

Special Article – Gait Rehabilitation

Cost Effectiveness of an Electromechanical Gait Trainer for Ambulation Training after Stroke in A Singaporean Community Hospital: A Single Blind Randomised Trial

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Background and Purpose: Electromechanical gait trainers (GT) combined with conventional physiotherapy may have equivalent or better efficacy than conventional physiotherapy alone when retraining ambulation in sub-acute stroke patients. However, no studies have measured effects on quality of life or health status, or evaluated cost effectiveness.

Methods: This randomised controlled trial involved 106 non-ambulant individuals recruited approximately one month post-stroke. Both groups received treatment 6 times per week for 8 weeks. The GT group received 20 minutes of GT training and 5 minutes of stance/gait training in contrast to 25 minutes of stance/gait training for the conventional physiotherapy group, and both groups completed 10 minutes of standing and 10 minutes of cycling. Health status was measured with the Stroke Impact Scale (SIS) at baseline, 4, 8, 12, 24 and 48 weeks. Relative cost effectiveness of one treatment over the other was also assessed.

Results: There were no significant group x time or group differences for any outcomes. Given this equivalence, a cost-minimisation analysis was conducted. GT combined with conventional physiotherapy was S\$4.63 less than conventional therapy alone per session per patient, and remained cost-saving across 99.45% of 10,000 simulations when the analysis was conducted probabilistically. Sensitivity analyses showed that this result depended on the number of times equipment was used across its lifetime in combination with therapist and therapy assistant (TA) pay ratios.

Conclusion: GT combined with conventional physiotherapy is as effective as conventional physiotherapy applied alone for sub-acute stroke survivors, and can be considered an efficient use of healthcare resources.

Keywords: Stroke; Walking; Gait trainer; Quality of life; Cost-effectiveness

Abbreviation

GT: Gait Trainers; **SACH:** St Andrew's Community Hospital; **FAC:** Functional Ambulation Category; **BI:** Barthel Index; **SIS:** Stroke Impact Scale; **ANOVA:** Analysis of Variance; **MMSE:** Mini Mental State Examination; **TA:** Therapy Assistant; **ICER:** Incremental Cost Effectiveness Ratio.

Ethics Approval

St. Andrew's Community Hospital Research Ethics Committee approved this study. Participants gave written informed consent before data collection began.

Source(s) of Support

Funding from St. Andrew's Community Hospital for all research costs, including S\$10 for each participant for transport at each follow-up.

Introduction

Strokes can be devastating, and one of the most disabling effects

can be the loss of the ability to walk. Approximately 80% of stroke patients are left with ambulation difficulties, which may be both severe and persistent [1]. It is also a common condition, affecting at least one in six middle-aged Americans [2]. Improving ambulation is therefore a major goal in stroke rehabilitation [3].

Conventional gait-retraining methods, where therapists facilitate normal movements, are effective in improving ambulation [4]. However, the patient's weight needs to be supported by therapists during the process, making this very labour intensive. Harness-assisted treadmill training can alleviate the weight-bearing problem, but the complex movements of gait are often difficult to control using this method [5]. This may explain why a Cochrane review [6] showed that such treadmill training is no more effective than conventional physiotherapy. To address the limitations of both of these approaches, 'robotic assisted locomotor trainers' that can both support weight and directly simulate the complex patterns of the gait cycle have been developed.

Of the two main types of robotic assisted locomotor trainers, 'gait-trainers' (GT) may be more effective than 'exoskeleton' devices,

based on their relative effects compared to conventional therapy [7-20]. Although the GT appears to work best when combined with conventional therapy, and applied to non-ambulant individuals in the acute or sub-acute stages [21], overall findings in comparison to conventional therapy have been conflicting. Some studies have found positive effects for GT approaches [8,9,11,13,21,22], but others have not noted a difference [7,10,12,23].

