Original Research Article

CLINICAL REHABILITATION

Clinical Rehabilitation
1–10

DOI: 10.1177/02692155211063554
journals.sagepub.com/home/cre
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A pilot economic evaluation of a feasibility trial for SUpporting wellbeing through PEeR-Befriending (SUPERB) for post-stroke aphasia

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Abstract

Objectives: To explore the feasibility of a full economic evaluation of usual care plus peer-befriending versus usual care control, and potential cost-effectiveness of peer-befriending for people with aphasia. To report initial costs, ease of instruments' completion and overall data completeness.
Design: Pilot economic evaluation within a feasibility randomised controlled trial
Setting: Community, England
Participants: People with post-stroke aphasia and low levels of psychological distress
Intervention: All participants received usual care; intervention participants received six peer-befriending visits between randomisation and four months
Main measures: Costs were collected on the stroke-adapted Client Service Receipt Inventory (CSRI) for health, social care and personal out-of-pocket expenditure arising from care for participants and carers at 4- and 10-months post-randomisation. Health gains and costs were reported using the General Health Questionnaire-12 and the EQ-5D-5L. Mean (CI) differences for costs and health gains were reported and uncertainty represented using non-parametric bootstrapping and cost-effectiveness acceptability curves.

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Results: 56 participants were randomised. Mean age was 70.1 (SD 13.4). Most ($n = 37$, 66%) had mild and many ($n = 14$; 25%) severe aphasia. There was ≥94% completion of CSRI questions. Peer-befriending was higher in intervention arm ($p < 0.01$) but there were no significant differences in total costs between trial arms. Peer-befriending visits costed on average £57.24 (including training and supervision costs). The probability of peer-befriending being cost-effective ranged 39% to 66%.
Conclusions: Economic data can be collected from participants with post-stroke aphasia, indicating a full economic evaluation within a definitive trial is feasible. A larger study is needed to demonstrate further cost-effectiveness of peer-befriending.

Keywords
Economic evaluation, feasibility study, peer-befriending, stroke, aphasia, mood

Received December 8, 2020; revised November 8, 2021; accepted November 8, 2021

Introduction

Stroke and aphasia have a profound impact on people's lives. Depression is a common sequel of stroke, with rates remaining high one year later at 33%.[1] It is associated with worse rehabilitation outcomes, increased carer strain, increased healthcare utilisation, and higher mortality.[2–4] There is evidence that the psychological needs of people with aphasia are even greater than those of the general stroke population. One study reported a 62% rate of depression in this group one year post-stroke.[5] Despite this, a Cochrane systematic review has indicated that people with aphasia are often excluded from stroke trials of psychological interventions.[6] There is a clear need for interventions that aim to improve wellbeing and mood, particularly for people with aphasia post-stroke and for research that measures the health economic impact of such interventions.

One intervention that has been shown to be clinically effective for people with low mood post-stroke aphasia is behaviour therapy.[7] In the cost-effectiveness evaluation of this intervention,[8] costs were compared and incremental cost-effectiveness ratios calculated. Participants ($n = 105$) with low mood were randomly allocated to behavioural therapy or usual care. As with the study reported in this paper, costs were assessed from a service use questionnaire. Effectiveness was measured based on a change in the Stroke Aphasic Depression Questionnaire Hospital version 21 (SADQH21) score.[9] The economic evaluation was undertaken from the perspective of the UK National Health Service and Social Services, with the study demonstrating improvements in mood and some savings in resource use, which was lower in the intervention arm over the six months follow-up. Overall, there were no statistically significant differences between the control and intervention groups in costs.

Evidence of benefit for psychological interventions for people with aphasia with no or low-level mood problems is still required. Such interventions might help avert some of the long-term psychological consequences of stroke and prevent the need for more complex and possibly more costly psychological therapies. One such intervention is peer-befriending, which aims to provide social and emotional support from people who share a health condition to bring about a desired social or personal change.[10]

In a meta-analysis of the clinical effectiveness of befriending across different populations (including dementia carers, older adults, men with prostate cancer, depressed females and new mothers), modest yet significant positive effects on depressive symptoms were reported.[11] Peer-befriending in stroke has only been evaluated within a hospital setting and excluded people with severe aphasia.[12] No evidence was found in the potential for the cost-effectiveness of peer-befriending for people with stroke and aphasia.

