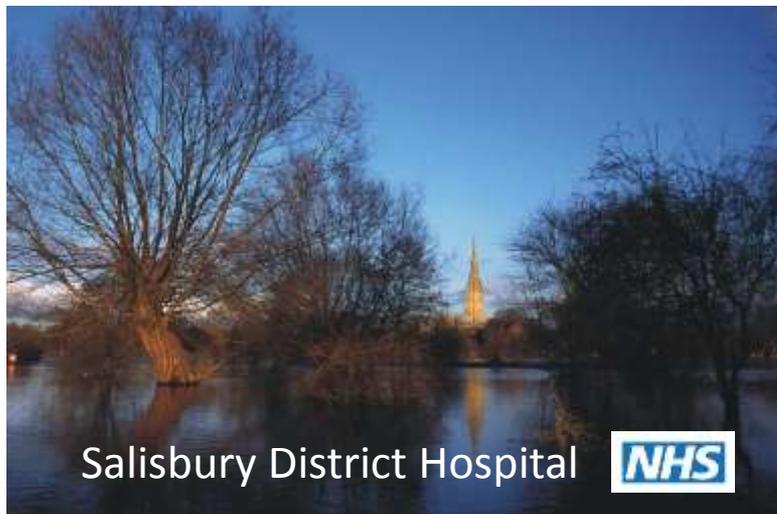


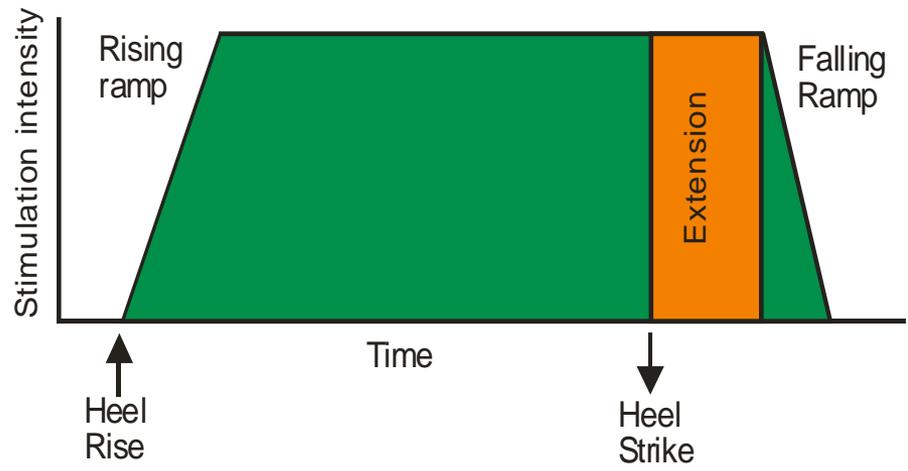
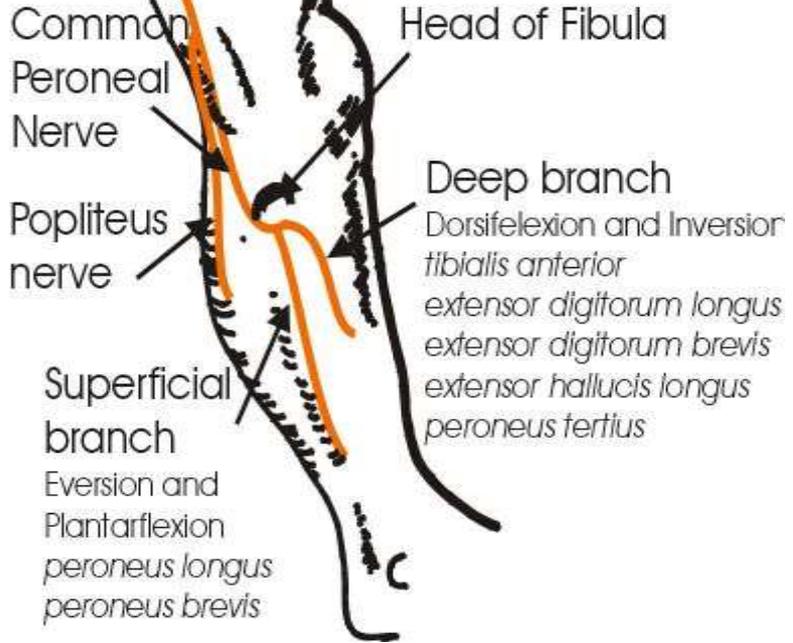
The Effectiveness of Peroneal Nerve  
Functional Electrical STimulation (FES) for  
the Reduction of Bradykinesia in  
Parkinson's Disease: A Pragmatic Two Site  
Feasibility Study for a Single Blinded  
Randomised Control Trial (**STEPS**).



