Clinical Rehabilitation

Cost analysis of the Communication and Low Mood (CALM) randomised trial of behavioural therapy for stroke patients with aphasia

Journal:	*Clinical Rehabilitation*
Manuscript ID:	CRE-2013-3245.R1
Manuscript Type:	Original Article
Keywords:	Aphasia, Clinical Evaluation, Cognitive impairment, economic evaluation, Health status

Abstract:

Objective
To evaluate the cost effectiveness of a behavioural therapy intervention shown to be clinically effective in comparison with usual care for stroke patients with aphasia.
Design
Randomised controlled trial with comparison of costs and calculation of incremental cost effectiveness ratio.
Setting
Community
Participants
Participants identified as having low mood on either the Visual Analog Mood Scale sad item (>50) or Stroke Aphasic Depression Questionnaire Hospital version 21 (SADQH21) (>6) were recruited.
Interventions
Participants were randomly allocated to behavioural therapy or usual care using internet-based randomisation generated in advance of the study by a clinical trials unit.
Main measures
Outcomes were assessed at six months after randomisation, blind to group allocation. The costs were assessed from a service use questionnaire. Effectiveness was defined as the change in SADQH21 scores and a cost-effectiveness analysis was performed comparing the behavioural group with the usual care control group. The cost analysis was undertaken from the perspective of the UK NHS and Social Services.
Results
At 6 months the SADQH21 score for the intervention group was 20.4 compared to the control group value of 17.3. This resulted in a mean increase of 0.7 in the control group, compared to a mean significant different decrease of 6 in the intervention group ($p = 0.003$). The Incremental Cost-Effectiveness Ratio indicated that the cost per point reduction on the SADQH21 was £263.
Conclusion
The behavioural therapy was found to improve mood and resulted in some encouraging savings in resource utilisation over the six months follow up.

Cost analysis of the Communication and Low Mood (CALM) randomised trial of behavioural therapy for stroke patients with aphasia

Ioan Humphreys[1] Shirley Thomas[2], Ceri Phillips[1], Nadina Lincoln[2]

[1] Swansea Centre for Health Economics, Swansea University.

[2] Division of Rehabilitation & Ageing, University of Nottingham.

Corresponding author: Shirley Thomas, Division of Rehabilitation & Ageing, University of Nottingham, School of Medicine, B Floor The Medical School, Queens Medical Centre, Nottingham, NG7 2UH, UK. Telephone: +44 (0)115 8467484, Fax: +44 (0)115 823 0231.

Email: shirley.thomas@nottingham.ac.uk

Abstract

Objective

To evaluate the cost effectiveness of a behavioural therapy intervention shown to be clinically effective in comparison with usual care for stroke patients with aphasia.

Design

Randomised controlled trial with comparison of costs and calculation of incremental cost effectiveness ratio.

Setting

Community

Participants

Participants identified as having low mood on either the Visual Analog Mood Scale sad item (≥50) or Stroke Aphasic Depression Questionnaire Hospital version 21 (SADQH21) (≥6) were recruited.

Interventions

Participants were randomly allocated to behavioural therapy or usual care using internet-based randomisation generated in advance of the study by a clinical trials unit.

Main measures

Outcomes were assessed at six months after randomisation, blind to group allocation. The costs were assessed from a service use questionnaire. Effectiveness was defined as the change in SADQH21 scores and a cost-

effectiveness analysis was performed comparing the behavioural group with the usual care control group. The cost analysis was undertaken from the perspective of the UK NHS and Social Services.

Results

The greatest difference was in home help costs where there was a saving of £56.20 in the intervention group compared to an increase of £61.40 in the control group. At 6 months the SADQH21 score for the intervention group was 20.4 compared to the control group value of 17.3. This resulted in a mean increase of 0.7 in the control group, compared to a mean significant different decrease of 6 in the intervention group ($p = 0.003$). The Incremental Cost-Effectiveness Ratio indicated that the cost per point reduction on the SADQH21 was £263.

Conclusion

Overall the behavioural therapy was found to improve mood and resulted in some encouraging savings in resource utilisation over the six months follow up.

Introduction

Mood disorders, including depression, anxiety and general psychological distress [1] are common following stroke. Depression is the most commonly investigated emotional consequence of stroke [1], with an average prevalence of 29%, which remains consistent up to 10 years post-stroke [2]. Effective treatment of depression following stroke is important as depression is associated with longer hospital stay [3], increased healthcare utilisation [4], worse rehabilitation outcomes [5,6], increased carer strain [7], lower quality of life [2, 8] and increased mortality [2, 9], and so has implications for health care costs and resources. Co-morbid long term physical health conditions and mental health problems have been found to increase health care costs [10].

Behavioural therapy is a practical approach which can be adapted for people with aphasia and aims to improve mood by increasing activity levels, particularly the frequency of pleasant events. In a recent randomised controlled trial [13] of behavioural therapy compared with usual care for treating low mood in stroke patients with aphasia, behavioural therapy was found to improve self-reported mood, self-esteem and observer-rated mood at three months after randomisation, and observer-rated mood at six months after randomisation [13]. A cost analysis was necessary to inform future research and service provision. The aim of this study was to assess the costs of behavioural therapy for stroke patients with aphasia and the subsequent impact on resource utilisation compared to those receiving usual care.