The SUpporting wellbeing through PEeR-Befriending (SUPERB) study aimed to evaluate the feasibility of a definitive trial on the clinical and cost-effectiveness of peer-befriending for people with aphasia post-stroke. To our best knowledge, SUPERB is the first feasibility trial and pilot economic evaluation of peer-befriending in this population. The primary trial[13] reported an 88% decrease (95% CI 0.01, 1.01) in the odds of high psychological distress caseness for the intervention arm. Procedures and outcome measures were acceptable, and severe adverse events were few and unrelated. This paper reports on the pilot economic evaluation of peer-befriending for people with aphasia within the SUPERB trial.

Methods

SUPERB was a feasibility (phase II), multicentre, randomised controlled trial (NCT02947776), comparing usual care with usual care plus peer-befriending for people with aphasia post-stroke and low levels of psychological distress. The protocol of the trial provides complete information on its methods.[14] The design and reporting of the study reported here adhered to the recommendations of the European Stroke Organisation Health Economics Working Group.[15] Ethical approval was granted by the National Health Service London-Bloomsbury Research Ethics Committee (ref 16/LO/2187).

Participants

People with stroke and aphasia experiencing low levels of emotional distress. Individuals who did not speak fluent English before their stroke had other diagnoses affecting cognition and mental health, severe uncorrected visual or hearing problems or severe or potentially terminal co-morbidities were excluded. Participants were randomly allocated 1:1 to usual care plus peer-befriending or usual care.

Intervention

Six 1-h home visits by a peer-befriender (a person having experienced aphasia and stroke in the past) over 3 months. Two additional visits were offered within the next 6 months for a gradual transition to the end of peer befriending. Visits included conversation, problem-solving, trips out (e.g. to a local group), and joint activities. Peer-befrienders were trained and had regular supervision (group monthly, individual as needed).

Measures

At 4- and 10-months post-randomisation, participants were visited by a blind assessor to complete a battery of outcome measures detailed in the study protocol,[14] including the General Health Questionnaire-12 (GHQ-12)[16] and EQ-5D-5L,[17] which were used as part of the economic evaluation reported here.

Resource use was collected by an unblinded assessor using the Client Service Resource Inventory (CSRI) previously adapted for people with stroke[18] from either the person with aphasia, a significant other, or another person with access to relevant information (e.g. another family member or a clinical research nurse) either in-person, telephone, or email. To maximise successful data collection with aphasic patients and their carers, the assessor read out items, and checked that they understood in order to self-report. Participants reported about the time since their stroke at 4 months, and about the past 6 months at 10 months.

The EQ-5D-5L and EQ Visual Analogue Scale (VAS) were completed by the person with aphasia. Our study was registered with the EuroQoL Foundation but with the layout and mode of administration of the EQ-5D not being standard: items were read by the interviewer and layout was modified, e.g., one dimension per page, larger font, keywords in bold, to facilitate people with aphasia completing the measure.

For the analysis, we converted responses to the EQ-5D-5L questionnaire into EQ-5D-3L utility scores by using the United Kingdom crosswalk algorithm,[19] which is currently recommended by the National Institute for Health and Care Excellence (NICE) for use in economic evaluations

in the United Kingdom.[20,21] EQ-5D-5L utility scores range from −0.594 (a health state worse than death) to 1 (full health).

Clinical effectiveness was measured using the GHQ-12, a measure of psychological distress. Total scores were summarised as 0–100 (rescaled from 0–12) to allow meaningful comparison with the EQ-5D-5L scores. As the EQ-5D-5L and VAS have higher scores representing better quality of life and the GHQ has lower scores for lower psychological distress, the latter scoring was reversed for the analyses to interpret an improvement in the scale as a positive change.

