引言人：柳玉芳

Journal Club

指導者：陳可欣副主任

報告日期：2016年08月30日

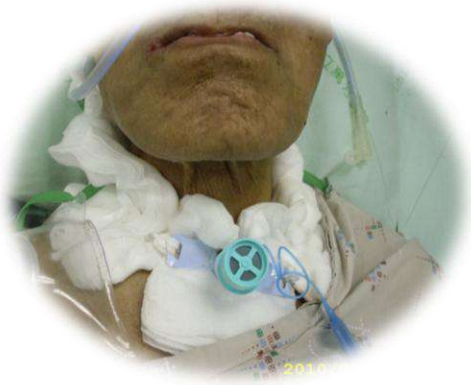
背景資料 Background Knowledge

個案溝通

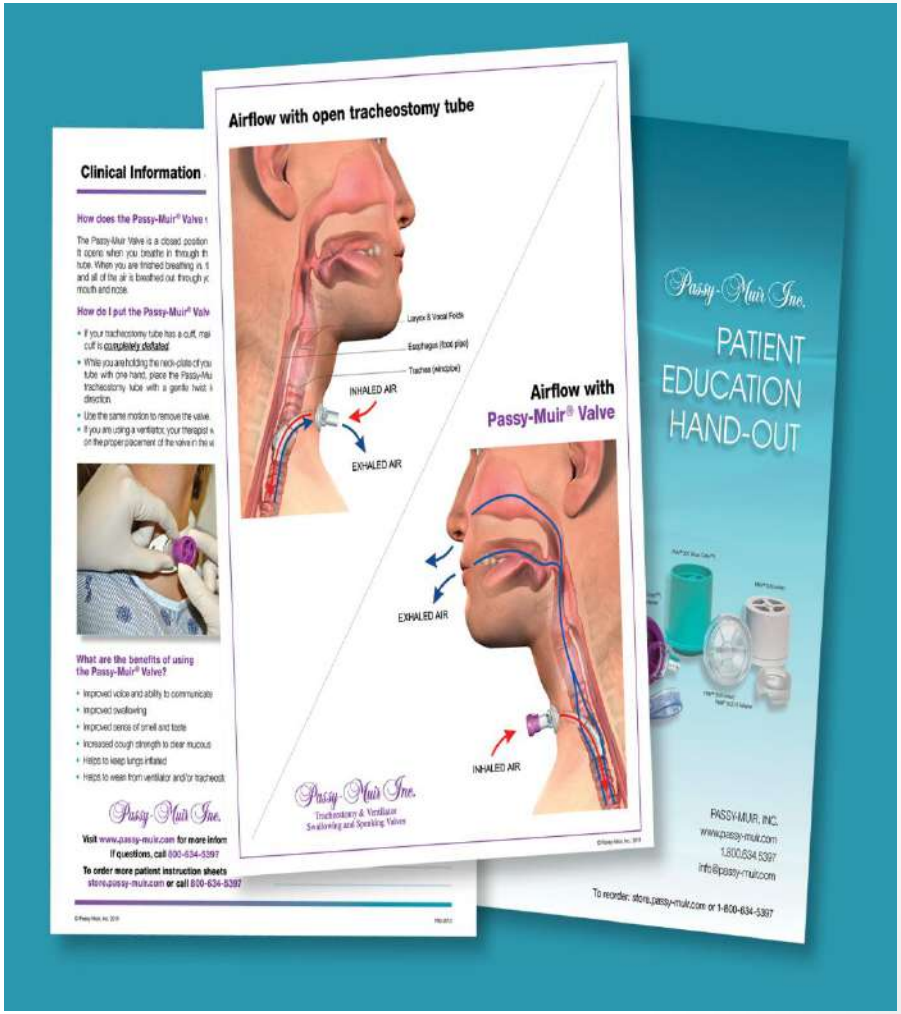
筆談

依嘴型，猜意思

圖示




David A. Muir
Passy-Muir® Valve Inventor
1962 – 1990


Clinical Information
Airflow with open tracheostomy tube
Airflow with Passy-Muir® Valve
INHALED AIR
EXHALED AIR
Passy-Muir Inc.
PATIENT EDUCATION HAND-OUT

1234

Critical Care Medicine:
June 2016 - Volume 44 - Issue 6 - p 1075–1081
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Clinical Investigations

Return of Voice for Ventilated Tracheostomy Patients in ICU: A Randomized Controlled Trial of Early-Targeted Intervention*

Freeman-Sanderson, Amy L. BachApplSc; Togher, Leanne PhD; Elkins, Mark R. PhD; Phipps, Paul R. PhD

