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**Health Service Management Study for Stroke: a Randomized Controlled Trial to
Evaluate two models of Stroke Care**

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Abstract

Background

The most effective and efficient model for providing organized stroke care remains uncertain. This study aimed to compare the effect of two models in a randomized controlled trial.

Methods

Patients with acute stroke were randomized on day one of admission to combined, co-located acute/rehabilitation stroke care or traditionally separated acute/rehabilitation stroke care. Outcomes measured at baseline and 90 days post-discharge included functional independence measure, length of hospital stay and functional independence measure efficiency (change in functional independence measure score \div total length of hospital stay).

Results

Among 41 patients randomized, 20 were allocated co-located acute/rehabilitation stroke care and 21 traditionally separated acute/rehabilitation stroke care. Baseline measurements showed no significant difference. There was no significant difference in functional independence measure scores between the two groups at discharge and again at 90 days post-discharge (co-located acute/rehabilitation stroke care: 103.6 ± 22.2 vs. traditionally separated acute/rehabilitation stroke care: 99.5 ± 27.7 ; $P=0.77$ at discharge; co-located acute/rehabilitation stroke care: 109.5 ± 21.7 vs. traditionally separated acute/rehabilitation stroke care: 104.4 ± 27.9 ; $P=0.8875$ at 90 days post-discharge). Total length of hospital stay was 5.28 days less in co-located acute/rehabilitation stroke care compared with traditionally separated acute/rehabilitation stroke care (24.15 ± 3.18 vs. 29.42 ± 4.5 , $P=0.35$). There was significant improvement in function independence measure efficiency score among participants assigned to co-located acute/rehabilitation stroke care compared with

traditionally separated acute/rehabilitation stroke care (co-located acute/rehabilitation stroke care: median 1.60, interquartile range: 0.87-2.81; traditionally separated acute/rehabilitation stroke care: median 0.82, interquartile: 0.27-1.57, $P=0.0393$). Linear regression analysis revealed a high inverse correlation ($R^2 = 0.89$) between functional independence measure efficiency and time spent in the acute stroke unit.

Conclusion

This proof-of-concept study has shown that co-located acute/rehabilitation stroke care was just as effective as traditionally separated acute/rehabilitation stroke care as reflected in functional independence measure scores, but significantly more efficient as shown in greater functional independence measure efficiency. Co-located acute/rehabilitation stroke care has potential for significantly improved hospital bed-utilization with no patient disadvantage.

Introduction

It is widely accepted, from systematic reviews of randomized controlled trials (RCTs), that organized multidisciplinary care in a stroke unit is associated with better patient outcomes compared with care in general medical wards.^[1,2] The benefits are independent of age, gender or stroke severity, and appear to be maintained after ten years.^[3,4]

The most effective and efficient model for providing organized stroke unit care remains uncertain. Three different models of organized stroke unit care have been compared indirectly in a meta-analysis of 14 RCTs: 1) acute (intensive) stroke units that discharge patients early, (usually about seven days); 2) rehabilitation stroke units that accept patients after seven days and focus on rehabilitation; and 3) comprehensive stroke units (CSUs) that accept patients acutely, and also provide rehabilitation for several weeks if necessary.^[5] CSUs appeared to demonstrate the greatest overall benefit, being the only model to achieve a significant reduction in length of stay (LOS) and the greatest reduction in combined death and dependency.^[5] Cross-sectional and “before-and-after” comparisons also suggest better LOS and/or functional outcome when CSU is compared with acute or rehabilitation stroke unit models.^[6-7] However, the latter study designs and indirect comparisons of different RCTs may be flawed.^[8] More reliable estimates arise from direct comparisons in RCTs but there have been no RCTs that directly compare CSUs with other models of stroke unit care.^[9]

Aim

The aim of the present study was to directly compare the effectiveness and efficiency of two major models and pathways of stroke care: the traditional stroke care pathway, where acute and rehabilitation stroke cares are separate (Traditional stroke care, TSC) and the

comprehensive stroke care pathway, where acute and rehabilitation stroke care are combined (Comprehensive stroke care, CSC).

Methods

1. Study Design, Setting, Ethics, and Participants

This was a prospective, single-blind, randomized controlled trial (Figure 1). To be eligible to participate, the recruiting hospitals were required to provide stroke care using a traditional care model, that is, where the acute stroke care was provided in acute stroke unit which is in a separate location to the rehabilitation phase of care (in rehabilitation unit). Participating rehabilitation units/hospitals were required to provide care to acute stroke patients if they were recruited in the CSC arm. Fairfield Hospital, Braeside Hospital, John Hunter Hospital and Rankin Park Rehabilitation Centre participated in the trial. The first two centres were in Sydney and the last two in Newcastle, Australia.

The study was approved by Human Research Ethics Committee in all participating hospitals and University of New South Wales Research Ethics Committee. Prior to recruitment into the study, informed written consent was obtained from all participants for participation in the study and for 90 day post-discharge telephone follow-up.

The study commenced in September 2008 and follow-up was completed in January 2011.

Patient inclusion criteria:

Consecutive stroke (ischaemic and haemorrhagic) patients admitted to the participating acute hospitals were enrolled in day one of admission if vacant beds existed in both acute and rehabilitation hospitals simultaneously at the point of randomization and the patient had an

acute stroke within the previous 24 – 48 hours and had sufficient neurological impairment and disability to require ongoing rehabilitation.

Patient exclusion criteria:

The following category of patients were excluded: 1) patients with transient ischaemic attack or stroke patients who did not require an in-patient rehabilitation phase of care within 24 – 48 hours of acute presentation (e.g. due to clinical recovery or a very mild stroke); 2) comatose stroke patients with a poor prognosis; 3) patients with severe co-morbidities such as advanced dementia; 4) stroke patients requiring neurosurgical intervention.

2. Baseline measures

At baseline, patient's age, gender, race-ethnicity, language, living arrangements, stroke risk factor profile, co-morbidities, medication, Scandinavia Stroke Scale (SSS) score, modified Rankin Scale (mRS), and functional independence measure (FIM)^[10] scores were recorded by research officers who were trained and accredited in undertaking these measures. The functional independence measure comprises 18-items, each of which is assessed against a 7 point ordinal scale developed to uniformly assess disabilities and functional capacities that include walking, dressing, toileting, bathing and communication. The higher the score for an item, the more independent the patient is able to perform the tasks as assessed by that item. Total scores range from 18 to 126. FIM is a mandatory requirement for funding purposes by the NSW Health Department and hence is routinely used by medical and allied health staff within NSW hospitals. It is also widely used in Australia.

3. Randomization

Patients were randomized into one of the two arms in the two participating acute hospitals. Patient randomization was generated centrally by a biostatistician using computer software program Stata11 (StataCorp LP, College Station, TX, USA). The generated results were concealed and stored locally. Clinicians at the rehabilitation services were not informed as to whether a patient was randomized into the study. Likewise, the research officers who conducted baseline measures and subsequent FIM assessments at discharge and 90 day telephone follow-up interview were also blind to group allocation.

4. Intervention

The “intervention” was the “early” commencement of rehabilitation process with a significant part of the acute care to be spent in a rehabilitation setting.

Patients allocated to the TSC arm were admitted into an acute stroke unit (ASU) and transferred to a rehabilitation unit at the end of their acute stroke phase (after completion of investigations and acute treatment and are medically stable as per usual practice).

In contrast, patients allocated to the CSC arm were pressed to be transferred to a rehabilitation bed, aiming within 24 – 48 hours after arrival at ASU (or the next working day if weekend). In other words, patients are still in acute stroke phase and might require attention to acute medical problems should they arise. Hence it was not equivalent to early transfer to a rehabilitation unit. This pathway fits the description of CSU. ^[1]

Patients in the TSC arm were cared for in two different stages (acute and rehabilitation) by different nursing and allied health teams, whereas patients in the CSC arm were cared for by

the same nursing and allied health team for a larger portion of their hospital length of stay (LOS).

All standard and best possible care was given to participants in both arms and the same treatment interventions were available to patients admitted to either arm (with the exception of rehabilitation process allowed to happen earlier after faster arrival in rehabilitation setting in the CSC arm).

5. Follow-up

All patients were followed up at 90-days post-discharge via telephone calls by two research officers (one in each pair of acute-rehabilitation units/hospitals) who were blind to the treatment allocation.

6. Outcome measures ascertainment

All FIM assessments were performed by the same research officer who had passed training sessions in performing the assessment tool, thus ensuring consistency of assessment (i.e. one research officer for each pair of acute-rehabilitation units/hospitals).

- Effectiveness:
 - the change in FIM score (admission compared to discharge and 90 days post-discharge follow up);
- Efficiency:
 - the total hospital LOS (acute and rehabilitation units combined),
 - FIM efficiency^[11] (change in FIM score ÷ total LOS) between stroke patients who received CSC and those who received TSC. The FIM efficiency is an indicator of the rate of functional improvement per day of hospital stay.

The LOS in all patients was decided by the team caring for the patient and the information extracted from medical records and counter-checked with the team by the research officers upon discharge of the patient. The rehabilitation teams were blind to the group allocation of the patients.

7. Statistical analysis

Statistical analysis was carried out with Prism 5.04 (GraphPad Software Inc. La Jolla, CA, USA.) by a statistician. For the comparison of the means between the TSC and CSC groups, Student's *t*-test for parametric data and Mann-Whitney *U*-test for nonparametric data were used. Chi-square test was used to test the significance of the association between two variables. $P < 0.05$ was considered statistically significant. A post hoc analysis was carried out using linear regression to assess FIM efficiency as a function of time (LOS) spent in ASU where each of CSC and TSC groups (two intervention and two control groups) were calculated as four points (Figure 2).

Results

A total of 47 individual patients, 25 males and 22 females, from four participating hospitals consented to participate in the study and were randomized. Of these, two patients died and four patients withdrew their consent while in the ASU phase, prior to the commencement of the intervention (Figure 1). The final analysis consisted of 20 patients (11 males, 9 females; mean age 73.5 years, range 55-88) in the CSC arm, and 21 patients (12 males, 9 females; mean age 72.6 years, range 34-99) in the TSC arm.

1. Baseline characteristics

Table 1 shows that there was no significant difference between the two arms in the prevalence of demographic and clinical characteristics of patients recruited into the study. Baseline admission stroke severity (as measured by the SSS score and mRS) also did not differ significantly between the two arms (Table 2), but there was a non-significant trend toward a higher FIM score, among patients assigned TSC (71.5 ± 32.8) compared to CSC (67.5 ± 28.0).

2. Outcome measures

Effectiveness

The mRS at discharge and discharge FIM score were comparable between the two arms. Upon discharge, the CSC group showed a greater improvement of FIM score compared to the TSC group (36.1 and 28 points respectively) although this did not reach statistical significance.

At 90 days postdischarge follow up, the FIM scores were not significantly different between the CSC and TSC groups (109.5 ± 21.7 and 104.4 ± 27.9 respectively; $P=0.8875$). There was a greater improvement in FIM in CSC arm compared with TSC (42 and 32.9 points respectively) but the difference did not reach statistical significance.

Efficiency

1. Length of hospital stay:

On average, patients from the CSC arm spent 5.28 days less in total in hospital when compared to patients from the TSC arm (24.2 ± 14.2 vs. 29.4 ± 20.6 , $P=0.35$). The CSC arm had a similar total LOS when compared to the TSC arm for patients with mild (mRS 1 or 2) or severe (mRS ≥ 5) stroke. However, for patients with moderate severity of stroke (mRS 3 or

4), the CSC arm enjoyed a 6.4 days shorter LOS in the rehabilitation phase (13.6 ± 11.6 vs. 20.0 ± 12.5 , $P=0.2162$) and a 7.7 days shorter in total LOS (19.2 ± 10.9 vs. 26.9 ± 14.2 , $P=0.1680$) when compared with the TSC arm.

If the withdrawals and deaths were included in an intention-to-treat analysis, the mean difference of total LOS between CSC arm and TSC arm would have been 6.62 days (21.83 ± 14.06 vs. 28.45 ± 20.65 , $P=0.207$). However, their inclusion in the analysis would have deviated from the prespecified inclusion criteria.

2. FIM efficiency:

Participants assigned to CSC arm demonstrated a significantly better FIM efficiency score when compared with the TSC arm (median 1.60, interquartile range (IQR) 0.87-2.81 and median 0.82, IQR 0.27-1.57 respectively, $P=0.0393$, Figure 3). The improvement of median FIM efficiency was almost 95% when CSC group was compared with TSC group. There were no statistically significant differences of stroke severity at baseline (i.e. admission SSS, mRS or FIM scores) between the two arms (Table 3). Linear regression analysis revealed a high inverse correlation ($R^2 = 0.89$) between FIM efficiency and LOS spent in the ASU (Figure 2). FIM data upon discharge were not available for the four withdrawals, and discharge FIM data would have been meaningless for the two deaths, hence FIM efficiency could not be calculated as per intention-to-treat analysis.

Discussion

It is well established that dedicated stroke unit care offers significant benefits in survival and dependency when compared with general medical ward care.^[1] However it is unclear if the different dedicated models of stroke units (or stroke care) are associated with differences in

health care efficiency or effectiveness (clinical outcomes). The present study is the first to directly compare the efficiency of two different stroke care (models), namely CSC and TSC, utilizing randomized controlled trial method and accepted performance indicators including FIM and FIM efficiency, which are recognized benchmarks for stroke care delivery in many countries in North America, Asia and Australia.^[12-15] The finding of improved FIM efficiency in CSC arm with reduced period of care in an acute stroke unit may have significant implications in health service management. The existing burden of care for stroke patients in hospital setting and the likely growth in this burden over the coming decades means that care pathways with improved efficiency and/or clinical outcomes would be highly desirable. Furthermore, healthcare leaders are increasingly reliant on healthcare system research findings in making business decisions and developing organizational policies to enhance the quality and efficiency of care.^[16] Therefore, improvement in the capacity to effectively and efficiently deliver stroke care is important and should be welcomed by health service providers.

The study is limited by its small sample size, but the logistics of this type of health service management study has made a larger scale study difficult, if not impossible. The difficulties are in part due to the logistical problems of establishing two care pathways (CSC alongside a TSC) and in part due to our requirement of simultaneous bed availability in both arms at the point of randomization. The small sample size might also have limited power in detecting differences in outcomes for LOS and change in FIM scores. On the positive side, the two patient groups in this study were well matched at baseline for demographics, stroke severity, and medical co-morbidities, which helped to minimize the potential for bias. Our study has found CSC to be similar to TSC in effectiveness in terms of clinical rehabilitation outcomes and more importantly, associates with a significant 95% improvement in FIM efficiency, an

international benchmark for measuring the performance of a rehabilitation service. This proof-of-concept study has shown that it is feasible to admit stroke patients very early (within 24 – 48 hours) into a previously designated rehabilitation environment and efficiently provide combined acute and rehabilitation care within the one co-located site.^[6-7,9]

Despite not reaching statistical significance, the advantage of an overall 5.28 days reduction in LOS in the CSC arm of our study is similar to previous studies showing a 7 – 14 days reduction in LOS when CSCs were compared to other dedicated models of stroke units and this difference is clinically important.^[6-7,9,17] Our study did not achieve the ideal CSC pathway for the majority of patients, namely the direct admission into a co-located acute and rehabilitation setting and therefore the very early commencement of rehabilitation on Day 1 (due to logistical reasons), and this delay may have made the overall rate of gain in functional improvement less marked than could be expected. This was borne out by the post hoc analysis of FIM efficiency versus acute LOS spent in ASU (Figure 2). Other potential benefits of an ideal CSC path that were not tested in our study included avoidance of duplication of admission or burden of communication (with no requirement for second admission, transfer of notes or discharge summaries) and familiarization of the same patient by the same multidisciplinary team (medical, nursing and allied health staff) as well as the continuity of care (same multidisciplinary team from acute care to rehabilitation).

Patients with moderate stroke severity seemed to benefit most in CSC path whereas mild or very severe stroke patients benefited less. This finding is consistent with other studies that have examined stroke rehabilitation outcomes.^[18-19] This has significant health economic implications because patients with moderate stroke severity constitute the majority of patients requiring rehabilitation.^[6-7] The present study also found a strong inverse correlation between

LOS spent in acute stroke unit and FIM efficiency, which suggests that the earlier the patients are given the opportunity to commence rehabilitation, the faster they may achieve a functional status allowing them to be safely discharged home. The finding that an early mobilization is beneficial has been echoed in another recent study.^[20] It is worth emphasizing that a CSC model would embrace early mobilization as well as an early start of other elements of rehabilitation such as self-care training and discharge planning. From a health economics perspective, any gain in total LOS may translate into a faster turnover for rehabilitation patients and lessen the possibility of patients experiencing bed block or a delay in accessing a rehabilitation bed. The possible continuation of functional improvement for up to three months poststroke achieved by early rehabilitation^[21-22] may be explained by early gain in neuroplasticity but warrants further exploration. Finally, less change in unfamiliar environments as in CSC model may reduce the likelihood of delirium in elderly stroke patients which is associated with worse outcomes^[23] and may potentially prove a setback in rehabilitation.

Our study and its results await reproduction in independent populations of larger size. If validated externally, the successful implementation of CSC will require the cooperation and support of all stakeholders, including medical administration, as well as retraining of staff including nursing staff. We hope that this paper can generate further discussion and research in health service management of stroke in a positive fashion that will ultimately bring benefit and improved efficiency to the care of stroke patients.

Table 1 Baseline characteristics of the Patients

Characteristic	TSC	CSC
Mean age (yrs)	72.6±14.1	73.5±9.9
Gender		
<i>Male</i>	12 (57.1)	11 (55.0)
<i>Female</i>	9 (42.9)	9 (45.0)
Smoking		
<i>Never smoked</i>	14 (66.7)	12 (60.0)
<i>Ex-smoker</i>	2 (9.5)	4 (20.0)
<i>Current smoker</i>	5 (23.8)	4 (20.0)
Drinking		
<i>Never</i>	6 (28.6)	8 (40.0)
<i>Light</i>	10 (47.6)	8 (40.0)
<i>Heavy</i>	5 (23.8)	4 (20.0)
Hypertension		
<i>No History</i>	4 (19.0)	5 (25.0)
<i>Untreated</i>	1 (4.8)	1 (5.0)
<i>Mono- / combined drug treatment</i>	16 (76.2)	14 (70.0)
Diabetes mellitus		
<i>No History</i>	16 (76.2)	15 (75.0)
<i>Untreated</i>	0 (0)	0 (0)
<i>Dietary / Oral / Insulin treatment</i>	5 (23.8)	5 (25.0)
Hypercholesterolemia		
<i>Never tested / No history (Chol < 5 mmol/l)</i>	9 (42.9)	6 (30.0)
<i>Untreated (Chol > 5 mmol/l)</i>	0 (0)	0 (0)
<i>Dietary / Drug treatment</i>	12 (57.1)	14 (70.0)
Atrial Fibrillation		
<i>History of Atrial fibrillation</i>	3 (14.3)	3 (15.0)
<i>On warfarin</i>	1 (4.8)	2 (10.0)
<i>Not on warfarin</i>	2 (9.5)	1 (5.0)
Ischaemic heart disease	4 (19.0)	5 (25.0)
Left ventricular failure	2 (9.5)	2 (10.0)
Valvular heart disease	2 (9.5)	1 (5.0)
Peripheral vascular disease	0 (0)	0 (0)
Family history of cerebrovascular disease	4 (19.0)	7 (35.0)

Data are shown as numbers of patients, with percentages of total in parentheses, except age was shown as mean ± SD. There were no significant differences in baseline characteristics between the CSC arm and TSC arm. CSC, comprehensive stroke care; TSC, traditional stroke care

Table 2 Summary of clinical data of patients

Features	TSC	CSC	p Value
SSS	37.4±13.9	34.9±12.6	0.52
mRS			
<i>Admission</i>	3.7±1.2	3.7±1.3	0.90
<i>Discharge</i>	2.3±1.2	2.1±1.1	0.64
FIM			
<i>Admission</i>	71.5±32.8	67.5±28.0	0.51
<i>Discharge</i>	99.5±27.7	103.6±22.2	0.77
90 days postdischarge	104.4±27.9	109.5±21.7	0.89

Data are shown as mean±SD

FIM, functional independence measure; mRS
modified Rankin Scale; SSS, Scandinavia
Stroke Scale

Table 3 SSS, mRS and FIM scores on admission

	Arm	SSS	mRS	FIM
Location 1	TSC1	44.1±7.4	3.6±1.2	77.3±27.7
	CSC1	39.0±15.0	3.0±1.3	72.8±34.1
Location 2	TSC2	33.7±15.4	3.7±1.2	67.8±36.0
	CSC2	32.2±10.5	4.1±1.2	64.0±24.0

Data are shown as mean ±SD, there were no significant differences in SSS, mRS and FIM scores on admission between the groups.

CSC, comprehensive stroke care; FIM, functional independence measure; mRS, modified Rankin Scale; SSS, Scandinavia Stroke Scale; TCS, traditional stroke care

