BMJ Open Cost-effectiveness of speech and language therapy plus scalp acupuncture versus speech and language therapy alone for communitybased patients with Broca's aphasia after stroke: a post hoc analysis of data from a randomised controlled trial

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ABSTRACT

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Objective This study aimed to assess the costeffectiveness of combined scalp acupuncture therapy with speech and language therapy for patients with Broca's

Design A within-trial cost-effectiveness analysis. Settings Community health centres.

Subjects A total of 203 participants with Broca's aphasia after stroke who had been randomly assigned to receive scalp acupuncture with speech and language therapy (intervention) or speech and language therapy alone (control).

Intervention Both groups underwent speech and language therapy (30 min per day, 5 days a week, for 4 weeks), while the intervention group simultaneously received scalp acupuncture.

Primary outcomes All outcomes were collected at baseline, and after the 4-week intervention and 12week follow-up. Cost-effectiveness measures included the Chinese Rehabilitation Research Center Standard Aphasia Examination (CRRCAE) and Boston Diagnostic Aphasia Examination (BDAE). Cost-utility was evaluated using quality-adjusted life-years (QALYs). Incremental cost-effectiveness ratios were expressed, and sensitivity analysis was conducted.

Results The total cost to deliver the intervention was €4001.72, whereas it was €4323.57 for the control group. The incremental cost-effectiveness ratios showed that the intervention was cost-effective (€495.1 per BDAE grade gained; €1.8 per CRRCAE score gained; €4597.1 per QALYs gained) relative to the control over the 12 weeks. The intervention had a 56.4% probability of being cost-effective at the ¥50 696 (€6905.87) Gross Domestic Product (GDP) per capita threshold. Sensitivity analyses confirmed the robustness of the results.

Conclusions Compared with speech and language therapy alone, the addition of scalp acupuncture was cost-effective in Chinese communities. As the costs of acupuncture services in China are likely to differ from other countries, these results should be carefully

Strengths and limitations of this study

- ▶ This study was the first to investigate the costeffectiveness of combining scalp acupuncture therapy with speech and language therapy for community-dwelling patients with Broca's aphasia after stroke.
- ▶ The majority of the parameters used in the model, including costs and utilities, were collected from Chinese community-based health service centres, which reflects the situation in low-income and middle-income countries.
- The uncertainty in cost-effectiveness was adequately estimated and illustrated, enabling an appropriate interpretation of the results.
- ► The analysis was performed from a prospective societal perspective and did not consider the costs from the Chinese healthcare services perspective.
- The results were limited by the relatively short analysis period and the potential differences in acupuncture services and costs among other countries.

interpreted and remain to be confirmed in other populations.

Trial registration number ChiCTR-TRC-13003703.

INTRODUCTION

Approximately one-third of stroke survivors suffer from impaired communication abilities, and 30%-42% of these patients have long-term symptoms of aphasia.¹ The most common, Broca's aphasia, is caused by lesions on anterior brain regions.² Patients often require long-term care, which causes substantial economic and mental health burdens on the family and society. In China, hospitalisation costs (per capita) for cerebral

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haemorrhage and cerebral infarction were \$17787 and \$9387 in 2016, respectively, representing a 61.4% and 31.4% increase from 2010.³

Intensive speech and language therapy (SLT) promotes the functional reorganisation of the central nervous system. However, high-intensity and high-dose interventions may not be acceptable to all patients.⁴⁵ Therefore, other treatments adjunct to SLT might be useful.⁶ Recent evidence suggests that scalp acupuncture may have beneficial effects on comprehension, oral expression, repetition, denomination, reading and writing in postapoplectic aphasia.⁷ Acupuncture may be a useful complementary therapeutic approach to targeted language interventions provided by community rehabilitation therapists.⁸ Broca's area in the inferior frontal gyrus mediates an activation cascade from the sensory representations of words in the temporal cortex to their corresponding articulatory gestures in the motor cortex.⁹ The language centre of Broca's area, projected onto the scalp, spans the lower 40% of the anterior oblique line of vertex temporal and the anterior temporal line. As such, this area can be punctured to stimulate the language centre, increase blood supply and boost the processes for rebuilding axonal connections.¹⁰

Community medical resources promoting full engagement with rehabilitation treatment for poststroke patients have reduced the disability rate below 40% and increased activities of daily living by 35%.¹¹ Simultaneously combining language function training with scalp acupuncture not only makes up for the deficit of targeted functional stimulation and training with acupuncture alone (such as listening, speaking, reading and writing) but also alleviates the tedious and time-consuming nature of language function training.¹⁰ However, while combination therapy may be more effective, it involves additional costs. Considering the social burden of aphasia after stroke, this study aimed to evaluate the cost-effectiveness of scalp acupuncture therapy (SAT) combined with SLT for community patients with Broca's aphasia after stroke compared with SLT alone.