Methods

Cost analysis was conducted as part of a multicentre randomised controlled trial evaluating behavioural therapy compared to usual care for treating low mood in stroke patients with aphasia (ISRCTN56078830). Ethical approval was granted by Nottingham Research Ethics Committee 1. Full details of trial participants and procedures are given in a previous publication [13].

In summary, stroke patients with aphasia were identified from hospital stroke wards, community stroke services, speech and language therapists, and stroke communication groups in the community. Patients who were blind, deaf, had dementia or were unable to speak English prior to the stroke, or were receiving treatment for depression at the time of their stroke were excluded. Participants who consented had their mood assessed using the 'sad' item of the Visual Analog Mood Scales [14] (VAMS) and a relative or carer completed the Stroke Aphasic Depression Questionnaire 10-item hospital version [15 (SADQH10). Participants identified as having low mood on either measure (VAMS sad $\geq$50 or SADQH10 $\geq$6 [16]) were invited to take part in the trial. There are two versions of the SADQH – 10 items and 21 items. We used the 10 item version as a baseline screen and the 21 item version for the follow ups. We then prorated the baseline scores to create a 21 item score to enable us to compare scores on the same metric at all the time points.

Participants were randomly allocated to behavioural therapy or usual care (1:1 ratio, stratified by recruitment centre and whether participant was recruited in hospital or in the community) using internet-based randomisation generated in advance of the study by a clinical trials unit.

Participants allocated to receive behavioural therapy were offered up to 20 treatment sessions over three months, with sessions lasting approximately one hour. Therapy was delivered at the participant's place of residence by an assistant psychologist who received weekly supervision from a consultant clinical psychologist. Therapy was tailored to the individual's needs and treatment strategies included activity monitoring, activity scheduling and graded task assignments. All trial patients received all other services that were available to them as local practice.

The cost analysis was undertaken from the perspective of the UK NHS and Social Services. All costs are expressed in British Pound Sterling (GBP). The cost of the behaviour therapy intervention was based on the salary of one Band 5 assistant psychologist to deliver the intervention (Point 19 £23,589 p.a.) and one Band 8b clinical psychologist to provide supervision to the assistant psychologist (Point 39 £48,983 p.a.) (salaries as at 01/12/12). Therefore the cost of the intervention amounted to £211 per hour. The unit costs of the resources were based on PSSRU 2011 [22] as shown in Table 1.

Table 1 about here

Three and six months after randomisation participants were visited by an independent assessor who was blind to group allocation to complete the outcome assessments. The primary outcome was the Stroke Aphasic Depression Questionnaire 21-item hospital version (SADQH-21); [15]) at six months after randomisation. The SADQH-21 was completed by a relative or carer. A decrease in score indicates an improvement in mood. Secondary outcomes included the

'sad' item from the Visual Analog Mood Scales [14], Visual Analogue Self-Esteem Scale [17], Nottingham Leisure Questionnaire [18], Carer Strain Index [19] and Satisfaction with Care ratings [20].

Resource use by patient was collected by questionnaire, by an assessor who was unaware of group allocation at three months and six months after randomisation. The assessor asked how often the following resources had been used in the previous three months: visits to or from; General Practitioner, Speech and Language Therapist, Occupational Therapist, Physiotherapist, Mental Health Nurse and practice nurse. The use of home help services was also recorded. As participants in the trial had communication problems the response options in the questionnaire were recorded as 'Never', 'Sometimes' and 'Often'. In order to quantify the number of times that a person utilised resources when they responded 'sometimes' and 'often', the frequency was estimated from the mean number of visits over a 3-month period reported in previous research [21]. This estimate was substituted for the response 'sometimes' and the mean number plus one standard deviation for the response category 'often'.

Tests for normality of the data were undertaken, as well as Levene's test for Equality of Variances and T-Tests for Equality of Means. Lack of data normality was seen in the three month costs for Speech and Language Therapy, Physiotherapy, Practice Nurse, and overall total costs at 6 months. Additional non-parametric Mann-Whitney U tests were conducted on these data.

Chi square tests were conducted to compare the frequency with which resources were used by participants in the usual care and behavioural therapy groups at

three and six months follow up (see Table 2). All comparisons were not-significant ($p>0.05$).

The main analysis evaluated the total costs of the intervention and resource use 6 months after randomisation, but costs at 3 months follow up were also recorded. Additionally, because of the relatively short follow-up period, further analysis was undertaken where any % increases or decreases seen between the groups were incrementally extrapolated over 24 months and tests for differences undertaken.

A cost-effectiveness analysis was performed comparing the behavioural therapy group with the usual care control group. Effectiveness was defined as the change in SADQH21 scores and a cost-effectiveness analysis was performed using this outcome measure. The incremental cost-effectiveness ratio, i.e. the difference in average costs divided by the difference in average effects between groups, was also calculated. In order to capture the uncertainty around the estimates, 1000 nonparametric bootstrap replications were generated from the sets of multiply imputed data, and mean cost and effect were plotted in a cost effectiveness plane. As there are no published data on the threshold willingness to pay value for additional effectiveness associated with the group programme described, the probability that the programme be considered cost effective was calculated for a range of threshold values and presented in a cost effectiveness acceptability curve.