Figure 1 Study Design

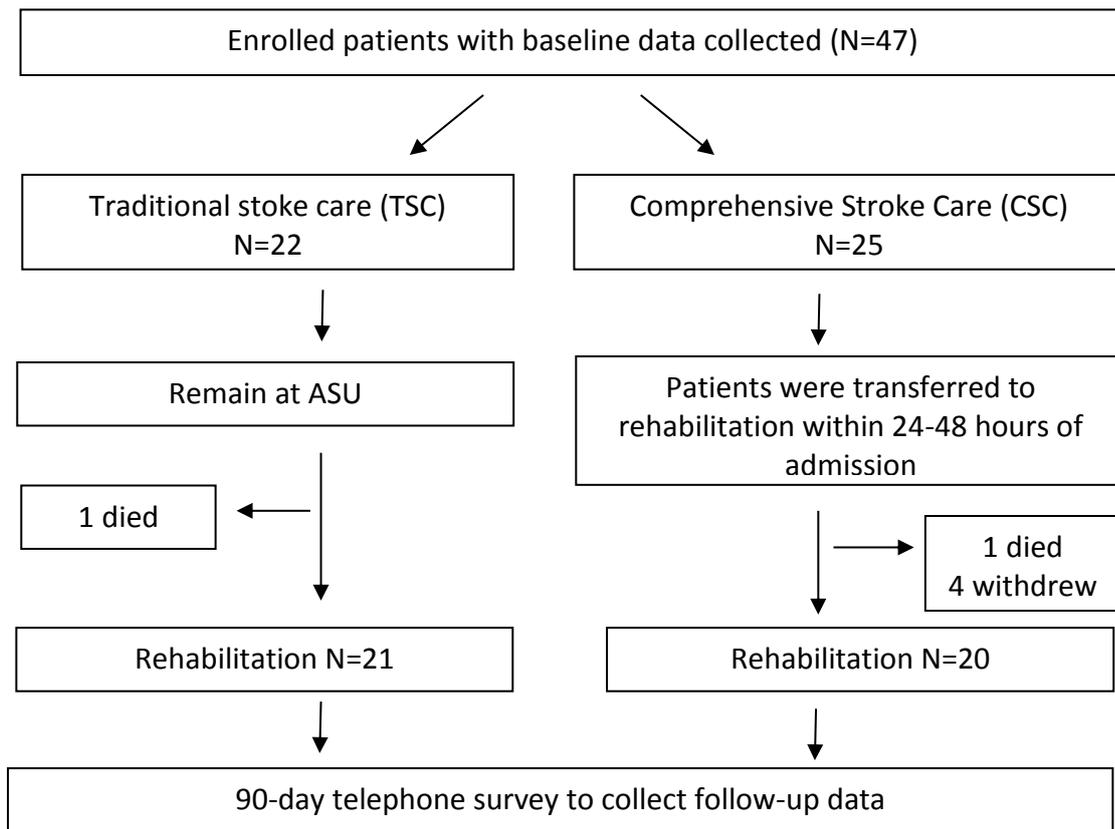


Figure 2

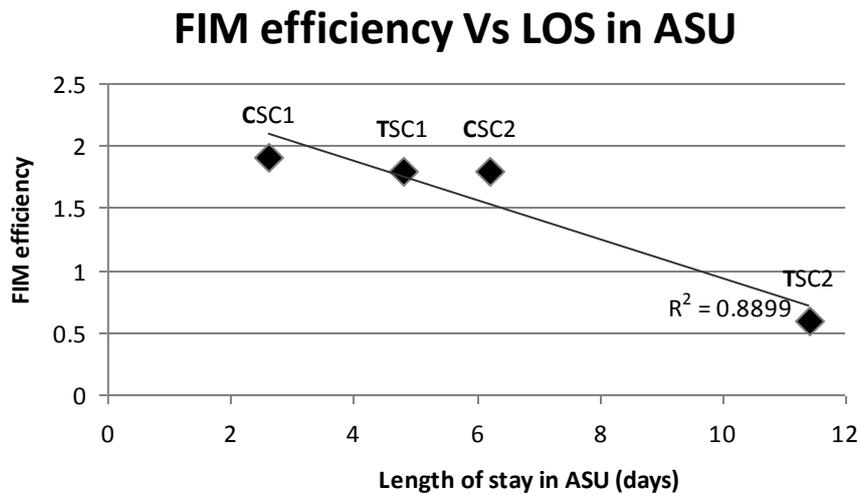


Figure 2: FIM efficiency as a function of time (length of stay in ASU) in patients from hospitals in location 1 (CSC1 & TSC1) and hospitals in location 2 (CSC2 & TSC2). ASU, acute stroke unit; CSC, comprehensive stroke care; FIM, functional independence measure; LOS, length of stay; TSC, traditional stroke care

Figure 3

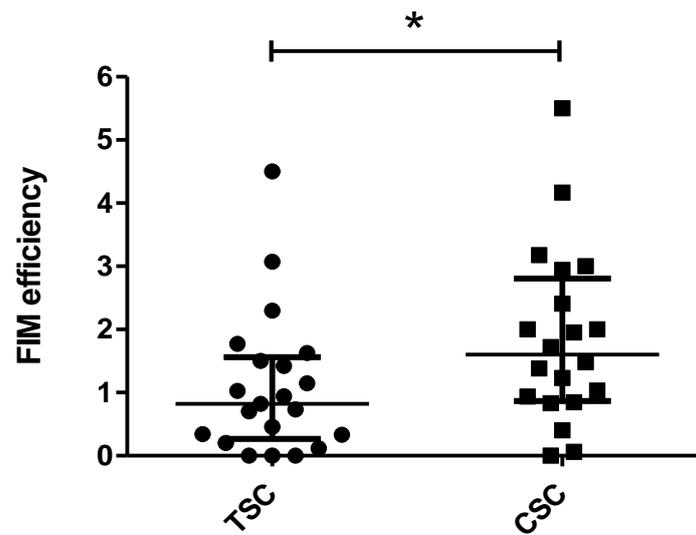


Figure 3 CSC arm demonstrated significantly higher FIM efficiency score when compared with the TSC arm. Data are shown as median with interquartile range.

* $p=0.0393$

CSC, comprehensive stroke care; FIM, functional independence measure; TSC, traditional stroke care

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