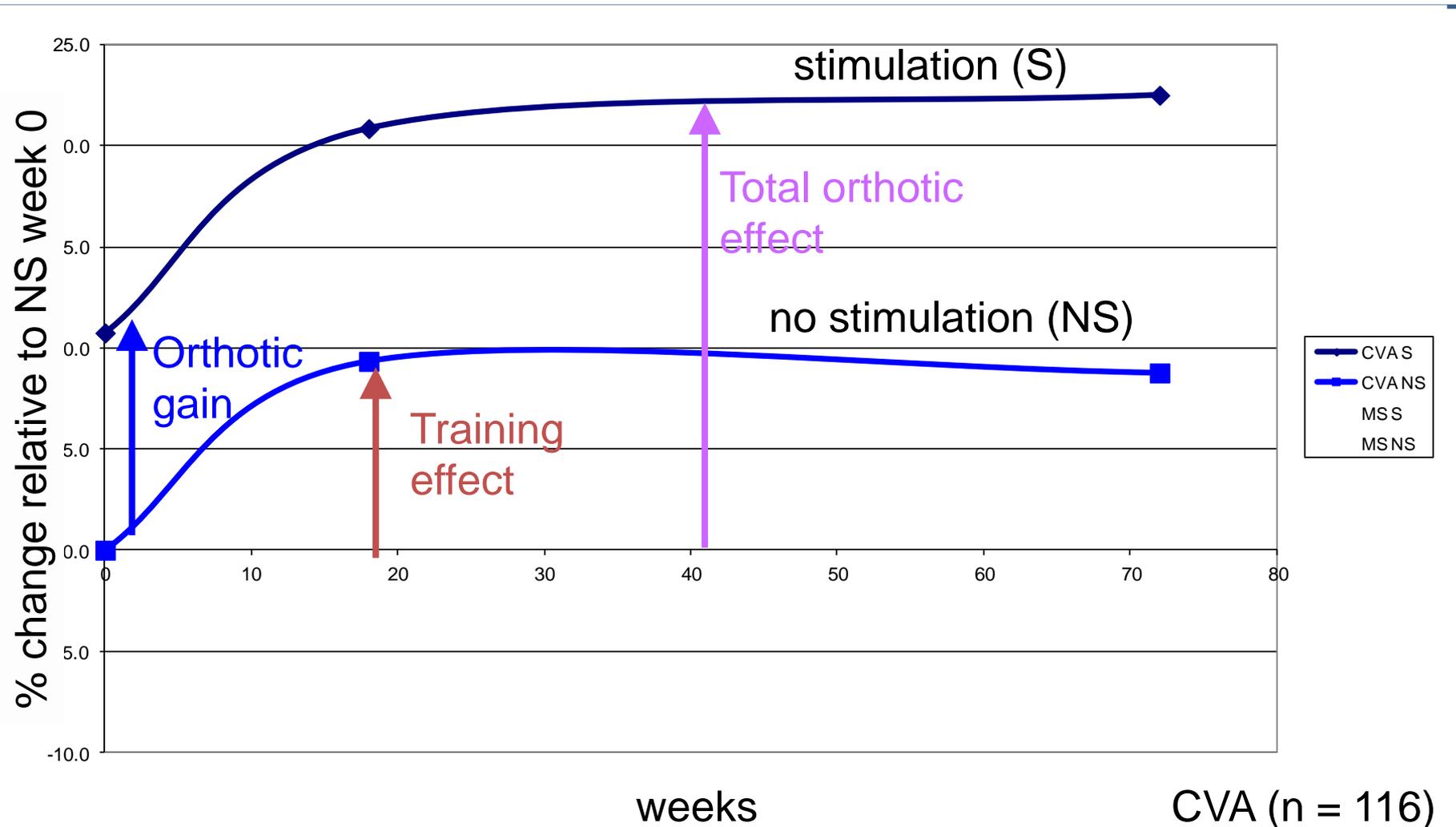
# Parkinson's Disease

- Bradykinesia: Slowness of movement
- Hypokinesia: Reduced movement size
- Akinesia: Difficulty in initiation of movement leading to freezing in gait or upper limb activities
- Reduce distal muscle power is a common feature, particularly the tibialis anterior (Cioni et al. 1997)

# Anatomy & Function



# % change in median walking speed for CVA – compared with NS week 0



Initial walking speed: CVA = 0.57 m/s

CVA (n = 116)

**Geraldine Mann, Stacey Finn, Paul Taylor**  
**A Pilot Study to investigate the Feasibility of**  
**Electrical Stimulation to Assist Gait in Parkinson's**  
**Disease. Neuromodulation Volume 11 Number 2,**  
**143-149, 2008**

## **Hypothesis**

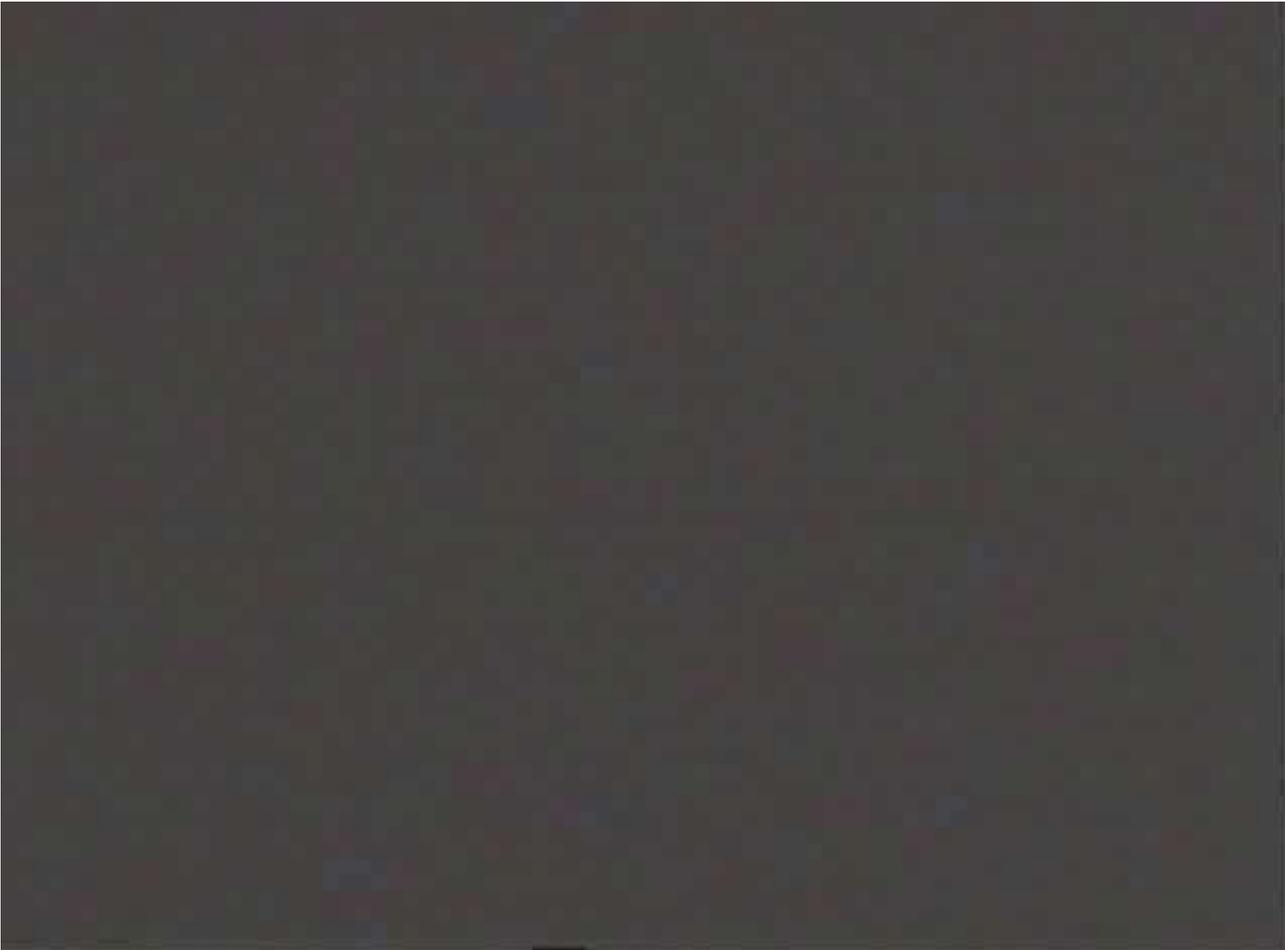
- FES to the common peroneal nerve to improve heel strike in people with Parkinson's Disease may act to provide a user controlled cutaneous and proprioceptive external cue through provision of active movement to maintain a normal gait pattern and reduce episodes of start hesitation and 'freezing' during gait.
- 1 month baseline, 2 months FES use, 1 month follow up
- N=10

