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**TITLE: 'STAYING SAFE' – A NARRATIVE REVIEW OF FALLS PREVENTION IN PEOPLE WITH PARKINSON'S -'PDSAFE'.**

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**'STAYING SAFE' – A NARRATIVE REVIEW OF FALLS PREVENTION IN PEOPLE WITH PARKINSON'S -'PDSAFE'.**

**Implications for Rehabilitation**

- **Parkinson's disease demonstrates a spectrum of motor and non-motor symptoms, where falling is common and disabling.**
- **Current medical and surgical management has minimal impact on falls, rehabilitation of falls risk factors has strong evidence but the most appropriate intervention to reduce overall fall rate remains inconclusive.**
- **Addressing all components of the International Classification of Function in a multifactorial model when designing falls rehabilitation interventions may be more effective at reducing fall rates in people with Parkinson's than treating isolated risk factors.**
- **The clinical model for falls rehabilitation in people with Parkinson's should be multi-dimensional.**

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**Background:**

Parkinson's disease demonstrates a spectrum of motor and non-motor symptoms. Falling is common and disabling. Current medical management shows minimal impact to reduce falls, or fall related risk factors such as deficits in gait, strength and postural instability. Despite evidence supporting rehabilitation in reducing fall risk factors, the most appropriate intervention to reduce overall fall rate remains inconclusive.

This paper aims to 1) synthesise current evidence and conceptual models of falls rehabilitation in Parkinson's in a narrative review; and based on this evidence 2) introduce the treatment protocol used in the falls prevention, multi-centre clinical trial 'PDSAFE'.

**Method:** Search of four bibliographic databases using the terms 'Parkinson\*' and 'Fall\*' combined with each of the following; 'Rehab\*', 'Balanc\*', 'Strength\*', 'Strateg\*' and 'Exercis\*' and a framework for narrative review was followed.

3557 papers were identified, 416 were selected for review. The majority report the impact of rehabilitation on isolated fall risk factors. Twelve directly measure the impact on overall fall rate.

**Discussion:** Results were used to construct a narrative review with conceptual discussion based on the 'International Classification of Functioning', leading to presentation of the 'PDSAFE' intervention protocol.

**Conclusion:** Evidence suggests training single, fall risk factors may not affect overall fall rate. Combining with behavioural and strategy training in a functional, personalised multi-dimensional model, addressing all components of the 'International Classification of Functioning' is likely to provide a greater influence on falls reduction.

'PDSAFE' is a multi-dimensional, physiotherapist delivered, individually tailored, progressive, home-based programme. It is designed with a strong evidence based approach and illustrates a model for the clinical delivery of the conceptual theory discussed.

**Key words:** Parkinson's, Falls, Rehabilitation, International Classification of Function

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**Introduction**

Falling is a common and disabling consequence of Parkinson's with 40-70% of patients falling each year and one third falling repeatedly [1]. These figures are double those reported for comparative older populations [2] and although the incidence of falling increases with disease severity, falls are common even in the early stages of the condition [3]. The risk of injury resulting from a fall is high with 65% injuring themselves through falling (from a sample of 1000) and 33% sustaining a fracture [4]. Falls are reported to affect more than 1% of people older than 60 years [5] with meta-analysis of the worldwide data [6] showing a rising prevalence of Parkinson's with age. This presents a major health challenge with an aging population and at current standards is estimated to cost the National Health Service in excess of £212million a year [7].

The diverse nature of Parkinson's presents a spectrum of motor and non-motor symptoms with current medical management focusing on direct pharmaceutical or surgical treatment of the disease specific deficits in the brain. Whilst pharmaceutical intervention has shown a positive effect on gait stability [8] it has also shown a decreasing effect over time on deficits of gait, strength and balance, postural instability and cognition [9]. Further to this, dopamine replacement medication has been associated with impaired aspects of posture and motor control [10], suggesting a negative effect of medication on falls risk. Any 'Parkinsonian' symptom therefore is a sum of the primary impairments as a consequence of the disease plus the adaptive compensatory strategies that evolve [11].

It has long been accepted that exercise is a fundamental pillar of treatment for people with Parkinson's (alongside medical and surgical management) and its positive effects on symptoms are well supported in the literature. here are two aims of this review:

1) Present a conceptual discussion of the current evidence base for the treatment of falls in people with Parkinson's, presented as narrative review.

