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PD REHAB
Trial Update

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PD REHAB - Randomised controlled trial to assess the clinical- and cost-effectiveness of physiotherapy and occupational therapy in Parkinson's disease.

- 750 participants
- 40 centres
- Randomised between PT & OT (starting within 4 weeks) versus no therapy.
- Follow up 15 months



PD REHAB Participants

Inclusion Criteria

- Idiopathic PD defined by the UK PDS Brain Bank Criteria
- Report limitations in activities of daily living
- The investigator is uncertain that the patient will require OT and/or PT during the 15 months of the trial

Exclusion Criteria

- Dementia as usually defined clinically by the patient's physician.
- Received OT or PT in the last one year *



PD REHAB

What's Changed?



PD REHAB

What's Changed?

- Letters of invitation for potential participants have been approved by ethics and are available. – Requested by sites that hold lists of people with PD who wish to be informed of potential research that they may be eligible for.
- Initial Assessment and therapist log forms have been improved, approved and updated after feedback from the therapists



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What's Changed?

- Reduced the amount of requests for SAE forms as the previous system was overly complicated with little extra benefit.



PD REHAB Therapist Forms

Initial Assessment

1. Question added:

**Will the participant receive any further Occupational therapy /
Physiotherapy? Yes No**

2. Process changed:

Initial assessment to be returned following assessment

Therapist Logs

1. Clarification:

One to one/ **joint**/ group session



PD REHAB AEs & SAEs

Given that PD REHAB is an extremely low risk trial, we are recording a limited range of AEs & SAEs:

- Falls
- Equipment failure

Serious enough to require medical attention, either GP, ambulance or hospital visit.

We will request further information on being informed by the participants of any of these events occurring.



PD REHAB AEs & SAEs

Given that PD REHAB is an extremely low risk trial, we are recording a limited range of AEs & SAEs:

- Falls
- Equipment failure

Serious enough to require hospital visit.

We will only request further information on being informed that a participant has been hospitalised.

