Specialist rehabilitation for people with Parkinson's disease in the community: a randomised controlled trial

Heather Gage,[1]* Linda Grainger,[1] Sharlene Ting,[1] Peter Williams,[2] Christina Chorley,[1] Gillian Carey,[1] Neville Borg,[1] Karen Bryan,[3] Beverly Castleton,[4] Patrick Trend,[5] Julie Kaye,[3] Jake Jordan[1] and Derick Wade[6]

[1]School of Economics, University of Surrey, Guildford, UK
[2]Department of Mathematics, University of Surrey, Guildford, UK
[3]Division of Health and Social Care, University of Surrey, Guildford, UK
[4]Outpatient Department, The Runnymede Hospital, Chertsey, UK
[5]Department of Neurology, Royal Surrey County Hospital, Guildford, UK
[6]Oxford Centre for Enablement, Nuffield Orthopaedic Centre, Oxford University Hospitals NHS Trust, Oxford, UK

*Corresponding author

Declared competing interests of authors: Funding received from the South East Coast Dementias and Neurodegenerative Disease Research Network and the NHS South East Coast.

Published December 2014
DOI: 10.3310/hsdr02510

Scientific summary

Rehabilitation for people with Parkinson's disease

Health Services and Delivery Research 2014; Vol. 2: No. 51
DOI: 10.3310/hsdr02510

NIHR Journals Library www.journalslibrary.nihr.ac.uk

Scientific summary

Background

Parkinson's disease (sometimes referred to as Parkinson's) is a degenerative neurological condition that affects mainly older people, but there are also significant numbers with young onset. Although frequently designated as a movement disorder, it additionally inflicts a range of distressing non-motor symptoms, (problems with pain, sleep, speech, swallowing, constipation, incontinence, sexual dysfunction, communication and social isolation). There is currently no known cure for Parkinson's disease, and treatment revolves around maintaining quality of life through symptom relief. The mainstay of management is a pharmacological regimen, which gradually becomes less effective and more complicated as the disease progresses. This is supported by rehabilitative therapies, assistive technologies and, occasionally, surgery. Given the range of symptoms and the complexity of managing Parkinson's disease, a collaborative multidisciplinary team (MDT) approach to rehabilitation is recommended. However, the effectiveness of the MDT approach has not been widely researched.

The Specialist Parkinson's Integrated Rehabilitation Team Trial (SPIRiTT) builds on the findings of a previous multidisciplinary rehabilitation programme, co-ordinated by a Parkinson's nurse specialist (PNS) in a day-hospital setting. This intervention resulted in significant immediate gains for patients in mobility, independence, well-being and health-related quality of life, but, in the absence of continuing input, these benefits had largely dissipated 4 months after the intervention ended. SPIRiTT delivers rehabilitation to people in their own homes, and evaluates whether or not the fading of benefit when specialist input is withdrawn can be avoided by providing continuing support from trained care assistants. Participants in SPIRiTT received an equivalent package of specialist rehabilitation to that used in the day-hospital study so that comparisons can be drawn between the models of domiciliary and day-hospital provision.

The SPIRiTT model of service delivery is based on recent NHS policy which promotes the provision of services closer to patients' homes, co-ordination of care by specialist nurses, supported self-management, personalised care planning, rehabilitation and carer support. The use of trained assistants is consistent with workforce policy which advocates the integration of non-registered health and social care workers with enhanced roles in MDTs, to implement and deliver therapy and monitor and support patients.

Objectives

1. Implement a specialist neurological rehabilitation service for people with Parkinson's and their family carers, delivered in their own homes, comprising MDT assessment, care planning and treatment (following the protocol previously evaluated in a day hospital).
2. Provide ongoing support from trained care assistants to those receiving the rehabilitation.
3. Evaluate the clinical effectiveness of the specialist rehabilitation service, and the value added by ongoing support from trained care assistants embedded in the MDT, compared with usual care, (largely non-specialist and non-team based).
4. Assess the costs of the specialist rehabilitation intervention, and of the ongoing care assistant support, and calculate relative cost-effectiveness, including consideration of savings from service use offsets.
5. Investigate the acceptability of the new service delivery models from the perspectives of all stakeholders (commissioners, MDT members, care assistants, managers, patients and family carers).
6. Deliver guidance for commissioners, providers and policy-makers.

Methods

Design
Pragmatic three-parallel group randomised controlled trial.