METHODS

Study design

This within-trial economic evaluation used data collected from a multicentre, parallel-group, cluster randomised controlled trial of SAT plus SLT in Broca's aphasia after stroke. The Consolidated Health Economic Evaluation Reporting Standard was adhered to when reporting this study. The full trial protocol has been published at www. trialsjournal.com/content/15/1/290.¹²

Target population

Patients with Broca's aphasia after stroke were recruited from thirteen community health centres. Patients were included in the study if they were: (1) aged between 18 and 80 years; (2) diagnosed with stroke according to the criteria of the Fourth National Cerebral Vascular Disease Conference¹³ and confirmed as the first stroke by CT or MRI; (3) no more than 2 years poststroke and (4) suffering from Broca's aphasia after stroke, determined by a neurologist or rehabilitation physician and a speech and language therapist, in accordance with the Chinese Rehabilitation Research Center Standard Aphasia Examination (CRRCAE) standard. Participants were excluded if they: (1) had aphasia due to another encephalopathy (eg, traumatic brain injury, brain tumour, neurodegenerative diseases or brain parasitic diseases); (2) had aphasia due to dementia; (3) had speech impairment due to dysarthria; (4) had a stroke with serious uncontrolled complications, such as severe pulmonary infection, shoulder-hand syndrome or deep vein thrombosis; (5) had severe visual or auditory impairment; (6) had serious heart, kidney, liver or nervous system disease; (7) had a history of epilepsy and (8) had received an alternate intensive intervention which may have affected the results during the last 4weeks.

Randomisation and blinding

Each participating community health centre was randomly assigned to either the scalp acupuncture plus SLT (intervention) or the SLT alone (control) group by restricted randomisation generated by an independent statistician. The random allocation sequence was blinded to the screeners who conducted the baseline tests for the patients and protected by a specified project manager who was not involved in participant recruitment. Both the group allocation and baseline measurements were concealed from the outcome assessors.

Interventions

In the SLT sessions (which were the same between the intervention and control groups), the intervention group received SLT immediately after insertion of the needles for scalp acupuncture. The acupuncture needles remained in place throughout SLT. All participants completed the 4-week intervention and 12-week follow-up.

Scalp acupuncture therapy

The needling sites included the lower 40% of the anterior oblique line of vertex-temporal MS 6 (Ding nie qian xie xian) and the anterior temporal line MS 10 (Nie qian xian). The anterior oblique line of vertex-temporal, which links EX-RN 1 (Qian Si shen cong) to GB 6 (Xuan li), is on the temporal side of the head and obliquely passes through the bladder and gallbladder meridians. The anterior temporal line is a part of the gallbladder meridian on the temporal side of the head, linking GB 4 (Hanyan) to GB 6 (Xuanli).

Patients assumed either sitting or lying supine for correct manipulation. The area was routinely sterilised before needles were inserted. Number 30 Hwato needles 0.30 mm in diameter and 40 mm in length were obliquely inserted rapidly $(10^{\circ}-20^{\circ})$ into the gales aponeurotic of the scalp. For point prescription, the needles were then parallelly pierced 25–35 mm deep, along the lines

described above. Acupuncture was maintained for 30 min with rapid twirling performed for 2–3 min once every 10 min, at a frequency of 180–300 twirls per minute to reach de qi. After each needle was withdrawn, a dry sterilised cotton ball was pressed on the puncture site as quickly as possible to prevent bleeding. Scalp acupuncture treatment was conducted by general practitioners who had more than 2 years of experience. A 30 min of SAT was administered once a day, 5 days a week, for 4 weeks.

Speech and language therapy

SLT was based on the 'Technical specification of common rehabilitation therapy' (2012) published by the Chinese Association of Rehabilitation Medicine.¹⁴ The therapists prescribed training programmes, including various aspects of listening, speaking, reading, writing or calculating, appropriate for each patient's ability. Furthermore, the degree of difficulty was changed to match the patient's progress. A 30 min of SLT was administered per day, 5 days a week, for 4 weeks.