Results

Participants

There were 105 participants originally recruited to the CALM trial, with 51 (49%) randomly allocated to behavioural therapy and 54 (51%) to the usual care control group. 57 (63%) of the participants were men and the mean age was 67 years (SD 13.5). The groups were comparable at baseline on disability and communication difficulties. The extent of resources used and their associated costs were calculated for both the three month and six month follow up assessment points. Finally, baseline levels of disability, mood or aphasia as groups were comparable at baseline on these characteristics.

Because of the way that that the values from Shaw [21] were used to estimate the number of times a resource was used in each three month period, the data was skewed and not normally distributed. Therefore, the categories of resources used (Never, Sometimes and Often) were cross tabulated with group allocation and chi-squared analysis conducted.

Out of the 105 patients randomly allocated, there were missing data and withdrawals in both groups. Outcome assessments (including resource utilisation data) were completed with 88 participants at 3 months (48 usual care, 40 behavioural therapy) and 87 at six month (45 usual care, 42 behavioural therapy) follow up (see Figure 1).

Figure 1 about here

Missing data for these cases was dealt with using the 'Last value carried forward/backward' [23] approach, which is widely used in the calculation of

health status data where particular time points are missing for some individual patients whilst still being available at other relevant time points.

Intervention costs

The total cost of the intervention per patient differed across the intervention group as participants received between 4 and 18 therapy sessions (range 4-18, mean 9.3, SD 2.6) with each session lasting a mean of 58 minutes (range 30-89, SD 10.7) [13]. Therefore, the cost of the intervention across the 41 Behavioral Therapy participants was £1961 per participant.

Missing data

The resource use questionnaire was not completed by 7 participants from the behavioural therapy group and 4 participants from usual care group at both the three month and six month follow up. Eight of these participants subsequently withdrew completely from the study (2 Usual Care, 6 Behavioural Therapy) along with a further 3 participants (3 Behavioural Therapy). Additionally, due to the high levels of missing data from 3 participants (2 Usual Care and 1 Behavioural Therapy), these participants, together with the 11 who withdrew from the study, were eliminated from further analysis.

The same method was also adopted for the missing data for the SADQH21 analysis There were 4 partially completed SADQH21 questionnaires (3 Usual Care, 1 Behavioural Therapy) that required the above missing data method and 1 participant (1 Behavioural Therapy) that was discounted completely as all scores were missing.

Therefore, the final complete case analysis was based on 50 (54.9%) Usual Care participants and 41 (45.1%) Behavioural Therapy participants. These included, 34 (37.4%) women and they had a mean age of 65.9 years (SD 13.53)

Table 2 about here.

Service use costs

At three months, the cost per patient was less in the behavioural therapy group for Speech and Language Therapist, Occupational Therapist, Physiotherapist and Home Help contacts compared with usual care. At six months the follow up, the cost per patient was greater in the behavioural therapy group for General Practitioner, Mental Health Nurse and Practice Nurse contacts (see Table 3).

When the per patient cost of the intervention (£1961) was added in to the total difference in costs over 3 months, the overall difference in costs between the control group (£-11.60, SD 798.3) was statistically significant compared with the intervention group (£1821.50, SD 923.2) ($p < 0.01$). However this would be expected because of the increase due to the Intervention cost. Results are shown in Table 3.

Table 3 about here.

24 month extrapolation of 6 month resource use data

The relatively short follow up period of three months (between the three month and six month follow ups), necessitated extrapolating the % increase/decrease in resource utilisation for the 3 month period incrementally to 24 months. GP visits led to an increase of £191.80 in the intervention group compared to an

increase of £15.40 costs per patient in the control group. With overall total costs, there was a greater increase of costs seen in both arms of the trial. However, the intervention arm had the most cost savings with visits to or from the Speech and Language Therapist of £88.80 per patient compared to £79.10 the control. Visits to the occupational therapist led to a saving of £75.80 per patient in the intervention group, as compared to a £51.60 increase in the control group.

The largest cost saving was seen was in Home Help costs where there was a saving of £256.50 in the intervention group compared to an increase of £952.30 in the control group. Cost differences between the control group and the intervention group resulted in an overall increase of £1541.70 in the control group, as compared to an overall increase of £1,388.90 in the intervention group. This resulted in a saving of £152.80, but none of the differences were statistically significant (p=0.26) (Table 4).

Overall, differences between the control group and the intervention group resulted in per patient cost savings of £93.15 in the intervention group, compared to a cost per patient increase of £39.90 in the control, but none of the differences were statistically significant (p=0.36) (Table 4).

Table 4 about here.

Differences in the costs of the intervention resulting from the number of sessions received were also explored. Using an incremental extrapolation to 24 months based on the % increase/decrease over the three months between three and six month follow ups, GP visits led to a cost per patient of £77.89 in the 10 – 18 session group compared to £373.27 in the 4 – 9 session group. There were cost per patient savings of £119.00 in the Speech and Language Therapist 10 – 18

session group, compared to £35.65 in the 4 – 9 session group. Results are shown in Tables 5 and 6.

Tables 5 and 6 about here.