No studies, apart from our clinical efficacy study [23], have monitored quality of life or health status as an outcome. Such an outcome should encapsulate all aspects of a patient's return to health [21]. In addition, no previous study has examined the cost effectiveness of a GT approach compared to a conventional physiotherapy approach, despite a Cochrane review call for a cost-effectiveness study [21]. Cost effectiveness is of particular relevance in the context of stroke, due to the large economic burden associated with it. The aim of this study was to evaluate the cost effectiveness of a combined GT approach relative to conventional therapy, using a health status variable.

Methods

This cost-effectiveness study is based on the same participants and interventions as a published clinical effectiveness study [23]. For brevity the combined GT and conventional physiotherapy group will be referred to as the 'GT approach group' where appropriate.

Participants

Patients were recruited from all inpatients admitted for stroke at St Andrew's Community Hospital (SACH), Singapore. All patients gave informed consent and the study was approved by the hospital ethics research committee, conforming to the Helsinki Declaration.

Inclusion criteria were unilateral hemorrhagic/ischemic stroke, age between 18 and 80 years, and independent ambulation pre-stroke. Exclusion criteria were >8 weeks post-stroke, Functional Ambulation Category (FAC) >4, cardiovascular instability, Mini Mental State Examination (MMSE) score <16, communication deficits and lower limb joint contractures.

The study was powered for the primary outcome measure as described in the clinical effectiveness study [23]. The target size for each group was 53 patients.

Randomisation and blinding

Randomisation to the two parallel groups (GT combined with conventional physiotherapy *versus* conventional physiotherapy) was performed in a 1:1 allocation ratio using computer randomisation. An independent department generated the random allocation sequence, and transferred the sequence to a series of serially numbered opaque envelopes, which were not opened and revealed until after acceptance into the study and the baseline tests. Data assessors were blinded to group allocation. An intention-to-treat approach was used, and participants failing to complete either intervention were asked to return for follow up.

Interventions

In line with previous findings [8,9,11,13,21], it was decided that the group receiving GT should also receive some conventional physiotherapy to optimise effectiveness. This group was compared

to an independent group only receiving conventional physiotherapy.

The GT approach group received 20 minutes of electromechanical gait training and 25 minutes of conventional physiotherapy (5 minutes of stance/gait, 10 minutes of cycling, 10 minutes of tilt-table standing) 6 days/week for 8 weeks. The conventional physiotherapy group received 45 minutes of conventional physiotherapy (25 minutes of stance/gait, 10 minutes of cycling, 10 minutes of tilt-table standing) 6 days/week for 8 weeks. Stance/gait training focused on postural alignment, lower limb stepping exercises in supported standing, and over-ground walking.

Patients in the GT approach group were strapped to the GT harness, which initially gave from 10 to 20% weight support, and was reduced as appropriate. The patients placed their feet into the two footplates of the electromechanical GT machine (Reha-Stim), and took step lengths of 48cm, with a 'velocity' of 1.4-1.8 km/h.

During the 8-week training both groups also received occupational therapy and optional acupuncture. No study-based intervention was provided for participants after the 8-week training, but all were encouraged to continue community ambulation. A diary was provided to record any walking and leg exercises after discharge.

Demographic data and potential confounders

Data were collected on age, time from stroke, gender, weight, height, side of involvement, spasticity at baseline, depression and the use of ankle supports and knee gaiters.

Outcome measures

All outcome measures were measured at baseline, and then at 4, 8, 12, 24 and 48 weeks in the inpatient treatment area at SACH. Health Status was measured by the Stroke Impact Scale (SIS) version 3.0. This is a valid and reliable measure of functioning and social well-being for stroke survivors [24,25], full details of which are provided in our previous work [23]. Other outcomes included the FAC, Barthel Index (BI), gait velocity and gait endurance, but the methodology and results for these are described elsewhere [23].

Statistical analysis

Because the sample size was considerably larger than 30, normality of sampling distributions was implied by the Central Limit theorem [26].

