This study was funded by the NIHR HTA ref: (HTA 13/14/01). The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health.
Please note that these are emerging findings which will be subject to peer and editorial review before publication on the NIHR Journals Library website.
Background

NIHR HTA commissioned call 13/14
How feasible is a study to investigate the clinical and cost-effectiveness of a psychological intervention for people with post-stroke depression?

Which psychological intervention to investigate?

Communication and Low Mood (CALM): a randomized controlled trial of behavioural therapy for stroke patients with aphasia

Shirley A Thomas¹, Marion F Walker¹, Jamie A Macniven², Helen Haworth³ and Nadina B Lincoln¹
How feasible is a study to investigate the clinical and cost-effectiveness of behavioural activation therapy for people with post-stroke depression?

**Primary objective:** To determine the feasibility of proceeding to a definitive trial

**Secondary objective:** To determine the feasibility of the delivery of the behavioural activation therapy intervention with people with post-stroke depression
Design

Identification of stroke survivors from stroke services and voluntary organisations (3 mths – 5 yrs post stroke) at 3 sites

Assessed for eligibility (PHQ-9 ≥10 or VAMS sad ≥ 50 )
Baseline assessments

Randomised (target sample size = 72)

Behavioural activation (BA) therapy
Maximum 15 (average 10) sessions from assistant psychologist or IAPT therapist over 4 months

Usual stroke care
Receive all other services routinely available as local practice

6 month outcome measures
Outcome measures with participants
Interviews with 8 participants and 5 carers from each group, and all therapists

Exclusions
Behavioural activation (BA) therapy

- Identifying enjoyable activities
- Activity and mood monitoring
- Setting and reviewing goals
- Graded tasks
- Activity scheduling
- Problem solving

Behavioural Activation approaches
Six month outcome assessments

1. Patient Health Questionnaire-9 (PHQ-9)
2. Visual Analogue Mood Scales (VAMS) Sad item
3. Stroke Aphasic Depression Questionnaire - Hospital version (SADQ)
4. Nottingham Leisure Questionnaire (NLQ)
5. Nottingham Extended Activities of Daily Living (NEADL)
6. Carer Strain Index (CSI)
7. EuroQol EQ-5D – standard version and version for people with cognitive problems for patients and carers
8. Healthcare resource use questionnaire
Feasibility outcomes

Primary endpoints

a. Feasibility of recruitment to the main trial
b. Acceptability of the research procedures and measures
c. Appropriateness of the baseline and outcome measures
d. Retention of participants at outcome
e. Potential value of conducting the definitive trial
756 Screened

574 Sent pack or home visit arranged

69 Eligible at screening

49 Consented

49 Randomised

26* Behavioural activation

20 received intervention
6 did not receive intervention

18 assessed
5 lost to follow up, 2 withdrew consent, 1 investigator decision

23 Usual care

23 received usual care

21 assessed
1 lost to follow up, 1 investigator decision

*1 participant randomised in error
## Baseline demographic characteristics

<table>
<thead>
<tr>
<th></th>
<th>Intervention (n=25)</th>
<th>Control (n=23)</th>
<th>Overall (n=48)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age:</strong> Mean(SD)</td>
<td>62.6 (14.5)</td>
<td>68.8 (12.1)</td>
<td>65.6 (13.6)</td>
</tr>
<tr>
<td><strong>Range</strong></td>
<td>31-88</td>
<td>40-97</td>
<td>31-97</td>
</tr>
<tr>
<td><strong>Gender:</strong> Male (%)</td>
<td>17 (68%)</td>
<td>12 (52%)</td>
<td>29 (60%)</td>
</tr>
<tr>
<td><strong>Time from stroke:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 3 months</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>3 mths-1 year</td>
<td>16 (64%)</td>
<td>14 (61%)</td>
<td>30 (63%)</td>
</tr>
<tr>
<td>1 to 2 years</td>
<td>7 (28%)</td>
<td>5 (22%)</td>
<td>12 (25%)</td>
</tr>
<tr>
<td>2 to 4 years</td>
<td>2 (8%)</td>
<td>4 (17%)</td>
<td>6 (13%)</td>
</tr>
<tr>
<td><strong>Laterisation of stroke:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Left</td>
<td>11 (44%)</td>
<td>9 (39%)</td>
<td>20 (42%)</td>
</tr>
<tr>
<td>Right</td>
<td>12 (48%)</td>
<td>10 (44%)</td>
<td>22 (46%)</td>
</tr>
<tr>
<td>Unknown</td>
<td>2 (8%)</td>
<td>4 (17%)</td>
<td>6 (13%)</td>
</tr>
<tr>
<td><strong>Stroke type:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ischaemic</td>
<td>19 (76%)</td>
<td>18 (78%)</td>
<td>37 (77%)</td>
</tr>
<tr>
<td>Haemorrhagic</td>
<td>6 (24%)</td>
<td>4 (17%)</td>
<td>10 (21%)</td>
</tr>
<tr>
<td><strong>Previous stroke:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes (%)</td>
<td>6 (24%)</td>
<td>11 (48%)</td>
<td>17 (35%)</td>
</tr>
<tr>
<td><strong>Depression treatment:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes (%)</td>
<td>10 (40%)</td>
<td>12 (52%)</td>
<td>22 (46%)</td>
</tr>
</tbody>
</table>
Primary clinical outcome: PHQ-9

