Community-based Rehabilitation Training after Stroke (ReTrain): results of a pilot randomised controlled trial (RCT)

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**Action for Rehabilitation from Neurological Injury: ARNI**

ARNI is an exciting development in the field of stroke rehabilitation:

- *progressively recovering lost strength, balance and movement by functional task-related practice and stroke-specific resistance training techniques.*

- *designing self-recovery programmes with the aim of self-reliance.*

ARNI is a registered charity formed in response to the very real demand throughout the UK from stroke survivors, who uniformly state that they are 'stuck in limbo' after coming home from rehab.

[http://www.arni.uk.com](http://www.arni.uk.com)
Patient & Public Involvement

Does ARNI work?.....
Should I (Jim) be doing it?
and is it worthwhile?

PenCLAHRC question generation prioritisation and adoption process: the ReTrain project is born in 2009
MRC framework for developing and evaluating complex interventions 2008

Feasibility and piloting
- Testing procedures
- Estimating recruitment and retention
- Determining sample size

Development
- Identifying the evidence base
- Identifying or developing theory
- Modelling processes and outcomes

Evaluation
- Assessing effectiveness
- Understanding change process
- Assessing cost effectiveness

Implementation
- Dissemination
- Surveillance and monitoring
- Long term follow-up

Motivators for uptake and maintenance of exercise: perceptions of long-term stroke survivors and implications for design of exercise programmes

Intervention Fidelity: Developing an Experience-Based Model for Rehabilitation Research

Informing the design of a randomised controlled trial of an exercise-based programme for long term stroke survivors: lessons from a before-and-after case series study

Synthesising practice guidelines for the development of community-based exercise programmes after stroke
Community-based Rehabilitation Training after stroke: protocol of a pilot randomised controlled trial (ReTrain)

Sarah G Dean, Leon Pollawski, Anne Forster, Rod S Taylor, Anne Spencer, Martin James, Rhodia Allison, Shirley Stevens, Meriel Norris, Anthony I Shepherd, Raffa Calins

ABSTRACT

Introduction: The Rehabilitation Training (ReTrain) intervention aims to improve functional mobility, adherence to poststroke exercise guidelines and quality of life for people after stroke. A definitive randomised controlled trial (RCT) is required to assess the clinical and cost-effectiveness of ReTrain, which is based on Action for Rehabilitation from Neurological Injury (ARN). The purpose of this pilot study is to assess the feasibility of such a definitive trial and inform its design.

Methods and analysis: A 2-group, assessor-blinded, randomised controlled external pilot trial with parallel mixed-methods process evaluation and economic evaluation. 48 participants discharged from clinical rehabilitation despite residual physical disability will be individually randomised 1:1 to ReTrain (25 sessions) or control (exercise advice booklet). Outcome assessment at baseline, 6 and 9 months include Rivermead Mobility Index; Timed Up and Go Test; modified Patient-Specific Functional Scale; 7-day accelerometry; Stroke Self-efficacy Questionnaire.

Strengths and limitations of this study

- This pilot randomised controlled trial study meets the Medical Research Council (MRC) guidance on the development and evaluation of complex interventions and includes comprehensive patient and public involvement.
- This preliminary evaluation of a late stage rehabilitation programme addresses the gap in the evidence related to what facilitates stroke recovery in the longer term.
- This small scale study is designed to estimate effect sizes but has insufficient statistical power to detect differences in outcomes between groups.
- The follow-up period is relatively short compared with what would be planned for a fully funded definitive trial.

Peer-reviewed journal publications, open access sources and media releases.

Pilot or Feasibility Study?

Research Aim

To evaluate the feasibility and acceptability of a community-based stroke rehabilitation programme (ReTrain) based on improving functionality.