# Parkinson Syndrome walking without and with FES

Increased step length

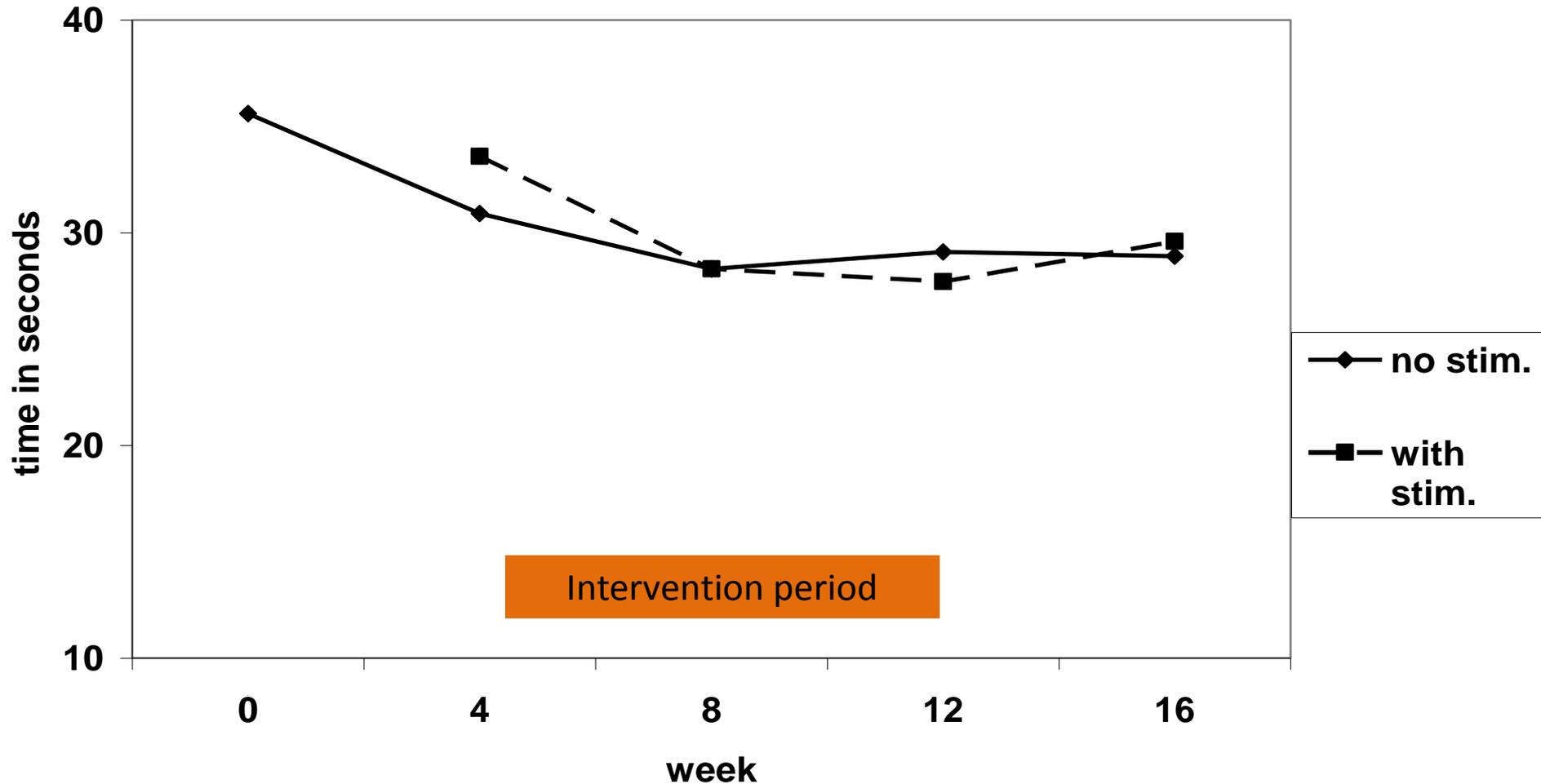
Reduced number of falls

Training effect



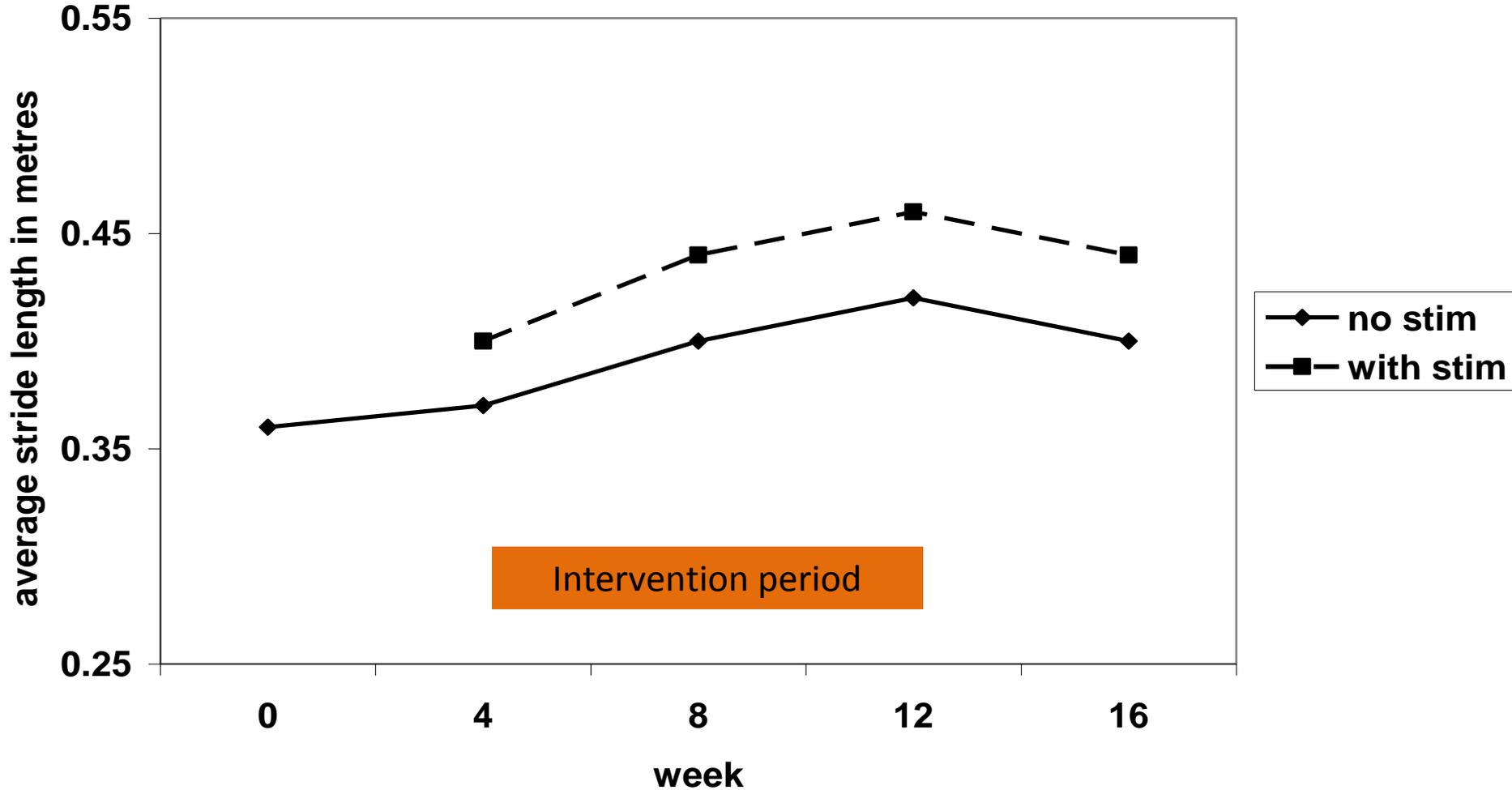
Geraldine E. Mann, Stacey M. Finn, Paul N. Taylor A Pilot Study to investigate the Feasibility of Electrical Stimulation to Assist Gait in Parkinson's Disease. Neuromodulation Volume 11 Number 2 2008