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CARE MED
MEDICINE - SCIE

Critical Care Medicine
Impact factor:6.736

Key Indicators

Year	Total Cites Graph	Journal Impact Factor Graph	Impact Factor Without Journal Self Cites Graph	5 Year Impact Factor Graph	Immediac Index Gr	graph	Cited Half-Life Graph	Citing Half-Life Graph	Eigenfacto Score Graph	Article Influence Score Graph	% Articles in Citable Items Graph	Normalize Eigenfacto Graph	Average JIF Percentile Graph
2015	36,267	7.422	6.755	6.736	2.854	308	8.3	6.8	0.06155	2.384	90.58	6.99569	89.394
2014	33,132	6.312	5.679	6.289	2.572	304	8.0	6.8	0.06565	2.307	96.05	7.35285	87.037
2013	33,784	6.147	5.509	6.404	2.598	346	7.6	7.0	0.06326	2.011	93.06	6.97293	90.741
2012	32,733	6.124	5.415	6.401	2.614	363	7.2	6.6	0.06902	2.046	93.39	Not A...	94.444
2011	30,570	6.330	5.762	6.484	2.142	310	6.7	6.6	0.08036	2.168	91.94	Not A...	94.231
2010	30,064	6.254	5.743	6.453	2.695	308	6.5	6.9	0.08486	2.157	92.53	Not A...	93.478
2009	28,896	6.373	5.663	6.698	2.040	401	6.1	6.6	0.08262	1.995	92.52	Not A...	93.182

JCR Impact Factor

JCR Year	CRITICAL CARE MED... Rank	CRITICAL CARE ...le	JIF Percentile
2015	4/33	...ned	
2014	4/27	...ned	
2013	3/27	...ned	
2012	2/27	...ned	
2011	2/26	...ned	
2010	2/23	...ned	

Critical Care Medicine
排名：4/33

RCT Appraisal sheets(RAMbo)

Appraisal Tool [RCT]

步驟1: 研究探討的問題為何? (PICO)

步驟2：研究的品質有多好? (內在效度)

步驟3: 研究結果的意義為何? (效益)

前景問題 *Foreground Question* [1]

P

- > Age 18 tracheostomy placement (in ICU)
- Spontaneously breathing, awake, obey verbal

I

- Early intervention. (in-line Passy Muir “Ventilator Speech and Swallowing Valve 007” (PMV))

C

- Standard therapy (a Por tex orator speaking valve (Smiths-Medical, Sydney, Australia)

O

- Hastened return to phonation

問題類型：●治療型　○預後型　○診斷型　○傷害型

RCT Appraisal sheets(RAMbo)

Appraisal Tool [RCT]

步驟1:研究探討的問題為何?

步驟2: 研究的品質有多好? (內在效度)

步驟3: 研究結果的意義為何? (效果)

步驟 2: Validity（族群代表性合適、結果可靠、精確）？

2-1.招募(Recruitment)-受試者是否具有代表性 p1076

MATERIALS AND METHODS
Ethics approval was given by the local Area Health Service Protocol X09-0380 and HREC/09/RPAH/643. The trial was prospectively registered on www.ANZCTR.org.au, protocol number ACTRN12610000075088.

Participants and Setting

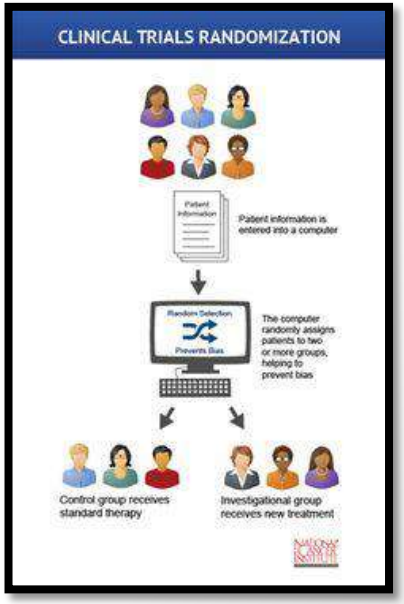
- The Royal Prince Alfred Hospital, a tertiary referral hospital in Australia
- Patients from the intensive care department which has 52 beds including general, cardiothoracic, and neurosurgical beds.
- Eligibility criteria
  1. > 18 years old
  2. Formation and placement of the tracheostomy > 48 hours
  3. Air-filled cuffed tracheostomy tube in situ
  4. Actively mechanically ventilated with positive end-expiratory pressure ≦ 10 cm H2O pressure, Fio2 ≦ 40%
  5. Spontaneously breathing
  6. triggering ventilatory support
  7. Voiceless ≧ 48 hours
  8. Awake and able to obey verbal commands

步驟 2: Validity（族群代表性合適、結果可靠、精確）？

YES

2-2. 分派(Allocation)-分派方式是否隨機且具隱匿性.....? p.1076

- A prospective randomized controlled trial was conducted with concealed allocation, blinded assessment of some outcome measures, and intention-to-treat analysis.
- All tracheostomy patients were consecutively screened during the scheduled recruitment periods and enrolled if eligibility criteria were met.
- Written consent was gained from each participant or person responsible.
- Participants were randomly allocated to an intervention or control group using computer-generated, permuted-block randomization, with concealed allocation via sealed opaque envelopes.