The results will inform the decision to proceed to a definitive RCT.
Design: Overview

• Pilot RCT, 48 stroke survivors, randomised to either the 24 week ReTrain programme or to a control group (advice booklet)

• Based in community venues in both Exeter and South Devon

• Parallel economic and process evaluation (including interviews with participants and trainers, video analysis of techniques, session checklists)
Design: Population

Inclusion criteria include:

- Clinical diagnosis of stroke
- ≥ 1 month post discharge from NHS rehabilitation
- Willingness to be randomised to either group
- Capacity to consent
- Able to walk independently (with or without mobility aids; with self-reported difficulties climbing stairs or slopes/uneven surfaces)

Exclusion criteria:

- Under 18
- Have contraindications to moderate exercise
Design: Outcomes

Primary
1. Rivermead mobility index
2. Timed get up and go
3. A modified patient-specific functional scale
4. Physical activity – diary & 7 day accelerometry (wrist worn)

Secondary
1. Fatigue assessment scale
2. Quality of Life (EQ-5D-5L, SF-12, stroke specific QoL and self-efficacy)
3. Exercise beliefs and exercise self-efficacy questionnaires
4. Carer burden index
5. Economic evaluation (i.e. service receipt)
The intervention: ReTrain programme

**Week 1**
- One-to-one: Participants home, Set goals

**Weeks 2-11**
- Group exercise: 2hrs twice weekly, Community venue, Strengthening exercises, Functional task practice, Teaching ARNI techniques

**Week 12**
- One-to-one: Participants home, Review goals

**Weeks 13-24**
- Drop-ins: Community venue, Once a month for 3 months
Objective 1a: Assess the feasibility and acceptability of recruitment & randomisation

Results:

- 50 participants recruited, one month earlier than predicted
- 45 successfully randomised via Exeter CTU
- 4 post randomisation withdrawals; only one (from control group) a result of discontent with randomised allocation
ReTrain Recruitment Timeline

Cumulative number of patients consented

- 4 per month (previous research)
- 5 per month (expected)
- Actual
GP=40; Early Supported Discharge=1; Community Rehab= 21; Stroke Association=16; Stroke Group= 11; Word of Mouth=2; Media=5; Exeter 10,000 database=18 (Total= 114)

114 Screened

23 declined
41 Ineligible

50 Consented

5 Withdrawn
3= not eligible; 1= unwell; 1=GP letter not returned

45 Randomised

20 received intervention
1 did not receive intervention

ReTrain (n=23)

2 Withdrawn
1= family crisis; 1= unwell

Control (n=22)

2 Withdrawn
1= unwell; 1= unhappy with randomisation outcome

6 Month Follow-up

21 assessed

9 Month Follow-up

21 assessed

19 assessed
1 missing

20 assessed
# ReTrain Study: Core Baseline Participant Demographics

<table>
<thead>
<tr>
<th></th>
<th>ReTrain (N= 23)</th>
<th>Control (N=22)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gender: Male (%)</strong></td>
<td>16 (70%)</td>
<td>14 (67%)</td>
</tr>
<tr>
<td><strong>Age (years): mean (SD)</strong></td>
<td>70 (12)</td>
<td>71 (10)</td>
</tr>
<tr>
<td></td>
<td>42-91</td>
<td>47-88</td>
</tr>
<tr>
<td><strong>Time Since Stroke (no. months)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 12</td>
<td>3 (13%)</td>
<td>3 (14%)</td>
</tr>
<tr>
<td>12-24</td>
<td>4 (17%)</td>
<td>4 (18%)</td>
</tr>
<tr>
<td>25-48</td>
<td>5 (22%)</td>
<td>5 (23%)</td>
</tr>
<tr>
<td>49-72</td>
<td>2 (9%)</td>
<td>5 (23%)</td>
</tr>
<tr>
<td>73-96</td>
<td>4 (17%)</td>
<td>2 (9%)</td>
</tr>
<tr>
<td>97+</td>
<td>5 (22%)</td>
<td>3 (14%)</td>
</tr>
<tr>
<td><strong>Time Since Stroke Minimisation Categories</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;=3 months</td>
<td>1 (4%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>&gt;3 months</td>
<td>22 (96%)</td>
<td>22 (100%)</td>
</tr>
<tr>
<td><strong>Type of Stroke, n (%)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Haemorrhagic</td>
<td>3 (13%)</td>
<td>1 (5%)</td>
</tr>
<tr>
<td>Ischaemic</td>
<td>15 (65%)</td>
<td>15 (68%)</td>
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<tr>
<td>Both</td>
<td>0 (0%)</td>
<td>1 (5%)</td>
</tr>
<tr>
<td>Missing</td>
<td>5 (22%)</td>
<td>5 (23%)</td>
</tr>
<tr>
<td><strong>Simplified Modified Rankin Scale (sMRS) n (%)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>1 (4%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>1</td>
<td>2 (9%)</td>
<td>1 (5%)</td>
</tr>
<tr>
<td>2</td>
<td>4 (17%)</td>
<td>9 (41%)</td>
</tr>
<tr>
<td>3</td>
<td>16 (70%)</td>
<td>12 (55%)</td>
</tr>
<tr>
<td><strong>sMRS minimisation categories: n(%)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;=2</td>
<td>7 (30%)</td>
<td>10 (45%)</td>
</tr>
<tr>
<td>&gt;2</td>
<td>16 (70%)</td>
<td>12 (55%)</td>
</tr>
</tbody>
</table>
Objective 1b: Assess the feasibility and acceptability of allocation concealment and outcome assessment blinding procedures