2) Use the evidence discussed to present an evidence-based model of falls prevention used as the intervention in the multi-centre clinical trial 'PDSAFE' (for full trial protocol see [12]).

It is hoped that the combination of both aims will lead to a practical and helpful tool to promote and deliver evidence based practice both in the clinical and research environment of falls in Parkinson's.

## **Method**

The construction of this review followed recommended guidelines of "best-evidence synthesis" [13]. The intention of which is to describe and synthesize the available literature on falls prevention interventions in Parkinson's and provide conclusions from this evidence. The process followed: identification of search terms and data resources; establishing inclusion criteria; screening of search results; synthesis of findings; conclusions drawn.

A literature search was conducted using the bibliographic databases: Cumulated Index of Nursing and Allied Health Literature, Medline, Web of Science (Core collection), Cochrane and Physiotherapy Evidence Database between the period 1990 and June 2017.

The search terms 'Parkinson\*' and 'Fall\*' were searched in isolation and combined with the Boolean operator 'AND'. This search was then combined with each of the following; 'Rehab\*', 'Balanc\*', 'Strength\*', 'Strateg\*' and 'Exercis\*'. The Cochrane database was searched for by 'Parkinson\*' only and the Physiotherapy Evidence Database by 'Parkinson\*' and 'Fall\*' only. Additional 'English language' filter was also used.

After completing the electronic search, papers were reviewed through title and abstract, as well as citation review. Due to the broad search specifications for this topic and explorative nature of the review, all papers investigating falls rehabilitation or falls risk factors in Parkinson's were initially included.

A total of 3557 papers were identified after excluding duplicates. Initial review of the combined search results by title and abstract lead to 409 papers being selected with an additional seven by citation searching. The majority of studies report the impact of rehabilitation on a single falls risk factor (i. e. balance, strength, gait) or general rehabilitation effects in Parkinson's. Twenty-six papers had a specific

focus on falls with twelve research papers investigating the effects of an intervention including a specific outcome measure of fall rate.

These papers were then critiqued and synthesised by the lead author with all topics discussed with AA and KCS. Due to the heterogeneous nature of studies, results were used to construct a narrative review with conceptual discussion, leading to presentation of the evidence-based 'PDSAFE' intervention protocol. Discussion was aligned with the International Classification of Functioning, Disability and Health model (ICF) [14] and represented in figure format (Figure 1). The model portrays human functioning and disability in three domains: - body functions and structures; activity and participation; which are the dynamic interaction of health conditions, personal factors and environmental factors.

The 'Template for Intervention Description and Replication checklist and guide' [15] has been used to present the protocol for the 'PDSAFE' intervention. This template is an extension of the 'Consolidated Standards of Reporting Trials' 2010 statement (item 5) and the 'Standard Protocol Items:

Recommendations for Interventional Trials' 2013 statement (item 11) and aims to improve the reporting of interventions for both academic and clinical purposes.

## **Discussion**

One of the major causes of hospital admissions for people with Parkinson's is falling over, which is described as both common and disabling [16, 17]. There are a multitude of isolated risk factors discussed in the literature that contribute to a fall, comparison of which is beyond the scope of this review. The strongest predictor, identified from meta-analysis being a previous fall [18, 19]. However, disease severity, duration of disease ([20, 21], self-reported disability [20] and impaired mobility [3] have also shown to increase overall risk. The presence of such factors clearly demonstrates longitudinal risk; however, it provides little insight into the specific mechanisms or modifiable factors of a fall, and thus rehabilitation potential.

## **Modifiable falls risk factors**

Possible modifiable falls risk factors in Parkinson's include variables of motor control, such as anticipatory and reactive balance, reduced leg muscle strength, proprioception and gait speed, increased gait variability and freezing of gait, all of which are associated with and are predictors of falls [22, 23]. When considering 'Body functions and structures' from the ICF model (ICF, Figure 1), analysis of falls diaries suggests activities where gait has to be adapted or the centre of mass shifted in relation to the base of support are related to falls [24].

In addition to the motor symptoms, impaired cognition and orientation (the effective integration of perception, attention and memory) [22] (Body functions and structures, ICF, Figure 1), and mis-judgement and distraction [24] (Personal Factors and Environment – ICF, Figure 1) have also shown significant association with falls. Additional personal factors (ICF, Figure 1) including measures of reduced balance confidence [25], fear of falling [26, 27] and reduced confidence in being able to get up off the floor [27] are also associated with increased fall risk.

