Exercise- and strategy-based physiotherapy-delivered intervention for preventing repeat falls in people with Parkinson's: the PDSAFE RCT

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Disclaimer: This report contains transcripts of interviews conducted in the course of the research and contains language that may offend some readers.

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Scientific summary

The PDSAFE RCT

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Scientific summary

Background

People with Parkinson's disease are twice as likely to fall as the healthy older population. In those with Parkinson's disease, falling is associated with a host of risk factors, including disease severity, duration of disease, self-reported disability and impaired mobility. The strongest predictor of falling, identified from meta-analysis, is having had a previous fall. Evidence suggests that an exercise-based intervention might reduce fall risk, although published research findings are inconclusive.

Objective

The primary aim was to examine the clinical effectiveness and cost-effectiveness of an exercise- and strategy-based intervention (known as PDSAFE) for fall reduction.

Method

This two-group multicentre, single-blinded, randomised (50 : 50) controlled clinical trial of people with Parkinson's disease at risk of falls also comprised a 3-month pre-randomisation monitoring of falls, an economic evaluation and a nested qualitative study of the views of participants.

Participants

Eligibility criteria were as follows: a consultant's diagnosis of Parkinson's disease; living in their own home; independently mobile; experienced at least one fall in the previous 12 months; scored ≥ 24 on the Mini-Mental State Examination (MMSE); had the cognitive ability to give informed consent; able to understand and follow commands; and able to complete a guided personalised exercise and strategy programme.

Outcomes

The primary outcome was risk of repeat falling between 0 and 6 months post randomisation with the fall rate ratio during the same period as a secondary analysis. Data on falls were collected via monthly self-completed diaries. A fall was defined as an event that resulted in a person coming to rest unintentionally on the ground or lower level; a near-fall was an event in which the person would have landed on the ground or lower level if saving reactions, such as stepping or reaching, had not taken place.

Secondary outcomes were balance [measured by the Mini-Balance Evaluation Systems Test (Mini-BESTest)]; functional strength (measured by the Chair Stand Test); falls efficacy [measured by the Falls Efficacy Scale – International (FES-I)]; near-falls, an event in which the person would have landed on the ground or lower level if saving reactions, such as stepping or reaching, had not taken place; freezing of gait (FoG) (measured by the new freezing of gait questionnaire); and the results of the Geriatric Depression Scale (GDS) (15-question version); the 39-item Parkinson's Disease Questionnaire (PDQ-39), a quality-of-life measure designed specifically for people with Parkinson's disease; the EuroQol-5 Dimensions (EQ-5D), a measure of health-related quality of life; and the Physical Activity Scale for the Elderly (PASE). Disease severity was recorded using the International Parkinson and Movement Disorder Society – Unified Parkinson's Disease Rating Scale (MDS-UPDRS) and cognitive ability was measured using the Montreal

Cognitive Assessment (MoCA). Outcomes were assessed before randomisation and at 6 and 12 months after randomisation. Owing to restricted funding, the last 132 participants recruited were followed to 6 months (primary outcome only).

Pre-stated analysis

The primary outcome was risk of repeat falling between 0 and 6 months post randomisation using self-completed monthly falls diaries with falls rate ratio (incidence rate of falls in time period) and prespecified subgroups as secondary analysis plus secondary outcomes. Outcomes were assessed before randomisation and at 6 and 12 months post randomisation.

Results

A total of 541 people with Parkinson's disease were screened for eligibility and pre-randomisation fall monitoring by a trial assessor in their own home. Of these, 67 were excluded at this time [reasons for not being randomised included being medically unfit ($n = 24$), inadequate completion of falls diaries ($n = 6$), no longer met eligibility criteria ($n = 12$), or changed their mind or did not like the sound of intervention ($n = 18$)]. The remaining 474 participants completed a baseline assessment and were randomised into one of two groups: control ($n = 236$) or PDSAFE intervention ($n = 238$). Males constituted 56% of the trial participants, the mean age was 72 years and the Hoehn and Yahr scale ranges were 1–4 stage.

Loss to follow-up

Sixty-six participants did not engage with the intervention for a number of reasons, such as admission to a care home, deteriorating health, a change of mind about participation, reluctance to commit to the therapy or assessment procedures, and death. Some participants did not provide a reason for non-engagement. A further 20 participants withdrew from the control group.

Therapy content

The PDSAFE intervention, delivered by a physiotherapist, was individually tailored and structured around fall avoidance strategies and balance and strengthening exercises, selected from a menu with six levels of progression. The median number of therapy sessions was 12 (interquartile range 11–12 sessions) and the mean was 11 sessions (standard deviation 2.4 sessions).

Effectiveness

No difference in repeat falling within 6 months of randomisation was found [PDSAFE to control odds ratio (OR) 1.21, 95% confidence interval (CI) 0.74 to 1.98; $p = 0.447$]. Analysis of secondary outcomes demonstrated better balance (Mini-BESTest: mean difference 0.95, 95% CI 0.24 to 1.67; $p = 0.009$) and falls efficacy (FES-I: mean difference –1.6, 95% CI –3.0 to –0.19; $p = 0.026$), with near-falling significantly reduced with PDSAFE (OR 0.67, 95% CI 0.53 to 0.86; $p = 0.001$) at 6 months. Prespecified subgroup analysis (disease severity and FoG) revealed a PDSAFE differing effect. A decrease in falling among those in the moderate group classified by disease (interaction $p = 0.009$) and retrospective falling at entry to the trial (interaction $p = 0.050$). Increased repeat falling following PDSAFE between 0 and 6 months was found among those at the severe end of the disease spectrum and FoG (interaction $p = 0.025$) with a trend of increasing falls among those with cognitive impairment (interaction $p = 0.088$).

Participant views

Most people enjoyed participating in the therapy and reported benefits, although they had mixed views about equipment. The biggest barriers were time and motivation, whereas social support facilitated participation. In order to optimise the benefits of the therapy, people with Parkinson's disease need help for them to mobilise sustained support and encouragement from social support networks.

Economic evaluation

The results showed that the PDSAFE intervention was not likely to be cost-effective for the overall Parkinson's disease population for the NHS perspective over the 6-month time horizon. Compared with the control group, the PDSAFE intervention group had an incremental cost of £925 (95% CI £428 to £1422) and an incremental quality-adjusted life-year (QALY) gain of 0.008 (95% CI 0.006 to 0.021), generating an incremental cost-effectiveness ratio (ICER) of £120,659 per QALY. Although this ICER would not be deemed to be within the realms of what is considered cost-effective, sensitivity analyses reveal cost-effective scenarios.

Conclusions

The physiotherapy programme PDSAFE was not effective in reducing repeat falling across a heterogeneous sample of people with Parkinson's disease. However, fall risk, balance, functional strength, self-efficacy and near-falls improved. Secondary analysis also showed diverse responses to PDSAFE falls management according to FoG and disease severity. A negative effect was found among those participants at the worse end of the spectrum and a positive effect was found among those participants with moderate disease.

Trial registration

This trial is registered as ISRCTN48152791.

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