# Time taken to complete 20m. walk with turn with and without stimulation



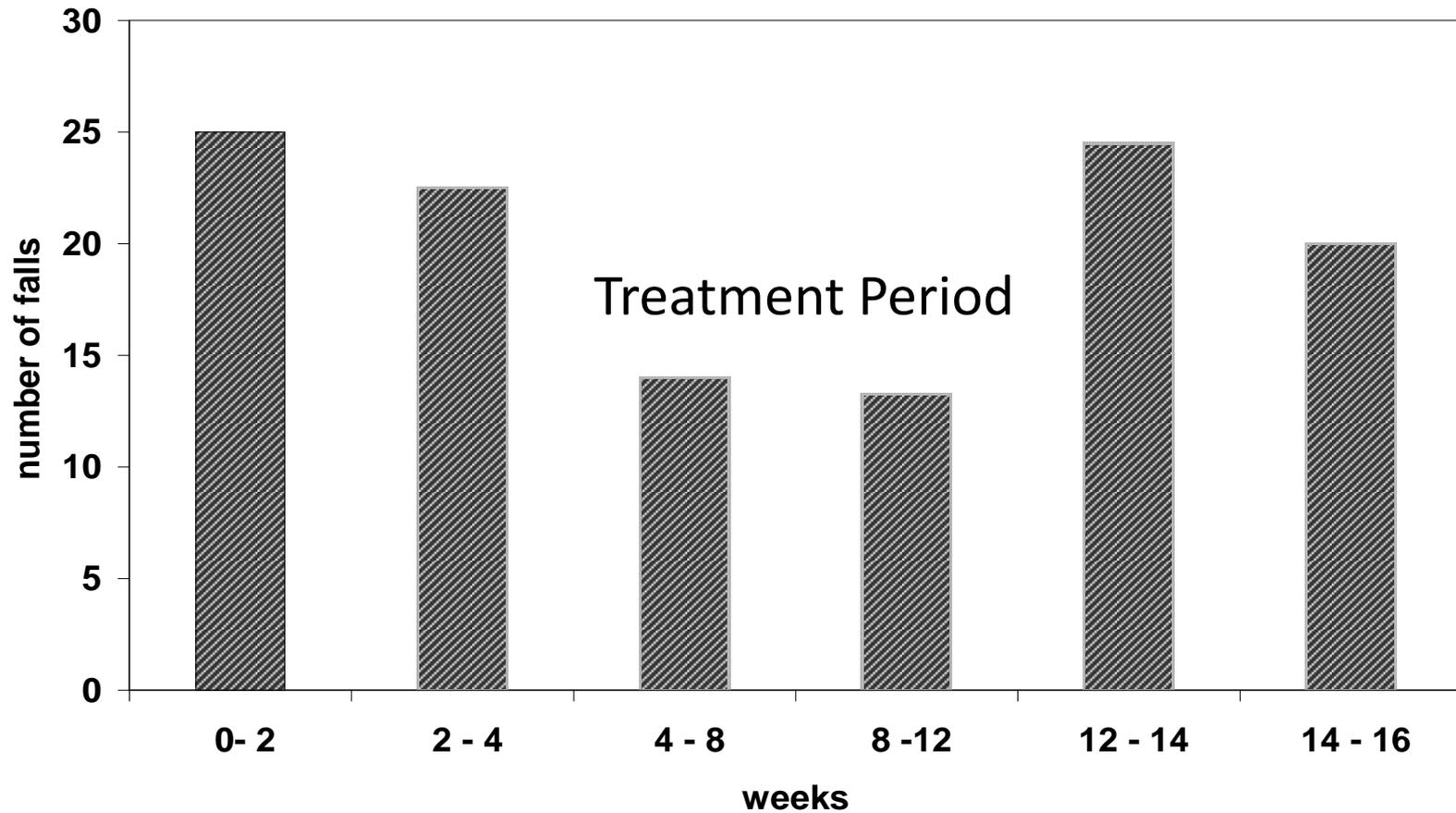
No immediate (orthotic) effect – but effect over treatment period - maintained

# Average Stride Length during 3 minute walk with and without stimulation



Immediate effect – sig. improvement over treatment period – partially maintained

## Total number of falls each week



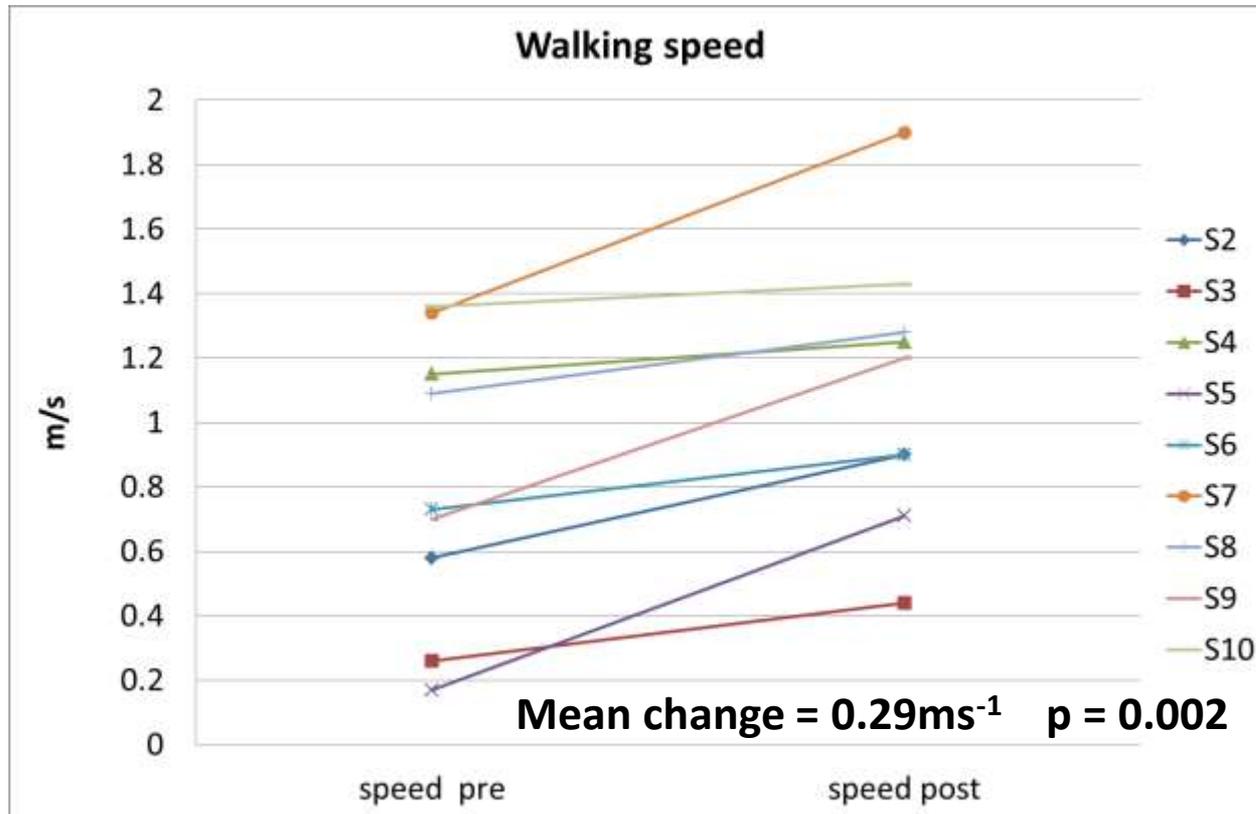
Intervention period

Popa L and Taylor P. Functional electrical stimulation may reduce bradykinesia in Parkinson's disease: A feasibility study. Journal of Rehabilitation and Assistive Technologies Engineering January - December 2015

2 week case series with 11 participants

- Session 1 Assessments only
- Session 2 Set up of FES
- Session 3 Next day – follow up
- Session 4 2 weeks later – final assessments

# 10 m walking speed

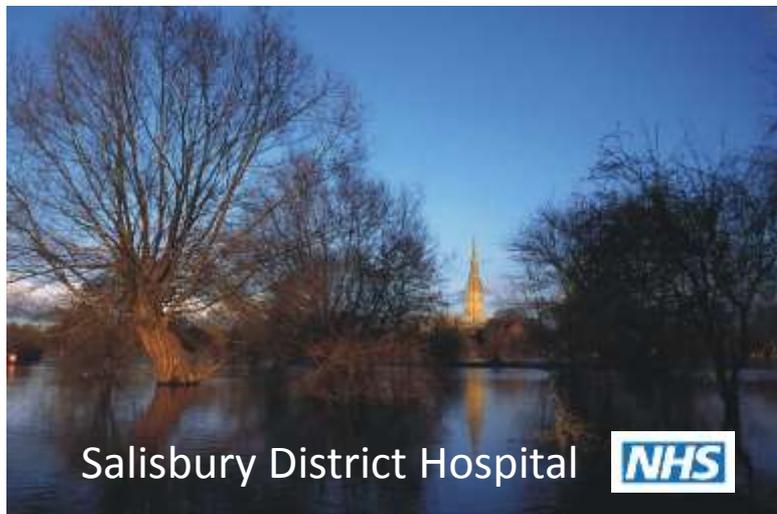


There was a statistically significant improvement in walking speed

2 weeks FES use

- All participants walked faster after 2 weeks
- 8 out of 9 achieved a substantial change in walking speed ( $>0.1\text{ms}^{-1}$  Perera et al.)
- Slowest 5 improved functional walking category (Perry et al.)