Baseline analysis: To evaluate baseline equivalence, the two groups were initially compared for demographic variables, other potential confounders such as spasticity levels, and the baseline values of the outcome variables. If any potential confounders differed across groups to a degree that could potentially influence the outcome [26] then they were later added to the Generalised Linear Measures analysis as a covariate or factor.

Follow-up analysis: Any missing data were imputed on the basis of the most recently available data as described in our previous work [23]. For all outcomes, data at 4, 8, 12, 24 and 48 weeks were compared across both groups using a Generalised Linear Measures approach (Generalised Estimating Equations), assuming an AR(1) correlation model. For each outcome, time was entered as the within-subject variable, with group entered as the factor and time entered as the covariate. As previously stated, any suspected confounders were

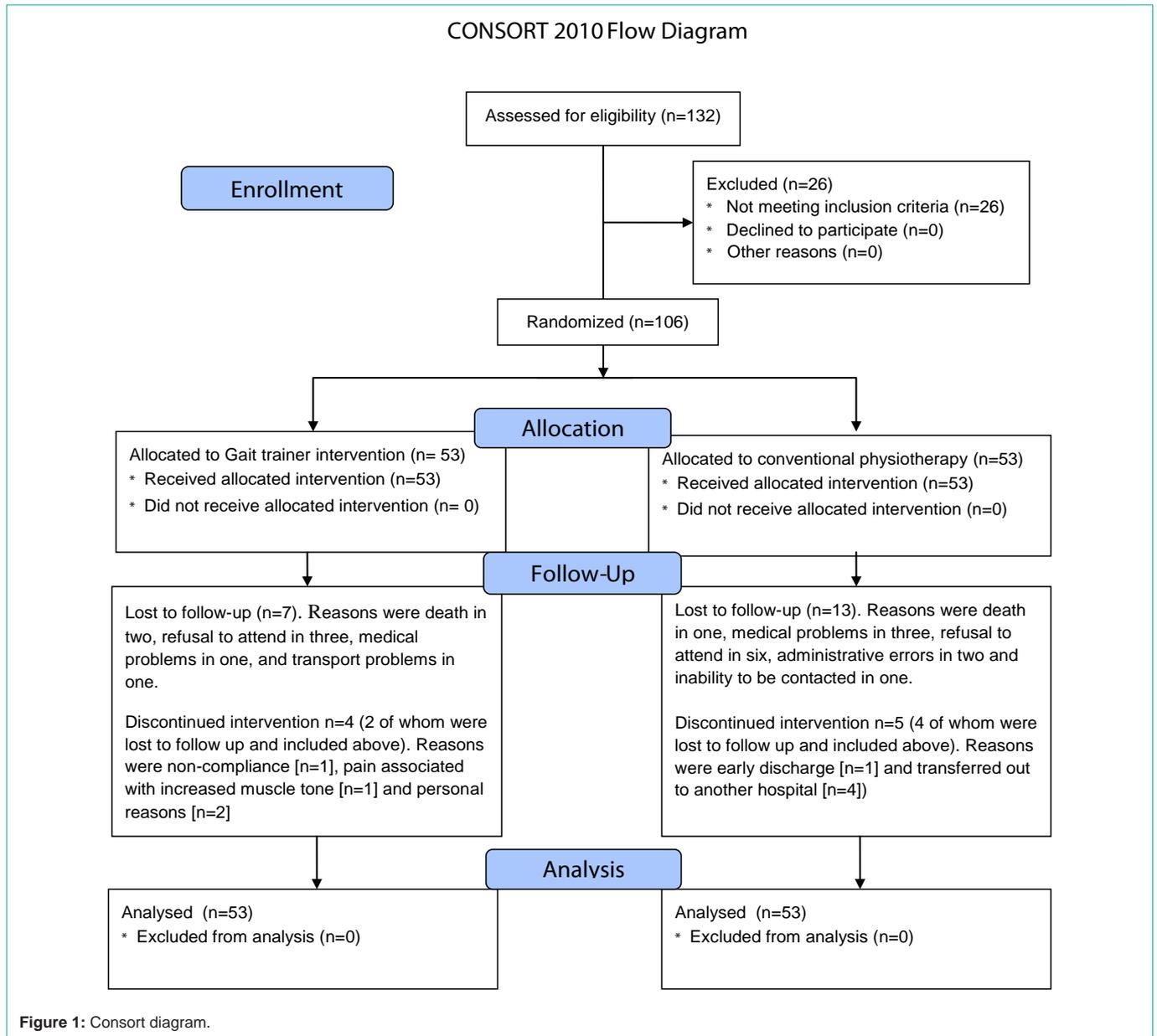


Figure 1: Consort diagram.

also added as covariates or factors. A type III full log quasi-likelihood function analysis was adopted for all outcomes. For the SIS outcomes a linear scale response model was used. Beta co-efficients with 95% confidence intervals were derived. For the group x time analysis these represented the difference in slope between the GT and control groups.

Cost-effectiveness analysis

The cost effectiveness of one treatment, relative the other, is assessed by dividing the difference in costs between treatments by the difference in outcomes between treatments [27-29]. The cost of each treatment was calculated by identifying and estimating the resource use required to undertake each procedure, using figures derived from the Human Resource department at SACH. The physical scale of the SIS was chosen as the health status outcome as the SIS domains cannot be combined to produce an overall score, and the physical subscale

was deemed to be the subscale most relevant to improvements in ambulation.

An incremental cost effectiveness ratio was calculated using the following formula:

$$ICER = \frac{Cost_{GT} - Cost_{CT}}{SIS(physical)_{GT} - SIS(physical)_{CT}}$$

To account for uncertainty around input point estimates the analysis was run probabilistically. A probability distribution was defined for each input and a Monte Carlo simulation was run whereby a value for each input was randomly selected from its respective distribution, and mean costs and outcomes were calculated by averaging across all simulations. Probability distributions were defined for each parameter by fitting distributions using the package R Risk distributions in R software.

The following probabilistic sensitivity analyses were conducted to

Table 1: Baseline characteristics.

	GT (n=53 unless stated) Mean (sd)	Control (n=53 unless stated) Mean (sd)	P (based on independent t test analysis)
Age (years)	62.1(10.3)	60.7(10.7)	0.505
Days since stroke	27.2(11.3)	29.8(14.1)	0.282
MMSE	23.8(4.2)	25.1(4.1)	0.126
Weight (kg)	62.7(13.3)	65.2(13.0)	0.337
Height (cm)	163.2(7.7)	165.9(9.2)	0.096
Acupuncture sessions	17.6(30.3)	31.3(59.0)	0.187
Additional non-study exercise or walking in first 8 weeks (mins)	72.0(253.2) (n=52)	103.6(332.4) (n=50)	0.591
Additional non-study exercise or walking post-discharge (mins)	13,638 (12,823) (n=37)	12,688 (13,340) (n=34)	0.761
BI	48.1(37.5)	49.3(32.9)	0.864
Gait velocity (m/s)	0.25(0.17)	0.23(0.13)	0.382
Gait endurance (m)	48.1(37.5)	49.3(32.9)	0.863
SIS Physical	40.2(15.7)	34.8(13.5)	0.062
SIS memory and thinking	77.8(20.8)	76.0(23.8)	0.687
SIS mood and emotion	67.0(20.1)	66.4(18.0)	0.877
SIS communication	83.4(19.8)	83.8(21.0)	0.933
SIS participation	50.1(21.0)	44.5(18.8)	0.146
SIS recovery	39.6(24.9)	37.0(23.6)	0.576
	GT Number (%)	Control Number (%)	P (based on chi square analysis)
Sex (female)	18/53 (34%)	13/53(24.5%)	0.286
Side (left)	29/53 (54.7%)	32/53 (60.4%)	0.556
Ethnicity (Chinese)	31/53 (58.5%)	33/53 (51.6%)	0.707
depression	22/53 (41.5%)	18/53 (34%)	0.423
spasticity	18/53 (34%)	13/53 (24.5%)	0.196
FAC =0	9/53 (17.0%)	7/53 (13.2%)	0.180
FAC=1	28/53 (52.8%)	38/53 (71.7%)	
FAC=2	15/53 (28.3%)	8/53 (15.1%)	
FAC=3	1/53 (1.9%)	0/53 (0%)	
FAC (≥4)	0/53 (0%)	0/53 (0%)	