Finally, from a personal and environmental context (Figure 1 - ICF), sedentary behaviour [26, 28], greater limitations in activities of daily living [26], greater fall related activity avoidance with reduced participation [29] have also all been associated with frequent fallers and an increased falls risk.

Canning et al. [2] provide a useful meta-analysis of the isolated falls risk factors in Parkinson's. However, when trying to relate them back to the clinical setting, examining risk factors individually, fails to demonstrate the complex interplay of falls mechanisms. With regards to possible treatment intervention, purely selecting and treating risk factors independently for example, interventions that focus on balance only, strength only or cueing only are unlikely to be universally relevant or achieve long term change. This is not only due to the diverse nature of falls mechanisms but also the presentation of Parkinson's being a progressive, degenerative and patient specific condition, that is highly variable both between and within individual patients. Thus, a combination of motor and non-motor body functions and structures as well as environmental and behavioural factors all potentially contribute to an increased risk of falling (demonstrated and referenced across Figure 1). This suggests a multidimensional aspect to fall

mechanisms in Parkinson's, and presents the need to address all dimensions when designing intervention protocols.

### Treatment of falls in Parkinson's

There is substantial evidence for the role of rehabilitation in the management of the presented isolated fall risk factors in Parkinson's, discussion of which are beyond the scope of this paper. Large randomised controlled trials, level four evidence, systematic and meta-analysis reviews, collated in the European Physiotherapy guidelines for Parkinson's [30] demonstrate positive effects on the falls risk factors of: balance [31 - 35], gait [34, 35], strength [34 - 38], cognition and strategy selection [39], activity [40], Quality of life [34, 41] and activity dependent mechanisms of neuro-protective and neuro-regenerative potential [42 - 45].

Despite strong evidence, the efficacy of reducing overall falls rates by treating independent falls risk factors has historically not been addressed [34, 46, 47, 48]. Therefore, the literature identified in this review includes twelve randomised controlled trials addressing the impact of an intervention in people with Parkinson's with a primary or specific outcome measure of fall frequency/rate (see 'Effects of rehabilitation' in figure 1). Of the twelve, eight papers show a significant reduction in falls rate following Tai Chi [50, 51], general exercise and strategy training [52], strength or strategy training with education [53] balance training [54], treadmill training with virtual reality [55], technology- assisted balance and gait training [56] or purposeful balance perturbations [57]. Whereas, three show no significant change; following strength and balance training [58]; or home based exercise training [59 - 61].

Meta-analysis of eight of the above papers ([52, 55, 56, 59] not included) has shown long-term (rate ratio = 0.413,  $P < .05$ ) and short-term (rate ratio = 0.485,  $P < .05$ ) reduction in falls rate by up to 60% following balance and gait training in people with Parkinson's however, a reduction in the number of fallers was not found [62]. Whilst meta-analysis enables synthesis of results, it is virtually impossible to extract any potential mechanisms or underlying 'therapeutic effect' on falls outcome owing to the heterogeneous



nature of the included studies. They include a combination of group, supervised and independent practice in both clinical and home environments ranging from six weeks to two years of intervention and inconsistent follow-up periods. What is more, the trials either did not indicate or have too great a diversity of treatment protocols and dosage. When addressing this problem, Van der Marck et al.[63] suggest there is no accepted program that can specifically address the 31 multi-dimensional, risks factors identified as contributors to falls in people with Parkinson's. Therefore, in order to ascertain key components of a falls prevention program one must look more closely at specific intervention protocol aside from testing statistical effect.

#### Uni-dimensional or multi-dimensional models of treatment?

Synthesis across the above mentioned twelve studies with a specific outcome on falls incidence depicts a pattern: A positive effect on isolated falls risk factors (such as balance, strength, gait) is found following those protocols that train using exercise alone [58, 60, 61]. These studies solely trained risk factors independently through exercise prescription, i.e. balance training and/or strength training. The sole focus of rehabilitating an isolated physical impairment will be referred to as a **uni-dimensional model**. The positive effect on the specific trained variable, i.e. balance or strength outcome, is unsurprising considering the positive effect of task specific training on performance i.e. if you training balance, balance outcomes improve. However the overall functional effect on reducing falls remains ineffective or unclear. Those studies that include a combination of strategy training either through cognitive and educational training [52, 53] [55] or training a motor response to de-stabilisation alongside exercise training [50, 51,54 56, 57] of specific impairments, appear to show an additional global and significant effect on reducing falls or near falls. Such models will be referred to as **multidimensional models** as they incorporate more than one dimension of falls risk rehabilitation (ie physical and cognitive, physical and behavioural, behavioural and cognitive etc). The exception to this apparent pattern is a recent paper by Morris et al. [59], which found no statistically significant effect on falls reduction in people with Parkinson's following a home program of strength and strategy training with education (mult-dimensional) compared to non-specific life