SADQH-21 results

A decrease in SADQH-21 score indicates an improvement in mood. The mean SADQH-21 for the control group at baseline was 19.7 compared to 23.6 for the intervention group– a difference of 3.9 (p=0.08). In the behavioural group the 6 month score was 20.4 compared to the control group score of 17.3. This resulted in a mean increase of 0.7 in the control group, compared to a mean decrease of 6 in the behavioural group (p = 0.003)

When comparing the SADQH-21 results by attendees in each group, the mean baseline value for the 4 – 9 session group was 24.3 compared to 22.9 in the 10 – 18 session group. At 6 months, the 4 – 9 session group results showed a mean difference of -7 as compared to -5.5 at 6 months for the 10 – 18 months, but no differences were statistically significant (Table 7).

Table 7 about here.

The treatment group was associated with an incremental cost effectiveness ratio of £263 per additional point reduction in the SADQH21. Uncertainty in the incremental cost effectiveness ratio was estimated through bootstrapping. A cost effectiveness acceptability curve was plotted which showed a 100% probability that the adjustment group would be considered cost effective if purchasers were willing to pay up to £263 per point reduction in the SADQH21 score.

Discussion

The primary analysis was a cost analysis of behavioural therapy compared with usual care for treating low mood in stroke patients with aphasia. Cost results from the CALM trial indicated some encouraging differences between the behavioural therapy group as compared to the usual care group resulting in savings in certain areas of resource utilisation over the six months follow up period. Before the mean intervention costs of £1,961 were added in, there were overall savings of £139.24 in the intervention group compared to £11.59 in the control group, with the greatest difference in home help costs. There was a saving of £56.20 in the intervention group compared to an increase of £61.40 in the control group. Additionally, as seen from the incremental %increase/decrease over 24 months analysis, there was some evidence to suggest these effects may persist over time. Overall there was an increase in costs seen in both groups, with the largest difference in home help costs with a cost per patient saving of £256.50 in the intervention group compared to an increase of £952.30 in the control group. Overall there were costs of £1541.70 in the control group compared to £1,388.90 in the intervention group – a saving of £152.80.

The analysis of the SADQH-21 data showed that participants benefitted from behavioural therapy [13]. The behavioural therapy group showed a decrease of 6 on the SADQH-21 indicating an improvement in mood, whereas the control group increased by 0.7. This difference was statistically significant ($p = 0.003$) Additionally, in the 'group session' analysis, there was a decrease of 7 in the SADQH21 score in participants who had 4 – 9 sessions compared to a 5.5 decrease in those who received 10 - 18 sessions. This suggests that those who

received fewer behavioural therapy sessions benefited more in terms of mood improvement and this reduced the costs of the therapy. Those who were not benefitting were given more sessions.

The study was limited by the resource use measure, which was a self-report questionnaire with simplified response categories (Never, Sometimes, Often) to facilitate completion by participants with aphasia, although carers were able to assist with completion where necessary. It is possible that participants did not accurately recall service use over the previous three months, but this should have been present to the same degree across both groups.

We did not include a formal measure of health-related quality of life so were unable to calculate quality adjusted life years (QALYs) or an incremental cost-effectiveness ratio. Such a measure should be included in future studies but would need to be suitable for patients with aphasia.

Although we recorded whether or not participants received antidepressant medication (recorded as yes/no), we did not have further detail on type, duration and dose and therefore were unable to include this in the cost analysis. Such information should be obtained in a future study.

A recent study by Ekers *et al* [24] looking at 'behavioural activation' by non-specialists resulted in a promising incremental cost effectiveness ratio (ICER) of £5756 and a 97% probabilistic analysis that the therapy was cost effective at NICE'S threshold of £20,000 when using the Beck Depression Inventory–II (BDI-II) as the Health Related Quality of Life (HRQoL) measure. However, this was based on a per participant cost of £247.

Additionally, a 2012 study by Humphreys *et al* [25] aimed to evaluate the Cost-effectiveness of an adjustment group for people with multiple sclerosis and low mood. The ICER indicated that the cost per point reduction on the BDI-II was £118. This indicated that in the short term, the adjustment group programme was cost effective when compared with usual care, for people with multiple sclerosis presenting with low mood. However, the authors reported that the longer-term costs needed to be assessed.

There was a significant effect of the intervention on mood (SADQH21) The Cost-effectiveness acceptability curve illustrates the 'acceptable' cost-effective ratio. i.e. the maximum threshold willingness to pay for a unit of effect . Our results indicate that the treatment was more likely to be cost effective compared to usual care for stroke patients with aphasia presenting with low mood, assuming a willingness to pay threshold of more than £263 per point reduction in the SADQH21. The cost-effectiveness of the intervention depends on how much purchasers are willing to pay for reductions in depression scores. Further economic evaluations of psychological interventions should focus on costs that are expected to vary between groups as a result of an intervention.

Overall the behavioural therapy was found to improve mood and resulted in some savings in resource utilisation over the six months follow up. These results are promising and suggest further evaluation of behavioural therapy is warranted. The follow up period was six months after randomisation (and three months after the intervention period finished) which did not allow us to assess whether costs and savings were maintained. A longer follow up period with a larger sample size is required to evaluate the accuracy of the 24 month

extrapolation conducted in this analysis. Future research should also assess the optimum number of therapy sessions.

Clinical Messages

- A behavioural treatment group for stroke patients with aphasia has the potential to reduce the overall costs of clinical services in the long term
- There was a significant improvement in mood in the intervention group after 6 months
- Every point reduction on the SADQH21 scale cost £263

Acknowledgements

The Communication and Low Mood (CALM) study was funded by The Stroke Association, UK (TSA 2007/03).

