Stroke Prevention Rehabilitation Intervention Trial of Exercise (SPRITE) -
A Randomised Pilot Study

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Introduction

• Stroke: - killed 6.5 million people in 2015
  - Approx. 20% of TIAs have a stroke within 90 days

• After a TIA/minor stroke, survivors often have residual functional impairment
  • post-event fatigue + psychological issues
    – Clinicians (+ patients) need clearer guidance re optimal early prevention

• Cardiac rehab for TIA and ‘minor’ stroke patients?
  – TIA and stroke - atherothrombotic disease

• Cardiac rehabilitation post MI (Lawler et al, ‘11):
  - re-infarction (OR 0.53, 0.38-0.76)
    – Home-based CR = longer term sustainability
Research aims

To pilot ‘The Healthy Brain Rehabilitation Manual’ (an adapted home-based CR programme)

- with added pedometer intervention +
- telephone follow-up (GP or stroke nurse)
- in acute period (<4 wks) after first TIA or ‘minor’ stroke of atherosclerotic origin
- 4 recruitment sites

• Obtain initial estimate of the effectiveness of the intervention in improving CVD risk

• Identify - numbers of eligible patients
  - rates of agreement to research contact
  - rates of participant recruitment
  - rates of completion of outcome measures
Intervention - The Healthy Brain Rehabilitation Manual

• Framework:
  – MRC guidelines + 6SQUID guidelines
  – Initial manual development and refinement
    • 2 systematic reviews
    • Qualitative review with patients + stakeholders
    • Feasibility study

• Healthy Brain Rehabilitation Manual
  – Home-based rehabilitation
  – 6 sections
  – Each section addresses:
    • Mental health,
    • Physical activity
    • + one other CV risk factor
Methods

• Recruitment – Ulster; Antrim; Royal; Craigavon

• Invited to NICRF – assessment + randomisation:
  - Group 1: Control, usual care
  - Groups 2 + 3: ‘The Healthy Brain Rehabilitation Manual’ + pedometer
  - Group 2: GP telephone follow-up
  - Group 3: stroke nurse telephone follow-up

• Aim – 40 in total
• 12 wk follow-up

• Telephone follow-up at 1, 4 + 9 wks:
  – answer questions
  – review goals/plans/targets
  – motivational interviewing + 5 A’s

• Focus group with patients and 2 stroke nurses:
  – Acceptability of intervention + research
Inclusion/Exclusion criteria

• Inclusion criteria:
  – 18 yrs or older
  – Within 4 wks of…..
  – a TIA or ‘minor’ stroke due to atherosclerosis or small vessel occlusion
  – ‘Minor’ stroke = 2 or less on NIHSS
  – Diagnosis made by clinic consultant

• Exclusion criteria:
  – >1 TIA and/or stroke
  – TIA/’minor’ stroke not directly related to atherosclerosis/small vessel disease
  – Unable to give informed consent
  – < 18 yrs of age
  – >4 wks after initial TIA/‘minor’ stroke
Recruitment

• Recruited from May – Dec ‘17
• 443 total TIAs/minor strokes
  – 318 ineligible for study
• 125 (28.2%) eligible
• 44 (35.2%) agreed to the initial telephone contact
• 40 (90.9%) entered the study
• 39 (97.5%) completed the study
  – 1 drop out – end of week 1
Results

- 12 patients (8M, 4F) were randomised to Group 1 (control)

- 14 randomised to each of:
  - Group 2 (GP follow-up) (10 M, 4 F)
  - Group 3 (stroke nurse follow-up) (6M, 8F)

- Amendment:
  - 2 patients had home baseline assessments (others were at NICRF)
Results – Group 2

- SBP – mean decrease of 10mmHg
- DBP – mean decrease of 8mmHg
- Steps/day – mean increase of 1,200
  - Average 2MWT – increase of 16m
  - Averaged TUGT – decrease by 3s
- HADs score – mean reduction by 3
  - Similar improvements in EQ5D-5L
- Med diet score – mean increase by 3
  - Weight – mean reduction of 1.5kg
  - Waist circumference – mean reduction of 1.5cm
Results – Group 3