skill training (uni-dimensional). However, it is likely that this was a result of the limitations to the study discussed later in this paper (e.g dose and intensity).

Indeed, significant correlation between balance skills and executive function, cognitive impairment and ability to switch between tasks has been demonstrated [64]. Alongside findings from review that suggest slower learning rates and the recruitment of multiple and different neural networks for learning in Parkinson's requires training of specific motor learning principles [65]. All of which suggest a 'multi-dimensional' and interlinking mechanism of falls in Parkinson's which is likely to require equally as integrated and multi-dimensional rehabilitation models.

#### Examples of models of treatment.

An example of the uni-dimensional treatment models is shown by the three randomized controlled trials [58,60,61]. All studies included specific balance and strengthening exercises and cueing exercises for those that experienced freezing of gait. Whilst all showed significant improvements in measures of balance, gait and physical activity, they all failed to show a significant reduction in falls rate following intervention (  $p = 0.10$ ,  $p = 0.423$  and  $p = 0.18$  respectively). Whilst significance testing in this scenario can be miss-leading due to the variability of falls rate reporting prior to testing, using the Incidence rate ratio (IRR) to report falls adjusts for baseline fall rate using negative binominal regression. Despite this being reported in two of these trials, both failed to show a significant reduction in falls rate using this method ([57] – IRR 0.68 (95% CI 0.43 to 1.07) and [60] – IRR 0.73 (95% CI 0.15-1.17)).

An example of the combined approach is shown by Georgy et al. [52] who demonstrated a one year improvement in isolated falls risk factors such as freezing of gait ( $p = 0.005$ ) and Tinetti balance scores ( $p = 0.001$ ), alongside a significant reduction ( $p = 0.041$ ) in the number of fallers (53% not having any fall in the year period compared to 20% prior to intervention). Participants completed a weekly and then bi-weekly, 90 minute, exercise and movement strategy training programme with ongoing, but reduced, effect at two-years. Whilst this was a convenient, small sample of 15 people with Parkinson's it does show the potential long term, activity change possible with a combined impairment and behavioural model.

With a larger sample size, Mirelman et al. [55], were able to demonstrate a positive effect (6.00 [95% CI 4.36-8.25] falls per 6 months;  $p < 0.0001$  vs before training) on falls reduction when combining cognitive training, through virtual reality, with physical gait training on a treadmill when compared to physical training alone ( $n = 302$ ). Whilst this is not something that is likely to be available to all due to the need for equipment and is not functionally driven, it does demonstrate that perhaps it is the combination/interaction of cognitive strategy and physical training that is the fundamental ingredient in falls intervention not solely a response to isolated functional training and task practice.

This concept is mirrored by Li et al. [50] who found 24 weeks of Tai Chi reduced the incidence of falls compared to a 'stretching intervention' (incidence rate ratio, 0.33; 95% CI, 0.16 to 0.71) and 'resistance training' (non-significant) (incidence rate ratio, 0.47; 95% CI, 0.21 to 1.00) as well as a significant improvement ( $P = < 0.001$  for all comparisons) in physical falls risk factors such as gait parameters and postural stability ( $n = 195$ ). Whilst specific cognitive and strategy training is not taught in Tai Chi, the need to process, copy, and perform more complex and integrated movements in a 'multi-dimensional model' appears more efficacious than purely training the isolated components of strength and flexibility in a 'uni-dimensional model' as in the other two groups. These results are also reflected by Gao et al. [51] showing significant improvement in the Berg Balance scores ( $p = 0.002$ ) and reduction in number of falls ( $p = < 0.05$ ) in 37 people with Parkinson's receiving 36, one-hour sessions of Tai Chi over 12 weeks compared to a matched control group.