We would like to thank the study therapists and researchers Manreesh Bains, Emma Ford, Claire Healy, Jessica Holmes, Deborah Hunte, Paul Ince, Jenny Taylor and Faye Yuill; the NIHR Stroke Research Network and NIHR Mental Health Research Network for adopting the study and for assistance with recruitment and outcome assessments; Jane Barton, Shonagh Scott and Winnifred Kuipers for providing local supervision of study therapists and our co-applicants Jamie Macniven, Marion Walker and Helen Haworth. We also thank staff from the clinical stroke services who identified potential participants, and the patients and carers who participated in the study.

References

1. Lincoln NB, Kneebone II, Macniven JAB, Morris R. Psychological Management of Stroke. Wiley; 2012. :283-284

2. Ayerbe L, Ayis S, Wolfe C.D.A, Rudd A.G Natural history, predictors and outcomes of depression after stroke: systematic review and meta-analysis BJP 2013 202:14-21

3. Saxena S, Car J, Eldred D, et al., Practice size, caseload, deprivation and quality of care of patients with coronary heart disease, hypertension and stroke in primary care: national cross-sectional study, BMC Health Services Research, 2007, 7, :96-96

4. Ghose SS, Williams LS, Swindle RW. Depression and Other Mental Health Diagnoses After Stroke Increase Inpatient and Outpatient Medical Utilization Three Years Poststroke 2005 43 12 :1259-1264

5. Pohjasvaara T, Vataja R, Leppavuori A, Kaste M, et al. Depression is an independent predictor of poor long-term functional outcome post-stroke. European Journal of Neurology 2001 8(4):315-9.

6. Van de Weg FB, Kuik DJ, Lankhorst GJ. Post-stroke depression and functional outcome: a cohort study investigating the influence of depression on functional recovery from stroke. Clin Rehabil. 1999;13:268–72.

7. Cameron C, Petrie P, Wigfall V, Kleipoedszus S, Jasper A Final report of the social pedagogy pilot programme: development and implementation. 2011

London: Thomas Coram Research Unit

8. Bays CL. Quality of Life of Stroke Survivors: A Research Synthesis Journal of Neuroscience Nursing: 2001

9. Bartoli F, Lillia N, Lax A, et al, Depression after Stroke and Risk of Mortality: A Systematic Review and Meta-Analysis 2013 (2013), 11 pages

10. Appleby J, Thompson J, Galea A How is the NHS performing? King's Fund May 2012

11. Kauhanen ML, Korpelainen JT, Hiltunen P, Määttä R, Mononen H, Brusin E, et al. Aphasia, depression, and non-verbal cognitive impairment in ischaemic stroke. *Cerebrovasc Dis*. 2000;10:455-461.

12. Thomas SA, Lincoln NB. Predictors of emotional distress after stroke. *Stroke*. 2008;39:1240-1245.

13. Thomas SA, Walker MF, Macniven JA,Haworth H, Lincoln NB Communication and Low Mood (CALM): a randomized controlled trial of behavioural therapy for stroke patients with aphasia Clin Rehabil. 2013 May; 27(5): 398–408.

14. Stern RA. Visual analog mood scales professional manual. Odessa, FL: Psychological Assessment Resources Inc.; 1997.

15. Lincoln NB, Sutcliffe LM, Unsworth G. Validation of the stroke aphasic depression questionnaire (SADQ) for use with patients in hospital. *Clinical Neuropsychological Assessment*. 2000;1:88-96.

16. Bennett HE, Thomas SA, Austen R, Morris AMS, Lincoln NB. Validation of screening measures for assessing mood in stroke patients. *Br J Clin Psychol*. 2006;45:367-376.

17. Brumfitt S, Sheeran P. *Vases: Visual analogue self-esteem scale*. Bicester: Winslow Press Ltd; 1999.

18. Drummond AER, Walker, MF. The Nottingham Leisure Questionnaire for stroke patients. *Br J Occup Ther* 1994; 57: 414–18.

19. Robinson RG, Starr LB, Kubos KL, Price TR. A two-year longitudinal study of post stroke mood disorders: findings during the initial evaluation. *Stroke*. 1983;14:736-741.

20. Lincoln NB, Flannaghan T. Cognitive behavioral psychotherapy for depression following stroke: A randomized controlled trial. *Stroke*. 2003;34:111-115.

21. Shaw L, Rodgers H, Price C, Van Wijck F, ShackleyP, Steen P, Barnes M, Ford G, Graham L BoTULS: a multicentre randomised controlled trial to evaluate the clinical effectiveness and cost-effectiveness of treating upper limb spasticity due to stroke with botulinum toxin type A May 2010 Health Technology Assessment

22. Unit costs of Health and Social Care 2011 http://www.pssru.ac.uk/archive/pdf/uc/uc2011/uc2011.pdf

23. Brazier J, Ratcliffe J, Salomon JA, Tsuchiya A 2007. Measuring and valuing health benefits for economic evaluation. Oxford: Oxford University Press.

