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Specialist Parkinson's Integrated Rehabilitation Team Trial

Submission date
29/04/2010

Recruitment status
No longer recruiting

Registration date
29/04/2010

Overall study status
Completed

Last Edited
03/02/2015

Condition category
Nervous System Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Parkinson's disease is a neurological condition that causes movement problems and other distressing symptoms. People with Parkinson's gradually lose their independence and a great strain is placed on family members. The cost to the health and social care services of treating people with Parkinson's disease is high. There is a need for research into the most cost-effective way of providing rehabilitation and support to people with Parkinson's in the community.

The research group conducting this research comprises clinicians, academics, patients and carers with an established track record of research into rehabilitation for people with Parkinson's disease. It has completed a trial of a programme of day hospital rehabilitation, which found that specialist multidisciplinary rehabilitation, coordinated by a Parkinson's disease nurse specialist, resulted in significant immediate gains for patients in mobility, independence, wellbeing and quality of life, but that these benefits had largely disappeared four months after the treatment ended. Moreover, it showed that day hospital treatment was expensive because of overhead costs and the need for hospital transport for patients with advanced disease. The new trial will explore if costs can be reduced by delivering rehabilitation to people with Parkinsons in their own homes, and if short-term benefits can be maintained through providing ongoing support from Parkinsons care assistants after the specialist intervention has finished.

Who can participate?
People with Parkinsons disease who were aged over 18 years, and live-in carers of participating people with Parkinsons disease aged over 18 years.

What does the study involve?
Participants were randomly allocated to three groups: those in group A were assessed and managed by a specialist neurology multidisciplinary team (MDT) according to a care plan agreed between the professionals, patient and carer. Patients in group B additionally received four months of ongoing support from a trained care assistant. Group C received normal care (no coordinated MDT care planning or ongoing support) and an information pack. Therefore, building on the previous studys findings, the research provided an equivalent package of specialist rehabilitation to patients in their own homes to that used in the day hospital study so that valid comparisons could be drawn between the models. It also collected feedback from

users and providers about the acceptability of the interventions. The findings will provide guidance to local managers planning services.

What are the possible benefits and risks of participating?
The study findings could benefit other people with Parkinson's disease and their carers if the intervention is shown to be effective and acceptable. It could assist them to maintain or improve their health and independence, prevent complications and reduce carer strain in a cost-effective manner. Risks to participants were considered small, and no higher than those of usual care. However, as it was possible that encouragement to increase exercise could have resulted in falls that might not otherwise have occurred, these were monitored.

Where is the study run from?
School of Economics, University of Surrey.

When is study starting and how long is it expected to run for?
The study started in September 2009 and will be completed in November 2012.

Who is funding the study?
The Health Services and Research Delivery Programme - National Institute of Health Research;
The South East Coast DeNDRon (Dementias and Neurodegenerative Disease Research Network);
The NHS South East Coast.

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
8182

Study information

Scientific Title

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

Acronym
SPIRiTT

Study objectives
Parkinson's is a neurological condition that causes movement problems, and many other distressing symptoms. People with Parkinson's gradually lose their independence, and a great strain is placed on family members. The cost to the health and social care services of treating people with Parkinson's is high. The Service Delivery and Organisation review has identified a need for research into the most cost-effective way of providing rehabilitation and support to people with Parkinson's in the community, which this proposal addresses.

The trial's research group comprises clinicians, academics, patients and carers with an established track record of research into rehabilitation for people with Parkinson's. It has completed a robust trial of a programme of day hospital rehabilitation, which found that specialist multidisciplinary rehabilitation, coordinated by a Parkinson's nurse specialist, resulted in significant immediate gains for patients in mobility, independence, wellbeing and health-related quality of life, but that, in the absence of continuing input, these benefits had largely dissipated four months after the intervention ended. Moreover, it showed that day hospital treatment was expensive because of overhead costs and the need for hospital transport for patients with advanced condition.

The current trial builds on the findings of this previous work. It will provide an equivalent package of specialist rehabilitation to patients in their own homes to that used in the day hospital study so that valid comparisons can be drawn between the models. It will investigate whether the fading of benefit when specialist input is withdrawn, (a common feature of time-limited rehabilitation interventions), can be avoided in a cost-effective way by providing continuing support from trained care assistants. It will also collect feedback from users and providers about the acceptability of the interventions.

Please note that as of 18/10/2012, the anticipated end date for this trial was updated from 31/05/2012 to 14/11/2012.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Surrey Research Ethics Committee approved on the 19/01/2010 (ref: 10/H1109/1)

Study design
Randomised interventional prevention trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied

Topic: Dementias and Neurodegenerative Diseases Research Network; Subtopic: Parkinsons Disease; Disease: Parkinson's disease

Interventions
Multidisciplinary team intervention:
Multidisciplinary rehabilitation will be provided over six weeks. Initial assessment by specialist multidisciplinary team of Parkinsons nurse specialist (coordinator), physio-, occupational and speech and language therapists; agreed care plan tailored to individual needs.

