

**Research Bank**

Journal article

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**Implementation of evidence-based treatment protocols to manage fever, hyperglycaemia and swallowing dysfunction in acute stroke improves 90-day outcomes: QASC, a cluster randomised controlled trial**

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## Abstract

**Background:** We assessed patient outcomes 90 days after hospital admission for stroke following a multidisciplinary intervention targeting evidence-based management of fever, hyper glycaemia, and swallowing dysfunction in acute stroke units (ASUs).

**Methods:** In the Quality in Acute Stroke Care (QASC) study, a single-blind cluster randomised controlled trial, we randomised ASUs (clusters) in New South Wales, Australia, with immediate access to CT and on-site high dependency units, to intervention or control group. Patients were eligible if they spoke English, were aged 18 years or older, had had an ischaemic stroke or intracerebral haemorrhage, and presented within 48 h of onset of symptoms.

**Intervention:** ASUs received treatment protocols to manage fever, hyperglycaemia, and swallowing dysfunction with multidisciplinary team building workshops to address implementation barriers. Control ASUs received only an abridged version of existing guidelines. We recruited pre-intervention and post-intervention patient cohorts to compare 90-day death or dependency (modified Rankin scale [mRS]  $\geq 2$ ), functional dependency (Barthel index), and SF-36 physical and mental component summary scores. Research assistants, the statistician, and patients were masked to trial groups. All analyses were done by intention to treat. This trial is registered at the Australia New Zealand Clinical Trial Registry (ANZCTR), number ACTRN12608000563369.

**Findings:** 19 ASUs were randomly assigned to intervention (n=10) or control (n=9). Of 6564 assessed for eligibility, 1696 patients' data were obtained (687 pre-intervention; 1009 post-intervention). Results showed that, irrespective of stroke severity, intervention ASU patients were significantly less likely to be dead or dependent (mRS  $\geq 2$ ) at 90 days than control ASU patients (236 [42%] of 558 patients in the intervention group vs 259 [58%] of 449 in the control group, p=0.002; number needed to treat 6.4; adjusted absolute difference 15.7% [95%

CI 5.8–25.4]). They also had a better SF-36 mean physical component summary score (45.6 [SD 10.2] in the intervention group vs 42.5 [10.5] in the control group,  $p=0.002$ ; adjusted absolute difference 3.4 [95% CI 1.2–5.5]) but no improvement was recorded in mortality (21 [4%] of 558 in intervention group and 24 [5%] of 451 in the control group,  $p=0.36$ ), SF-36 mean mental component summary score (49.5 [10.9] in the intervention group vs 49.4 [10.6] in the control group,  $p=0.69$ ) or functional dependency (Barthel Index  $\geq 60$ : 487 [92%] of 532 patients vs 380 [90%] of 423 patients;  $p=0.44$ ).

**Interpretation:** Implementation of multidisciplinary supported evidence-based protocols initiated by nurses for the management of fever, hyperglycaemia, and swallowing, dysfunction delivers better patient outcomes after discharge from stroke units. Our findings show the possibility to augment stroke unit care.

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## **INTRODUCTION**

Although organised stroke unit care significantly reduces death and disability from cerebrovascular,<sup>1</sup> three physiological variables are not yet universally well-managed despite their importance for long-term patient recovery.<sup>2-4</sup> In the first days of an acute stroke, temperature above 37.5°C occurs in 20-50% of patients;<sup>2</sup> up to 50% of patients become hyperglycaemic;<sup>3</sup> and 37-78%<sup>4</sup> experience dysphagia; all result in increased morbidity and mortality.<sup>2-4</sup> Hence, international guidelines recommend that fever and elevated blood glucose levels be monitored and managed proactively and that every stroke patient has their swallowing status evaluated before receiving food, fluid or oral medication.<sup>5,6</sup> All these recommendations are the responsibility of the stroke multidisciplinary team.<sup>7</sup> Care is not always consistent with these recommendations however.<sup>6,8</sup> We designed the Quality in Acute Stroke Care (QASC) study, a cluster randomised controlled trial (CRCT),<sup>9,10</sup> to evaluate the effect on 90-day post-stroke patient outcomes of multidisciplinary team building workshops and a standardised interactive education program to implement evidence-based treatment protocols for the management of fever, hyperglycaemia and swallowing dysfunction. These three parameters were selected because they involve multidisciplinary teamwork, which has been demonstrated to improve healthcare processes and patient outcomes,<sup>11</sup> a priority for stroke care.

## **METHOD**

Our single blind CRCT design randomised Acute Stroke Units (ASUs) to minimise contamination because our team building intervention was designed for implementation at the ASU level.<sup>12</sup> Pre-and post-intervention outcomes were assessed at the patient level. The trial protocol previously has been published.<sup>9</sup>

## **Participants**

ASUs eligible to participate were those located in large, tertiary referral centres in New South Wales (NSW), Australia who provided care for stroke patients in a geographically defined location with immediate CT access and on-site high dependency units (Australian National Stroke Unit Program Category A or B) (n=20). Category A ASUs have access to on-site neurosurgery while Category B do not.<sup>13</sup> Patients were eligible if they: spoke English, were aged over 18 years, had a diagnosis of ischaemic stroke or intracerebral haemorrhage and presented within 48 hours of onset of symptoms to a participating ASU. Patients were excluded if they did not have a telephone or were admitted for palliative care.

### ***Pre-intervention patient cohort***

Prior to randomisation, a pre-intervention patient cohort was recruited (August 2005 to October 2007) to provide a baseline sample prior to implementation of the intervention. Patients consented to medical record access and to participation in a telephone survey 90-days following hospital admission.

### ***Post-intervention patient cohort***

Using identical procedures and instruments, a second post-intervention patient cohort was recruited (February 2008 to August 2010) to provide a follow-up sample after intervention implementation.

## **Outcome Measures**

All outcome measures pertained to the level of the individual (patient) and all used tools previously validated for telephone administration.<sup>14-16</sup>

### ***Primary outcomes: 90 days post-hospital admission***

1. death or dependency (dependency: modified Rankin Scale (mRS)  $\geq 2$ )<sup>17</sup>
2. functional dependency [Barthel Index (BI)]<sup>18</sup>
3. mean SF-36 mental component summary (MCS) score<sup>19</sup>
4. mean physical component summary (PCS) score<sup>19</sup>

We also undertook subgroup analyses by stroke severity.

#### *Secondary outcomes: Processes of care*

1. mean temperature for the first 72 hours following ASU admission
2. mean finger-prick blood glucose level for the first 72 hours following ASU admission
3. proportion with swallowing screening undertaken within the first 24 hours of ASU admission
4. discharge diagnosis of aspiration pneumonia (ICD 10)
5. length of hospital stay

#### **Data Collection**

##### *90-day patient outcome instrument*

An independent organisation was contracted to conduct Computer Assisted Telephone Interviews (CATIs) with patients 90-days following hospital admission. The two interviewers underwent on-line training and competency assessment for mRS administration.

##### *Processes of Care*

Blinded retrospective medical record audits were undertaken using data documented prospectively. Four auditors collected: age; sex; stroke sub-type (Oxfordshire Community Stroke Project classification);<sup>20</sup> time from onset of symptoms to ASU presentation; stroke severity (Los Angeles Motor Scale (LAMS)),<sup>21</sup> administration of thrombolysis; all temperature and blood glucose levels within the first 72 hours of admission to an ASU;



swallowing screening performed within the first 24 hours of ASU admission; and discharge diagnosis of aspiration pneumonia. Auditors attended a 2-day training program. Two auditors abstracted data from 95% of medical records, enabling clarification of uncertainties. For quality assurance purposes, for the first 700 audits, 10% were re-audited with agreement occurring 95% of the time.

### **Randomisation**

ASUs were stratified (Category A or B) and then by absolute numbers of pre-intervention cohort patients recruited. 'High' recruiters had consented more than two patients per month; 'low' recruiters two or fewer per month. De-identified stratification details were provided to an independent statistician who used random number generating software to randomise within strata with allocation concealed until provided to the Project Officer who assigned ASUs to their groups. Clinical Research Assistants blind to trial design enrolled patients. Patients were blind to ASU group allocation but not clinicians delivering our intervention. Research assistants who undertook the CATIs and the medical record audits were blind to trial aims, design and group allocation; the trial statistician was blind to group allocation.

### **Intervention**

Our **Fever, Sugar, Swallowing (FeSS)** intervention targeted all ASU clinicians, focusing on barrier identification,<sup>22</sup> reinforcement of multidisciplinary teamwork,<sup>23</sup> local adaptation<sup>24</sup> and use of site champions.<sup>25</sup> Using recommendations from Australia's national clinical guidelines for stroke,<sup>6</sup> panels of experts developed clinical treatment protocols for management of fever, hyperglycaemia and swallowing for the first 72 hours following ASU admission (Box 1). We aimed to trigger prompt nursing assessment and bedside treatment. Specifically, two teambuilding workshops were conducted to identify local barriers to multidisciplinary care<sup>22</sup>

and enablers to implementation of the nurse-initiated treatment protocols. Two additional site-based interactive and didactic educational outreach meetings,<sup>26, 27</sup> then were conducted for clinicians to discuss the protocols. On-going activities comprised reminders,<sup>28</sup> site visits, telephone and email support (Box 1). Protocols and further information about implementation of the intervention are available at [www.acu.edu.au/qasc](http://www.acu.edu.au/qasc).

Control group ASUs received only an abridged version of existing guidelines.<sup>29</sup>

The intervention ran from May 2007 to August 2010. Following implementation, we allowed a three month 'bedding down' period prior to recruitment of the post-intervention cohort.

### **Data Analysis**

Intention-to-treat analyses were undertaken using SAS v9.2 software. The Barthel Index is usually reported as a dichotomized variable but the cut points vary; we report both  $BI \geq 60$  and  $BI \geq 95$ , the two most conventionally reported cut points in order to allow for comparison with published data.<sup>18</sup> Continuous and categorical data were summarised using conventional descriptive statistics. All outcomes including the sub-group analyses were adjusted for pre-intervention levels and for clustering within ASUs, using a logistic regression model fitted within a generalised estimating equation framework for dichotomous outcomes and a random intercept linear regression model for continuous outcomes. The linear and logistic models included the predictor variables of period (before and after), intervention and the interaction between period and intervention. The P-value from the Wald test for the interaction term was used to determine if the pre-post change in the intervention group was statistically different to

the change in the control group. The confidence intervals reported are those for the interaction term from the logistic or linear model but to obtain estimates of absolute difference, the models for dichotomous outcomes were refit using an identity link function. P-values for the interaction term from these models were almost identical to the logistic models.. In order to control the type 1 error rate from the four primary outcome measures, our Alpha level was set at 0.0125.

We calculated each patient's mean temperature and blood glucose levels for the first 72 hours of their admission to the ASU and, using these, then determined a mean intervention and control ASU temperature and glucose level. Three elements were required to meet the criteria for swallowing screening, namely, assessment of level of consciousness; cranial nerve assessment; and water swallow test.

### **Sample Size**

There were 19 clusters with a mean cluster size of 39 consenting patients in the pre-intervention cohort (median 31; minimum 10, maximum 83). In the post-intervention cohort the mean cluster size was 59 consenting patients (median 58; minimum: 13, maximum 145). We achieved our desired sample size consistent with our earlier statistical assumptions.<sup>9</sup>

This trial was approved by the Human Research Ethics Committee of Australian Catholic University and the relevant ethics committees of all participating hospitals. The trial was governed by a Steering Committee comprising all investigators and an Expert Advisory Committee comprising independent researchers and stroke clinicians.

## **RESULTS**

Nineteen (95%) ASUs agreed to participate. Figure 1 represents cluster and participants' flow over the course of the trial.

### **Pre-Intervention Data**

Data for the pre-intervention patient cohort have been published.<sup>10</sup> Age, sex, 90-day death, 90-day death and dependency, 90-day functional dependency (BI) and health status (PCS score and MCS score) were similar for the intervention and control groups.

### **Post-Intervention Cohort**

Of the 1292 eligible patients, 166 (13%) declined to participate [intervention: n=81 (11%); control: n=85 (15%)], resulting in 1126 (87%) consenting patients. Patients who agreed to participate were similar to those who did not consent in terms of age ( $P=0.14$ ) and sex ( $P=0.19$ ). There were no significant differences between consenting patients who provided full 90-day data and those who subsequently declined; 10% of patients were lost to follow-up or withdrew (n=117) [intervention: n=68 (11%); control: n=49 (9.8%)]. There was no difference between the number of patients who provided 90-day data and the number of relatives who provided 90-day proxy data [intervention: n=433 (81%); control: n=325 (76%),  $P=0.236$ ]. Age, sex, pre-morbid level of dependency (mRS), stroke location, stroke severity, and time between onset of stroke symptoms and arrival at ASU were similar for patients in the intervention and control groups although fulltime employment appeared slightly lower in the control group. (Table 1). Only 7% (n=77) received thrombolysis and the majority of these were in the control group (n=60, 78%).

### **90-day Outcomes**

After adjusting for baseline levels, patients from intervention ASUs were significantly less likely to be dead or dependent at 90-days (mRS  $\geq 2$ ) than patients from control ASUs (n=236 42% vs n=259, 58%, P=0.002) (Figure 2) (number needed to treat (NNT) approximately 6.4; adjusted absolute difference: 15.7% (95% CI: 5.8 to 25.4). There was no significant difference in 90-day mortality between patients from intervention and control ASUs (n=21, 3.8% vs n=24, 5.3%, P=0.36) nor for functional dependency where BI  $\geq 60$  (intervention n=487, 92% vs control n=380 90%, P=0.44) or BI  $\geq 95$  (intervention n=367 69% vs control n=254 60%, P=0.07) (Table 2).

Patients from intervention ASUs were significantly more likely to have better SF-36 physical health scores indicating improved physical functioning (mean PCS score 45.6 vs 42.5, P=0.002) (adjusted absolute difference 3.4 (95% CI: 1.2 to 5.5)) but there were no significant differences for mental health (mean MCS score 49.5 vs 49.4, P=0.69) (Table 2).

Our exploratory sub-group analyses by stroke severity demonstrated that patients with a mild stroke (LAMS = 0) from intervention ASUs were significantly less likely to be dead or dependent at 90-days (mRS  $\geq 2$ ) (n=56) than those from control ASUs (n=71) (25% vs 39%, P=0.02) and reported better physical health (PCS score mean 48.3 vs 45.0; p=0.008) than those from control ASUs. Similarly, patients with a more severe stroke (LAMS  $\geq 1$ ) from intervention group ASUs were significantly less likely to be dead or dependent at 90 days (mRS  $\geq 2$ ) (n=178) than those from control ASUs (n=181) (54% vs 70%, P=0.04) and had better physical health (PCS score mean 43.6 vs 40.8; p=0.04) than patients from control ASUs. Further, intervention ASU patients with more severe strokes (n=17) were also less likely to have died at 90-days than patients from control ASUs (n=23) (5.2% vs 8.8%, P $\leq$ 0.001).

## Processes of Care

Medical records were unavailable for 40 patients (3.6%) resulting in collection of processes of care data for 1086 patients (intervention: n=603; control: n=483) (Table 3). Patients in intervention ASUs had a significantly lower mean temperature during the first 72 hours of admission to the ASU (36.5°C vs 36.6°C, P=0.001) compared with patients in the control ASUs. Post-hoc explanatory analyses demonstrated a statistically significant reduction in the number of patients from intervention ASUs who had at least one high ( $\geq 37.5^\circ\text{C}$ ) temperature (n=105, 17% vs n=131, 27%, P<0.001). In addition, patients from intervention ASUs had significantly lower mean blood glucose levels during the first 72 hours following ASU admission (6.8 mmol/L versus 7.0 mmol/L, P=0.02). Patients in intervention ASUs were significantly more likely to receive a swallowing screen within the first 24 hours of ASU admission (n=242) compared with patients in the control group (n=24) (46% vs 7%, P<0.001) (Table 3). There were no differences between aspiration pneumonia rates between groups [n=13, 2.2% vs n=13, 2.7%, P=0.82]. The mean (SD) length of hospital stay was 11.3 (10.3) days for patients from intervention ASUs and 13.7 (12.7) days for patients from control ASUs (P=0.14).

## Discussion

Our results demonstrate that patients of ASUs allocated to receive our multidisciplinary intervention to support proactive evidence-based management of fever, hyperglycaemia and swallowing were significantly more likely to be alive and less dependent at 90-days post-admission. Specifically, we found a 15.7% adjusted absolute difference in rates of 90 day death and dependency. The clinical significance of these results is more remarkable when

compared against other established clinical and organisational interventions, namely administration of aspirin within 48 hours,<sup>30</sup> stroke unit care<sup>1</sup> and thrombolysis within 4.5 hours.<sup>31</sup> All deliver absolute benefit for independent survival of no more than 10%; all have higher NNT (aspirin NNT:79<sup>30</sup>; stroke unit NNT: 18<sup>1</sup>; thrombolysis: NNT: 8<sup>32</sup> to 14<sup>31</sup> depending on onset to treatment time) than our intervention to realise a benefit, with tPA available only to a very specific ischaemic stroke population, unlike our intervention which has relevance for all stroke patients. Hence, the 15.7% improvement and NNT of 6.4 seen with our FeSS intervention will be of immediate importance for clinicians, patients and their carers.

Furthermore, our data show that patients from ASUs who received our intervention also had significantly improved processes of care. The mean temperature decreased significantly by 0.1 (from 36.6°C to 36.5°C) in intervention ASU patients and, while this small difference occurred within the afebrile temperature range, our analyses incorporated all patients including those who never had a fever, making this change all the more potentially important. That there were fewer patients with a fever in the intervention group also is of interest, possibly due to improved observation and early intervention. The mean glucose level also significantly decreased in patients receiving care in intervention ASUs (7.02 to 6.81 mmol/L), demonstrating the positive effect of our intervention on glucose management.

Although the proportion of swallowing screenings attended was significantly higher in patients from intervention ASUs when compared with patients from control group ASUs, the absolute performance appears low. We used very conservative screening criteria, however, and intentionally did not capture screening occurring outside the ASU, nor swallowing assessments that could also have had a screening component occurring within 24 hrs of

admission. Although not shown to be significant, the promise of reduced length of stay also could represent substantial savings for hospitals.

Despite being implemented with multidisciplinary support from physicians, speech pathologists and nurses, our clinical protocols were delivered by bed-side nurses. Protocolled care enabled nurses to be proactive in their management of fever, hyperglycaemia and swallowing. Role delineation within multidisciplinary teams has clear benefit for patients, ensuring that critical physiological parameters are monitored and managed. We are confident that future behaviour change interventions could still further raise the quality of care received by stroke patients in Australian hospitals. Replicability of our intervention would enable wider implementation in other ASUs with clinical leadership and change management provided by stroke networks and non-government organisations such as stroke charities.

On a methodological note, we achieved excellent engagement (19 out of the 20 NSW ASUs), also recruiting large cohorts of patients with a modest rate of loss-to-follow-up (10%, n=117). Of note, our death and dependency results remained significant ( $P=0.004$ ) when a sensitivity analysis was undertaken where we assumed all patients lost to follow-up were dead or disabled ( $mRS \geq 2$ ). Our extension of the data endpoints to encompass both 90-day patient outcomes and processes of care is exceptional in stroke research and we encourage similar scope in future studies.

Similar to many acute stroke studies,<sup>33</sup> our study was limited in that patients with severe strokes were under-represented. This under-representation was probably due to our deliberate exclusion of patients with severe stroke who were for palliation only. Exclusion of these patients also may account for the non-significant differences between groups in



functional dependency and mortality. However, our sub-group analyses showed significant improvements for death and dependency outcomes for both mild and severe strokes in our intervention group (14% in the mild stroke cohort and 16% in the more severe stroke cohort) showing a clear benefit for both mild and more severe strokes.

Other opportunities to improve patient outcomes have emerged. Prompt recognition of stroke in emergency departments and better triage are crucial for those eligible for thrombolysis and if new treatments such as the FeSS intervention<sup>34</sup> or early rehabilitation<sup>35</sup> are to be started, then timely admission to an ASU is imperative. As our intervention focussed on care of patients admitted to ASUs, our findings are not necessarily generalisable to stroke patients cared for in general medical wards. They also are only generalisable to patients admitted to ASUs within 48 hours of symptom onset and who receive the protocol-led care for the first 72 hours following admission to an ASU. Because access to a stroke unit for all stroke patients is not always achievable and delays often occur, we recommend future trials to examine the effect of similar multidisciplinary interventions in general wards and emergency departments.

Our trial provides compelling evidence that better management of fever, hyperglycaemia and swallowing in acute stroke patients during the initial 72 hours of admission to an ASU can result in decreased rates of death, dependency and improved processes of care. Furthermore, ours is one of the few to clearly show the effect of good nursing care on death and dependency. Additionally, it is one of the first implementation trials in acute stroke to harness the stroke unit network in Australia. To our knowledge, it also is one of the largest multidisciplinary rigorously evaluated interventions in acute stroke. The importance of our intervention lies in its ability to augment the benefits of stroke unit care. Further research as to its potential to

benefit stroke patients unable to access immediate stroke unit care and also its value for populations other than stroke is warranted.

### **Conflicts of Interest**

There were no conflicts of interest. None of our funding sources were involved in the writing of the manuscript or the decision to submit the manuscript for publication.

### **Contributions**

SM, as chief investigator conceived, designed, obtained funding, supervised the study and wrote the first draft of manuscript; CL, JW, JG, RG, CDE, NWC, CL, ME, DC & CQ helped conceive, design and obtain funding for the study; SD coordinated the study and supervised data collection; PD assisted with data collection; SM, CDE, PM, JG, CL, SD, PD assisted with data analyses; SM, CDE and PM had complete access to the data. SM, JW, JG, CDE, PM, NWC and CL assisted with data interpretation. All authors contributed to subsequent versions of the manuscript and had responsibility for the decision to submit the manuscript.

## **Research in Context**

### ***Systematic review***

In the first days of an acute stroke, temperature above 37.5°C occurs in 20-50% of patients; up to 68% of patients become hyperglycaemic; and 37% to 78% experience dysphagia, resulting in increased morbidity and mortality and enlarged infarct size. We searched MEDLINE and CINAHL databases using the search term 'stroke' (all inclusive) combined with: 'fever'; 'pyrexia'; 'hyperthermia'; 'hyperglycaemia'; and 'glucose' and determined there were no systematic reviews of treatments to effectively manage either physiological parameter. Similarly, we also combined the term 'stroke' with 'dysphagia'; 'swallow/ deglutition'; and 'swallowing disorders/ deglutition disorders'. Evidence from a systematic review demonstrated that stroke patients with dysphagia are at risk of pneumonia and that this risk is higher in patients who aspirate. Use of a formal dysphagia screen can decrease the risk of pneumonia. In addition, no studies have examined the combined effect of systematic management of fever, hyperglycaemia or swallowing. International guidelines recommend monitoring and prompt treatment of these three variables. There is no 'magic bullet', however, with which to change bedside care and ensure multidisciplinary teams comply with evidence-based clinical practice guidelines. Systematic reviews of strategies with this goal in mind persistently argue that more implementation research is needed to identify effective strategies and to ensure resources are not wasted on activities of questionable value. In response, our research tested a multidisciplinary intervention designed to raise standards of care in acute stroke units using a cluster randomised controlled trial. Barrier identification, educational meetings, use of local opinion leaders and reminders have shown promise in earlier studies in diverse clinical settings and we incorporated these elements in our intervention and evaluated long-term patient outcomes of 90-day death and dependency. We also examined processes of care.

### ***Interpretation***

The QASC trial provides high-quality evidence that a guideline implementation strategy to support multidisciplinary team work focussed on evidence-based management of three key physiological parameters delivers significantly better post-discharge outcomes for stroke patients. Clinical leaders of stroke services can adopt this strategy with confidence that their outcomes will improve.

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**Table 1: Demographic and Clinical Characteristics of the Post-intervention Cohort**

Variable	Statistic/Category	Group	
		Control (n=500)	Intervention (n=626)
Age group	<65	137 (28%)	195 (31%)
	65 to <75	130 (26%)	150 (24%)
	75 to <85	158 (32%)	181 (29%)
	85+	73 (15%)	99 (16%)
Gender	Male	298 (60%)	376 (60%)
	Female	202 (40%)	250 (40%)
Oxfordshire Stroke Classification Project (OCSF) <sup>†</sup>	Total Anterior Circulation Infarct	27 (9.1%)	42 (7.2%)
	Partial Anterior Circulation Infarct	121 (41%)	298 (51%)
	Lacunar Infarct	82 (28%)	93 (16%)
	Posterior Circulation Infarct	54 (18%)	113 (19%)
	Intracerebral Haemorrhage	12 (4.1%)	39 (6.7%)
Los Angeles Motor Scale	0 (mild stroke)	203 (41%)	262 (42%)
	≥1 (more severe stroke)	290 (59%)	360 (58%)
Aborigine or Torres Strait Islander	Yes	6 (1.4%)	5 (0.9%)
Marital Status	Never married	20 (4.7%)	41 (7.7%)
	Married	269 (63%)	323 (60%)
	Widowed/Divorced/Separated	136 (32%)	171 (32%)
Highest level of education	No school certificate	145 (34%)	130 (25%)
	School Certificate	177 (42%)	187 (35%)
	Higher School Certificate	43 (10%)	93 (18%)
	University/TAFE/College	59 (14%)	119 (22%)
Employment status	Retired	297 (70%)	357 (67%)
	Employed full-time	28 (6.6%)	74 (14%)
	Permanently unable to work or ill	60 (14%)	43 (8.0%)
	Employed part-time or casual	18 (4.2%)	46 (8.6%)
	Unemployed/Home duties/Volunteer work/Student	22 (5.2%)	15 (2.8%)
Premorbid mRS	No symptoms at all	376 (88%)	477 (89%)
	No significant disability despite symptoms	18 (4.2%)	18 (3.4%)
	Slight disability	18 (4.2%)	22 (4.1%)
	Moderate disability	11 (2.6%)	18 (3.4%)
	Moderately severe disability	2 (0.5%)	2 (0.4%)
Time from onset of symptoms to ASU (mins)	Mean (SD)	826 (701)	953 (648)