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Median (IQR)</th>
<th>Mean (SD)</th>
<th>Control</th>
<th>Median (IQR)</th>
<th>Mean (SD)</th>
<th>Mean Diff in PHQ-9</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unadjusted</td>
<td>6.5 (5, 15)</td>
<td>10.1 (6.9)</td>
<td>21</td>
<td>14 (10, 17)</td>
<td>14.4 (5.1)</td>
<td>-4.3</td>
<td>(-8, -0.5)</td>
</tr>
<tr>
<td>Adjusted</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>-3.8</td>
<td>(-6.9, -0.58)</td>
</tr>
</tbody>
</table>

- All analyses used a mixed effects model with clustering by centre
- Adjusted model adjusted for baseline PHQ-9

Please note that these are emerging findings which will be subject to peer and editorial review before publication on the NIHR Journals Library website.
Secondary clinical outcomes

Analyses completed using multiple linear regression models adjusting for baseline and centre.
Sample size estimate for definitive trial

Using PHQ-9 as outcome, 90% power, 5% significance

Please contact the presenter for further information.
Health economics results

- Value of information analysis indicated that conducting a definitive trial would represent good value for money.

- Results suggest that the BA therapy is likely to be of borderline cost-effectiveness from an NHS and PSS perspective, but may be cost saving from a societal perspective.

<table>
<thead>
<tr>
<th>Response rate</th>
<th>Baseline</th>
<th>6 months follow up</th>
</tr>
</thead>
<tbody>
<tr>
<td>EQ-5D-5L (Standard version)</td>
<td>97.9%</td>
<td>79.2%</td>
</tr>
<tr>
<td>Resource use questionnaire</td>
<td>97.9%</td>
<td>83.3%</td>
</tr>
</tbody>
</table>
Fidelity assessment

- Mean 8.5 therapy sessions (SD 4.4, range 0-14); 90% attendance, mean 57.32 mins per session (DS 13.3, range 10-125)
- Most time was spent on between-session tasks (18.3%) and activities (18.1%)
- Less use of graded tasks and problem solving recorded
- Distribution of time was as expected
- Methods of checking fidelity were feasible
Qualitative results

You try to do things and you struggle because [...] you’re not cutting the picture down, you’re just trying to look at the whole thing. But this encourages you to break things down into little bits, rather than the whole thing, which is a better way of doing it. [Participant]

I thought that maybe having the therapy three months post-stroke was a bit too soon, just because people are still adjusting to what’s happened [...]. I felt like it wasn’t so much of a priority for them. [Therapist]

Well, it might be worth sometimes to think about some sort of follow-up on a, on a sort of annual basis, sort of thing? See how things were going. [Carer]
Conclusions

• Feasibility was demonstrated across the majority of the selected outcomes
• Strategies identified for improvements
• BA was feasible and acceptable and seemed to improve mood (but trial was not powered for efficacy)
• Value of information analysis suggests that conducting a definitive trial would represent good value for money
• The main issue outstanding is whether a sufficient number of participants could be recruited within a reasonable timeframe for a definitive trial
**BEADS:** Shirley Thomas, Avril Drummond, Nadina Lincoln, Rebecca Palmer, Roshan dasNair, Nicholas Latimer, Gemma Hackney, Laura Mandefield, Stephen Walters, Rachael Hatton, Cindy Cooper, Timothy Chater, Timothy England, Patrick Callaghan, Elizabeth Coates, Katie Sutherland, Sarah Jacob Eshtan, and Gogem Topcu

For further information or to express your interest in being a site for a future study please contact me.

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