A possible conceptual mechanism for an effective multi-dimensional approach across 'Body function and structure (Figure 1- ICF) may be; 1) the effect of exercise driving neural plasticity and neuro-protective mechanisms against progressive degeneration [66]; in collaboration with 2) additional beneficial effects of strategy training on cognitive flexibility, efficiency and increased context-specific motor-learning [65]. Indeed, the degeneration of the basal ganglia in Parkinson's affects many physiological systems essential for safe function such as sensory integration, anticipatory postural adjustments, limits of stability and functional motor agility [67]. The deficits in cognitive processes involving executive function, attention and working memory which underpin resource capacity and allocation [68] and the emerging effect of visuo-cognition on functional performance and environment integration [69] have also all been demonstrated.

In summary, the findings would suggest the key conceptual principles of successful falls rehabilitation in Parkinson's appear to suggest a need for multi-dimensional, integrated training. This should not just be cognitive and physical tasks in isolation or practiced reciprocally, but practiced in combination, in a variety of environments, with additional contextual practice through functional strategy training. The combination of which supports the dynamic interplay between the degenerative and re-generative mechanisms of the condition ('Body Function and Structure', 'Environmental factors' in figure 1).

Two conclusions can be suggested from this synthesised pattern: -

- 1) A combination of training specific falls risk factor impairments in body function and structure in addition to environmental strategy training and personal behavioural training in a multi-dimensional model across the ICF (Figure 1) is necessary to ensure a functional effect of reducing falls; and/or
- 2) The possibility that purely training isolated falls risk factors, only addressing body function and structure impairments, in a uni-dimensional model is non-transferable to reducing overall falls rates.

#### Additional contributing factors to treatment (Disease severity, adherence and intensity)

As well as the direct effect of disease symptoms on falls risk, a significant effect of disease severity has been found [58 - 61](see 'Personal factors' in figure 1). All studies showed those with less severe disease presentation have a significant improvement in falls rate following exercise programmes. Importantly, this outcome is lost when results are combined across all disease spectrums. Specifically, Morris et al. [59] found a multi-dimensional therapy intervention to be associated with reduced falls rate in-frequent fallers, yet in-effective for high frequency fallers. As their sample had four times as many frequent fallers in the intervention group (reporting >100 falls each over the study period) it is likely that their over-all negative effect on intervention outcome was masked by the impact of disease severity and fall history. In addition, not all those included in the trial had previously experienced a fall, thus the rehabilitation effect on the fall mechanism is unclear.

Efficacy of interventions based on 'isolated falls risk' [70] and the relationship between activity, falls frequency and falls mechanism [71] has also shown a non-linear effect with disease progression. Thus, it is possible that having both impairment specific and behavioural strategies allows flexibility to rehabilitate differing falls mechanisms at differing stages of the condition. For example in relation to the ICF, exercise modification of impairments of 'Body function and structure' as falls risk factors at the early stage of the disease, followed by cognitive adaptation and behaviour modification in 'Personal' and 'Environmental' to ensure safety at the later stages as a 'multiple resource model' [72]. This enables capacity in both function and processing by challenge, as well as single task training for specific impairments or in those where multiple tasks and demanding processes may create a falls risk. It also accommodates for the variable nature of the disease on a day-to-day basis with appropriate rehabilitation at any given presentation. Thus simply classifying all fallers the same with regards to disease stage, fall frequency, mechanism and activity across the ICF fails to appreciate the individual nature and therefore need for individualised, multi-layered, context specific treatment. This may also be a reason why those studies that combine results across all disease severity, with no-flexibility of the intervention to the falls mechanism, fail to show a significant effect in reducing falls overall.

Whilst we as clinicians can argue it is the content of falls rehabilitation that gives the required effect there is evidence to suggest exercise programmes that cannot be identified as beneficial by the participants are less likely to be adhered to [73]. Addressing mechanisms to maintain safety in function from both a physical, cognitive and strategy perspective, with personal meaning and purpose are likely to gain greater motivation and adherence than impairment based models of rehabilitation focusing solely on the 'Body function and structure'. This is particularly important due to the high incidence of symptoms such as depression, apathy and fatigue; all found to be barriers to maintaining exercise in people with Parkinson's [73, 74]. Interventions where programmes are tailored to individual need, encompass gradual progression, instilling perceived changes in physical ability with particular focus on components of 'Activity' and 'Participation' are favoured by people with Parkinson's [73, 75, 76]. Without independent adherence and motivation, it is unsurprising that long-term follow-up of impairment training shows minimal

effect [58], whereas those with additional strategy training across all ICF domains (Figure 1- ICF) does [52]. In addition, falls occurring outside the home may also be prevented with attentional strategies and environmental adaptations such as using a stick and reducing dual tasking [77]. Multi-dimensional models may also drive motivation and adherence, with a functional and environmental effect to improve outcomes and reduce falls (please see figure 1).