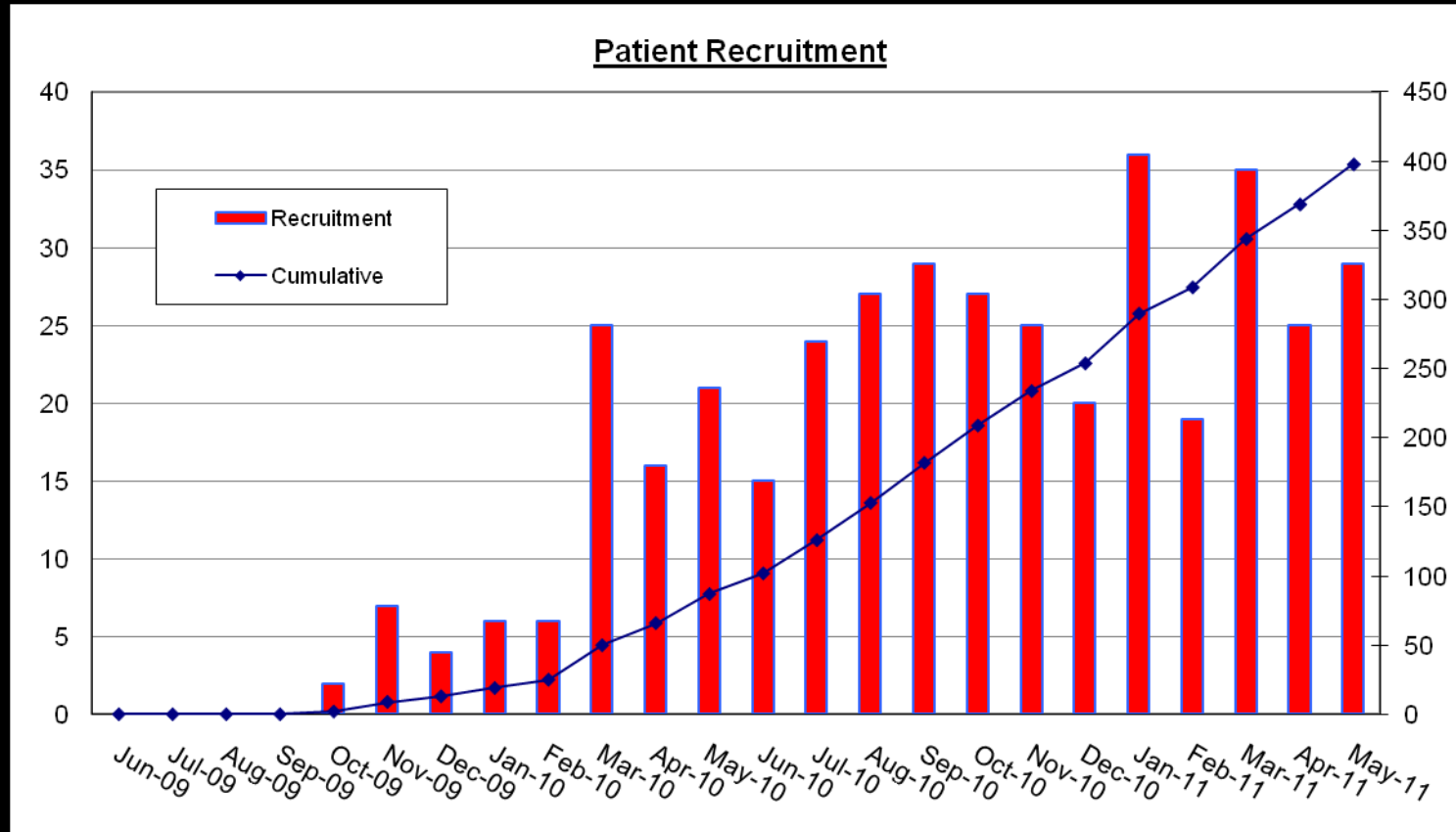


PD REHAB Recruitment

- 420 patients recruited in ~ 24 months
- 12 months remain
- ~ 330 recruitments to hit target of 750