Standard care

According to the Chinese Guidelines for the Prevention and Treatment of Cerebrovascular Diseases (2010), standard care includes: (1) identifying the type of stroke and its risk factors by imaging or laboratory examination and performing etiological treatments; (2) blood pressure was managed after stroke; (3) patients were receiving antiplatelet aggregation treatments; (4) patients received basic treatments for complicated heart disease and (5) patients were encouraged to control their weight, engage in physical exercise, quit smoking, limit alcohol consumption, reduce salt intake, eat more fruits, vegetables and low-fat dairy products, and to maintain an optimistic mood.

Outcome measures

Outcomes were measured using face-to-face assessments and self-report questionnaires. Those collecting outcome data at baseline and four and twelve weeks post the intervention were independently performed by experienced and blinded assessors.

The costs were evaluated from a societal perspective and included all expenses related to the interventions irrespective of who payed.¹⁵ Individual costs were investigated using separate economic case report questionnaires for each participant (online supplemental file A) and were measured in Chinese Yuan. To provide a broader understanding of the costs, Renminbi was converted to Euros using the average exchange rate from June 2014 to January 2016 (7.341; http://fx.sauder.ubc.ca/data.html). Direct individual costs were incurred from the duration of hospitalisation, visits to the emergency department, general medical treatments, visits to a specialised physician and nursing care. Direct non-medical costs included the carer's transportation expenses to and from treatment sessions. Regarding indirect costs from a societal perspective, the per-day cost of sick leave from work during rehabilitation (both participants and their family members) was assessed using a human capital approach ((China's per capita Gross Domestic Product (GDP) in 2015÷365 days)×the number of days sick from work). As the time frame of the analyses was only 12 weeks, neither costs nor outcomes were discounted.

The aphasia grading standard of severity from the Boston Diagnostic Aphasia Examination (BDAE) was taken as the primary outcome of treatment effectiveness.¹⁶ As the original BDAE edition was not suitable for Chinese participants, a revised BDAE-Chinese (BDAE-C),^{17 18} based on Chinese culture and language, has now been established as the standard for Chinese patients. The BDAE-C aphasia grading standard of severity has six grades: 0 (worst) to 5 (best).

The CRRCAE¹⁹ was also used to assess treatment effectiveness. The CRRCAE consists of two parts (online supplemental file B). The first part includes twelve questions to test the patient's speech. The second part contains nine subtests (auditory comprehension, repetition, speaking, reading aloud, reading comprehension, copying, description, dictation and calculation). The intraclass correlation coefficient of test–retest reliability exceeded 0.9, Cronbach's α of internal consistency was 0.941 and its relationship with the Western Aphasia Battery was 0.948 (on aphasia quotients).

The utility of treatment was measured in qualityadjusted life years (QALYs), transformed from the raw Short form 36 (SF-36) health survey questionnaire data by parametric preference weights. This generic health status measure provides scores for QALYs^{20 21} using an algorithm based on health status valuations elicited from a large representative sample of the general population in the UK. The QALYs scores ranged from zero to one. The maximum possible QALYs score differed slightly across participants due to different treatment durations.

Statistical analysis

The analyses were conducted on the modified intentionto-treat principle. Missing data were estimated using multiple imputation. Linear mixed modelling was used to evaluate the treatment effects on the primary outcome measures and QALYs. Treatment group and time points were considered fixed factors, patients were a random factor and the group by time interaction was included in the model. All estimates were adjusted for clinical outcomes. The incremental cost-effectiveness ratios (ICERs) were calculated as a measure of the additional costs necessary to achieve greater treatment outcomes.²²

The ICERs were evaluated with the cost-effectiveness threshold recommended by the WHO,²³ as there is no unified standard on the value of QALYs in China.²⁴ Treatment strategies that save costs while obtaining health benefits are the most cost-effective and represented by an ICER less than zero. When the ICER is between zero and GDP per capita, the treatment strategy has high cost-effectiveness. Between one and three times GDP per capita, the ICER shows cost-effectiveness. Finally,

treatment strategies with ICERs greater than three times GDP per capita are not cost-effective. China's per capita GDP was $\$50\,696$ in 2015.²⁵ Although QALY-based and DALY-based ratios for the same intervention can vary, differences tend to be modest and do not materially affect comparisons to common cost-effectiveness thresholds.²⁶ Bootstrap resampling with 1000 replications drawn from each of the imputed datasets was used to estimate the uncertainty associated with the estimates. These were used to estimate cost-effectiveness acceptability curves (CEACs).²⁷

Sensitivity analyses were performed to check the robustness of the results. Three analyses were performed, including (1) based on complete cases only, (2) by removing extremely high-cost and low-cost cases of health utilisation (ie, winsorised at the 95% level) and (3) by converting the SF-36 to QALYs utility score using the non-parametric Bayesian preference weights.²⁸

All data were analysed using SPSS V.24 (IBM) and TreeAge pro 2019. Statistical significance was set at p<0.05.

Patient and public involvement

Neither the patients nor the public were involved in designing, conducting, reporting or disseminating this study.

RESULTS

From June 2014 to January 2016, we evaluated 2448 patients with Broca's aphasia after stroke who were visiting the participating community health centres. Of the 290 eligible patients randomised, six patients (two in the intervention group and four in the control group) refused baseline evaluation immediately after randomisation. A further 81 patients were eliminated due to the absence of baseline economic measures and non-completion of the questionnaires. Finally, 203 patients were included in the cost-effectiveness analysis. A flow diagram of the trial is shown in figure 1. Baseline socio-demographic and clinical characteristics were not significantly different between the intervention and control

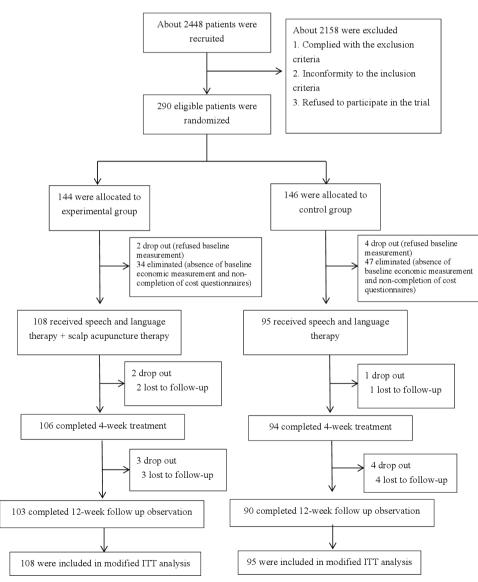


Figure 1 Flow diagram of the trail. ITT, intention-to-treat analysis.

	Cost analysis set		Full analysis set		
Categories	Intervention group, n=108	Control group, n=95	Intervention group, n=142	Control group n=142	
Age median (IQR)	58 (15)	63 (18)	58 (17)	60 (16)	
Gender N (%)					
Male	73 (67.6)	68 (71.6)	102 (71.8)	96 (67.6)	
Female	35 (32.4)	27 (28.4)	40 (28.2)	46 (32.4)	
Education mean years (SD)	9.54±3.55	10.42±3.50	9.65±3.56	10.36±3.52	
BMI median (IQR)	23.66 (2.99)	23.99 (3.08)	23.49 (3.17)	23.61 (3.30)	
SBP mean mm Hg (SD)	129.13±14.55	131.85±14.37	129.89±15.37	132.95±14.77	
DBP mean mm Hg (SD)	82.60±8.68	80.49±9.50	81.73±9.17	81.11±9.51	
Duration of disease mean months (SD)	6.31±5.55	5.88±4.97	6.31±5.67	6.12±5.04	
Type of stroke N (%)					
Haemorrhagic	76 (70.4)	63 (66.3)	100 (70.4)	87 (61.3)	
Ischaemic	32 (29.6)	32 (33.7)	42 (29.6)	55 (38.7)	
Hemiplegia side N (%)					
Right	95 (88.0)	82 (86.3)	126 (88.7)	123 (86.6)	
Left	8 (7.4)	5 (5.3)	8 (5.6)	7 (4.9)	
Bilateral	3 (2.8)	6 (6.3)	4 (2.8)	8 (5.6)	
None	2 (1.9)	2 (2.1)	4 (2.8)	4 (2.8)	
Handedness N (%)					
Right	102 (94.4)	93 (97.9)	136 (95.8)	139 (97.9)	
Left	6 (5.6)	2 (2.1)	6 (4.2)	3 (2.1)	

BMI, body mass index; DBP, diastolic blood pressure; SBP, systolic blood pressure.

group for either the cost-effectiveness analysis dataset or the full dataset (table 1).

Table 2 summarises the changes in BDAE proportions, mean CRRCAE scores and mean QALYs between the intervention and control groups from baseline to the end of the 4-week intervention and 12-week follow-up period. The 4-week improvement in BDAE and CRRCAE was sustained over the 12-week follow-up period after controlling for baseline imbalances (p<0.001). The QALYs increased between baseline and 4weeks, with the intervention group being higher than the control group and remaining higher after 12 weeks (p<0.001).