Finally, to be effective, and in appreciation of basic training principles outlined by the American College of Sports Medicine [78] all types of training should not only be 'specific' to the targeted function and 'varied' to increased functionality, but should contain an element of 'progressive overload' to challenge the physiological systems through intensity and repetition. Whilst intensity of the intervention has been shown to be a major influencing factor in other neurological conditions [79] and in falls prevention programmes in the elderly [80], evidence of its effect in Parkinson's outside of animal models is limited [81].

Intensity has been found to influence efficacy of balance training in people with Parkinson's through meta-regression analysis showing highly challenging exercise programmes to have a bigger effect on balance-related activity performance than standardised programmes [46]. Further to this, intensive, repetitive, progressive exercise interventions in people with Parkinson's have also shown promising effects on specific falls risk factors and aspects of neuro-plastic adaptation [66, 81, 82]). Specifically, Morris et al. [59] attribute a low dosage (six weeks, 60 minute sessions twice-a-week) to the failure to reduce falls rate in a combined strength and strategy training model, as compared to a positive outcome in their previous trial over eight weeks using the same intervention design. This suggests that intensity of exercise is a crucial aspect when activity dependent neuroplasticity is required in addition to improved performance. However further research is needed to ascertain the conversion of this to reducing the global multidimensional aspects falls frequency.

It is important to note, the majority of 'intensive interventions' reference an increase in the number of sessions as a method of increasing intensity, which does not consider the distinct difference between the intensity and time as detailed in the 'FITT' principles of exercise physiology [83] (Frequency, Intensity, Time and Type). Monticone et al. [82] demonstrated an in-patient exercise program for people with

Parkinson's stated as high intensity with regards to the number of minutes exercising (90 minutes) and number of sessions per week (daily) produced greater improvements in the falls risk factors of balance, mobility and strength than a low dose control group. Whilst 'intensity' may incorporate elements of frequency and duration the repetitions, difficulty/complexity of activity and perceived effort should also be addressed as components. The importance of maintaining the intensity through progression and in line with the degenerative aspect of Parkinson's should also be considered. Current guidelines for falls prevention in the elderly using meta-regression suggest a minimum of twice a week for 25 weeks is required to reduce falls incidence [80]. With an average intervention dose reported as 18 hours over seven week, [46] it is unlikely that these meet the requirements to drive a physiological or behavioural change. It is likely therefore that the modest doses reported by the majority of Parkinson's rehabilitation trials [70] are insufficient to drive the necessary physiological adaptation required to bring about a combined effect of balance, strength and mobility to reduce falls.

Application to clinical practice - Conceptualisation of falls prevention in Parkinson's using the ICF model.

Having identified a need for a multi-dimensional model of falls prevention in Parkinson's and conceptualised the effect across all rehabilitation domains, representation through the ICF summarises the theory presented in this review. The ICF, designed by the World Health Organisation [14], to define disability helps to draw together the evidence presented to represent a biopsychosocial model taking into consideration the impaired body and/or mind as well as the influence of how an individual participates in everyday life activities [85]. Figure 1, represents the context of falls in Parkinson's from the evidence presented showing a clear need for not only impairment driven rehabilitation models but those encompassing both impairment modification as well as behavioural, cognitive and environmental adaption.

**Figure 1 - FIGURE of ICF falls specific**

Evidence suggests a multi-dimensional, personalised, intensive programme including balance, strength and cognitive, environmental strategy training specifically tailored to individual fall risk factors are all components essential for the rehabilitation of falls in people with Parkinson's. This rationale supports the design of the 'PDSAFE' intervention as a multi-dimensional, physiotherapist delivered, individually tailored and progressive, home-based programme, tested in a large (n = 541) multi-centred, single-blinded, randomised control trial. A description of the intervention protocol is given in table 1 as per the 'Template for intervention and replication guidelines' [15] and a description of the full study protocol is available [13].