Perspectives, costs and discounting

We adopted the UK National Health Service (NHS) plus PSS (personal social services) perspective (see Appendix for unit costs). A secondary analysis was also adopted as a perspective to include travel and out-of-pocket costs for individuals. National pricing and reimbursement agencies generally recommend discounting costs and effects at 3% annually[22]: data are presented undiscounted due to our shorter follow-up (10 months post-randomisation).

Statistical analyses

Microsoft Excel (2016) was used to perform all analyses. In terms of descriptive statistics and feasibility of health economic data collection, we report outcomes on the proportion of participants completing data collection, the completeness of data for the CSRI, the source of data and time to complete data at 4- and 10-month assessment points. We also specify the data-collection method statistics, e.g., in-person, telephone, or email. For the analyses, unit costs[23] were applied to obtain individual service use data. We report costs per participant in each arm and total costs per arm.

The cost elements for delivering the SUPERB peer-befriending intervention comprised training of befrienders, supervision of befrienders, and befriender costs during intervention visits. Training costs were for two facilitators (£27.50 per hour) to provide three 6-h training sessions. Supervision costs comprised supervisor time (£27.55 an hour) for group and individual sessions and befriender time to attend group sessions (£20.50 per session). Visiting costs included a £20.50 fee for each peer-befriender visit.

Further analyses were performed to calculate incremental cost-effectiveness ratios associated with the intervention. These ratios measure the difference in average costs between the two trial arms divided by the difference in average health outcomes to create a point estimate of the cost per unit of health outcome improvement. If the extra cost at which the new intervention *buys* an extra unit of health outcome is deemed acceptable, the new intervention is *recommended*.

We used nonparametric bootstrapping[24] with repeat re-sampling from the costs and effectiveness data to estimate confidence intervals for the incremental cost-effectiveness ratio associated with the peer-befriending intervention. This bootstrapping generates the probabilistic distributions of the mean costs and effects for the two study arms. The generated distributions are used to construct cost-effectiveness acceptability curves, which provide confidence levels around the cost-effectiveness of the intervention of interest at different thresholds.

Cost- effectiveness acceptability curves allow decision-makers to assess the overall probability that an intervention is cost-effective for a given *willingness to pay for a unit of health improvement*. In our case, we study whether the peer-befriending model of care can be cost-effective compared with standard care for a range of thresholds (ceiling ratios, λ). These thresholds represent what society might be willing to pay for a unit gain in health or a change improvement in a condition-specific outcome (GHQ-12).

Results

Participant characteristics and results of the main clinical study are reported in the main outcome study,[13] including a CONSORT diagram showing participants' journey through the study. There were 62 participants recruited to the SUPERB trial; six dropped out prior to randomisation. The remaining 56 participants were randomised to the

intervention ($n = 28$) or control group ($n = 28$). Twenty-seven (48%) of the participants were female, and the mean age was 70.1 (SD 13.4). The majority of the sample were white ($n = 38$, 68%) and retired ($n = 39$, 70%). Most participants ($n = 46$, 82%) had sustained an ischaemic stroke classed as partial anterior circulation stroke ($n = 42$, 75%) in the left hemisphere ($n = 49$, 88%). Participants were on average (median [IQR]) 39.5 [15–86.5] days post-stroke. They were predominantly non-wheelchair users ($n = 44$, 79%) walking unaided ($n = 30$, 68%). Severity of aphasia (based on Western Aphasia Battery-Revised[25] ranged from mild ($n = 37$; 66%), moderate ($n = 5$; 9%) to severe and very severe ($n = 14$; 25%). In terms of cognitive ability (based on Cognitive Linguistic Quick Test,[26] the majority were within normal limits ($n = 13$, 23%) or had mild problems ($n = 16$, 29%); 17 (30%) had moderate and 10 (18%) severe cognitive problems.