test the robustness of the analyses' conclusion in relation to changes in key parameters, and also to test the applicability to different settings.

Sensitivity analysis 1: In Singapore the ratio between TA and therapist pay is about 0.44, which may be low compared to western countries. Hence the cost analyses were repeated at the ratio of 0.6.

Sensitivity analysis 2: As salary costs are likely to be slightly lower in Singapore than in western countries the cost analysis was repeated with 20% increases in salary costs for both therapists and therapy assistants (TAs).

Sensitivity analysis 3: In the base case it was assumed the equipment would be used 8 times a day. In smaller practices this number may not be possible due to resource constraints. Therefore the analysis was re-run assuming only 4 uses per day.

Sensitivity analysis 4: A two-way sensitivity analysis was conducted by simultaneously changing TA to therapist pay ratio and number of equipment uses by the same levels as mentioned in sensitivity analyses 1 and 3 above.

Sensitivity analysis 5: Finally a three-way sensitivity analysis was conducted that simultaneously changed: wages, TA to therapist pay ratio and the number of equipment uses per day.

Results

Recruitment occurred from June 2011 to July 2014, with the last follow up occurring in June 2015. Recruitment was stopped once the sample target size had been reached. 106 patients were randomly allocated to the groups. Seven patients were lost to follow up in the GT approach group and 13 were lost to follow up in the conventional physiotherapy group at 12 months (Figure 1). Imputation of data meant that analysis was performed on a full data-set.

Baseline

The groups were well-matched for baseline demographic variables. One moderate group difference existed for the quantity of acupuncture sessions but acupuncture was not associated with any outcome so this was not considered a potential confounder. However, there were also small baseline differences for the outcomes,

Table 2: Health status outcome measures at 4, 8, 12, 24 and 48 weeks. Beta co-efficients for the group x time analysis can be interpreted as the difference in the gradients (of the outcome over time) between the GT group and the control group. N=53 in GT and n=53 in control group. con = control group, sd= standard deviation.

Outcome variable	4 weeks		8 weeks		12 weeks		24 weeks		48 weeks		Generalised estimating equation analysis. Beta co-efficient (β) (95% CI)
	GT	Con	GT	Con	GT	Con	GT	Con	GT	Con	
SIS physical	56.9 (18.4)	53.7 (22.0)	65.2 (19.9)	61.1 (23.5)	66.0 (24.0)	65.8 (27.4)	65.2 (24.2)	66.2 (23.9)	67.8 (27.2)	66.2 (24.8)	Group x time effects $\beta = -0.007$ (-0.144 to 0.130) P= 0.921 Time effects $\beta = 0.149$ (0.069 to 0.228) P<0.001 Group effects $\beta = -1.778$ (-7.892 to 4.355) P=0.569
SIS memory and thinking	83.3 (18.4)	81.1 (23.2)	86.3 (18.8)	84.4 (16.9)	85.0 (20.4)	85.0 (18.3)	85.2 (19.9)	84.0 (17.6)	86.4 (21.6)	85.0 (16.2)	Group x time effects $\beta = 0.04$ (-0.123 to 0.131) P= 0.949 Time effects $\beta = 0.048$ (-0.022 to 0.118) P=0.180 Group effects $\beta = 0.652$ (-5.258 to 6.561) P=0.829
SIS mood and emotion	69.3 (17.8)	71.4 (20.0)	72.3 (20.5)	73.8 (20.2)	74.8 (18.1)	72.0 (20.1)	75.7 (18.1)	72.4 (21.6)	76.2 (18.8)	74.8 (20.2)	Group x time effects $\beta = 0.016$ (-0.125 to 0.156) P= 0.829 Time effects $\beta = 0.077$ (-0.014 to 0.167) P=0.097 Group effects $\beta = -0.373$ (-5.966 to 5.219) P=0.896
SIS communication	87.6 (18.1)	85.8 (19.0)	101.3 (91.9)	86.9 (17.1)	89.8 (13.5)	88.4 (17.4)	90.5 (15.1)	88.3 (15.6)	90.6 (14.5)	88.3 (15.1)	Group x time effects $\beta = -0.085$ (-0.307 to 0.117) P= 0.453 Time effects $\beta = 0.040$ (-0.037 to 0.117) P=0.310 Group effects $\beta = 6.088$ (-3.398 to 15.573) P=0.208
SIS participation	58.7 (21.3)	58.4 (20.6)	63.0 (22.4)	57.3 (22.3)	66.5 (21.9)	61.9 (22.4)	66.8 (24.6)	67.5 (24.0)	69.4 (26.3)	68.8 (19.6)	Group x time effects $\beta = -0.029$ (-0.210 to 0.152) P= 0.751 Time effects $\beta = 0.199$ (0.098 to 0.301) P<0.001 Group effects $\beta = 0.972$ (-5.951 to 7.895) P=0.783
SIS recovery	58.6 (23.0)	56.0 (23.7)	65.1 (23.1)	60.9 (23.2)	64.5 (21.1)	60.7 (23.4)	65.3 (21.0)	60.7 (21.3)	63.6 (27.1)	60.1 (24.3)	Group x time effects $\beta = -0.007$ (-0.175 to 0.162) P= 0.939 Time effects $\beta = 0.029$ (-0.078 to 0.136) P=0.596 Group effects $\beta = 2.761$ (-4.212 to 9.734) P=0.438

particularly SIS physical and SIS participation (Table 1).

Follow up

Since the baseline differences in the SIS physical and SIS participation had the potential to directly affect any group or group x time effects in the generalised linear model analysis for the SIS physical and SIS participation outcomes, the respective baseline values were

added in as covariates to the analyses for those two outcomes. After generalised estimating equations analysis there were no significant group or group x time effects for any health status outcomes or other outcomes [23]. However there were significant time effects (independent of group) for SIS physical and SIS participation (Table 2). No adverse effects were reported.

Table 3: Staff cost per session for GT combined with conventional therapy.

Staffing activity	No. staff	Minutes (Distribution)	Total (minutes x no. staff)
TA doffing and donning	2	10 Lognormal ($\mu=2.30, \sigma=0.07$)	\$5.09
TA gait training	1	20 Lognormal ($\mu=3, \sigma=0.04$)	\$5.09
Therapist, adjunctive training	1	5 Lognormal ($\mu=1.61, \sigma=0.07$)	\$3.18
TA cycling and standing	1	20 Lognormal ($\mu=3, \sigma=0.04$)	\$5.09
Total			\$18.44

Table 4: Annualised per patient equipment costs required for GT.

Equipment cost per patient		Distribution
Cost of equipment	\$85,000	-
Equipment lifespan (years)	10	Lognormal ($\mu=2.30, \sigma=0.27$)
Days of use per year*	301	-
Uses per day	8	Lognormal ($\mu=2.08, \sigma=1.57$)
Discount rate	3.5%	-
Annualisation factor	8.61	-
Annualised marginal per-test cost Ψ	\$4.10	

*Assuming equipment is used 6 days a week minus 11 days for public holidays.
 Ψ Calculated by: (cost of equipment)/(annualisation factor)/(uses per lifetime).