**Table 1 – PDSAFE protocol description as per 'Template for intervention and replication guidelines' guidelines.**

PDSAFE is delivered in the home, tailored to the individuals specific falls mechanism and functional presentation, and personalised to rehabilitate the primary strategy/s that contributed to the fall/s (Figure 2). Not only does this allow the protocol to align with all components of the ICF (Figure 1) as a person centred approach, it also follows the consensus based clinical practice recommendations for falls management in Parkinson's [63]. From this, personalised exercise prescription, within a menu of exercises allows an individualised program to be designed specific to the falls related risk factors (impairments) that contribute to the primary 'problematic' strategy (as recommended by the European Guidelines for Physiotherapy in Parkinson's', [30]). The specific 'impairment' training enables physiological improvements in 'Body function and structure' of Parkinson's symptoms and deficits which allows functional 'activity' training and strategy task practice in everyday life 'participation' (Figure 2 in combination with Figure 1, ICF). In this way, the rehabilitation of the falls related activities and their contributing falls risk factors not only works towards reducing the risk of a similar fall/s again, but also embeds the training in every day function and thus is more likely to have a greater overall effect across all components of the participants life (and thus full ICF model). Intensity is maintained across all aspects of the 'FITT principle' to drive physiological adaptation. 'Frequency' is regulated to a minimum of 3 times a



week; 'intensity' must be perceived as 'moderately hard/hard' for all activities of the program; 'time' is set to a maximum of an 60 minutes; and finally 'type' of exercise is tailored and specific to each individuals falls mechanism. With the consideration of all factors, it is therefore possible to design a multi-dimensional program that does not loose intensity as a result of its many components. In addition to this, the high intensity, continual progression and titrated support from intensive to independent practice, maintains focus and adherence, encourages personal commitment and investment, as well as fosters an understanding and empowerment of the rehabilitation process towards the individual. The addition of visual feedback both 'in therapy time' and as review through personalised digital videos also aids accurate independent practice and continuation of therapy. Thus continual progress can be made and adaption to the neurodegenerative properties of the condition to maintain safety.

In appreciation of the mechanisms of neuro-rehabilitation and exercise prescription, the PDSAFE intervention protocol is structured in a way that enables intensive, repetitive practice that is salient to the individual and their specific falls profile, thus meeting the needs for effective neuro-plastic change. In addition the embedding of the training in strategy task related practice across all functional activities enables rehabilitation to take place across all levels of life participation and not just in relation to a specific task, goal or previous fall behaviour.

The unique structure and delivery of PDSAFE (Figure 2) therefore enables it to reflect the evidence base for falls prevention in Parkinson's meeting the holistic recommendations of the ICF framework (Figure 1) and facilitate onward progression and independent self-management of the condition by the individual. The novelty lies in both the content (disease specific exercises and strategies for instability, use of motor relearning and cognitive awareness) and delivery (personalised feedback using digital videos for adherence and self-management).

**Figure 2- Conceptual model of PDSAFE falls prevention protocol intervention**

## **Conclusion**

The need for strong, efficacious, evidence based management of falls in Parkinson's, aligned with the ICF [14] enabling a truly personalised holistic treatment is well established. Evidence suggests that a multi-dimensional intervention (across the ICF) incorporating balance, strength and cognitive and environmental strategy training may be more effective than interventions focusing on independent risk factors (isolated to 'Body function and structure' within the ICF) such as balance and/or strength alone. Key factors that contribute to the efficacy of such interventions, for example: - adherence, motivation and intensity have also been identified. In appreciation of this, the PDSAFE intervention protocol is a multi-dimensional strategy, strength and balance training program with an appreciation of the need for training across the ICF. (Figure 1 and 2 combined).

## **DECLARATION OF INTEREST**

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## **FIGURE CAPTIONS**

Figure 1 - Figure of ICF in relation to Fall's in Parkinson's

Figure 2- Conceptual model of PDSAFE falls prevention protocol intervention

Table 1 – PDSAFE protocol description as per 'Template for Intervention Description and Replication checklist and guide'.