# The Effectiveness of Peroneal Nerve Functional Electrical STimulation (FES) for the Reduction of Bradykinesia in Parkinson's Disease: A Pragmatic Two Site Feasibility Study for a Single Blinded Randomised Control Trial (**STEPS**).



Funded by the RfPB



# Questions to be asked

- Can we recruit and retain enough participants?
- What are the barriers to recruitment or staying in the study?
- What do the participants think of the study design?
- Are we measuring the right things? – what is important pwPD?
- How big does the final study have to be to give meaningful results?

We need to test the envisaged final study by trying out a small version of the study



UNIVERSITY OF  
Southampton

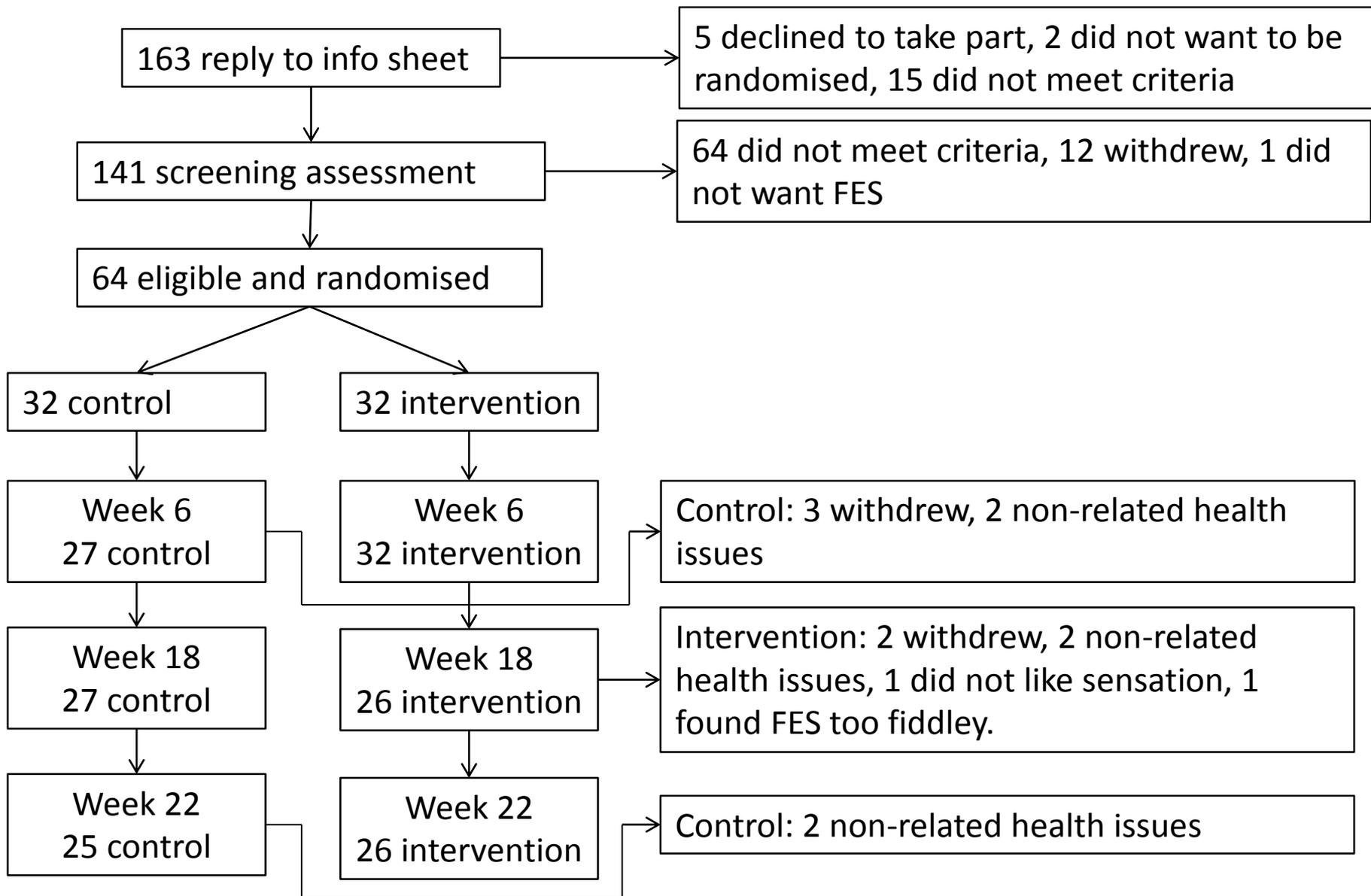
# Study details

- 68 participants at 2 centres
  - Group 1 standard care
  - Group 2 standard care with FES
- 18 week intervention period
- 4 week follow up
- Same outcome measures as subsequent RCT
  - UPDRS, 10mWS, MiniBESTest, PDQ39, FES-I, Falls diary, EQ-5D-5L, health resource use.
- Completed May 2018



**Objective 1:** Determine recruitment, willingness to be randomised and loss-to-follow rates.

- 64 out of 68 recruited in 18 months
- Recruitment rate was 1.8 participant per month per centre
- 2 did not want to randomised. 1 early withdrawal may be due to disappointment at allocation
- All participants who entered the study were followed through
- 80% (51 out of 64) completed the study



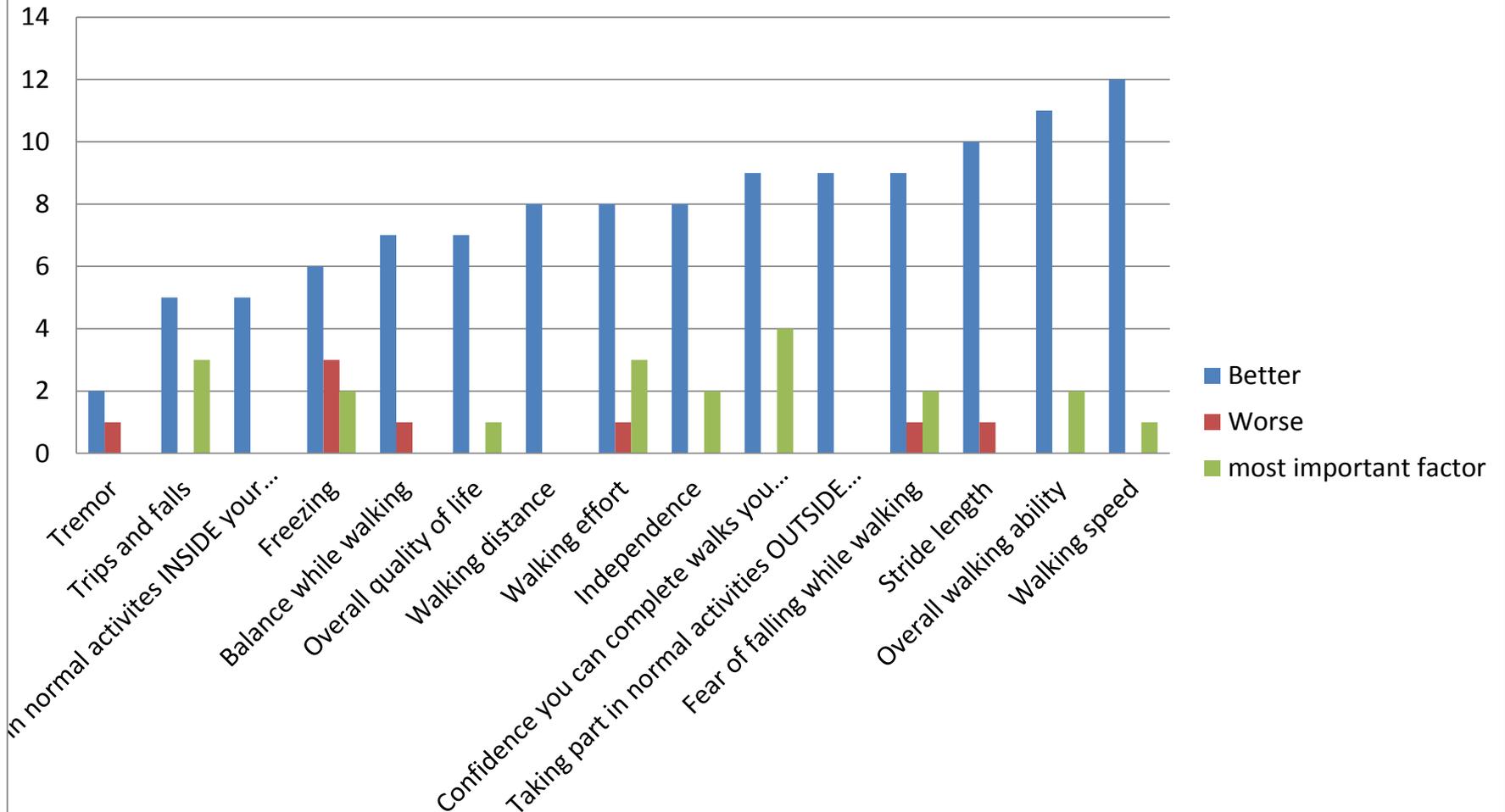
## **Objective 2:** Participant views on obstacles to recruitment and retention in study.

Generally positive comments. Some obstacles identified:

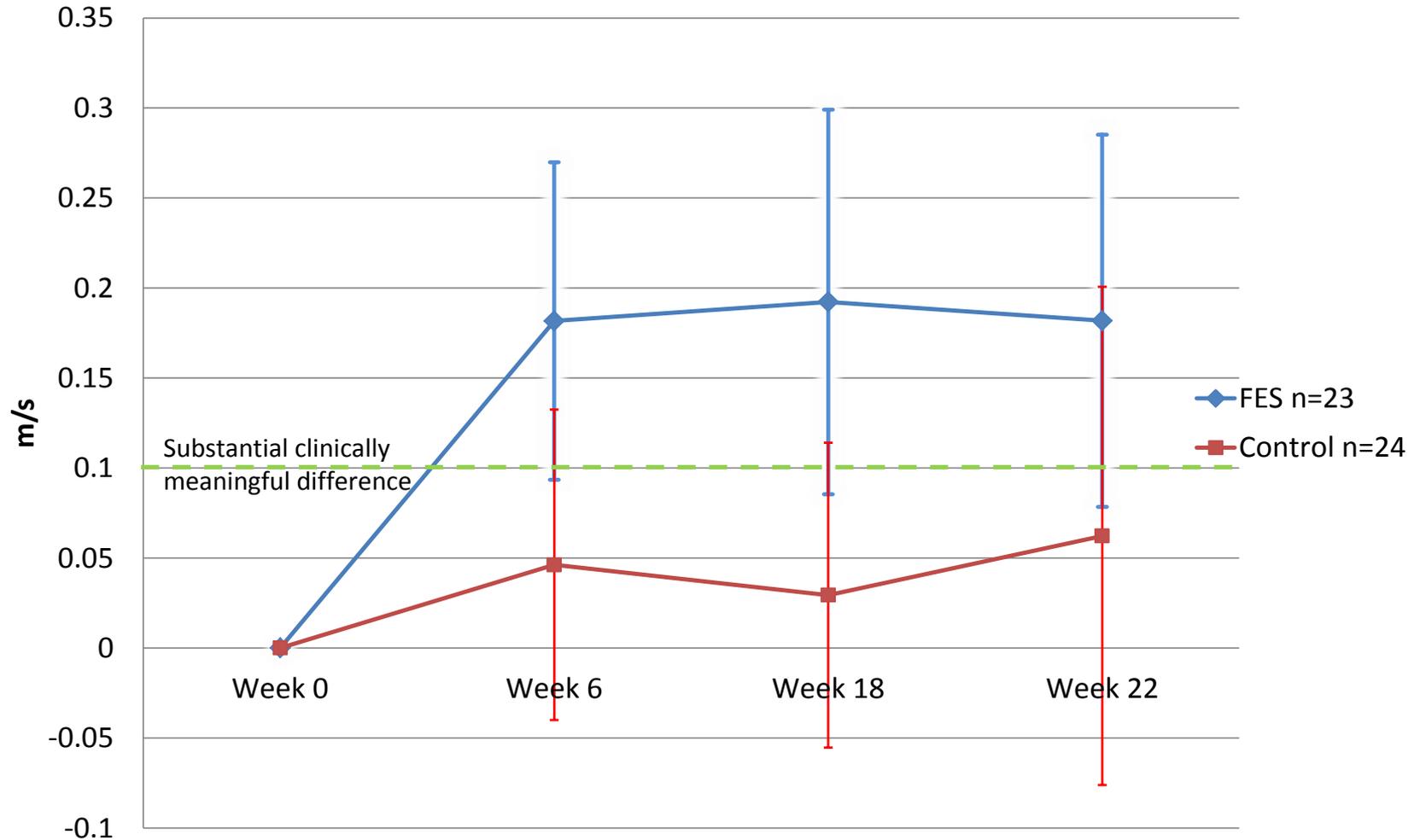
- Time commitment if working
- Some felt the control group should receive intervention at end
- Transport issues
- Some found the assessment sessions long
- Push test unpopular

# Objective 3: Participant views on what would constitute a meaningful primary outcome measure.

Frequency of self-reported factors of walking that were moderately or considerably changed and the factors identified as the most important to the participants. N=25

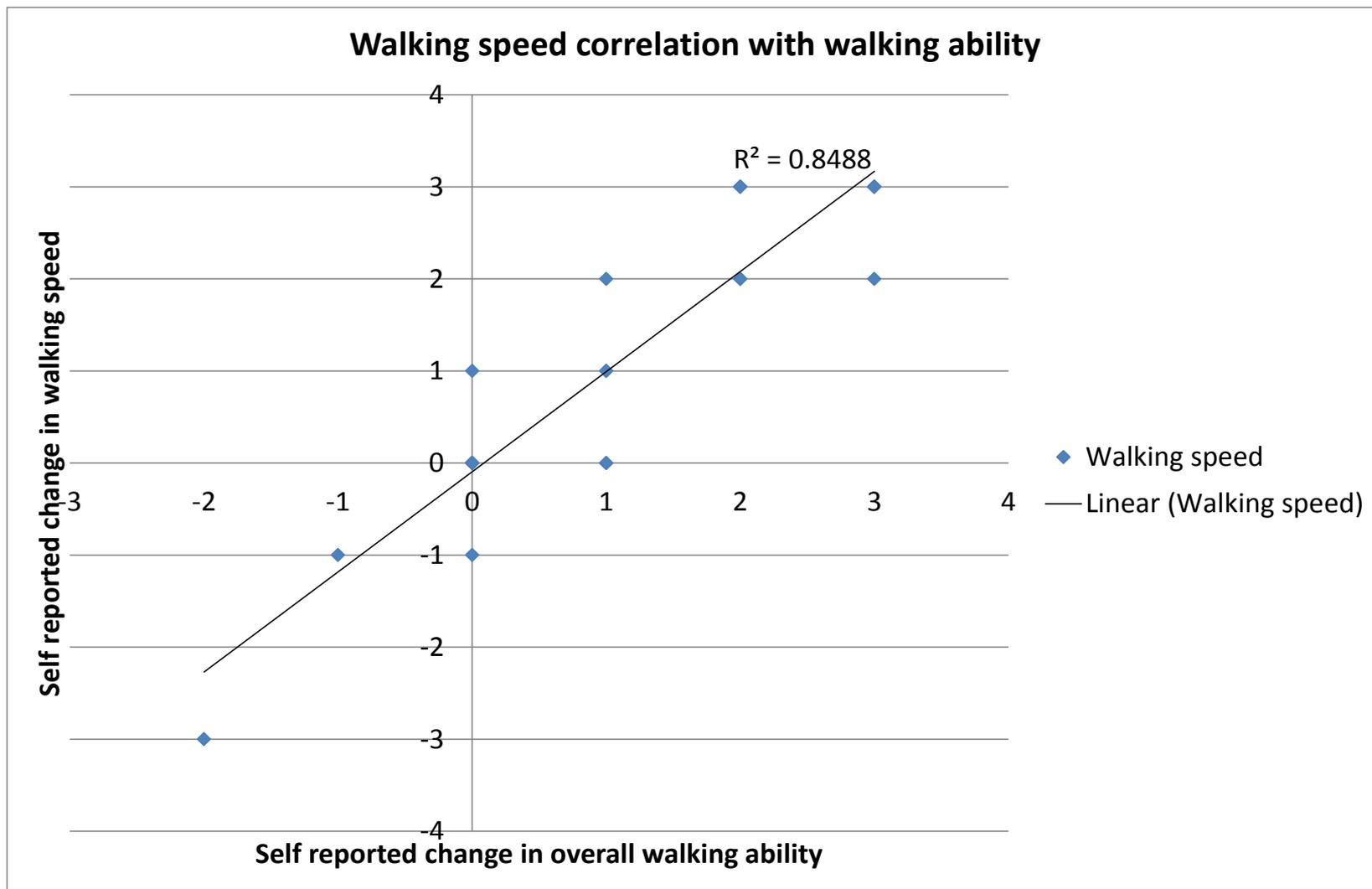


### Mean change in walking speed with 95% confidence limits

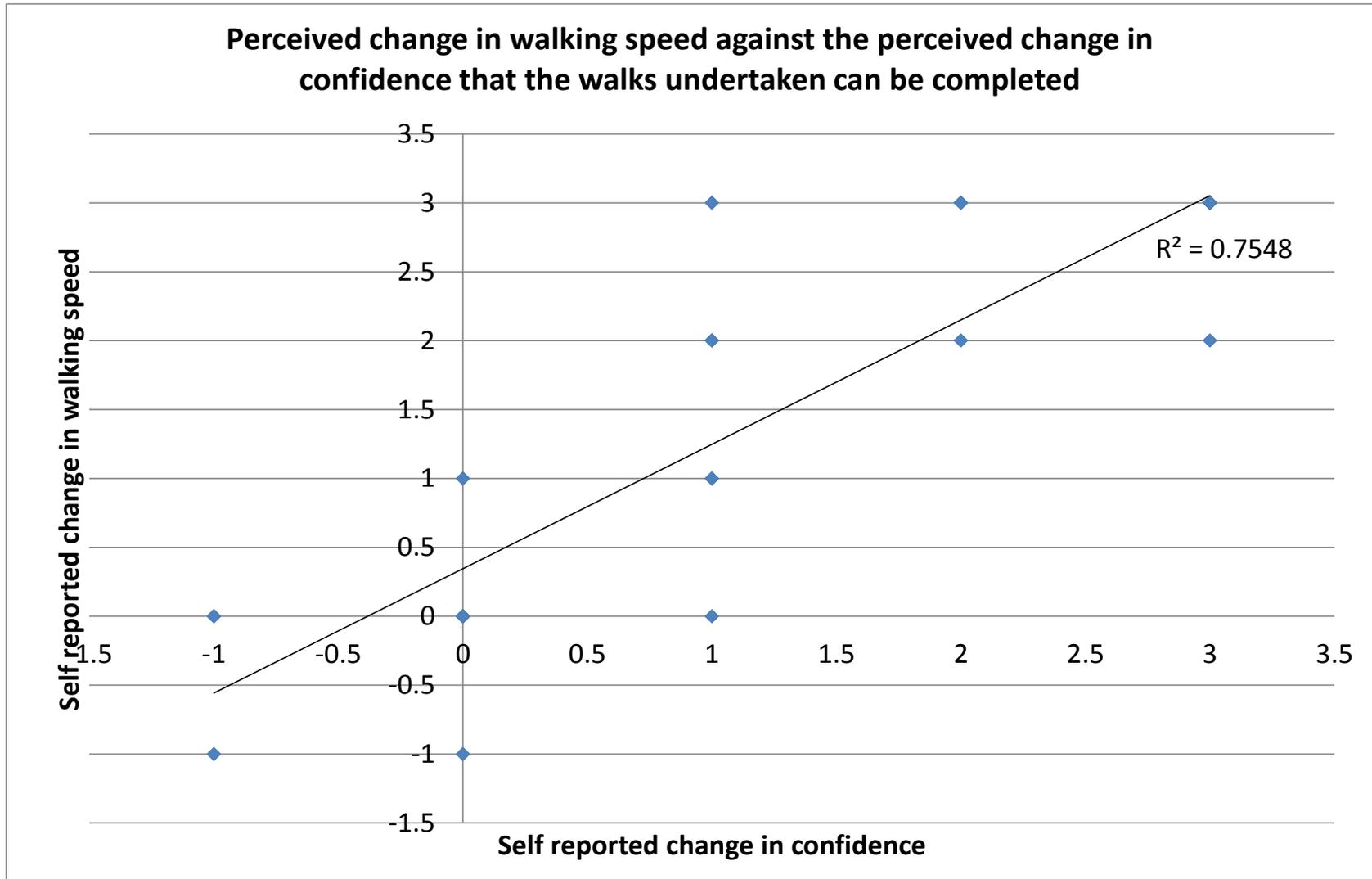


Clinical meaningful and statistically significant changes in 10m walking speed

The high correlation between perceived change in **walking speed** and perceived change in **walking ability** supports the use of walking speed as a primary outcome measure



Also a high correlation between perceived change in **walking speed** and perceived change in **confidence**, the most frequently reported most important factor.



**Objective 4:** To obtain an estimate of the variability of outcome measures to inform sample-size calculation.

**Objective 5:** To obtain an estimate of the within-subject correlations to inform sample-size calculation.

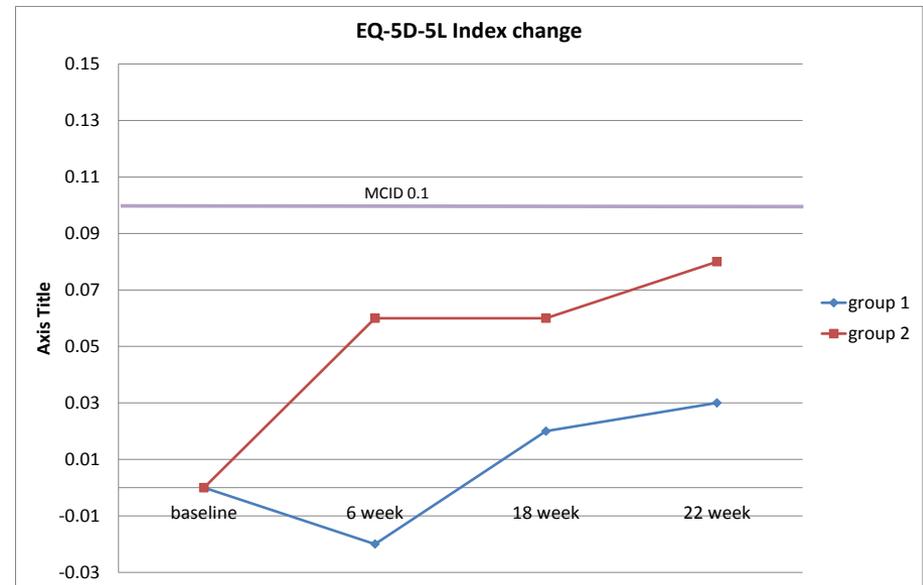
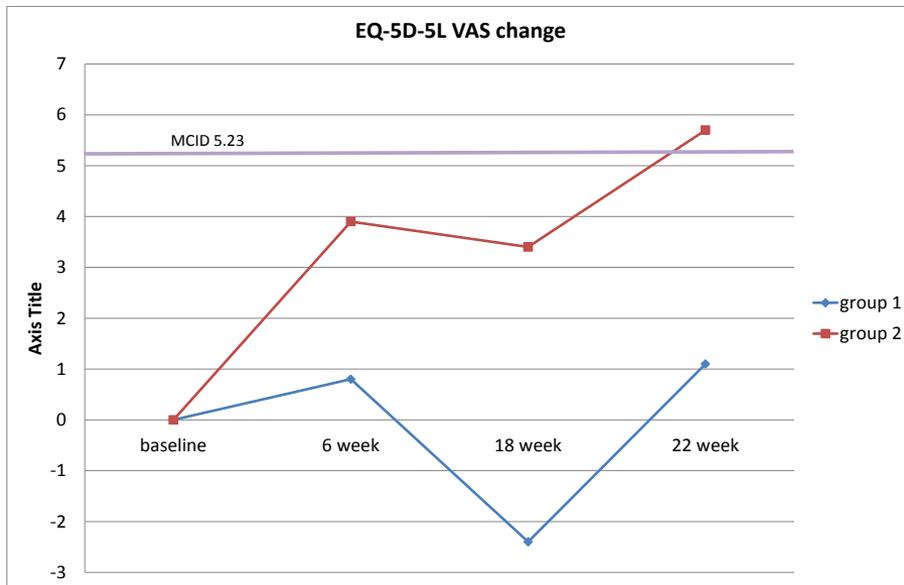
Estimated sample size at 90% power:

- $n = 278$  to  $470$
- Based on walking speed

(Range based on the confidence limits of the standard deviation and correlation coefficients)

# Objective 6: To develop and refine resource use data collection methods to inform a future cost-effectiveness analysis.

- Economic evaluation methods were tested
- Improved EQ-5D-5L score for FES users



**Objective 7:** To obtain estimates of likely time frame and costs for a full RCT.

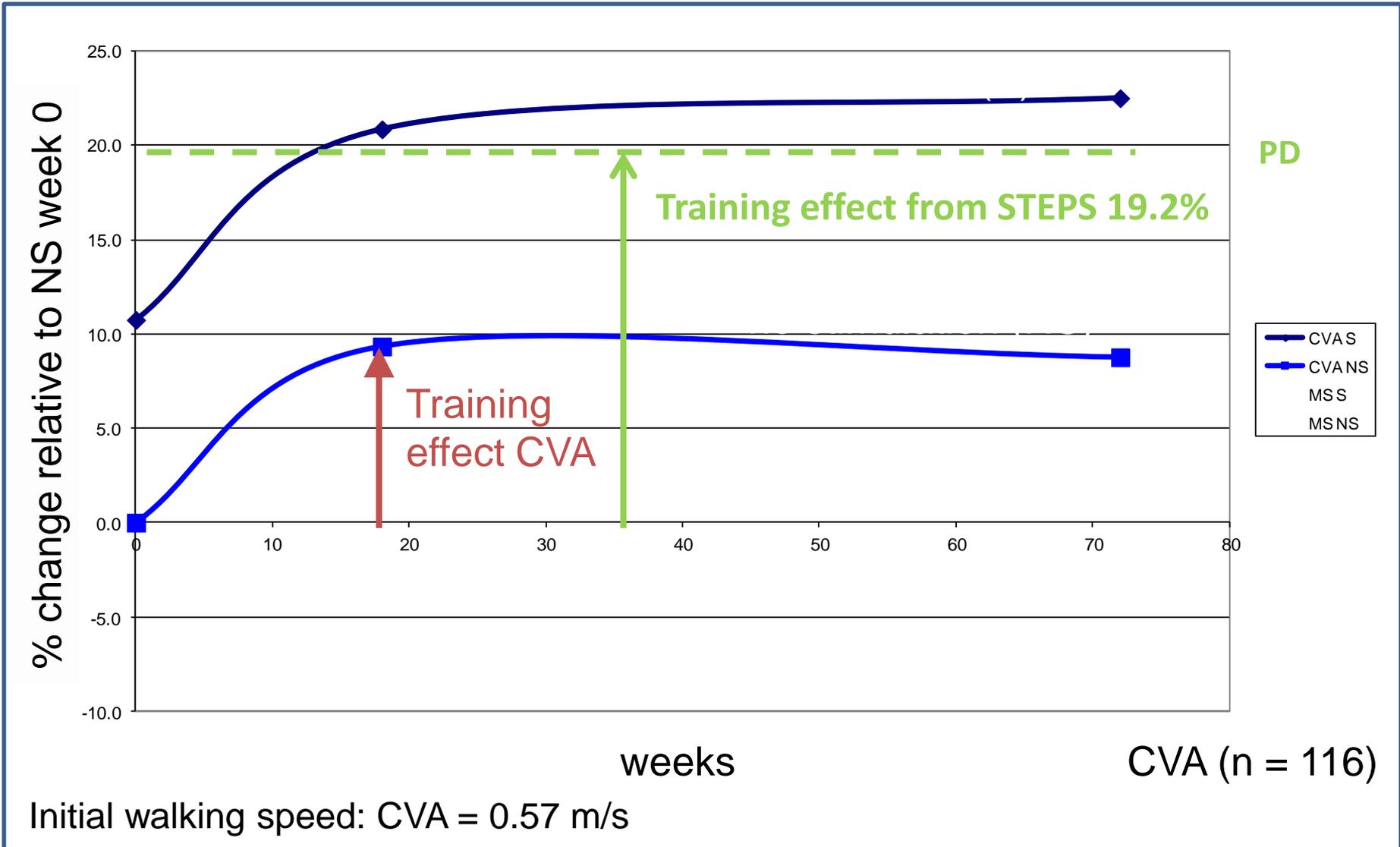
To obtain a sample size of 278 to 470,

- Between 5 and 9 centres
- Recruiting at a rate of 1.8 per month for 30 months.
- The study would be complete in 36 months.

# Recommendations for the application of FES in PD

- Treat gait deficit symptomatically
- Use FES on the more disabled side?
- Keep the current intensity as low as practical
- Use gentle rising ramps (150ms) unless otherwise indicated.
- Use “start at 50%”
- Use carer support

# Double the training effect seen with stroke



# Thank you

## The STEPS Team

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James Lee	Salisbury	Elsa Marques	Bristol University
Sheila Nell	PD Society	Peter Thomas	Bournemouth University

The National Clinical FES Centre  
[www.odstockmedical.com](http://www.odstockmedical.com)

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This presentation presents independent research funded by the NIHR under its Research for Patient Benefit (RfPB) Programme (Grant Reference Number PB-PG-1014-35012). The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health.