24. Ekers D, Godfrey C, Gilbody S, Parrott S, Richards DA, Hammond D, Hayes A. Cost utility of behavioural activation delivered by the non-specialist. Br J Psychiatry. 2011 199 (6):510-1

25. Humphreys I, Drummond AE, Phillips C, Lincoln NB. Cost-effectiveness of an adjustment group for people with multiple sclerosis and low mood: a randomized trial. Clin Rehabil. 2013 Jul 8. [Epub ahead of print]

Figure 1: Consort diagram of patients randomised and lost to follow-up

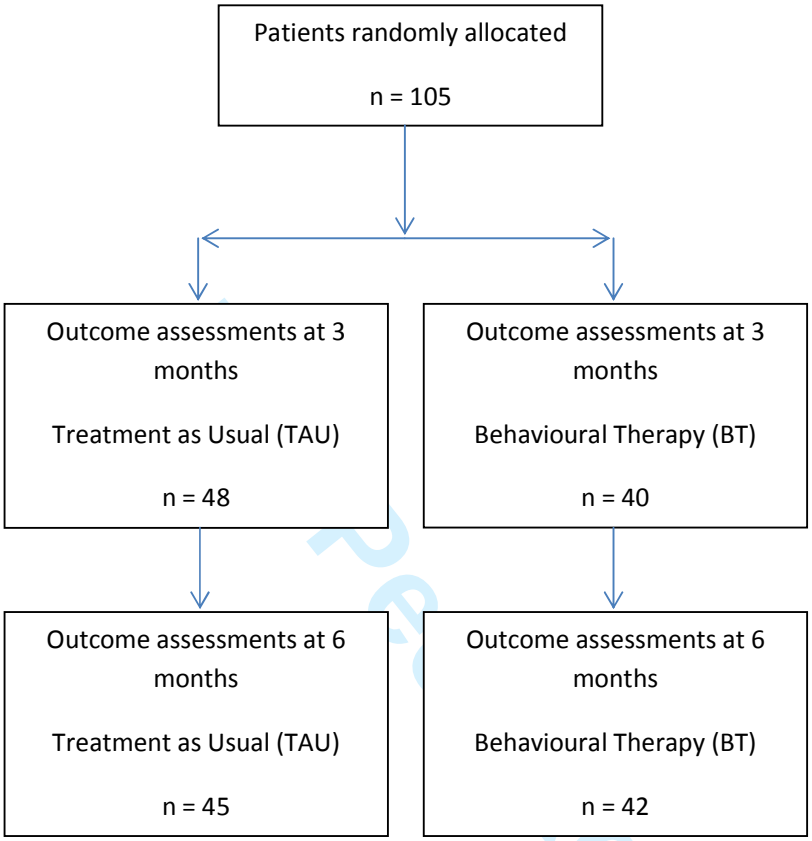

Table1: Unit Costs 2011

Resource	Unit cost (£)	Source
General practitioner	36	PSSRU 2011
Speech and Language Therapist	34	PSSRU 2011
Occupational Therapist	34	PSSRU 2011
Physiotherapist	34	PSSRU 2011
Mental Health Nurse	76	PSSRU 2011
Practice nurse	51	PSSRU 2011
Home-care services	32	PSSRU 2011
Band 8b Clinical Psychologist	76	PSSRU 2011
Band 5 Assistant Psychologist	135	PSSRU 2011

Table 2: Category counts for resource use at 3 months and 6 months follow up

		3 months			6 Months		
Resource	Category	Frequency	Usual care	Behaviour therapy	Frequency	Usual care	Behaviour therapy
General Practitioner	Never	0	10	13	0	10	10
	Sometimes	3	30	22	3	28	20
	Often	4	10	6	4	12	11
Speech and Language Therapist	Never	0	26	19	0	32	23
	Sometimes	5	11	7	5	9	5
	Often	10	13	15	10	9	13
Occupational Therapist	Never	0	40	29	0	39	31
	Sometimes	8	6	7	8	7	8
	Often	17	4	5	17	4	2
Physiotherapist	Never	0	34	25	0	38	28
	Sometimes	13	6	8	13	5	7
	Often	26	10	8	26	7	6
Mental Health Nurse	Never	0	45	38	0	47	36
	Sometimes	3	4	2	3	3	3
	Often	6	1	1	6	2	2
Practice Nurse	Never	0	30	20	0	23	19
	Sometimes	3	15	15	3	19	17
	Often	4	5	6	4	8	5
Home Help	Never	0	39	26	0	37	27
	Sometimes	24	2	2	24	2	3
	Often	48	9	13	48	11	11

Table 3: Differences over 3 months (including Intervention costs)

