these patients (for the other eleven patients' only baseline data are available). Twelve patients did not receive PT or OT by 3 months post-randomisation, but did start therapy after 3 months; baseline and 3 month data are available for all patients (except two, one had baseline only and one has 3 month only).

[!] Nine patients randomised to no therapy had some PT and/or OT before their 3 month NEADL form was completed, all patients had baseline and 3 month data available.
* Partially withdrawn patients did not wish to complete patient forms, but agreed to clinical follow-up