• Average steps/day – increase of 1,900
  – Mean 2MWT – increase of 18m
  – Mean TUGT – reduction >2secs

• HADs score – mean decrease by 4
  – Similar improvements in EQ5D-5L

• Med diet score – >3 average increase
  – Average weight reduction - >1kg
# Statistically significant results (ANCOVA)

<table>
<thead>
<tr>
<th>Variable</th>
<th>Group 2 (GP follow-up) (p-value)</th>
<th>Group 3 (stroke nurse follow-up) (p-value)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Systolic blood pressure (mmHg)</td>
<td>0.005</td>
<td></td>
</tr>
<tr>
<td>Average 2 minute walk test (metres walked)</td>
<td></td>
<td>0.028</td>
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<tr>
<td>Weight (kg)</td>
<td>0.019</td>
<td></td>
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<tr>
<td>Waist circumference (cms)</td>
<td>0.004</td>
<td></td>
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<tr>
<td>Mediterranean Diet Questionnaire score</td>
<td>0.000</td>
<td>0.000</td>
</tr>
</tbody>
</table>
Qualitative findings

• 4 patients (1 M; 3 F); 2 stroke nurses
  – 3 participants - Gp 3;
  – 1 participant – Gp 2
• Age range: 50-83 yrs

• To determine participants’ views of
  • Manual;
  • Study design
  • Changes for a RCT

• Thematic analysis: 3 main themes
  – Use of the manual
  – Study design
  – Suggested changes

“….in general it was very good….. a very positive thing to be involved with, with lots of positive feedback from the patients themselves.” (N1)
Suggested changes for future work

- Electronic version of the manual
  - “I think it’s (an app on the phone) a good idea...” (83yo, female)

- Cognitive tests
  - “you could maybe do some mental tests as well?” (57yo, female)

- Accelerometers
  - Longer wear time
  - Feedback on performance

- Open questions
  - “....instead of asking a set number of questions, leave it a bit more open and ask the person how did they find everything, do they have any questions?” (60yo, male)

- Food diary

- Longer duration follow-up
  - “Yes 6 months would be good and I think people would benefit from it as well.” (N1)

- TIA or ‘minor’ stroke sequelae
  - “my fear is taking another one....” (78yo, female)
Discussion

• ‘A priori’ hypotheses were achieved:
  – 35.2% of eligible patients who were invited to consent to a telephone contact agreed
  – 90.9% of patients who received initial telephone contact consented to participate
  – 97.5% of these completed the full study

• Intervention groups improved CV risk factors

• Intervention acceptable; welcomed
  – Focus group findings
  – Recruitment and retention rates

• Need to further develop & evaluate the intervention’s effectiveness in managing CVD risk factors within an appropriately powered RCT
Next steps......

• Electronic version - food diary
• “What matters to you?”, section at start
  – Encourage more open approach
• Follow-up extended to 6 mths
• Add study measurements:
  – SF-36
  – Montreal Cognitive Assessment tool
• Recruit directly from TIA and ‘minor’ stroke clinics
Strengths and Limitations

• Rigorous research methods developing the intervention

• Blinded nurse follow-up

• Appropriate research measurements:
  – Physical activity assessed objectively
  – BP measured using BpTru (equivalent to 24 hour BP monitoring)

• Patients from a broad range of socio-economic + educational attainment levels

• BUT - limited data for wheelchair participant
  - stratified randomisation to ensure balance within groups
Conclusion

• ‘The Healthy Brain Rehabilitation Manual’
  – Developed as per MRC guidelines

• Pilot study:
  – Adapted home-based cardiac rehab programme acceptable
  – Potentially significant secondary cardiovascular prevention
  – Refinement of the RCT
    • Longer follow-up
    • Intervention alterations