	TAU			CBT				
Mean per patient costs for Baseline	N	Mean	Std. Dev	N	Mean	Std. Dev	Difference	p-value
GP Cost Baseline	50	£90.72	£49.88	41	£76.21	£55.35	14.5 (-7.4 to 36.4)	0.192
SLT Cost Baseline	50	£121.92	£142.76	41	£149.85	£154.12	-27.9 (-89.8 to 34.0)	0.373
OT Cost Baseline	50	£79.70	£174.09	41	£118.09	£202.66	-38.4 (-116.9 to 40.1)	0.334
PT Cost Baseline	50	£231.06	£360.61	41	£260.72	£357.09	-29.7 (-179.9 to 120.6)	0.696
MHN Cost Baseline	50	£23.56	£71.40	41	£21.87	£82.54	1.7 (-30.4 to 33.8)	0.917
Nurse Cost Baseline	50	£62.22	£81.06	41	£81.35	£85.81	-19.1 (-53.9 to 15.7)	0.278
Home Help Cost Baseline	50	£307.20	£600.93	41	£524.49	£717.15	-217.3 (-491.8 to 57.2)	0.119
Total Cost Baseline	50	£916.38	£898.86	41	£1,232.59	£1,009.89	-316.2 (-714.1 to 81.7)	0.118
	TAU			CBT				
Mean per patient 3 months	N	Mean	Std. Dev	N	Mean	Std. Dev	Difference	p-value
GP Cost 3 Months	50	£92.74	£51.28	41	£89.74	£55.80	2.9 (-19.3 to 25.3)	0.790
SLT Cost 3 Months	50	£88.74	£131.41	41	£125.80	£153.81	-37.1 (-96.5 to 22.4)	0.218
OT Cost 3 Months	50	£85.27	£175.95	41	£82.60	£158.93	2.7 (-67.9 to 73.2)	0.940
PT Cost 3 Months	50	£168.98	£321.50	41	£206.57	£330.55	-37.6 (-173.9 to 98.7)	0.585
MHN Cost 3 Months	50	£14.14	£56.52	41	£38.00	£108.35	-23.9 (-58.9 to 11.2)	0.180
Nurse Cost 3 Months	50	£86.29	£86.26	41	£82.35	£82.56	3.9 (-31.5 to 39.4)	0.825
Home Help Cost 3 Months	50	£368.64	£644.24	41	£468.29	£684.30	-99.7 (-377.0 to 177.7)	0.477
Total Cost 3 Months	50	£904.80	£901.04	41	£1,093.34	£865.04	-188.5 (-559.1 to 181.9)	0.315
	TAU			CBT				
Overall	N	Mean	Std. Dev	N	Mean	Std. Dev	Difference	p-value
Overall Costs (Baseline + 3 Months)	50	£1,821.18	£1,613.17	41	£2,325.93	£1,700.48	-504.7 (-1196.7 to 187.1)	0.151
Difference in costs over 3 months	50	-£11.59	£798.31	41	-£139.24	£802.93	127.6 (-207.4 to 462.7)	0.451

Difference in costs over 3 months + Intervention Costs	50	-£11.59	£798.31	41	£1,821.51	£923.21	-1833.1 (-2191.7 to -1474.5)	**0.000**

Table 4: Incremental and % differences in costs per patient over 24 months (not including intervention costs)

	% Increases or savings after 3 months		Incremental increases or savings over 24 months	
	Usual Care	Behavioural Therapy	Usual Care	Behavioural Therapy
General Practitioners	£94.80	£105.70	£15.40	£191.80
Speech and Language Therapist	£64.60	£105.60	-£79.10	-£88.80
Occupational Therapist	£91.20	£57.80	£51.60	-£75.80
Physiotherapist	£123.60	£163.70	-£150.10	-£166.10
Mental Health Nurse	£8.50	£66.00	-£13.70	£1,777.00
Practice Nurse	£119.70	£83.40	£765.30	£7.30
Home Help	£442.40	£418.10	£952.30	-£256.50
Total Cost	**£944.70**	**£1,000.20**	**£1,541.70**	**£1,388.90**

Table 5: Differences over 3 months by number of treatment sessions received costs

Behavioural therapy	4 - 9 Sessions			10 - 18 Sessions				
	n	Mean	Std. Dev	n	Mean	Std. Dev	Difference	p-value
General Practitioner Cost 3 months	21	£74.4	£56.6	20	£78.1	£55.4	-3.72 (-39.1 to 31.7)	0.833
Speech and Language Therapist Cost 3 months	21	£117.4	£141.3	20	£183.9	£163.1	-66.6 (-162.8 to 29.7)	0.170
Occupational Therapist Cost 3 months	21	£39.8	£100.0	20	£200.3	£249.1	-160.4 (-279.3 to -41.6)	**0.009**
Physiotherapist Cost 3 months	21	£192.8	£267.6	20	£332.0	£427.4	-139.2 (-363.2 to 84.9)	0.216
Mental Health Nurse Cost 3 months	21	£11.2	£51.4	20	£33.1	£106.3	-21.8 (-74.2 to 30.5)	0.404
Practice Nurse Cost 3 months	21	£67.5	£75.1	20	£95.9	£95.5	-28.4 (-82.5 to 25.8)	0.296
Home Help Cost 3 months	21	£365.7	£624.8	20	£691.2	£784.0	-325.5 (-772.2 to 121.2)	0.149
Total Cost 3 months	21	£868.9	£801.6	20	£1,614.5	£1,082.1	-745.6 (-1345.1 to -146.0)	**0.016**
	4 - 9 Sessions			10 - 18 Sessions				
	n	Mean	Std. Dev	n	Mean	Std. Dev	Difference	p-value
General Practitioner Cost 6 months	21	£93.6	£58.1	20	£85.7	£54.5	7.92 (-27.7 to 43.5)	0.655
Speech and Language Therapist Cost 6 months	21	£111.1	£153.2	20	£141.3	£156.8	-30.2 (-128.2 to 67.8)	0.536
Occupational Therapist Cost 6 months	21	£108.2	£191.5	20	£55.8	£114.4	52.4 (-47.9 to 152.7)	0.297