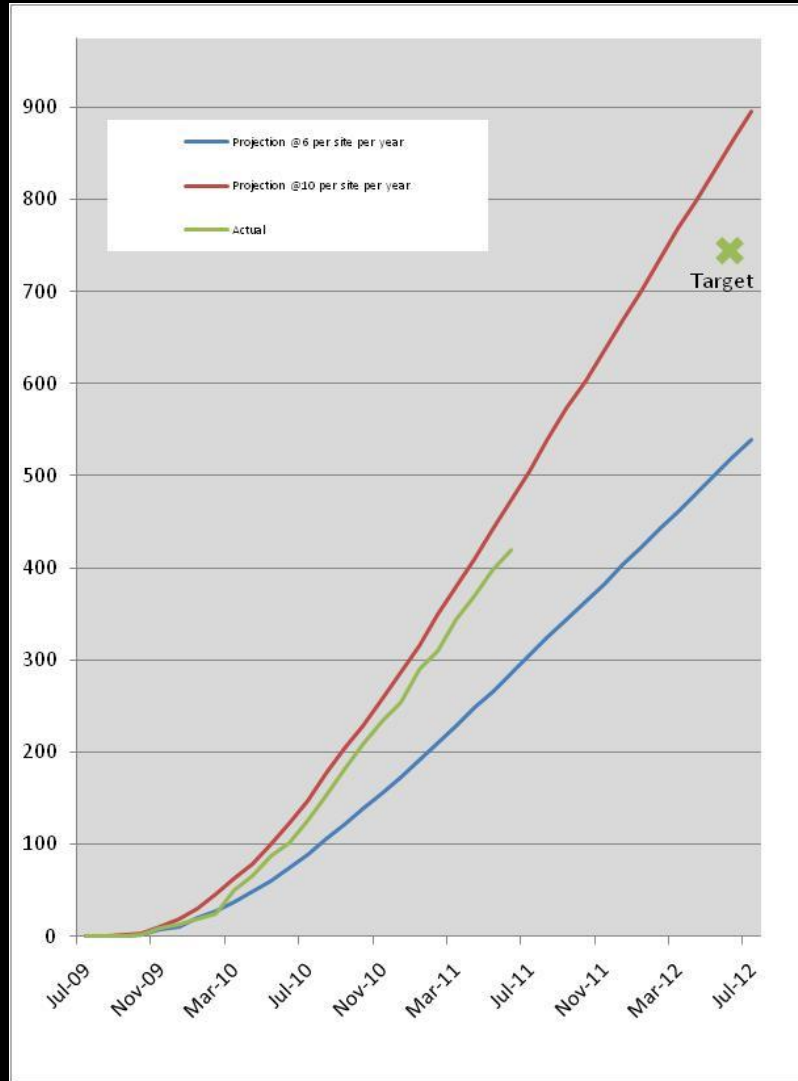


PD REHAB Recruitment





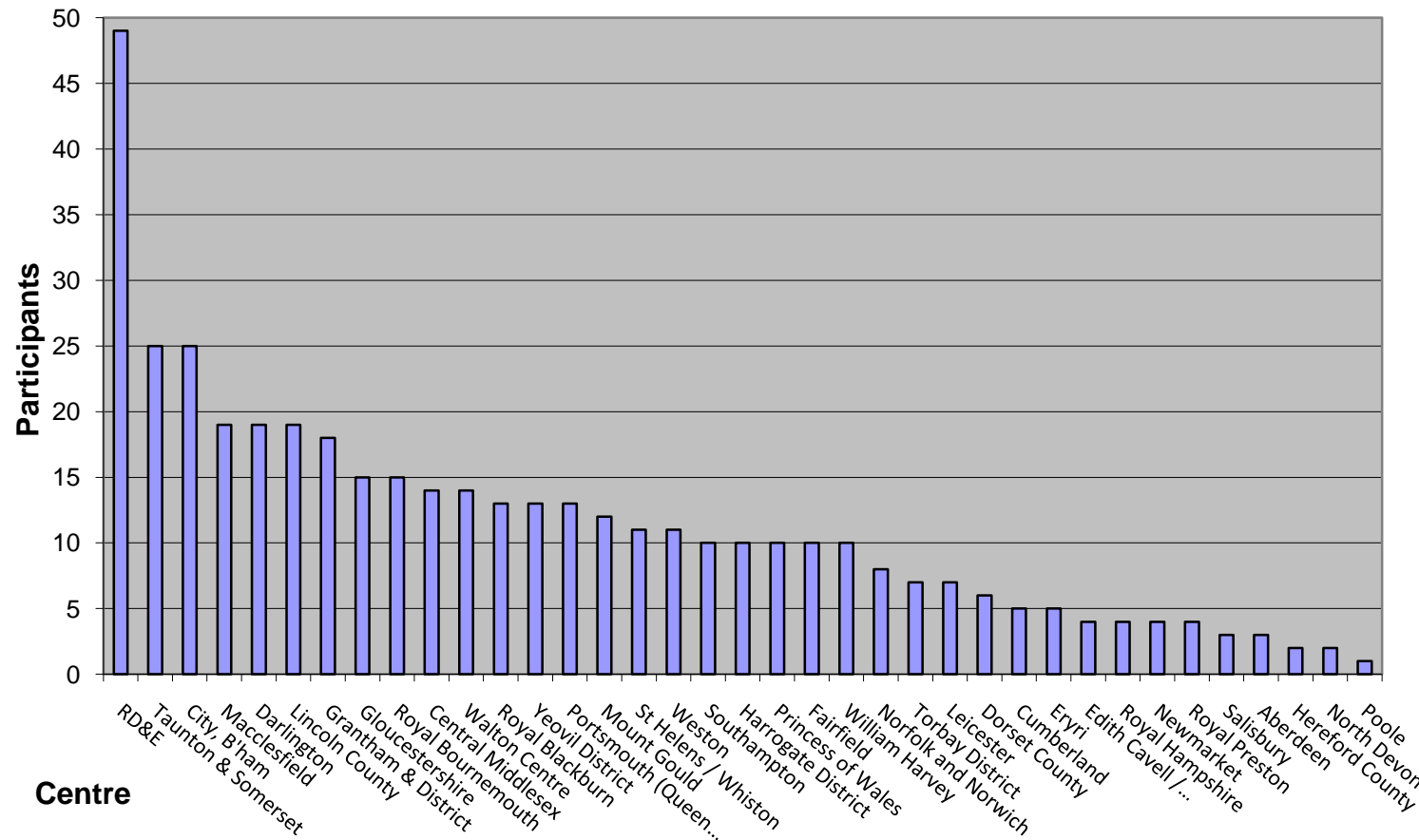
PD REHAB Projections



Projections calculated for 39 sites. If 40 sites are active, the final projections are:
575 participants @6 or
962 participants @10
per site per year.