We report 10-month data here and 4-month data in the supplement. Regarding the feasibility of collecting health economic data, at 10 months we had completed CSRI data for 51 of the 56 participants. The primary source of data was from a participant ($n = 23$), significant other ($n = 20$), a combination of the two ($n = 4$) or other sources (e.g. nurse, carer; $n = 4$). CSRI data was collected either face-to-face ($n = 18$), by telephone ($n = 31$) or email ($n = 2$). Data took on average (range) 18.6 (10–60) minutes to collect face-to-face and 18.7 (10–45) minutes to collect by telephone. Data was collected within a 30-day window of the intended assessment date for 43 (86%) of participants. Additional information was sought from secondary sources (e.g. research nurses, significant others) for 16 participants. There was at least a 98% completion rate for all CSRI questions, except for the item that measured costs associated with anyone not living with the participant, which returned a completion rate of 96%. Missing data for these items was assumed as a zero cost

In terms of resource use and cost outcomes, there were no statistically significant differences in health and social care costs between the control and intervention arms at 10-months except for outpatient appointments (higher in control, $p = 0.04$) and as expected peer-befriending (higher in the intervention arm, $p < 0.01$). All costs with percentages, p values and 95% confidence intervals around the mean differences between arms of the study at 10-months can be viewed in Table 1.

Training costs totalled £991.80, including two research team members providing 18 h of training (~six-hour training × three times) to 10 befrienders for them to be able to provide the befriending intervention.

Supervision costs (individual and group supervision) totalled £4262.58, for one of the research team member to provide 25 monthly group supervision sessions to befrienders (£1053.79) and ~18 h of individual supervision as and when needed (£502.79); and 132 befriender attendances in the 25 group supervision sessions (132 paid at £20.50 per session, £2706.00).

Befriender visit costs accounted for the other elements of the intervention costs, which comprised 143 intervention visits. For each of these visits, the befrienders were paid a fee of £20.50 per visit/session (£2931.50). Overall, befrienders did not claim travel expenses; they mostly used public transport in London and had free passes.

Averaging the training and supervision costs alongside the cost per befriender visit led to an average cost of £57.24 per befriender visit.

Using the EQ-5D-5L VAS data at 10 months to measure health improvements resulted in an incremental cost-effectiveness ratio of -£4175 (difference in average combined health and social care costs between the two trial arms divided by the difference in average health outcomes, £5747-£3376 /5.19–5.76). This indicated that the intervention was more costly and less effective.

The EQ-5D-5L data was then converted using value sets mapped to the EQ-5D-3L (as recommended by NICE). This resulted in a negative incremental cost-effectiveness ratio of -£49,488. Cost-effectiveness acceptability curves produced as part of a nonparametric bootstrapping procedure based on a cost per unit of change in the EQ-5D-5L/3L health score indicated that there was only a 35% probability of the intervention being cost-effective for the reference case threshold of £30,000,

Table 1. Cost per patient by treatment arm (£ sterling) - 10 months service use.

Detail of costs[a]	Intervention arm $n=26$			control arm $n=25$			Mean difference (Intervention - Control)	(95%CI)		p
	Mean	*SD*	*Total cost %*	*Mean*	*SD*	*Total cost %*				
Health service use										
Residential care[a] 1 service user in Intervention arm	2087	6373	*35*	0	0	*0*	2087	−317	4491	0.11
Nursing home	1068	4576	*18*	1019	5094	*26*	49	−2534	2633	0.97
Hospital overnight stay	1123	3509	*19*	551	2283	*14*	571	−1008	2151	0.49
Day patient treatment	25	73	*0*	13	37	*0*	12	−19	43	0.47
Outpatient appointment	191	249	*3*	391	400	*10*	−201	−378	−23	0.04
Accident and emergency visit	38	75	*1*	34	61	*1*	4	−33	41	0.83
General Practitioner (GP) appointment	121	109	*2*	94	70	*2*	27	−22	75	0.30
Physiotherapist	96	341	*2*	60	123	*2*	35	−102	172	0.63
Occupational therapist	18	64	*0*	31	98	*1*	−13	−57	31	0.57
Speech and language therapist	93	230	*2*	151	512	*4*	−58	−270	154	0.61
Community-based health care professionals - i.e chiropodist, district nurse, counsellor, optician	250	957	*4*	367	1222	*9*	−117	−703	468	0.70
Dentist	2	6	*0*	4	12	*0*	−3	−7	2	0.34
Social services i.e home help or support worker	604	1726	*10*	632	2605	*16*	−28	−1207	1151	0.96
NHS/social services (other) i.e. social worker, dietician, smoking cessation, other	9	34	*0*	28	107	*1*	−18	−61	24	0.42
Total social and healthcare costs	5724	8432	*97*	3376	5999	*85*	2348	−1555	6251	0.26
Cost of peer-befriending	22	43	*0*	0	0	*0*	22	6	38	0.01
Individual										
Travel and out of pocket expenses i.e. private health care	171	463	*3*	617	1391	*15*	−446	−999	107	0.14
Total cost per case	5917	8458	*100*	3993	6493	*100*	1924	−2098	5946	0.37