Physiotherapist Cost 6 months	21	£212.4	£332.8	20	£200.4	£336.7	11.9 (-199.5 to 223.5)	0.909
Mental Health Nurse Cost 6 months	21	£22.4	£70.9	20	£54.3	£137.4	-31.9 (-100.5 to 36.7)	0.352
Practice Nurse Cost 6 months	21	£84.5	£79.5	20	£80.1	£87.6	4.4 (-48.5 to 57.3)	0.866
Home Help Cost 6 months	21	£292.6	£568.3	20	£652.8	£758.9	-360.2 (-782.4 to 61.9)	0.092
General Practitioner Cost 6 months	21	£924.8	£732.5	20	£1,270.4	£972.7	-345.6 (-887.8 to 196.6)	0.205
	4 - 9 Sessions			**10 - 18 Sessions**				
	N	**Mean**	**Std. Dev**	**N**	**Mean**	**Std. Dev**	**Difference**	**p-value**
Overall Cost	21	£1,793.6	£1,319.1	20	£2,884.8	£1,901.1	-1091.2 (-2120.5 to -61.8)	**0.038**
Diff in costs	21	£55.9	£786.3	20	-£344.1	£787.5	399.9 (-97.3 to 897.3)	0.112
Actual cost of session	21	£1,597.6	£330.7	20	£2,342.1	£386.6	-744.5 (-971.5 to -517.6)	**<0.001**
Total cost including session cost	21	£3,391.2	£1,313.0	20	£5,226.9	£2,020.1	-1835.7 (-2906.7 to -764.7)	**0.001**
Change in costs over 3months	21	£3,447.1	£1,520.8	20	£4,882.8	£2,062.4	-1435.7 (-2576.5to -294.9)	**0.015**

Table 6: Incremental and % differences in costs per patient over 24 months by low or high use of session costs (not including intervention costs and not including OT Outlier costs)

	Number. Of Sessions	
	4 - 9	10 - 18
	Incremental Changes over 24 months	
General Practitioners	£373.3	£77.9
Speech and Language Therapist	-£35.4	-£119.0
Occupational Therapist	*-	*-
Physiotherapist	£205.7	-£194.6
Mental Health Nurse	£2,849.6	£1,706.9
Practice Nurse	£322.6	-£57.4
Home Help	-£231.2	-£215.3
TotalCost	**£3,484.4**	**£1,198.6**

*Left empty because of outlier

Table 7: SADQH21 Analysis between baseline and 6 months

	Group	n	Mean	Std. Dev	Group	n	Mean	Std. Dev	95% Confidence Interval of the Difference	p - value
SADQH21 Baseline	Usual care	49	19.7	8.72	Behaviour therapy	39	23.6	12.33	-3.95 (-8.42 to 0.511)	0.082
SADQH21 3 Months	Usual care	49	16.6	9.94	Behaviour therapy	39	14.1	8.08	2.51 (-1.39 to 6.42)	0.204
SADQH21 6 Months	Usual care	49	20.4	9.80	Behaviour therapy	39	17.3	9.78	3.07 (-1.10 to 7.25)	0.147
SADQH21 Difference (between baseline and 6 months)	Usual care	49	0.7	8.78	Behaviour therapy	39	-6	12.80	7.03 (2.45 to 11.61)	0.003
	Group	n	Mean	Std. Dev	Group	n	Mean	Std. Dev	95% Confidence Interval of the Difference	p - value
SADQH21 Baseline	4 - 9	21	24.3	12.95	10 - 18	18	22.9	11.88	1.43 (-6.68 to 9.55)	0.723
SADQH21 3 Months	4 - 9	21	13.7	7.93	10 - 18	18	14.6	8.45	-0.89 (-6.21to 4.43)	0.737
SADQH21 6 Months	4 - 9	21	17.3	11.14	10 - 18	18	17.3	8.23	0 (-6.45 to 6.45)	1.000
SADQH21 Difference	4 - 9	21	-7.0	15.38	10 - 18	18	-5.5	9.33	-1.43 (-9.86 to 6.99)	0.732

(between baseline and 6 months)										

Objective

To evaluate the cost effectiveness of a behavioural therapy intervention shown to be clinically effective in comparison with usual care for stroke patients with aphasia.

Design

Randomised controlled trial with comparison of costs and calculation of incremental cost effectiveness ratio.

Setting

Community

Participants

Participants identified as having low mood on either the Visual Analog Mood Scale sad item (>50) or Stroke Aphasic Depression Questionnaire Hospital version 21 (SADQH21) (>6) were recruited.

Interventions

Participants were randomly allocated to behavioural therapy or usual care using internet-based randomisation generated in advance of the study by a clinical trials unit.

Main measures

Outcomes were assessed at six months after randomisation, blind to group allocation. The costs were assessed from a service use questionnaire. Effectiveness was defined as the change in SADQH21 scores and a cost-effectiveness analysis was performed comparing the behavioural group with the usual care control group. The cost analysis was undertaken from the perspective of the UK NHS and Social Services.

Results

At 6 months the SADQH21 score for the intervention group was 20.4 compared to the control group value of 17.3. This resulted in a mean increase of 0.7 in the control group, compared to a mean significant different decrease of 6 in the intervention group ($p = 0.003$). The Incremental Cost-Effectiveness Ratio indicated that the cost per point reduction on the SADQH21 was £263.

Conclusion

The behavioural therapy was found to improve mood and resulted in some encouraging savings in resource utilisation over the six months follow up.