Table 5: Cost per session for GT combined with conventional therapy.

Item	Cost
Staff time	\$18.44
Equipment cost	\$4.10
Total	\$22.54

Cost analysis

Costs were calculated as shown in Tables 3-5 above. GT combined with conventional therapy cost \$22.54 per patient per session. This cost comprises staff costs (\$18.44), and equipment costs (\$4.10), and details are shown above in Tables 3 and 4. Conventional physiotherapy alone cost \$27.35 per patient per session, comprising only staffing costs. Staff time costs assumed a wage of \$38.16 per hour for therapists and \$16.75 per hour for TAs. These costs included salary oncosts sourced from the SACH Human Resources department.

Cost-effectiveness analysis

At 48 weeks the groups did not differ in gains of SIS physical from baseline (Table 2). The mean (sd) improvement in SIS physical score from baseline to 48 weeks in the GT approach group was 27.56 (24.10) points, and the mean (sd) improvement in SIS physical score from baseline to 48 weeks in the conventional physiotherapy approach group was 31.31 (21.81) points. The between-group mean difference

Table 6: Cost per session for conventional therapy.

Staffing activity	No. staff	Minutes (Distribution)	Total (minutes x no. staff)
Therapist time	1	25 Lognormal ($\mu=3.22, \sigma=0.04$)	\$15.90
TA time	1	25 Lognormal ($\mu=3.22, \sigma=0.04$)	\$6.36
TA cycling and standing	1	20 Lognormal ($\mu=3, \sigma=0.04$)	\$5.09
Total			\$27.35

of 3.75 points improvement was not statistically significant ($p=0.403$) and so it was not deemed appropriate to reject the null hypothesis that the health status benefits in the two treatment approaches were equivalent. Moreover, the small difference in gain of 3.75 points is well below the minimal detectable difference for the SIS physical domain items [30]. Given this clear equipoise in terms of clinical efficacy, it was deemed that a cost-minimisation analysis was an appropriate analysis to conduct, whereby the intervention identified as having the lowest costs would be the most cost-effective option.

Using base case point estimates, GT was deemed the lowest cost option by \$4.80 per session and therefore the more cost-effective option. When the analysis was run probabilistically the mean cost difference averaged over 10,000 simulations remained in favour of the GT approach at \$4.63 per session. The probability of GT being cost saving, calculated by finding the percentage of simulations that showed GT to be cost saving relative to conventional therapy alone, was found to be 99.45%.

Sensitivity analyses

The impact on mean cost and the probability of the GT approach being cost saving in each sensitivity analysis is shown in table 7 below. Sensitivity analysis 1 showed that the cost effectiveness of GT is robust to changes in the ratio of pay between therapists and TAs. Therefore, all other things being equal, significant reductions in therapist pay will not alter the likelihood of GT training being cost-effective. Likewise, although it significantly reduced the cost difference between the two interventions, reducing equipment use per day by 50% still resulted in GT being the most cost-effective option. However when both pay ratio and uses per day were changed simultaneously, GT alone became the most cost-effective choice. Increasing salaries by 20% increased the cost savings from choosing GT as healthcare professional costs constitute a larger cost for GT alone.

The impact on mean cost and the probability of the GT approach being cost saving is shown in table 7 below.

Discussion

This study demonstrates that a GT approach and a conventional physiotherapy approach, as given to the population in this study, are equally effective methods for improving health status. Given the rigor of methodology, and the care taken to avoid systematic bias, it is probably reasonable to conclude that the two approaches are truly equivalent in terms of clinical effects on health status, and that the decision about which to use depends on considerations other than efficacy.

Despite both groups attaining similar improvements, the time and effort required by therapy staff were different. In the conventional physiotherapy group, a physiotherapist and at least one TA had to be present to walk and support the patients for the entire session. However, in the GT approach it took <5 minutes for two TAs to prepare patients for the GT. No constant physical contact was needed after patients were put on the GT for the 20 minute gait training, as a knee brace or TheraBand[®] could be used to control knee or body alignment in walking. This argument is highly related to the costs of the two approaches, which are dependent on the costs of manpower as well as the cost of the GT machine.