The average direct medical costs per participant were \$4780.70 for the intervention group and \$6059.49 for the control. The total costs for the intervention (\$29376.59 (€4001.72)) and control treatments (\$31739.31 (€4323.57)) were not significantly different. There were no notable differences in cost categories, except for the significantly lower direct non-medical costs in the intervention group (\$2391.55 (€325.78)) compared with the control (\$4382.86 (€587.04)) at the end of the 12-week follow-up. Indirect costs were the greatest category contributing to overall costs (table 3).

The ICERs were all less than zero, indicating the costeffectiveness of the intervention strategy and making it the preferred scheme (table 4). Point estimates from the base-case analysis showed that the intervention group was more cost-effective and had similar total costs compared with the control group, resulting in an incremental cost per QALY ratio of Υ –39 378.67 (\in –5364.21) at the end of the 12-week follow-up. The CEACs for these results are shown in figures 2 and 3. Figure 2 shows the probability that the intervention strategy will be cost-effective at various point improvements in QALY. From a societal perspective, if the willingness-to-pay threshold is set at Υ 50 696 (\in 6905.87) GDP per capita in 2015, the intervention group will have a 56.4% probability of being cost-effective (figure 3).

Sensitivity analyses showed similar results, indicating that, under all three evaluation scenarios, the intervention strategy was dominant with respect to the cost per additional CRRCAE score, BDAE grade improvement and per additional QALY gained (online supplemental file C).

DISCUSSION

This economic analysis shows that additional SAT was cost-effective as it saved costs compared with SLT alone in patients with Broca's aphasia after stroke. From a cost

Table 2Effectiveness and health outcomes for both randomised groups after 4 and 12 weeks ($\bar{x} \pm s$)							
Outcomes	Intervention group, n=108	Control group, n=95	Difference mean* (95% Cl)			Interaction P valve	
BDAE							
Baseline	1.78±0.95	1.44±0.68	_		<0.001	<0.001	
End of 4 weeks	2.55±1.08	1.74±0.79	0.47 (0.31 to 0.64)				
End of 12 weeks	2.96±1.23	1.98±0.96	0.65 (0.43 to 0.86)				
CRRCAE							
Baseline	286.27±239.64	104.86±120.87	_	_	<0.001	<0.001	
End of 4 weeks	459.53±272.90	173.34±159.64	118.00 (101.61 to 134.39)	<0.001			
End of 12 weeks	517.04±269.54	239.03±175.31	182.47 (166.17 to 198.76)	<0.001			
QALYs							
Baseline	0.53±0.10	0.51±0.09	_	_	<0.001	<0.001	
End of 4 weeks	0.60±0.10	0.52±0.09	0.04 (0.03 to 0.05)	<0.001			
End of 12 weeks	0.62±0.10	0.55±0.10	0.07 (0.06 to 0.08)	<0.001			

*Adjusted for baseline variables.

BDAE, Boston Diagnostic Aphasia Examination; CRRCAE, Chinese Rehabilitation Research Center Standard Aphasia Examination; QALYs, quality-adjusted life-years.;

structure perspective, scalp acupuncture in Chinese communities is usually less expensive than in developed countries and more accessible than other treatments for health promotion,²⁹ which may explain its cost-effectiveness in this study. Additionally, patients receiving combination therapy reduced their use of non-standard treatment interventions and medications, reflected in reduced direct non-medical costs and self-paid expenses. Combination therapy was less costly than SLT alone,

calculated according to the modified intention-to-treat principle

We consider that the base case is likely to be conservative as it excludes the cost savings associated with productivity gains. More importantly, our base-case analysis considers only the twelve weeks of the trial. The effects of acupuncture appear to be persistent as the differences between the groups were slightly larger after 12 weeks than immediately post-treatment. Although it is

	Intervention 4 weeks Mean costs, € (SD)			Follow-up 12 weeks Mean costs, € (SD)				
Cost categories	Intervention group, n=108	Control group, n=95	z	P value	Intervention group, n=108	Control group, n=95	z	P value
Direct medical costs	474.94 (467.0)	632.54 (800.68)	-0.18	0.86	651.23 (580.90)	825.43 (969.83)	-0.18	0.86
Medication	95.92 (109.31)	86.05 (80.04)	1.83	0.07	197.11 (228.64)	228.06 (385.92)	0.52	0.61
Rehabilitation evaluation	89.42 (100.11)	106.13 (129.80)	-0.24	0.81	113.69 (134.85)	144.9 (167.0)	-1.07	0.29
Rehabilitation therapy	285.49 (335.96)	249.6 (246.4)	0.73	0.47	320.14 (393.76)	257.42 (244.51)	1.05	0.29
Individual self- pay	299.03 (362.39)	288.34 (385.52)	1.11	0.27	427.2 (389.75)	462.47 (664.83)	0.98	0.33
Direct non-medical costs	260.49 (221.79)	285.01 (214.97)	-1.07	0.29	325.78 (274.8)	597.04 (591.53)	-2.98	0.003
Indirect costs	783.5 (1151.84)	1000.69 (2456.06)	-0.94	0.35	3024.7 (4137.07)	2901.1 (3913.88)	-0.04	0.97
Total costs	1518.93 (1436.97)	1918.24 (2603.75)	-1.45	0.15	4001.72 (4479.98)	4323.57 (4440.29)	-0.54	0.59

The Euro exchange rate against RMB was 7.341.

Table 4 The incremental cost-effectiveness ratios for both randomised groups after 4 and 12 weeks						
Outcomes	Time	Incremental Cost, € (95% CI)	Incremental Effect (95% CI)	ICER*		
BDAE difference	At intervention 4 weeks	-387.1 (-958.5 to 184.4)	0.47 (0.31 to 0.64)	-823.6		
	At follow-up 12 weeks	-321.8 (-1574.7 to 931.0)	0.65 (0.43 to 0.86)	-495.1		
CRRCAE difference	At intervention 4 weeks	-387.1 (-958.5 to 184.4)	118.00 (101.61 to 134.39)	-3.3		
	At follow-up 12 weeks	-321.8 (-1574.7 to 931.0)	182.47 (166.17 to 198.76)	-1.8		
QALY difference	At intervention 4 weeks	-387.1 (-958.5 to 184.4)	0.04 (0.03 to 0.05)	-9677.5		
	At follow-up 12 weeks	-321.8 (-1574.7 to 931.0)	0.07 (0.06 to 0.08)	-4597.1		

The Euro exchange rate against RMB was 7.341.

*For ICER related to baseline change in outcome after adjusting for baseline variables, the sign of the difference has been changed as a negative change in outcome represents an improvement.

BDAE, Boston Diagnostic Aphasia Examination; CRRCAE, Chinese Rehabilitation Research Center Standard Aphasia Examination; ICER, incremental cost-effectiveness ratios; QALYs, quality-adjusted life-years.

conceivable that our results do not reflect real-life costeffectiveness, the algorithm developed by Brazier tends to generate ICERs that are somewhat higher than those generated with other methods.³⁰ Therefore, our sensitivity analysis demonstrated the Bayesian QALYs evaluation method and confirmed that these results are robust.

The present study includes, to our knowledge, the first economic evaluation of acupuncture treatment in community-dwelling patients with Broca's aphasia after stroke. Obviously, such an approach also has its methodological limitations. In this study, neither providers nor patients were blinded to the treatment. Therefore, bias due to knowledge of the treatment received cannot be ruled out. To minimise social acceptability bias, all questionnaires were sent directly from and to the coordinating research institute. The treatment regimens were highly variable between patients because the specifics of acupuncture treatment and any cointerventions were left to the discretion of the speech therapists. The study inclusion criteria were broad, which resulted in a heterogeneous patient sample with many comorbidities. Another limitation arises from the duration of the study. The cost and effectiveness data were compared between the two groups for 4 weeks after baseline. The immediate treatment effects after the 4weeks continued for at least

12 weeks. Therefore, long-term health economic effects could not be investigated in the present study. Projecting our base-case scenario from 4weeks to 1 year supported the findings of other acupuncture trials that reported improvements in quality of life were maintained for up to 1 year.

There are only a few studies on acupuncture treatment in patients with Broca's aphasia after stroke. A systematic review and meta-analysis³¹ including 28 RCTs concluded that acupuncture seems to be effective in improving post-stroke aphasia, functional communication and language function. In agreement with the present study, the best curative effect was achieved with the combination of acupuncture with speech and language training. However, the possible deficiencies and limitations of the studies included in the metaanalysis should be considered, such as small sample sizes, the intensity of treatment, the study duration and the reliability of the measurements.

It is worth noting that the real-world implementation of SAT in low-income and middle-income countries and regions may be restricted by poor acupuncture services, inefficient systems and a deficiency of therapists.³² Alternatively, high-income countries and regions may be limited by high treatment costs. As such, socioeconomic

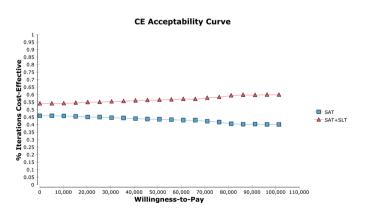


Figure 2 Cost-effectiveness (CE) acceptability curve for cost per quality-adjusted life-year analysis. SAT, scalp acupuncture therapy; SLT, speech and language therapy.