## **TABLES**

### **'STAYING SAFE' - THE NEED FOR AN INTEGRATED, MULTI-DIMENSIONAL MODEL FOR FALLS PREVENTION IN PEOPLE WITH PARKINSON'S - 'PDSAFE'.**

**Table 1 – PDSAFE protocol description as per 'Template for Intervention Description and Replication checklist and guide'.**

Guide Number	Checklist requirement	Protocol description
1	Protocol name	PDSAFE - A personalised, falls prevention programme of home exercises for balance training, muscle strengthening and task orientated movement strategy training.
2	Protocol rationale and theory of main elements	Personalised – Individual programme for each participant derived from falls mechanism and underlying disease specific impairments Balance, Strength and Strategy – Programme must include elements of all exercise prescription from a standardised menu of options. Intensive, repetitive, progressive – Elements of exercise prescription and neurorehabilitation followed.
3	Protocol materials	For the participant: Participant exercise folder (including safety guidelines, daily checklist, personalised balance and strength exercises, progression guidelines and intensity guidelines) Personalised digital video of falls prevention strategy training and exercises or Parkinson's UK digital video – 'Keeping Active' (comparison group) Weighted vest (up to 10kg, if required) Foam balance pad (if required) For the Physiotherapist: PDSAFE protocol documentation including intervention paperwork. Standardised strategy menu and balance and strength exercise menu. Tablet to record strategy training and give 'in-time' visual feedback. Pre-recorded library of strategy training vignettes. Laptop for burning personalised digital video's and uploading study documentation.
4	Procedures of protocol delivery	Randomisation to intervention or comparison (50:50) All participants contacted within 48 hours by telephone to inform of group allocation. Intervention participants seen first by week 2 and continuously until 6th month. Comparison participants seen first by week 6 and second at 12 <sup>th</sup> month.
5	Protocol providers	All sessions for both groups are Physiotherapy delivered – Advanced clinical reasoning required to align balance, strength and strategy components with falls mechanisms. All therapists complete compulsory 2-day initial training, monthly continued professional development and fidelity checks with lead therapist (once-a-month for first 3 months and then three monthly for duration of involvement in trial). Optional, weekly phone sessions with lead therapist as required.
6	Mode of protocol	All sessions for both groups are face-face and individualised. Participants are also left with an individualised exercise folder and digital

	delivery	video for strategy training practice independently.
7	Location of protocol delivery	All sessions for both groups are home/ community-based. This may include regularly visit to previous falls locations if feasible. Therapist training sessions at trial sites and available virtually or by telephone.
8	Protocol duration, intensity and dose	<p><u>Intervention:</u></p> <p>Supervised sessions include –</p> <ol style="list-style-type: none"> <li>1. 12, 1 hour, physiotherapy sessions. Moving from intensive supervision to independent practice – Twice weekly (sessions 1-4), weekly (sessions 5-7), monthly (sessions 8-12), 6 months independent practice.</li> <li>2. From assessment, selection of 1-3 falls mechanism strategies alongside a balance, strength and strategy exercise programme selected from standardised menu.</li> <li>3. Once the programme is selected, every session includes, fall history review, warm-up, exercise practice and progression, functional task practice with strategy training and use of video for ‘in-time’ visual feedback and making personalised digital video’s.</li> </ol> <p>Independent practice includes –</p> <ol style="list-style-type: none"> <li>1. Daily (or a minimum of 3 x week), independent practice of their exercise programme (approximately 30 minutes), including safety review, warm-up, exercise practice, progression review, functional practice of strategy training (may include watching their digital video) and compliance monitoring.</li> </ol> <p>Intensity – Participants are expected to rate their ‘perception of work’ at ‘moderate to hard’ or 6/10. Therapists’ progress and teach participants how to independently progress their programme to maintain this level.</p> <p>Comparison group:</p> <p>Supervised sessions include –</p> <ol style="list-style-type: none"> <li>1. Initial visit to provide Parkinson’s UK digital video and re-assure importance in the trial.</li> <li>2. Comparison treatment visit (following final trial assessment), 1 hour session to advise on personal strategy training and risk factor modification based on fall mechanisms.</li> </ol>
9	Protocol personalisation	<p>Detailed neurological physiotherapy assessment focusing on falls mechanism and potential underlying impairment guides individual selection of falls related strategy.</p> <p>Strategy training and contributing falls risk impairments inform the selection of individualised balance and strength exercise programme from a standardised menu.</p> <p>All training is progressed at a participant specific rate to maintain required intensity.</p> <p>Daily exercise practice is promoted but a minimum of 3 times a week is accepted to accommodate participants’ requirements.</p>