<sup>†</sup> P-values are adjusted for clustering within ASU



**Table 2: Primary Outcomes: Number (%) or mean (SD) 90-day post-hospital admission**

Outcome (ICC <sup>^</sup> )	Group		P <sup>†</sup>	Difference in absolute change (95% CI)
	Control (n=451)	Intervention (n=558)		
Death and dependency (mRS $\geq$ 2) (0.018)	259 (58%)	236 (42%)	0.002	15.7% (5.8% to 25.4%)
Barthel Index				
BI $\geq$ 95 (0.015)	254 (60%)	367 (69%)	0.07	9.5% (-0.5% to 19.5%)
BI $\geq$ 60 (0.009)	380 (90%)	487 (92%)	0.44	2.5% (-3.6% to 8.6%)
SF-36 Physical health (PCS score) (0.026)	42.5 (10.5)	45.6 (10.2)	0.002	3.4 (1.2 to 5.5)
SF-36 Mental health (MCS score) (0.011)	49.4 (10.6)	49.5 (10.9)	0.69	0.5 (-1.9 to 2.8)

<sup>†</sup> P-values are for the interaction term between intervention group and time period (pre or post intervention) and adjusted for clustering within ASU

<sup>^</sup> Intra-cluster correlation co-efficient (ICC)

**Table 3: Secondary Outcomes: Processes of care measures for fever, glucose and swallowing screening**

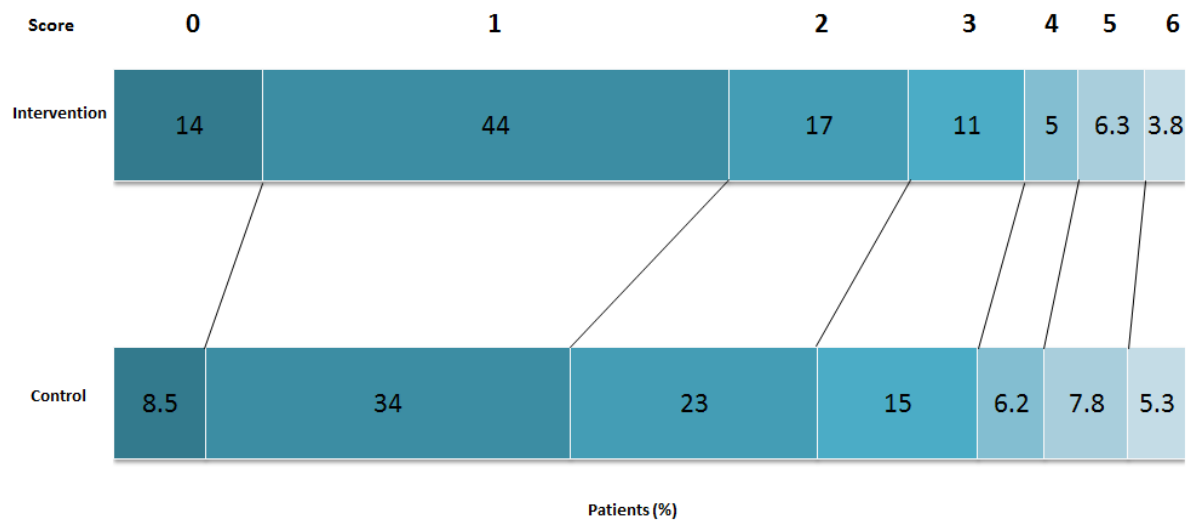
Outcome (ICC <sup>^</sup> )	Statistic	Group		P <sup>†</sup>	Difference in absolute change (95% CI)
		Control (n=483)	Intervention (n=603)		
<b>Fever</b>					
Mean temperature during first 72 hours in ASU (0.084)	mean (SD)	36.6 (0.30)	36.5 (0.27)	0.001	0.09 (0.04 to 0.15)
At least one temperature $\geq 37.5^{\circ}\text{C}$ in first 72 hours (0.009)	n (%)	131 (27%)	105 (17%)	<0.001	16.4% (8.3 to 24.6)
<b>Glucose</b>					
Mean glucose level during first 72 hours in ASU (0.056)	mean (SD)	7.0 (2.0)	6.8 (1.8)	0.02	0.54 (0.08 to 1.01)
<b>Swallowing Screening</b>					
Swallowing screening within 24 hours of admission to ASU (0.156) <sup>#</sup>	n (%)	24/350 (7%)	242/522 (46%)	<0.001	29.2% (22.0% to 36.4%)
<b>Length of hospital stay (days)</b>	Mean (SD)	13.7 (12.7)	11.3 (10.3)	0.144	1.5 (-0.5 to 3.5)

<sup>†</sup> P-values are for the interaction term between intervention group and time period (pre or post intervention) and are adjusted for clustering within ASUs

<sup>^</sup> Intra-cluster correlation co-efficient (ICC)

<sup>#</sup> excludes those screened in ED

**Figure 2: Distribution of 90-day modified Rankin Scale\***



\* % may not total to 100% due to rounding

### Box 1: Fever, Sugar, Swallowing (FeSS) Intervention Elements<sup>^</sup>

#### 1. Clinical treatment protocols for FeSS management by nurses for first 72 hours of ASU care: key elements

##### *Fever*

1. Temperature monitored & charted 4 hourly for 72 hours following admission to ASU.
2. Temperature  $\geq 37.5^{\circ}\text{C}$  treated with paracetamol (IV, PR or oral), unless clinically contraindicated.

##### *Sugar (Hyperglycaemia)*

1. Formal glucose measured (venous blood not finger prick) on admission to hospital or admission to the ASU.
2. 1-6 hourly fingerprick blood glucose levels for 72 hours following admission depending on previous blood glucose level.
3. On admission, if blood glucose level between 8 and 16 commence saline infusion.  
If blood glucose level  $> 11$  and known diabetic, commence insulin.  
If blood glucose level  $> 16$  and not a diabetic, commence insulin.
4. If blood glucose level  $> 11$  at any time in first 72 hours following admission, commence insulin.

##### *Swallowing*

1. Nurses underwent dysphagia screening education program, which consisted of all nurses attending an in-service administered by the speech pathologist using a DVD prepared specifically for this study.
2. Nurses underwent a competency assessment before being able to screen patients, consisting of an assessment of clinical knowledge tool, a written test and a clinical competency tool which had to be completed on three patients and was assessed by a Speech Pathologist.
3. Patients were screened using the ASSIST tool by either a nurse who passed the competency test or a Speech Pathologist within 24 hrs of admission to ASU; this then was clearly documented in the patient's medical record by use of a sticker.
4. Patients who failed the swallowing screening were referred to a Speech Pathologist for a swallowing assessment.

#### 2. Site-based education and support

1. Two multidisciplinary teambuilding workshops to identify local barriers and enablers to implementation of the FeSS nurse-initiated treatment protocols.
2. Two site-based educational outreach meetings consisting of a standardised education program about the FeSS treatment protocols delivered by the Project Officer (SD); Powerpoint slides then left with ASU Nurse Educator to deliver to those staff who did not attend.
3. Engagement of local stroke unit co-ordinators through support and feedback. The Project Officer visited each intervention ASU every six weeks. The Project Officer sent three monthly proactive emails to each site and also instigated scheduled telephone follow-up every three months. She also responded to any site-based request for support as needed. Newsletters were sent out yearly.

#### Key:

ASU: Acute stroke unit

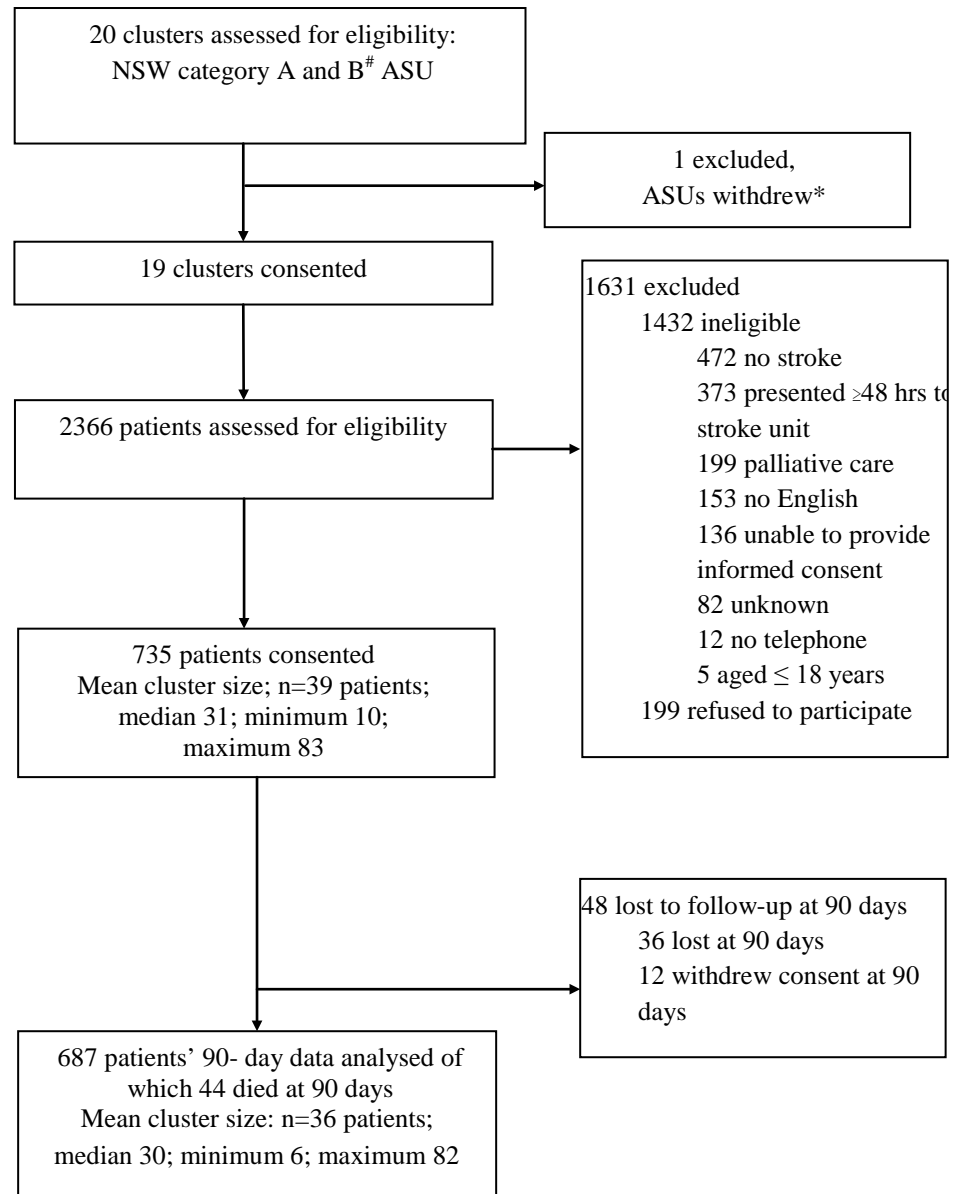
IV: Intravenous

PR: Per rectum

DVD: Digital video disc

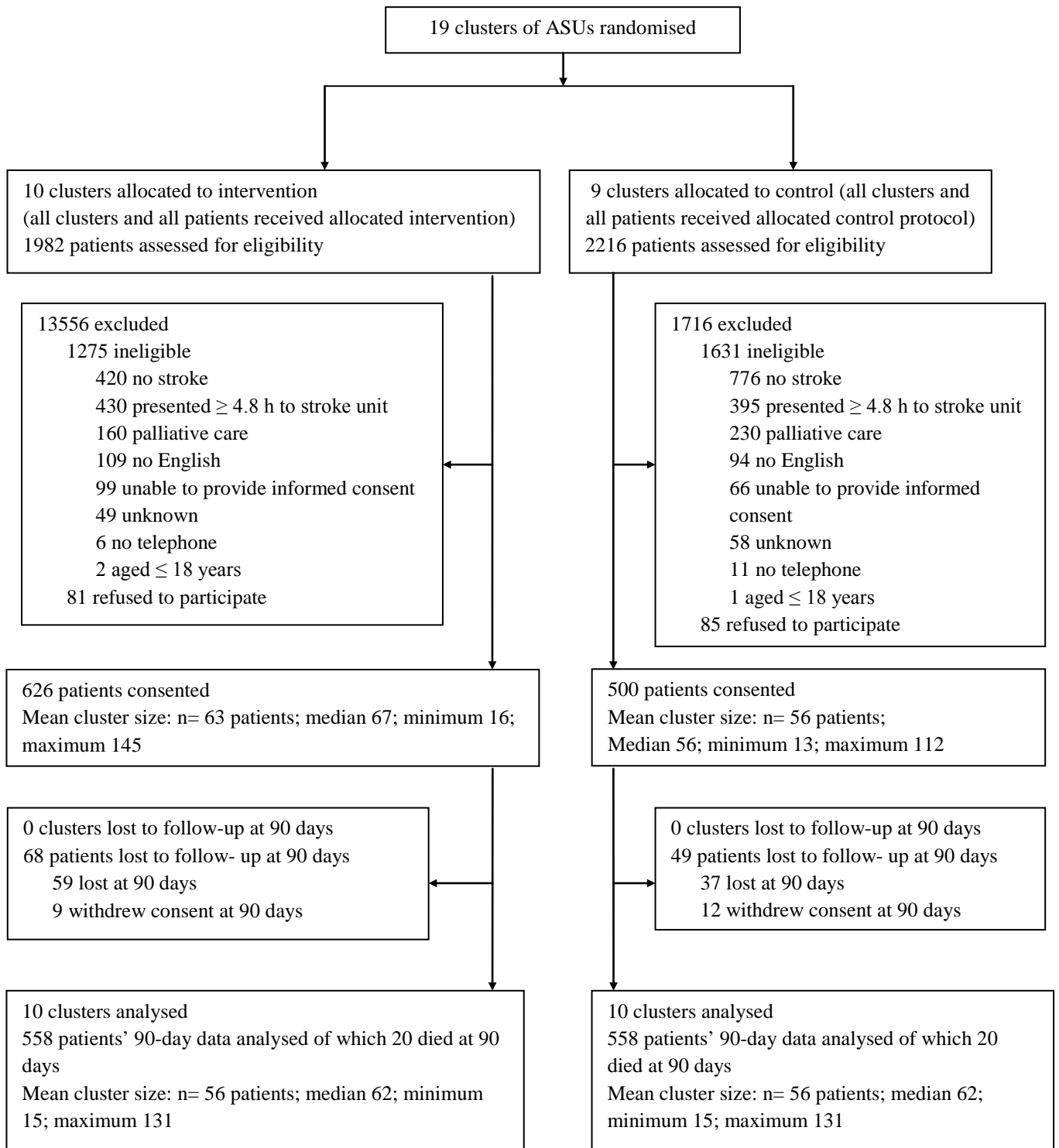
<sup>^</sup> FeSS treatment protocols and ASSIST dysphagia screening tool available on application to authors

Protocols and further information about implementation of the intervention are available at [www.acu.edu.au/qasc](http://www.acu.edu.au/qasc)



**Figure 1: Pre- intervention trial profile**

NSW= New South Wales. ASU= Acute Stroke Unit. # Australian National Stroke Unit Program Category A or B = stroke units with immediate CT access and on-site high dependency units; Category B do not have on-site neurosurgery.<sup>1</sup> \* This cluster withdrew prior to recruitment of any patients



**Figure 2: Post- intervention trial profile**