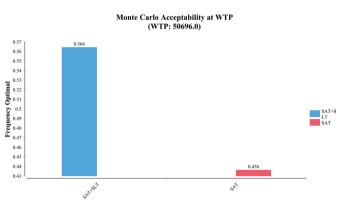


Figure 3 Monte-Carlo of cost-effectiveness when willingness-to-pay (WTP) threshold was ¥50 696. SAT, scalp acupuncture therapy; SLT, speech and language therapy.

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inequalities may influence those who can receive acupuncture. Thus, standardised education and training for the public, community physicians and government agencies should be improved so that the community can fully understand the benefits and cost-effectiveness of SAT.

The current study had several limitations. First, the treatments took place over a relatively short period, with a 12-week follow-up. Second, at the baseline assessment, 30% of the participants refused to respond to the economic questionnaires, resulting in incomplete cost data. Using completely random imputations for missing data would have introduced bias.³³ As an alternative, we used modified intention-to-treat principles to analyse cost-effectiveness.³⁴ Third, direct non-medical costs and indirect cost data were based on self-reported information. Consequently, the risk of recall and social desirability bias may have been introduced. These limitations would have led to an overestimation of the true cost-effectiveness of SAT in low-income and middle-income countries.

CONCLUSIONS

In conclusion, scalp acupuncture combined with SLT was cost-effective compared with SLT alone in patients with Broca's aphasia after stroke. This result was strongly influenced by the cost of acupuncture, as the treatment strategy only remains cost-effective when the cost of providing acupuncture is low. The costs of acupuncture services in China are likely to differ from other countries. Therefore, these results should be carefully interpreted and remain to be confirmed in other populations.

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Contributors ZL: data analysis, writing-reviewing and editing. JH: methodology, performed the experiment. YX: data curation. JW: performed the experiment. JT: project administration, funding acquisition. LC: project administration, supervision.

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Competing interests None declared.

Patient consent for publication Not required.

Ethics approval Ethical approvals were granted by ethics committees in all research centres, including the ethics committee of The Rehabilitation Hospital affiliated to Fujian University of Traditional Chinese Medicine (2013KY-006–01, approval received in July 2013), the ethics committee of The First Affiliated Hospital of Henan University of TCM (2014HL010, approval received in March 2014) and

the ethics committee of The Second Affiliated Hospital of Shandong University of Traditional Chinese Medicine (2013KY-006–01, approval received in March 2014).

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REFERENCES

- Wang W, Jiang B, Sun H, et al. Prevalence, Incidence, and Mortality of Stroke in China: Results from a Nationwide Population-Based Survey of 480687 Adults. Circulation 2017;135:759–71.
- 2 Acharya AB, Wroten M. *Broca aphasia*. StatPearls Publishing LLC, 2021.
- 3 Wang L, Liu J, Yang Y. The prevention and treatment of stroke still face huge Challenges—Brief report on stroke prevention and treatment in China, 2018. *Chinese Circulation Journal* 2019;34:105–19.
- 4 Brady MC, Kelly H, Godwin J, et al. Speech and language therapy for aphasia following stroke. Cochrane Database Syst Rev 2016:CD000425.
- 5 Brady MC, Kelly H, Godwin J. Speech and language therapy for aphasia following stroke. John Wiley & Sons, Ltd, 2016: 24.
- 6 Brady MC, Godwin J, Kelly H, et al. Attention control comparisons with SLT for people with aphasia following stroke: methodological concerns raised following a systematic review. *Clin Rehabil* 2018;32:1383–95.
- 7 Tang H-Y, Tang W, Yang F, et al. Efficacy of acupuncture in the management of post-apoplectic aphasia: a systematic review and meta-analysis of randomized controlled trials. BMC Complement Altern Med 2019;19:282.
- 8 Sun Y, Xue SA, Zuo Z. Acupuncture therapy on apoplectic aphasia rehabilitation. *J Tradit Chin Med* 2012;32:314–21.
- 9 Flinker A, Korzeniewska A, Shestyuk AY, et al. Redefining the role of Broca's area in speech. Proc Natl Acad Sci U S A 2015;112:2871–5.
- 10 Teng Y-ying. Clinical observation of scalp acupuncture plus speech rehabilitation for Broca's aphasia after cerebral stroke. *Journal of Acupuncture and Tuina Science* 2017;15:104–8.
- 11 Ru X, Dai H, Jiang B, *et al*. Community-Based rehabilitation to improve stroke survivors' rehabilitation participation and functional recovery. *Am J Phys Med Rehabil* 2017;96:e123–9.
- 12 Tao J, Fang Y, Wu Z, *et al.* Community-applied research of a traditional Chinese medicine rehabilitation scheme on Broca's aphasia after stroke: study protocol for a randomized controlled trial. *Trials* 2014;15:290.
- 13 The diagnosis of cerebrovascular diseases. *Chinese Journal of Neurology* 1996:60–1.
- 14 Chinese Association Of Rehabilitation Medicine. *Technical specification of common rehabilitation therapy*. Beijing: People's Medical Publishing House, 2012.
- 15 Drost RMWA, van der Putten IM, Ruwaard D, et al. CONCEPTUALIZATIONS of the societal perspective within economic evaluations: a systematic review. Int J Technol Assess Health Care 2017;33:251–60.
- 16 Fong MWM, Van Patten R, Fucetola RP. The factor structure of the Boston diagnostic aphasia examination, third edition. *J Int Neuropsychol Soc* 2019;25:772–6.