Setting
Contiguous communities around three district general hospitals in the county of Surrey, England, containing urban, suburban and rural localities and a broad mix of socioeconomic and ethnic groups.

Participants
People with Parkinson's, at all stages of the disease, and their live-in carers (where applicable).

Recruitment
People with Parkinson's were identified through hospital clinic lists; general practitioners; Parkinson's UK contacts; PNSs; community-based therapists; and word of mouth. Research nurses from the Primary Care Research Network and the Dementias and Neurodegenerative Diseases Research Network (DeNDRoN) assisted with recruitment. The interventions were delivered over 18 months, commencing September 2010.

Inclusion criteria
People with Parkinson's were included if they were 18 years of age or over; had a clinical diagnosis of Parkinson's disease; lived in the community (own home or minimally sheltered accommodation); lived in the catchment areas of three district hospitals in the county of Surrey; were able to read and write English in order to complete the self-report questionnaires; had not received a multidisciplinary package of care over the last 6 months; and had not taken part in rehabilitation research in the last 6 months. Live-in carers were included if they were 18 years of age or over and were able to read and write English in order to complete the self-report questionnaires. If a live-in carer did not want to take part in the research, the person with Parkinson's could still join the trial. However, carers were not accepted if the person with Parkinson's did not want to participate. Carers who did not take part in the research were included in the intervention.

Baseline data collection
Volunteers were entered into the trial in blocks (cohorts) of 30 (10 per group). They were visited at home by a research nurse. Consent was received and baseline data collection was completed (background demographic and health information and baseline outcome measures). Baseline data were checked to confirm participant eligibility.

Exclusion criteria
People with Parkinson's were excluded if they scored at the most favourable end of all outcome scales (as the trial would not be able to demonstrate improvement, and, in 6 months, had little likelihood of demonstrating reduction in any expected decline); and scored < 24 out of 30 on the Mini Mental State Examination (to ensure that those recruited could follow instructions associated with the rehabilitation intervention). Live-in carers were excluded if they scored at the most favourable end of all outcome scales (i.e. had no limitations).

Randomisation
Eligible volunteers were randomised to either group A (received MDT assessment and management for 6 weeks), group B (same MDT package and additionally received ongoing support for 4 months from a trained care assistant) or group C [received usual care: no co-ordinated MDT assessment and care, no ongoing support from a care assistant trained in Parkinson's (Parkinson's care assistant: PCA)]. A separate randomisation sequence was prepared for people with Parkinson's with and without live-in carers. In each instance, blocked randomisation was used to keep the group sizes even at 10 people with Parkinson's per group, that is to say a cohort of 30 people.

Specialist rehabilitation intervention (groups A and B)

A MDT comprising a PNS, a physiotherapist (PT), an occupational therapist (OT), and a speech and language therapist (SLT) visited the homes of participants to deliver a specialist rehabilitation package, tailored to individual needs, over 6 weeks (about 9 hours of individual therapy per patient). Educational materials were provided on aspects of Parkinson's disease. A client record form was left in the participant's home for the duration of the intervention, and was completed by each professional at each visit. There were two team meetings per cohort to discuss patient care plans and progress. Referrals to other professionals were made when indicated, including to a neurologist, a community mental health team and a Parkinson's UK support worker.

Ongoing support (group B)

In addition to the programme of specialist MDT rehabilitation, participants in group B received ongoing support for 4 months from a PCA, starting at the end of the 6-week MDT intervention. The PCAs received training in Parkinson's disease, were embedded in the MDT and worked under the supervision of the PNS. Contact was via home visits and telephone (about 1 hour per week per patient of support), through which the PCA monitored progress in implementation of the agreed care plan and reported back to the MDT.

Usual care/control (group C)

Participants in the control group continued to receive care as usual (no co-ordinated MDT care or ongoing support). They were sent generic information (available from Parkinson's UK) about Parkinson's disease (which was also given to people in groups A and B by the MDT). At the end of the trial, people in the control group were offered an assessment by a member of the MDT (of their choice), and advice and referrals were provided, as indicated.

Outcome assessments

Research nurses visited participants in their homes to conduct follow-up assessments at three points (6 weeks, 24 weeks and 36 weeks) over 6 months.

