Research involving older people: the SPIRiTT trial

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Overview

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SPIRiTT

- A comparison of specialist rehabilitation and care assistant support with specialist rehabilitation alone and usual care for people with Parkinson’s living in the community: a randomised controlled trial.
Team

- Dr Heather Gage (Health Economics)
- Peter Williams (Statistics)
- Prof Karen Bryan (Communication and user involvement)
- Julie Kaye (PD nurse specialist)
- Dr Beverley Castleton (Consultant in PD community medicine)
- Dr Patrick Trend (Consultant neurologist)
- Prof Derick Wade (Consultant neurologist and trials methodology expertise)

- Plus Sharlene Ting (Trial Manager) PT admin support and an MDT team (PD nurse specialists, PD support workers SLT, OT, PT)
Background: Parkinson’s Disease

• Chronic, progressive neurological condition
• Movement disorder and non-motor symptoms
• Affects 100-200 people per 100,000 (0.1-0.2%) of the UK general population
• Rising prevalence with age; 1% in people ≥ 80 years
• Higher prevalence in males
• Total annual cost £449M-£3.3B (depending on cost model and prevalence rate)

(NICE 2006; Findley 2007)
Background: Policies

- NSF Long Term Conditions (DH 2005)
  ✓ personalised care planning, rehabilitation, carer support

- Our health, our care, our say (DH 2006)
  ✓ integrated health and social care, provision of services closer to patients’ homes

- NICE guidelines for management of PD (NICE 2006)
  ✓ regular patient review, comprehensive care plans, central role for specialist nurses, access to PT/OT/SLT
Background: Previous study

- Single blind, cross-over RCT
- Day hospital setting
- 6 weeks MDT vs no intervention usual care
- \( n=137 \) PwP (\( n=68 \) carers)
- PwP: improvement in mobility, gait, speech, depression, health related QOL at 6 weeks
- Carers: less depression, higher health related QOL at 6 weeks
  - Benefits dissipated 4 months post-intervention
  - Costly (facility overhead, hospital transport)
Previous research

- RCT of enhanced care for people with PD provided in a day hospital setting.
  


Following early trial

- Development and evaluation of training for care assistants
  http://www.surrey.ac.uk/healthandsocialcare/people/Academic%20Staff/parkinsons_disease.htm


- Review of PD nurse specialist workloads and the potential for skill mix involving care assistants
Background: SPIRiTT

- Would domiciliary MDT rehabilitation be more cost-effective than in day hospital?
- How can immediate treatment benefits be maintained in the longer term?
  - Use of care assistants
    - NHS Workforce Strategy
greater use of non-registered staff with training
  - Parkinson’s Disease Care Assistant Training Study
Also

Ageing population

- Many people with PD having other health conditions
- Our study includes older people with PD, and people with co-morbid conditions
- Also people with early stage dementia (but most be able to give informed consent)
SPIRiTT: Hypotheses

• A package of domiciliary MDT specialist rehabilitation will benefit:
  ❖ PwP (mobility, independence, wellbeing, health related QOL)
  ❖ Family carers (reduced strain, health related QOL)
  ❖ Society (reduced use of health and social care services)

• Addition of PD care assistant support will help maintain treatment benefits

• Intervention will be acceptable to major stakeholders (barriers and facilitators to implementation will be identified)
Methods

• Design
  ❖ Pragmatic, single-blind, 3-parallel arm, repeated measures RCT

• Setting and location
  ❖ Community based, Surrey (and North Hampshire)

• Sample
  ❖ 270 PwP and 213 family carers (power=80%, size=5%, 2-tailed test)

• Inclusion criteria:
  ❖ Clinical diagnosis of PD
  ❖ Resides in community in own living area
  ❖ Has some limitation on at least one outcome measure
  ❖ Provides informed consent or assent given by family member
Recruitment and randomisation

• Volunteers will be entered into the trial in blocks of thirty (geographically defined in order to reduce travel time and costs to participants’ homes for the collection of the research data and delivery of the intervention).

• Research nurses will make a home visit to collect written consent(s) and record background information (age, gender, time since diagnosis, disease stage, co-morbidities, housing, caring arrangements, income and benefits, social support - Lubben Social Network Scale [43], cognitive function - mini mental state examination [44].

• A baseline assessment will also be conducted using the outcome measures selected for the trial.

• The intervention for each block of participants will start within two weeks of completion of baseline data collection.
Table 1: Trial outcome measures and instruments: baseline, 6, 24 and 36 weeks (participants)

- Parkinson’s disability / general activities: Self Assessment Parkinson’s Disease Disability Scale (PRIMARY OUTCOME) [46]
- Parkinson’s specific: Parkinson’s Disease Questionnaire [47]
  Non Motor Symptom Questionnaire [48]
- Mobility: Posture and gait items from the Unified Parkinson’s Disease Rating Scale [49]
  Timed up and go [50]
- Falls: Self report
- Speech: Single speech item from the Unified Parkinson’s Disease Rating Scale [49]
  Abridged Emerson and Enderby Screening Assessment Rating Scale [51]
  Frenchay Dysarthria Summary [52]
  Speech self report questionnaire [10-12]
- Pain: Visual analogue scale [53]
- Generic health related quality of life / QALYs: Euro Qol 5D, with utility index for calculation of quality adjusted life years (QALYs) [54]
- Self efficacy: Self Efficacy scale [55]
- Health and social care utilisation: Customised proforma and patient records
Live-in carers

- Carer strain: Modified caregiver strain index (PRIMARY OUTCOME) [56]
- General health: General health questionnaire – 12 [57]