[a]Costs are rounded, so totals and percentages provided may not reflect the absolute figures.

typically the upper end of the cost-effectiveness threshold for decision making that NICE recommend. This did not alter for higher thresholds of willingness to pay.

The incremental cost-effectiveness ratio at 10 months for utility based on an improvement change in mood (GHQ 12) was £373. The cost-effectiveness plane in Figure 1 shows that the replications for the joint distributions of costs and effectiveness were distributed across all four quadrants. A cost-effectiveness acceptability curve is shown in Figure 2. The analysis based on a cost per unit of change in mood suggests a probability of cost-effectiveness at 10 months exceeding 66%.

Discussion

Overall, it was feasible to collect resource use data from participants with aphasia provided communication facilitation was used, and reports were supplemented with information from others, such as carers and general practititoners (GPs). These supports ensured that more than 90% of data was collected from at least 90% of randomised participants. An average cost of £57.24 for providing one befriending visit, inclusive of training and supervision costs is an inexpensive means of support. The analysis indicated that there were no overall significant total cost differences between the usual care trial arm and the usual care plus peer-befriending trial arm model of care. The cost of outpatient visits was, however, significantly lower in the intervention arm at the 10 months follow up.

The feasibility of data collection may well have been helped by the stringent efforts that went into ensuring participants with aphasia could participate and self-report. The research team used a range of communication facilitation methods, as described earlier, and adopted a flexible approach where information on resource use could be obtained from a range of sources (participants with aphasia, significant other, local doctor, clinical research nurse) and means (in-person, telephone, email). This approach represents reasonable adjustment for people with aphasia and worked well for both the CSRI and the health economic instruments used in this study. A larger, definitive trial, will need to take account of the additional resources (e.g. time, staffing) required to gather high levels of complete data. Comparisons with the standard EQ-5D and GHQ-12 should also be made with caution most notably given this is a pilot economic evaluation. Despite this, the study demonstrated that the CSRI could be used to successfully collect pilot economic data from participants and others with a high degree of completeness and with low burden on the respondents, as indicated