Care assistant support:
Half of the participants receiving multidisciplinary rehabilitation will additionally receive ongoing support from a care assistant trained in the management of Parkinson's. The agreed care plan will be implemented following the end of the six week rehabilitation programme for 18 weeks, under the supervision of the Parkinson's nurse specialist and guidance of the multidisciplinary team.

Usual care:
Participants will be sent an information pack containing generic information about Parkinson's. At the end of the trial, participants will be offered an assessment by a member of the multidisciplinary team.

Follow up length: 9 months
Study entry: single randomisation only

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Self Assessment Parkinson's Disease Disability Scale - Person with Parkinson's, measured at baseline, 6, 24 and 36 weeks

Key secondary outcome(s))
1. Abridged Emerson and Enderby Screening Assessment Rating Scale - Person with Parkinsons, measured at baseline, 6, 24 and 36 weeks
2. Acceptability of intervention: semi-structured interviews - Person with Parkinson's and Live-in carer, measured at 24 weeks
3. Barthel ADL index - Person with Parkinson's and Live-in carer, measured at baseline, 6, 24 and 36 weeks
4. EuroQol 5D with utility index - Person with Parkinson's and Live-in carer, measured at baseline, 6, 24 and 36 weeks
5. Falls self-report - Person with Parkinsons, measured at baseline, 6, 24 and 36 weeks
6. Frenchay Activities Index - Person with Parkinson's and Live-in carer, measured at baseline, 6, 24 and 36 weeks
7. Frenchay Summary - Person with Parkinsons, measured at baseline, 6, 24 and 36 weeks
8. General Health Questionnaire-12 - Live-in carer, measured at baseline, 6, 24 and 36 weeks
9. Health and social care utilisation: customised proforma - Person with Parkinsons, measured at baseline, 24 and 36 weeks
10. Hospital Anxiety and Depression Scale - Person with Parkinson's and Live-in carer, measured

at baseline, 6, 24 and 36 weeks
11. Modified Caregiver Strain Index - Live-in carer, measured at baseline, 6, 24 and 36 weeks
12. Non Motor Symptoms Questionnaire - Person with Parkinsons, measured at baseline, 6, 24 and 36 weeks
13. Pain Visual analogue scale - Person with Parkinsons, measured at baseline, 6, 24 and 36 weeks
14. Parkinson's Disease Questionnaire-8 - Person with Parkinsons, measured at baseline, 6, 24 and 36 weeks
15. Posture and gait items from Unified Parkinson's Disease Rating Scale - Person with Parkinson s, measured at baseline, 6, 24 and 36 weeks
16. Self efficacy scale - Person with Parkinsons, measured at baseline, 6, 24 and 36 weeks
17. Short Form-36 Health Survey - Person with Parkinson's and Live-in carer, measured at baseline, 6, 24 and 36 weeks
18. Single speech item from Unified Parkinson's Disease Rating Scale - Person with Parkinsons, measured at baseline, 6, 24 and 36 weeks
19. Speech self report questionnaire - Person with Parkinsons, measured at baseline, 6, 24 and 36 weeks
20. Timed up and go - Person with Parkinsons, measured at baseline, 6, 24 and 36 weeks
21. Yale single item depression screening tool - Person with Parkinson's and Live-in carer, measured at baseline, 6, 24 and 36 weeks

Completion date
14/11/2012

Eligibility

Key inclusion criteria
Person with Parkinson's:
To be included in the study, the person with Parkinson's must:
1. Be 18 years and over, either sex
2. Have a clinical diagnosis of Parkinson's made by a specialist
3. Live in the community with his/her own living area (own home or minimally sheltered accommodation)
4. Live inside the catchment area of NHS Surrey
5. Be able to read and write English in order to complete the validated self-report questionnaires
6. Provide written consent
7. Have adequate cognitive function to engage with rehabilitation
8. Have some limitation on any of the outcome measures

Live-in carer:
To be included in the study, the carer must:
1. Live-in with the person with Parkinson's enrolled in the study
2. Be 18 years and over, either sex
3. Be able to read and write English in order to complete the validated self-report questionnaires
4. Provide written consent
5. Have some limitation on any of the carer outcome measures

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. People with Parkinson's having (or have had in the past six months) a multidisciplinary rehabilitation package of care
2. People with Parkinson's taking part (or have had in the past six months took part) in a rehabilitation based research study for Parkinson's

Date of first enrolment
01/03/2010

Date of final enrolment
14/11/2012

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Manager SPIRiTT Project,
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Sponsor information

Organisation
University of Surrey (UK)

ROR
https://ror.org/00ks66431

Funder(s)

Funder type
Government

Funder Name
Department of Health (UK) - Subvention Excess Treatment Costs (ref: SPIRiTT)

Funder Name
National Institute for Health Research (NIHR) (UK) - Service Delivery and Organisation (SDO) (ref: 08/1909/251)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2014		Yes	No
Protocol article	protocol	23/11/2011		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes