Feasibility of combining physiotherapy and electrical stimulation to improve gait in patients less than 6 months post stroke

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Background

• Specialist MDT rehabilitation increases the number of independent non-institutionalised individuals Zu et al., 2009

• The research challenge is to deconstruct ‘rehabilitation’ to identify the most effective elements

• Focus of this research study is gait rehabilitation, specifically Functional Electrical Stimulation (FES) to improve function in paralysed muscles
Background

- Chronic Stroke - NICE Guidelines 2009
Chronic stroke  % change in median walking speed with FES compared with week 0 (no FES)  

Swain et al., 2004

Initial median walking speed: CVA = 0.57 m/s  

CVA (n = 116)
Background

• Chronic Stroke - NICE Guidelines 2009

• Acute Stroke
  – 15 sessions over 3 weeks of cyclical exercise stimulation + physiotherapy improved walking ability, (RCT n=46, inpatient stroke) Yan et al., 2005
  – FES to correct dropped foot + physiotherapy (pilot RCT n=16, inpatient stroke) Salisbury et al., 2009

• No specific evidence on which to base clinical decisions regarding dropped foot stimulation and physiotherapy for people <6 months post stroke living at home
Hypothesis

• **Therapeutic effect** - Electrical stimulation integrated into outpatient physiotherapy gait rehabilitation improves walking speed (without electrical stimulation) more than physiotherapy alone for people less than 6 months post first stroke.

• **Orthotic effect** - Participants using electrical stimulation will walk faster when stimulation is turned on at Week 8 and Week 20 assessments.
Selection Criteria

• Inclusion
  – Adults less than 6 months post (first) stroke
  – Able to attend sessions and be active in therapy (medical referral to physiotherapy, MMSE >25)
  – Walking problems (RMI 6-10)
  – Tolerates stimulation sensation

• Exclusion
  – Pacemaker, pregnancy, uncontrolled epilepsy, poor skin condition
  – Previous neurological disease or other health condition limiting ability to complete protocol
Main Outcome Measures

- Walking speed (over 10m)
- Six minute walking distance
- Rivermead Mobility Index
- Canadian Occupational Performance Measure (COPM)
- Visual gait analysis from video by blinded assessor using Rivermead Visual Gait Assessment
**Method**

### Study Schedule

<table>
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<tr>
<th>Initial Contact</th>
<th>Week 1</th>
<th>Weeks 2-7</th>
<th>Week 8</th>
<th>Weeks 9-19</th>
<th>Week 20</th>
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<tr>
<td>Given Information Sheet</td>
<td>Informed consent recorded, Outcome Measures taken and participants randomly put in Group A or B</td>
<td>Treatment block, 2 appointments per week</td>
<td>Outcome Measures taken</td>
<td>No treatment, 12 week follow up period</td>
<td>Outcome Measures taken</td>
</tr>
</tbody>
</table>

### Patient Journey

- Discuss information sheet
- Check they meet study selection criteria
- Consent to participate in the study given

- Assessment 1: Outcome measures taken
- Randomise Participants allocated to Group A or B
- Assessment 2: Outcome measures taken
- Group A: Physiotherapy
- Group B: Physiotherapy and FES
- Assessment 3: Outcome measures taken
Demographics

• Recruited 20 participants

• Balanced groups
  – 10 in each group
  – Group A (5m 5f), Group B (6m 4f)
  – Mean age
    • Group A 64.5 years,
    • Group B 65.4 years
  – Mean (range) time since stroke
    • Group A 9.9 (3.6-20.1) weeks
    • Group B 10.7 (5.1-17.7) weeks
100% attendance at all assessments and appointments
Videos not available
Week 20

No Stimulation

VIDEO NOT AVAILABLE

Participant 18 keen to continue FES after the trial. Able to confidently walk alone outside with FES but not without.

With stimulation
Six Minute Walking Distance

• Comparing Group A (PT) to Group B (PT+FES) but measured with FES switched off

VIDEOS NOT AVAILABLE
Six Minute Walking Distance
(Mean, 95% Confidence Interval)

**Treatment phase**
(Student t-test)
Group A mean increase 83.3m (p=<0.01)
Group B mean increase 66.5m (p=<0.01)

**Follow up**
No significant change
No significant between group differences (ANCOVA)

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**Graph Details**
- **Group A (PT)**: Blue dashed line with blue markers.
- **Group B (PT+FES (off))**: Red line with red markers.

**Y-axis**: Six Minute Walking Distance (m)
**X-axis**: Week

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**Legend**
- **Group A (PT)**
- **Group B (PT+FES (off))**
Six Minute Walking Distance
Group B - Individual distances plotted

Week
Six Minute Walking Distance (m)

0 5 10 15 20 25 30 35 40
Six Minute Walking Distance
Group B subdivided into participants wanting to stop FES versus wanting to keep FES after follow-up

Wanting to keep FES
Mean Six Minute Walking Distance
Group B participants wanting to stop FES versus wanting to keep FES after follow-up

Test of common regression line
p=0.032
10m Walking Speed – Training Effect

• Significant improvement during treatment phase, Group A (PT) and Group B (PT+FES (off))
  – Group A (PT) mean(95%CI) 0.28m/s increase (0.15 to 0.42) p=<0.01
  – Group B (PT+FES (off)) mean(95%CI) 0.17m/s increase (0.05 to 0.30) p=0.01

• Improvement maintained during follow-up

• No significant between group differences

• Group B participants wishing to keep FES after the trial had slower walking speeds
  (test of common regression p=<0.01)
10m Walking Speed - Orthotic Effect

• Group B ‘FES on’ compared to ‘FES off’

• At Week 8
  – Significant orthotic increase
    • mean 0.04 m/s (p=0.01)
    • mean % change 8.7% increase

• At Week 20
  – Significant orthotic increase
    • mean 0.06 m/s (p=0.03)
    • mean % change 22.4% increase
Rivermead Mobility Index

• Significant improvement during treatment phase
  – Group A (PT) mean(95%CI) 3.2 increase (1.9 to 4.5) p=<0.01
  – Group B (PT+FES) mean(95%CI) 2.6 increase (1.5 to 3.7) p=<0.01

• Improvement maintained during follow-up
• No significant between group differences

• Group B participants wishing to keep FES after the trial had lower RMI scores
  (test of common regression p=0.06)
Canadian Occupational Performance Measure (COPM)

- Significant improvement in COPM performance and satisfaction during treatment phase
  * 2 point increase considered clinically significant (www.rehabmeasures.org)
    - Group A (PT) mean increase >3* points (p=<0.01)
    - Group B (PT+FES) mean increase >3* points (p=<0.01)
- Improvement maintained during follow-up
- No significant between group differences
- No difference between participants wishing to keep FES after the trial and other Group B participants.
Conclusions of Feasibility Study

• Protocol and outcome measures are feasible
• Consistent significant improvement during treatment phase maintained in follow-up
• Significant orthotic effect with FES
• Participants in Group B wishing to continue FES at the end of the trial generally had greater walking difficulties at Week 1, 8 and 20
• No evidence of training effect relative to physiotherapy alone
• Fully powered study required to confidently support or refute training hypothesis
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