Results:

- Participants concealed allocation well: only 2/41 (5%) revealed allocation during 6m and 9m follow-up

- Pool of assessors help manage un-blinding

- Assessment blinding procedures were robust and effective
Objective 2: Obtain an estimate of the outcome variance and retention rates

Results:

• Retention rates were within acceptable range for a definitive RCT

• 41/45 (91%) participants remained in the trial
  • Of those, 40/41 (98%) completed 6m follow up
  • All 41 (100%) completed 9m follow up

• Provisional sample sizes (pending choice of primary outcome) range from approximately 100 to 400 or up to 1,000 (excluding attrition)
Objective 3: Confirm the feasibility of ReTrain and its acceptability to participants

Results:

• Along with recruitment, retention & attendance the qualitative interviews confirm acceptability:

“it opened my eyes to what can be done…..”

Challenging “boot camp” but necessary; positive about post training tiredness: “I mean I was using muscles which I’d not used probably for years”

“you felt as if you were a human being with them….you were treated with respect…..I’ll never be able to speak highly enough of them”
Objective 4: Assess outcome measurement burden (including safety data)

Results:

• Between 0 - 4 (0% - 10%) missing cases for each scale at each time point
  • BUT accelerometry physical activity data at 9m where up to 8 (20%) missing cases (4/8 attributable to hardware/software failures)

• No concerns expressed re assessment load

• No major safety issues identified for ReTrain

• Range of data sources to help inform choice of primary and secondary outcomes for a definitive RCT - selection not yet finalised
Objective 5: Rehearse process evaluation methods, including intervention fidelity

Results: Rehearsed process evaluation methods and have assessed intervention fidelity through use of diaries, check lists, qualitative interviews and video
Objective 5 (cont): Rehearse process evaluation methods, including intervention fidelity

Results:

• Assessed participant fidelity of engagement with the intervention

• 16/23 (70%) ReTrain participants achieved a minimal acceptable level of 50% or more adherence (attendance & home exercise diaries)

• Finalising our assessment of trainer intervention delivery fidelity
Objective 6: Evaluate resource use

Results:

• Collected data for resource use, including medical notes review, and costs associated with the intervention delivery

• Preliminary assessment shows intervention costs range from £720-£880 per person

• A pilot economic model has been built and work is in progress to complete this evaluation
Lessons Learned & Next Steps

Can deliver on the research

Intervention is feasible to deliver & acceptable to participants

Need for flexibility within the standardisation, have some pointers for refinement

Remains an important question to answer

Aim to apply for definitive trial funding

MRC framework for developing & evaluating complex interventions 2008
Thank you
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http://clahrc-peninsula.nihr.ac.uk/