Outcome measures

Measures of relevance to daily functioning were chosen as the primary outcomes: the Self Assessment Parkinson's Disease Disability Scale (patients report ease or difficulty of doing 25 general activities on a five-point scale) and the Modified Caregiver Strain Index. Secondary outcomes included: for patients, disease-specific and generic health-related quality of life, psychological well-being, self-efficacy, mobility, falls, speech and voice; and for carers, strain, stress, health-related quality of life, psychological well-being, and functioning.

Sample size calculations

Two hundred and seventy people with Parkinson's (90 per group) were required in order to detect a difference between groups in the change in the disability score of 1.25, after allowance for loss to follow-up. We expected to recruit 71 carers per group (because 79% of people with Parkinson's in the day-hospital study had carers).

Statistical analysis

Groups were compared at baseline. All outcomes were analysed at each follow-up assessment point. The null hypotheses tested were that there were no differences between the groups with respect to changes in each primary and secondary outcome measure from baseline (week 0) to each follow-up point (weeks 6, 24 and 36), and between each sequential follow-up point (weeks 6–24 and weeks 24–36). Within-group changes were also analysed.

Acceptability of the intervention

Feedback from participants was obtained using semistructured questionnaires. All members of the MDT and the PCAs were asked to provide reflective feedback (open comments) at three points during the trial, and through 'exit' interviews. Data were analysed descriptively and using thematic analysis.

Economic evaluation

A NHS perspective was adopted. The costs of the intervention were calculated in 2011 Great British pounds. The use of health and social care services were collected by self-report at baseline, 24- and 36-week assessments by recall for the previous 3 months, to explore cost offsets arising from the interventions. Outcomes were evaluated with reference to costs.

Results

A total of 306 people with Parkinson's (182 live-in carers) were randomised [group A, $n = 102$ ($n = 61$); group B, $n = 101$ ($n = 60$); group C, $n = 103$ ($n = 61$)]. Of these, 269 (155) were analysed at baseline. The first (pilot) cohort was not included in the analysis as the MDT processes were under development. There were some differences between groups at baseline. People with Parkinson's in group B scored worse on the Frenchay Activities Index ($p = 0.01$) and tended to display higher disability (Barthel Activities of Daily Living, $p = 0.08$) than those in groups A and C. Higher proportions in C screened positive for depression (Yale Depression Screen, $p = 0.01$); groups A and B scored worse than C on some speech items ($p = 0.03$ to $p = 0.08$).

Attrition occurred at all stages, and a per-protocol analysis is reported for 227 people with Parkinson's (125 live-in carers) [group A, $n = 75$ ($n = 45$); group B, $n = 69$ ($n = 37$); group C, $n = 83$ ($n = 43$)]. An intention-to-treat analysis was also conducted. The results and conclusions from each analysis are similar.

Effects of the multidisciplinary team

Compared with group C (control), people with Parkinson's receiving the 6-week MDT intervention (groups A and B) experienced an immediate reduction in anxiety ($p = 0.02$); their carers recorded improved psychological well-being [Short Form questionnaire-36 items (SF-36) mental component summary (MCS), $p = 0.02$]. People with Parkinson's also had marginally improved disability (primary outcome, $p = 0.09$), non-motor symptoms ($p = 0.06$) and health-related quality of life [European Quality of Life-5 Dimensions (EQ-5D) Index, $p = 0.07$].

Effects of ongoing support from Parkinson's care assistants

There were significant differences in change scores between week 6 (end of MDT) and week 24 (end of PCA for group B) in favour of group B due to worsening in group A (no PCA support) in posture ($p = 0.001$), non-motor symptoms ($p = 0.05$), health-related quality of life (EQ-5D Index, $p = 0.07$), and self-efficacy ($p = 0.09$). Carers in group B (vs. group A) reported a tendency for reduced strain (primary outcome, $p = 0.06$).

Long-term follow-up

At 36 weeks post recruitment (3 months after PCA support for group B ended), there were few differences between the groups. There were significant differences between changes in people with Parkinson's in group B and in groups A and C in psychological well-being (SF-36 MCS, both $p = 0.05$) and Speech Self Report ($p = 0.02$, 0.03) due to significant deteriorations in A and C. Gait of people with Parkinson's improved in group B versus group A ($p = 0.09$); mobility (Timed Up and Go) improved in group A versus group C ($p = 0.06$). The psychological well-being of carers in group A declined versus group B (SF-36 MCS, $p = 0.04$).