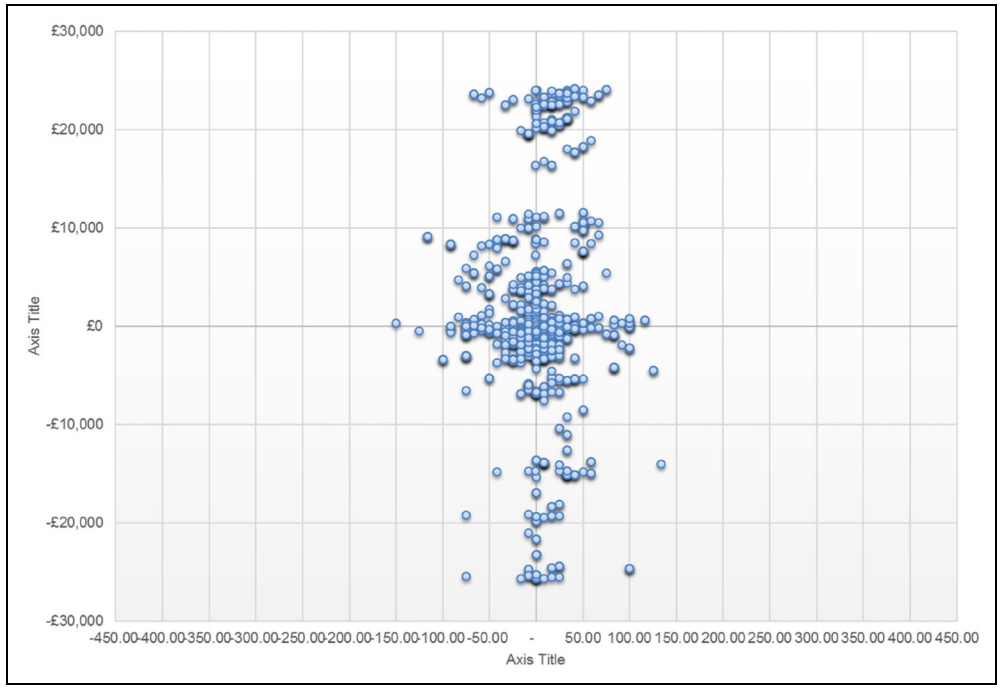

Figure 1. General health questionnaire-12 change at 10 months.

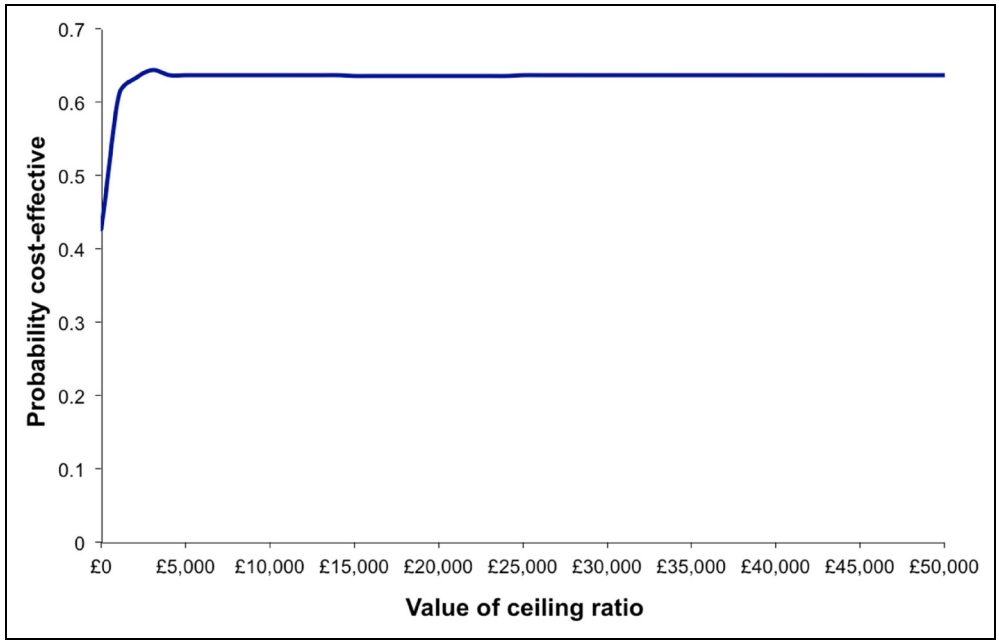

Figure 2. Cost-effectiveness acceptability curve for General Health Questionnaire-12 at 10 months

by completion times and acceptability data reported in the main results paper for the trial.[13]

Cost effectiveness of peer-befriending needs to be explored further in a larger study that includes considering costs alongside clinical outcomes for quality of life and mood. A larger study is desirable to explore the intervention costs more fully including within rural locations, as travelling costs may be a more significant factor. On the other hand, training was a major portion of the cost in this study, which suggests that scaling up provision, where a trained befriender provides more sessions, would lead to comparative cost reductions.

Our pilot analyses suggested that the intervention at best may have a 66% probability of being cost-effective. This was the case for the GHQ-12 at 10 months. However, other analyses using the EQ-5D-5L show a lower probability of the peer-befriending services measured in this study being cost-effective. Caution should be exercised in the interpretation of these results until such time as a larger study is conducted.

The results from this pilot feasibility study show some promise in comparison to other economic evaluations for people with post-stroke aphasia. Palmer et al.[27] in their trial with people with post-stroke aphasia found that utility scores collected resulted in an incremental cost-effectiveness ratio of £42,686 per quality-adjusted life-year gain for computerised speech and language therapy and usual care.

Our feasibility study also compares well with the economic evaluation of a behaviour therapy for people with aphasia and low mood in the communication and low mood (CALM) study,[8] in terms of approach used to collect data. In the CALM study resource use was measured with a self-report questionnaire with simplified response categories (never, some- times, often) to facilitate completion by participants with aphasia. In the SUPERB study, not only is the CSRI a more comprehensive cost data collection tool but carers were also able to assist with completion where necessary. Moreover, the CALM study did not include a formal measure of health-related quality of life and thus could not calculate quality-adjusted life year (QALYs) or any incremental cost-effectiveness ratio.

To the best of our knowledge, the SUPERB study is the first pilot cost-effectiveness analysis of a peer-befriending model for people with post-stroke aphasia that uses cost-effectiveness acceptability curves for assessing uncertainty around the distribution of costs and variability of costs. Cost- effectiveness acceptability curves are helpful as they provide decision-makers with information on whether to adopt (or not) a new intervention by quantifying the associated uncertainty. This is significant as economic consequences now need to be decided alongside treatment and clinical decision making. Our analysis provides initial data to support a full economic evaluation in a larger, definitive trial.

In terms of limitations, we asked participants to describe their service use. It is possible that people with aphasia and their carers did not accurately recall how they used services at follow up points for the previous months in question. That said any recall error would most probably be present across both groups, making the risk of bias to a particular arm minimal. As with the Palmer study,[27] there is a potential limitation around the relatively low intervention costs. Only a small QALY gain is required for the intervention to be cost-effective. However, caution should be exercised as SUPERB was a pilot feasibility trial and was not intended to be fully powered. The small number of participants reduces the ability to generalise findings and a larger multicentre randomised controlled trial is needed to draw more robust conclusions on cost-effectiveness.

A full economic evaluation could establish the true cost effectiveness of peer-befriending services for people with aphasia and how such services could be resourced. A larger trial would allow learning the costs of setting up and delivering the intervention and whether or not there is any potential to make it cost-effective by incorporating it into core services where economies of scale might reduce costs further. Future studies might also benefit from calculating health gains using the expected life years of the participants. Calculating QALYs by using the health gains over the remaining life years of the participants, depending on their age and severity, could give further insights into the longer-term value of such an intervention.

Clinical messages

- It is possible to collect economic data from people with aphasia post-stroke and their carers.
- Based on the cost per unit of change in mood (GHQ-12) at the 10 months follow-up, the peer-befriending model had a 66% probability of being cost-effective.

Declaration of conflicting interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding

The author(s) disclosed receipt of the following financial support for the research, authorship, and/or publication of this article: This work was supported by the The Stroke Association 2015 Priority Programme Award for Psychological Consequences of Stroke (grant number PPA2015/03).

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Supplemental material

Supplemental material for this article is available online.

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Appendix

Table 2. Unit costs

Type of resource use	Unit cost (2018)
Residential care (per day)	128
Nursing home (per day)	128
Inpatient hospital stay (per day)	270
Day patient	128
Out patient appointment	134
Accident and emergency visit	141
General Practitioner (GP) appointment	37
Physiotherapist (per session)	54
Occupational therapist (per session)	78
Speech and language therapist (per session)	97
Community-based health care professionals - i.e chiropodist, district nurse, counsellor, optician (per session)	34
Dentist	20
Social services i.e home help or support worker (per session)	18
NHS or social services (other):	
Dietician	86
Social worker	50