A Randomised Controlled Trial of the Effectiveness of PDSAFE to prevent Falls among People with Parkinson’s Disease

https://neurodegenerationresearch.eu/survey/a-randomised-controlled-trial-of-the-effectiveness-of-pdsafe-to-prevent-falls-among-people-with-parkinsons-disease/

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Country

United Kingdom

Title of project or programme

A Randomised Controlled Trial of the Effectiveness of PDSAFE to prevent Falls among People with Parkinson's Disease

Source of funding information

NIHR

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€ 2,645,290

Start date of award

01/05/2013

Total duration of award in years

4.3

The project/programme is most relevant to:

Parkinson's disease & PD-related disorders

Keywords
Research Abstract
DESIGN: Multi-centred, individually randomised two-group controlled trial proceeded by 3-months monitoring of individual fall rate and a pilot study. A qualitative study of personal insights

and an economic evaluation will run in parallel and be integrated with the main RCT. SETTING: Participants for the main trial will be identified from four areas in the south of England. We will work with the members of the DeNDRoN network as well as PD nurses and PD specialists to recruit participants. We will also approach Parkinson's UK local support groups, primary care consortia and outpatient services. TARGET POPULATION: People with a confirmed diagnosis of PD, live at home, have experienced at least one fall in the previous 12 months and can understand and follow instructions will be eligible for recruitment to the trial. RANDOMISATION: We will recruit 600 to the pre-randomisation falls collection period, we estimate with drop outs approximately 540 will be randomly allocated to one of two groups; intervention or control. Allocation will be stratified by centre and allocated in blocks with random size of 2, 4,6 or 8. The treating therapist will access allocation on the CTU website. HEALTH TECHNOLOGY: All participants will have usual care. The control group will receive a standardised DVD with a relaxation programme. The experimental group will participate in PDSAFE a personalised home-based programme of exercises and strategies for fall prevention to be delivered by physiotherapists with specific training in the intervention and use of DVD and tablet computer technology. The novelty of the treatment lies in both the content (disease specific exercises and strategies for limiting instability, use of motor relearning and cognitive awareness) and delivery (personalised feedback using DVD for adherence and self-management). The programme comprises: a] exercises for balance, gait and muscle weakness, b] strategies for reducing freezing, encouraging stability and gait efficacy, c] feedback model to promote learning and adherence. Personal sessions with required exercises and will be recorded on DVD and returned so information and instructions can be replayed at home; DVD will be developed with the PwPD. The frequency of the intervention sessions will be faded over time, one hour twice a week for a month, once a week for two months followed by once a month for 3 months. The control group will receive usual care and a DVD with a relaxation programme. MEASUREMENT OUTCOME: a] Pre-randomisation fall collection period: Those who meet the inclusion criteria will be asked to prospectively record fall events using a monthly diary sheet for 3 months between recruitment and randomisation. These findings will be used for comparison with post-intervention fall rate. b] The assessments will take place in participants' homes at baseline, 3, 6 and 12 months post-randomisation and will be completed by the assessor who will be blinded to group allocation. c] Baseline only: At baseline a medical history structured to include co-morbidities will be taken, disease severity, medication and hand grip will be recorded. d] Our primary outcome is risk of repeat falling between 0-6 months. Pre-specified analyses, particularly those related to disease severity, are likely to assume importance in the interpretation of the trial. In the event of not finding a difference in the pooled sample (ie all participants regardless of severity), we will continue with the pre-specified analysis relating to disease severity, and will accept treatment effect in only one of the sub-groups as evidence of effectiveness. e] Secondary outcomes will include risk of repeat falling 6-12 months, rate of falling 0-6 and 6-12 months, injurious falls and near falls (from the fall diary), a measure of balance, turning, mobility and quality of life.

Lay Summary
Further information available at:

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Investments > €500k

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