Acceptability

People with Parkinson's who received the MDT intervention reported that they had learnt a lot about the condition, and how to manage it; they valued the tailored advice and the opportunity to discuss their problems with knowledgeable professionals.

Costs of the intervention

The total cost per patient was £833 for the 6-week MDT, and an additional £600 for the 4 months of ongoing PCA support. There were no differences between groups in the cost of other service use. As no statistically significant differences in change scores between groups for either the patient or the carer primary outcome measures, or EQ-5D Index scores (for quality-adjusted life-years), at the final end point (6 months) were found, a full cost-effectiveness analysis was not undertaken.

Conclusions

Information on alternative specialist community rehabilitation models, such as that provided by the SPIRiTT trial, is important to enable evidence-based decisions to be made by service planners and commissioners. The SPIRiTT intervention incorporates key elements of interprofessional working (shared goal setting and care planning, effective communication channels and appropriate referrals to other specialities), and a client-centred approach that invites participants to prioritise their concerns. It also provides support for carers, which is a high policy priority, because it protects their health and improves their ability to cope.

The results showed that people with Parkinson's experienced reduced anxiety and a tendency for reduced disability and improved symptom control and health-related quality of life after the MDT intervention. There is also evidence that continuing PCA input provided some benefits [in symptom control, posture and (marginally) health-related quality of life] to people with Parkinson's while it lasted. Similarly, carers recorded improved psychological well-being at the end of the MDT intervention, and tendency to report reduced strain after the PCA support. Feedback from participants suggested that the MDT intervention was effective at increasing their understanding of the condition and signposting to other services.

Further research on the relative benefits and costs of alternative models of specialist multidisciplinary rehabilitation for people with Parkinson's in the community is required, including the means by which improvements gained from specialist MDT rehabilitation can be sustained. The potential of PCA support for people with Parkinson's and carers deserves further attention. A relatively small amount of PCA input in SPIRiTT helped to maintain patient functioning on some indicators, and to reduce carer strain, while it was provided, but more research is required on how the nature and 'dose' might affect longer-term outcomes.

Study registration

This trial is registered as ISRCTN44577970.

Funding

Funding for this study was provided by the Health Services and Delivery Research programme of the National Institute for Health Research, the South East Coast Dementias and Neurodegenerative Disease Research Network (DeNDRoN), and the NHS South East Coast.

Health Services and Delivery Research

ISSN 2050-4349 (Print)

ISSN 2050-4357 (Online)

This journal is a member of and subscribes to the principles of the Committee on Publication Ethics (COPE) (www.publicationethics.org/).

Editorial contact: nihredit@southampton.ac.uk

The full HS&DR archive is freely available to view online at www.journalslibrary.nihr.ac.uk/hsdr. Print-on-demand copies can be purchased from the report pages of the NIHR Journals Library website: www.journalslibrary.nihr.ac.uk

Criteria for inclusion in the *Health Services and Delivery Research* journal

Reports are published in *Health Services and Delivery Research* (HS&DR) if (1) they have resulted from work for the HS&DR programme or programmes which preceded the HS&DR programme, and (2) they are of a sufficiently high scientific quality as assessed by the reviewers and editors.

HS&DR programme

The Health Services and Delivery Research (HS&DR) programme, part of the National Institute for Health Research (NIHR), was established to fund a broad range of research. It combines the strengths and contributions of two previous NIHR research programmes: the Health Services Research (HSR) programme and the Service Delivery and Organisation (SDO) programme, which were merged in January 2012.

The HS&DR programme aims to produce rigorous and relevant evidence on the quality, access and organisation of health services including costs and outcomes, as well as research on implementation. The programme will enhance the strategic focus on research that matters to the NHS and is keen to support ambitious evaluative research to improve health services.

For more information about the HS&DR programme please visit the website: http://www.nets.nihr.ac.uk/programmes/hsdr

This report

The research reported in this issue of the journal was funded by the HS&DR programme or one of its proceeding programmes as project number 08/1909/251. The contractual start date was in September 2009. The final report began editorial review in December 2012 and was accepted for publication in January 2014. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HS&DR editors and production house have tried to ensure the accuracy of the authors' report and would like to thank the reviewers for their constructive comments on the final report document. However, they do not accept liability for damages or losses arising from material published in this report.

Published by the NIHR Journals Library (www.journalslibrary.nihr.ac.uk), produced by Prepress Projects Ltd, Perth, Scotland (www.prepress-projects.co.uk).