Table 7: Results from sensitivity analyses.

Sensitivity analysis	Mean cost GT (\$\$)	Mean cost CT (\$\$)	Cost difference per session (\$\$)	Probability of GT being cost effective
Base case	\$22.74	\$27.37	-\$4.63	99.45%
1 – (TA : Therapist pay)	\$31.08	\$34.69	-\$2.70	93.70%
2 – (20% wage increase)	\$26.44	\$32.84	-\$6.40	99.92%
3 – (4 uses of GT equipment per day)	\$27.16	\$27.37	-\$0.21	58.07%
4 – (1 and 3)	\$34.82	\$33.09	\$1.73	30.47%
5 – (1, 2 and 3)	\$39.96	\$39.73	\$0.24	51.32%

The cost analysis showed that of the two approaches the GT approach was less costly, by almost \$5 per session. Hence this study shows that because the two approaches are equivalent in terms of clinical benefits, the GT approach may be the more cost effective option. Uncertainty surrounding key parameters that would influence the costs of both interventions was explored using sensitivity analyses. These analyses showed that GT training was highly likely to be cost effective relative to conventional therapy alone for large practices that would be able to utilize the equipment more often. In smaller practices GT training was still cost effective but extra consideration needs to be considered for TA and therapist pay. The smaller the pay gap between these two professions the less likely GT will be the most cost effective option. However the impact of a smaller pay gap can be mitigated by higher salaries as shown in sensitivity analysis 5.

In this study a cost-minimization analysis was undertaken rather than a cost-effectiveness analysis. The undertaking of cost-minimization analyses should not be taken lightly and the appropriateness of this technique has been extensively critiqued [31]. It was felt that in this circumstance a cost-minimization analysis would be appropriate for two reasons. First of all, the two interventions are clinically equivalent when given as described in this study. For the variable used for the cost minimization analysis – the SIS physical subscale - the groups were not clinically nor statistically different.

Secondly, some of the most important effects that the interventions will have had on health were felt to have been captured by the SIS physical sub-scale. This is important, as appropriateness of cost minimization analysis partly depends on the extent to which the clinical effectiveness outcome truly represents all relevant aspects of health [31]. The SIS physical sub-scale encompasses the concept of improvement in ambulation ability [32], which is the main aim of the interventions, in tandem with being patient-reported and therefore of importance to the patient. In addition, the SIS physical sub-scale has been shown to be a valid and reliable measure for this population that is highly sensitive to change [24,33]. Finally, ceiling effects are low and so the SIS physical sub-scale is particularly suited to sensitive measurements of change in patients at 1-3 months post-stroke who have relatively good function [32]. We do not believe that survival is something that needed to be captured as we have no reason to think, based on our data, that the interventions influenced survival.

However, important mental effects such as cognition and mood were not captured by the single SIS physical variable, which may represent a potential limitation because the full scope of relevant aspects of health were not covered. Nevertheless, none of the other SIS subscales, describing mood and emotion, memory and thinking,

communication, participation or sense of recovery, showed any clinically or statistically significant between-group differences in improvement either. Given this similarity across these wide-ranging domains it is probably safe to conclude that the interventions were equivalent in terms of overall health status. Hence we can be fairly confident that the intervention with lower costs is indeed the more cost effective.

Conclusions

The GT approach is as effective as conventional physiotherapy in improving ambulation and health status in this sample of sub-acute stroke survivors. The approach involving the GT incurs lower costs than the conventional approach, implying that given the similar efficacy of the two approaches, the GT approach is a cost effective option. The generalizability of this finding should be considered alongside the number of times the equipment would be used over a lifetime and the gap in wages between therapists and TAs.

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