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- 17 Wang J, Yanling LV, Zhang Q. Reliability of Boston diagnostic aphasia examination Chinese version. *Chinese Journal of Rehabilitation* 1998:121–2.
- 18 Wang J, Zhang Q, Miaoling LV. The establishment and norm of Boston diagnostic aphasia examination Chinese version. *Chinese Journal of Rehabilitation* 1996:49–51.
- 19 Zhang Q, Ji S, Li S. Reliability and validity of Chinese rehabilitation research center standard aphasia examination. *Chinese journal of rehabilitation theory and practice* 2005:703-05.2005-09-25.
- 20 Poder TG, Fauteux V, He J, *et al.* Consistency between three different ways of administering the short form 6 dimension version 2. *Value Health* 2019;22:837–42.
- 21 Lam CLK, Brazier J, McGhee SM. Valuation of the SF-6D health states is feasible, acceptable, reliable, and valid in a Chinese population. *Value Health* 2008;11:295–303.
- 22 Claxton K. The irrelevance of inference: a decision-making approach to the stochastic evaluation of health care technologies. *J Health Econ* 1999;18:341–64.
- 23 Marseille E, Larson B, Kazi DS, *et al.* Thresholds for the costeffectiveness of interventions: alternative approaches. *Bull World Health Organ* 2015;93:118–24.
- 24 Group of China Guidelines. China guidelines for pharmacoeconomic evaluations (2011). *China Journal of Pharmaceutical Economics* 2011:6-09.2011-06-25.
- 25 International Monetary Fund. World economic outlook, 2017.

- 26 Feng X, Kim DD, Cohen JT, et al. Using QALYs versus DALYs to measure cost-effectiveness: how much does it matter? Int J Technol Assess Health Care 2020;36:96–103.
- 27 Löthgren M, Zethraeus N. Definition, interpretation and calculation of cost-effectiveness acceptability curves. *Health Econ* 2000;9:623–30.
- 28 Kharroubi SA, Brazier JE, Roberts J, et al. Modelling SF-6D health state preference data using a nonparametric Bayesian method. J Health Econ 2007;26:597–612.
- 29 Lim MY, Huang J, Zhao B, *et al.* Current status of acupuncture and moxibustion in China. *Chin Med* 2015;10:12.
- 30 Pickard AS, Wang Z, Walton SM, et al. Are decisions using costutility analyses robust to choice of SF-36/SF-12 preference-based algorithm? *Health Qual Life Outcomes* 2005;3:11.
- 31 Zhang B, Han Y, Huang X, *et al.* Acupuncture is effective in improving functional communication in post-stroke aphasia : A systematic review and meta-analysis of randomized controlled trials. *Wien Klin Wochenschr* 2019;131:221–32.
- 32 Pan Y, Zhang L, Li Z, *et al.* Cost-Effectiveness of a multifaceted quality improvement intervention for acute ischemic stroke in China. *Stroke* 2020;51:1265–71.
- 33 Little RJ, D'Agostino R, Cohen ML, et al. The prevention and treatment of missing data in clinical trials. N Engl J Med 2012;367:1355–60.
- 34 Dossing A, Tarp S, Furst DE, *et al*. Modified intention-to-treat analysis did not bias trial results. *J Clin Epidemiol* 2016;72:66–74.