Both groups:
- Activities of daily living: Barthel ADL index [58]
- Social activities: Frenchay Activities index [59]
- Psychological wellbeing: Hospital Anxiety and Depression Scale [60]
  Yale single item depression screening tool [61]
- Generic health related quality of life: Short form – 36 Health Survey [62]
**Intervention**

- Team members will visit the homes of participants to deliver a specialist rehabilitation package, tailored to individual needs.
- In order to make the outcome from the trial comparable to that of the previous study set in a day hospital, a similar programme of specialist rehabilitation will be provided comprising an initial assessment, and the formation of an agreed care plan reflecting the needs, wishes and expectations of the person with Parkinson's and carers.
- A group education component in the day hospital trial cannot be replicated in the domiciliary setting. As a substitute, the MDT will provide participants with a folder containing 13 fact sheets produced by Parkinson’s UK and the research team, covering various aspects of living with Parkinson’s including: medications, physiotherapy exercises, foot care, diet and nutrition, speech and language, relaxation techniques, sleep and fatigue, continence and bowel care, rights and benefits and advice for carers.
The rehabilitation intervention will be coordinated by the PNS, and will involve specialist input from each professional, over a period of six weeks.

The team will meet face-to-face four times in each six week cycle to discuss patient plans and progress, and communicate by email and telephone at other times.

Two hospital consultants (neurologist and geriatrician), both with a special interest in movement disorders, can be called upon by the MDT for medication changes or advice.

Referrals to a range of other professionals will be made as required, including community psychologist, social care manager, continence adviser, dietician and pharmacist.

Overall three days of professional time (including travel and meeting time) is allowed for each person with Parkinson’s in the trial, but some people may need more and others less than this. This input is largely equivalent to the 9-12 hours of individualised nursing and therapy input, and flexible access to other professionals, in the previous day hospital trial.
Ongoing support (Group B)

- Receive ongoing support for four months from a care assistant trained in Parkinson’s, starting at the end of the six week MDT intervention.
- The care assistants will be part of the MDT and will work under the supervision of the PNS.
- About one hour per week per patient is allowed for ongoing support, and contact will to be through a mix of home visits and telephone, through which the care assistant will monitor progress in implementation of the agreed care plan and report back to the MDT.
- If required, MDT members may provide input.
Blinding

• The research administrator will not disclose group allocation to the research nurses who undertake assessments,
• Participants will be asked not to discuss aspects of the trial and treatments with them.
• However, it is recognised that blinding of the research nurses may be compromised in trials of this nature.
• As a check on blinding, research nurses will be asked to guess participants' groups at the end of the trial. For data analysis, the group identifiers will not be disclosed to the statistician.
Community dwelling people with Parkinson’s disease identified by hospital doctors, GPs, specialist nurses, Research Networks (DeNDRoN, PCRN), Parkinson’s Disease Society contacts, word of mouth, and given information about study. Separate information for family carers. Patients and carers opt into study.

Research nurse makes home visit to collect consent and baseline information from people with Parkinson’s and family carers.

Randomisation
n=270 People with Parkinson’s; n=213 Family carers

Group A
MDT
n=90 People with PD
n=71 Family carers
6 weeks specialist rehabilitation

Assessment - 6 weeks
Assessment - 24 weeks
Assessment - 36 weeks

Group B
MDT + PDCA
n=90 People with PD
n=71 Family carers
6 weeks specialist rehabilitation and care assistant support

Care assistant support for 18 weeks
Assessment - 6 weeks
Assessment - 24 weeks
Assessment - 36 weeks

Group C
Usual care (control)
n=90 People with PD
n=71 Family carers
Usual care controls, given information pack

Assessment - 6 weeks
Assessment - 24 weeks
Assessment - 36 weeks
Multidisciplinary team

2 Parkinson’s nurse specialists (3.5 days)
2 Neurophysiotherapists (2 days)
1 Occupational therapist (1 day)
2 Speech and language therapists (1.5 days)
3 Care assistants (4 days)
Recruitment

Start dates for remaining cohorts

Cohort 6: 22\textsuperscript{nd} March 2011
Cohort 7: 9\textsuperscript{th} May 2011
Cohort 8: 20\textsuperscript{th} June 2011
Cohort 9: 1\textsuperscript{st} August 2011

Participants demographics ($n=158$)

Mean age: 72.5 years (SD 8.2; 49-91)
% Male: 62.7 ($n=99$)
% with recruited live-in carer: 62.7 ($n=99$)
# PwP withdrawn: 11 [A=2; B=3; C=6]
Analysis

- Check balance of the groups
- Comparison at time points
- Comparison across trial arms (interventions)
- Longer term impact (36 weeks)
- Multiple testing will need Bonferroni correction
- Economic evaluation
Also

- Interviews re acceptability of the interventions
- Interviews wit the MDT team re their experience of the trial
- Interviews with key stakeholders eg commissioners
- Extensive dissemination- academic, clinical and user focussed
- Packs for users, carers and clinicians will be downloadable via the project website.
PPI

- Guildford PD group involves users and carers
- Users and carers have been involved at all stages
- A user and carer sit on the advisory group.
- Team member (JK) has a remit to manage communication with local PD groups (essential to recruitment).
Challenges of working with older people

- Physical impediments – loss of hearing, visual acuity, dexterity
- Stamina – prone to fatigue
- Psychosocial issues – depression
- Cognitive issues – memory loss, lack of comprehension
- Co-morbidities, polypharmacy and mortality
- Risk of (serious) adverse events e.g. falls, hospitalisation
- Carers of partners/loved ones

✓ Require patience, understanding and flexibility
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Department of Health Disclaimer

The views and opinions expressed are those of the authors and do not necessarily reflect those of the Department of Health

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http://www.gpdrg.org/
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