Recruitment by Site





PD REHAB Sites

Aberdeen Royal Infirmary
Central Middlesex Hospital
City Hospital, Birmingham
Cumberland Infirmary
Darlington Hospital
Dorset County Hospital
Edith Cavell Hospital
Eryri Hospital, Caernarfon
Fairfield Hospital, Bury
Gloucestershire Royal Hospital
Grantham District Hospital
Harrogate District Hospital
Hereford District General
Hull Royal Infirmary
Leicester General Hospital
Lincoln County Hospital
Macclesfield Hospital
Mount Gould Hospital
NHNN
Newmarket Community Hospital

Norfolk & Norwich University Hospitals
North Devon District Hospital
Poole Hospital
Princess of Wales Hospital
Queen Alexandra Hospital Portsmouth
Royal Blackburn Hospital
Royal Bournemouth General Hospital
Royal Devon & Exeter Hospital
Royal Hampshire County Hospital
Royal Preston Hospital
Salisbury District Hospital
Southampton General Hospital
St Helens/Whiston Hospital
Taunton & Somerset Hospitals
Torbay Hospital
Walton Centre for N+N
Weston General Hospital
William Harvey Hospital
Yeovil District Hospital

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PD REHAB Therapy Sites

Aberdeen Royal Infirmary, Woodend Day Hospital
Central Middlesex Hospital, Willesden Centre for Health & Rehabilitation
Rowley Regis Hospital, City Hospital
Cumberland Infirmary
Shotley Bridge Hospital, Darlington Memorial Hospital,
Bishop Auckland General Hospital
Atrium Health Centre
City Health Clinic, Healthy Living Centre
Llandudno General Hospital
Fairfield Hospital
Gloucester Royal Hospital, Tewkesbury Hospital
Grantham & District Hospital, Pilgrim Hospital
Harrogate District Hospital
Herefordshire Community Hospitals, Bromyard Community Hospital
Hull Royal Infirmary, Westbourne Avenue NHS Centre
Loughborough Hospital, Leicester Royal Infirmary, Leicester General
Hospital, 1 Spinney Hill Road, Overton House
Lincoln County Rehab Team, Loath County Hospital
Macclesfield District General Hospital, Congleton War Memorial
Hospital, Knutsford Community Hospital
Mount Gould Hospital
National Hospital for Neurology & Neurosurgery
Newmarket Community Hospital

Norfolk & Norwich University Hospitals
Torrington Hospital
Aldernay Community Hospital
Pendre Day Hospital, Princess of Wales Hospital
Petersfield Hospital, St. James Hospital,
Queen Alexandra Hospital
Royal Blackburn Hospital
Christchurch Hospital, St. Leonard Day Hospital
Whipton Community Hospital
Royal Hampshire County Hospital
Royal Preston Hospital
Salisbury District Hospital
Ramsey Hospital, Bitem Park Surgery
St Helens/Whiston Hospital
Dene Barton Community Unit
Paignton Hospital
Queensway Day Hospital, Yeovil District Hospital
Walton Centre
Weston General Hospital
Kent & Canterbury Hospital, QE Queen Mother Hospital
William Harvey Hospital



Baseline Demographics

- **68% male**
- **61% have a carer**
- **Mean age at randomisation 71 years**
- **Mean time since diagnosis 56 months
(median time = 30 months)**



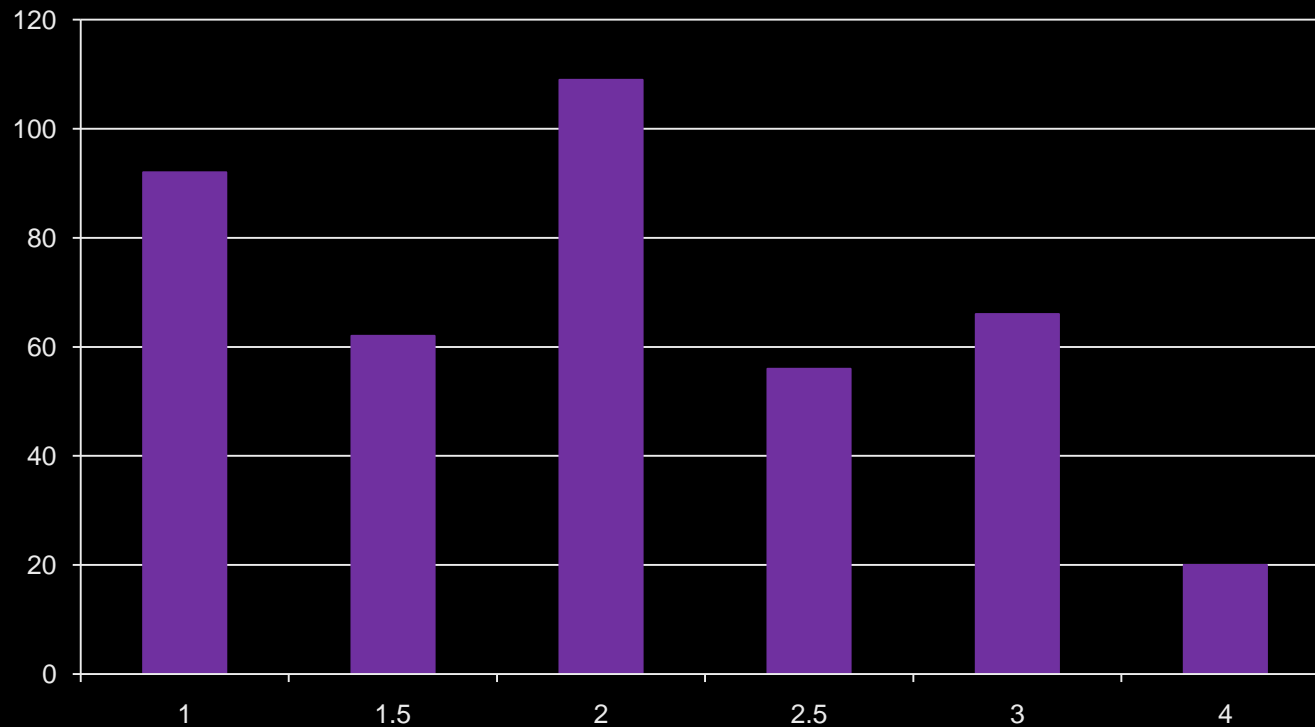
Hoehn & Yahr Staging

- ❑ Stage 1.0 Unilateral involvement only
- ❑ Stage 1.5 Unilateral and axial involvement
- ❑ Stage 2.0 Bilateral involvement without impairment of balance
- ❑ Stage 2.5 Mild bilateral involvement with recovery on retropulsion (pull) test
- ❑ Stage 3.0 Mild to moderate bilateral involvement, some postural instability but physically independent
- ❑ Stage 4.0 Severe disability, still able to walk and to stand unassisted
- ❑ Stage 5.0 Wheelchair bound or bedridden unless aided.



Hoehn & Yahr (2)

Hoehn & Yahr Scores at Baseline

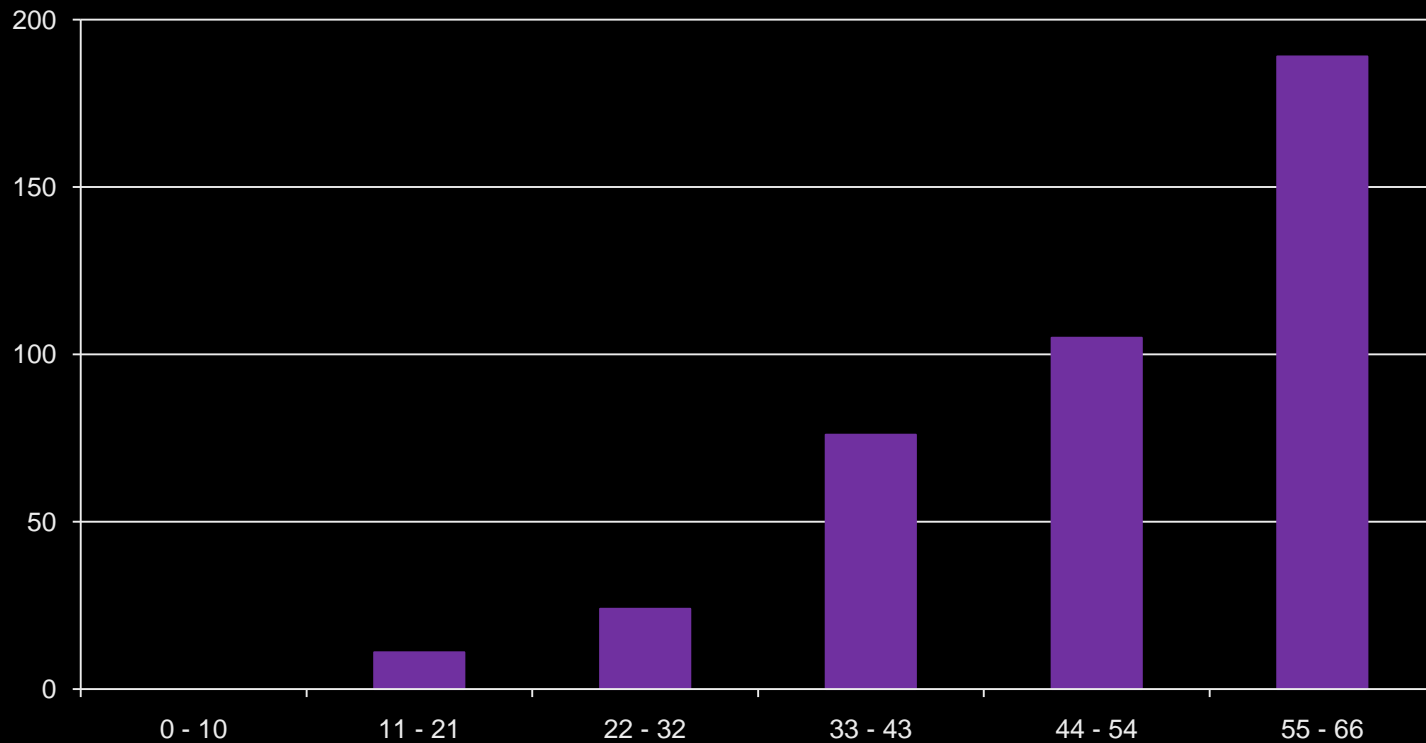


Most participants do not have postural instability at randomisation



Activities of Daily Living

NEADL Score at Baseline





SAEs

Per the protocol an SAE is a fall or equipment failure that requires hospitalisation

- 19 reported SAEs**
- 15 weren't hospitalised**
- 4 were hospitalised**
- 4 hospitalisations were related to falls**
- 0 were related to equipment failure**



Patient & Public Involvement

- **Newsletters**
- **Trial Steering Committee**
- **Disseminating Results**
- **10 Top Tip Guides for Patients**



PD REHAB

Data Quality



PD REHAB

Data Quality

- Use Version 9 forms only – including version 9.2 for the therapist forms and 9.1 for the exit form, with all other forms being version 9.0
- Ensure all consent forms are completed fully and accurately to GCP standards



PD REHAB

Process Quality

- Recruitment of ineligible patients



PD REHAB

Process Quality

- Patients not starting treatment promptly



PD REHAB

Process Quality

- Patient crossover rate



PD GEN



PD GEN DNA bank protocol is approved to allow participants in PD REHAB and their carers to provide PD GEN samples.

Sites need ethical approval for PD GEN as well as PD REHAB



PD REHAB Support

□ Website <http://www.pdrehab.bham.ac.uk/>

□ Contact us:

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Thank You

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