步驟 2: Validity（族群代表性合適、結果可靠、精確）？

2-3. ...每個組別在研究開始時的情況是否相同? p.1079

TABLE 2. Baseline Characteristics, Diagnostic Categories, and Tracheostomy Details of Participants

Characteristics	Randomized ($n = 30$)	
	Early Intervention ($n = 15$)	Control ($n = 15$)
Age (yr), mean (SD)	53 (21)	67 (11)
Gender, males, *n* (%)	11 (73)	6 (40)
Acute Physiology and Chronic Health Evaluation-II score (0–71), mean (SD)	19 (4)	18 (5)
Diagnostic category, *n* (%)[a]		
Neurology	3 (20)	4 (27)
Cardiothoracics	4 (27)	5 (33)
Respiratory	4 (27)	2 (13)
General medical	4 (27)	4 (27)
Tracheostomy insertion method, *n* (%)		
Percutaneous	13 (87)	14 (93)
Surgical	2 (13)	1 (7)
Tracheostomy size, *n* (%)		
7.0	1 (7)	2 (13)
7.5	1 (7)	1 (7)
8.0	8 (53)	11 (73)
9.0	5 (33)	1 (7)
Tracheostomy type, *n* (%)		
Portex cuffed nonfenestrated	14 (93)	13 (87)
Portex adjustable phlange	0 (0)	1 (7)
Cook cuffed nonfenestrated	1 (7)	1 (7)
Time from intubation for mechanical ventilation to tracheostomy (d), mean (SD)	13 (7)	13 (5)

[a]Specific diagnoses included the following: neurology—traumatic brain injury and acute disseminated encephalomyelitis; cardiothoracic—coronary bypass graft, mitral valve replacement, and aortic valve replacement; respiratory—pneumonia, respiratory arrest, exacerbation of chronic obstructive pulmonary disorder, and influenza (A & H1N1); and general—liver transplant, necrotizing pancreatitis, myocardial infarction, ileus, gun shot wound, and perforated bowel.

YES

步驟 2: Validity（族群代表性合適、結果可靠、精確）？

2-4.維持(Maintenance)-各組是否給予相同的治療? p.1077

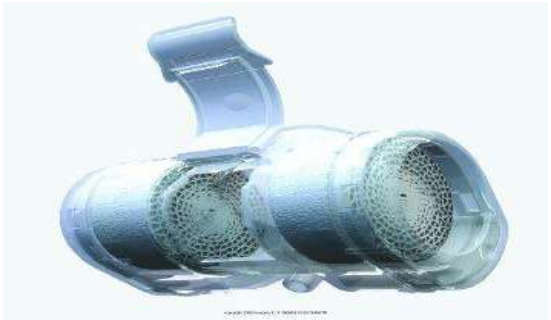
Early Intervention. Early intervention was defined as cuff deflation and use of an in-line Passy Muir "Ventilator Speech and Swallowing Valve 007" (PMV) during pressure support ventilation via the tracheostomy tube. The PMV is a one-way, positive-pressure valve with a unique design; the flange closes at the end of inspiration, which allows it to be used during mechanical ventilation, in contrast to all other speaking valves, in which the flange closes on expiration (19). Initially, the PMV was used for a period of up to 60 minutes as tolerated. On subsequent days, the PMV was used for increasing periods while the patient was on mechanical ventilation: up to 2 hours on day 2, up to 4 hours on day 3, and up to 8 hours on day 4 and beyond. However, the duration of PMV use was only increased if the participant tolerated the full preceding period. At the end of each early intervention session, the PMV was removed and the tracheostomy cuff was reinflated. During the application of the PMV, the participant was continuously monitored, and the early intervention session was ceased if the patient's clinical observations were outside the ranges defined in Table 1 or if an adverse event occurred. Once participants were taken off mechanical ventilation, they continued with cuff deflation and PMV as tolerated.

步驟 2: Validity（族群代表性合適、結果可靠、精確）？

2-4.維持(Maintenance)-各組是否給予相同的治療? p.1077

Standard Intervention (Control Group). Standard intervention was defined as cuff deflation and provision of a Portex orator speaking valve (Smiths-Medical, Sydney, Australia) after the participant was off mechanical ventilation. Standard intervention commenced after the participant was established on Swedish nose (Themovent-T) (heat and moisture exchange filter; Smiths-Medical) breathing trials and the medical team, nursing staff, or physiotherapist made a referral.

Portex orator speaking valve



<<Themovent-T>> - heat and moisture exchange Filter (Smiths-Medical)

步驟 2: Validity（族群代表性合適、結果可靠、精確）？

2-4.維持(Maintenance)-各組是否給予相同的治療? p.1077

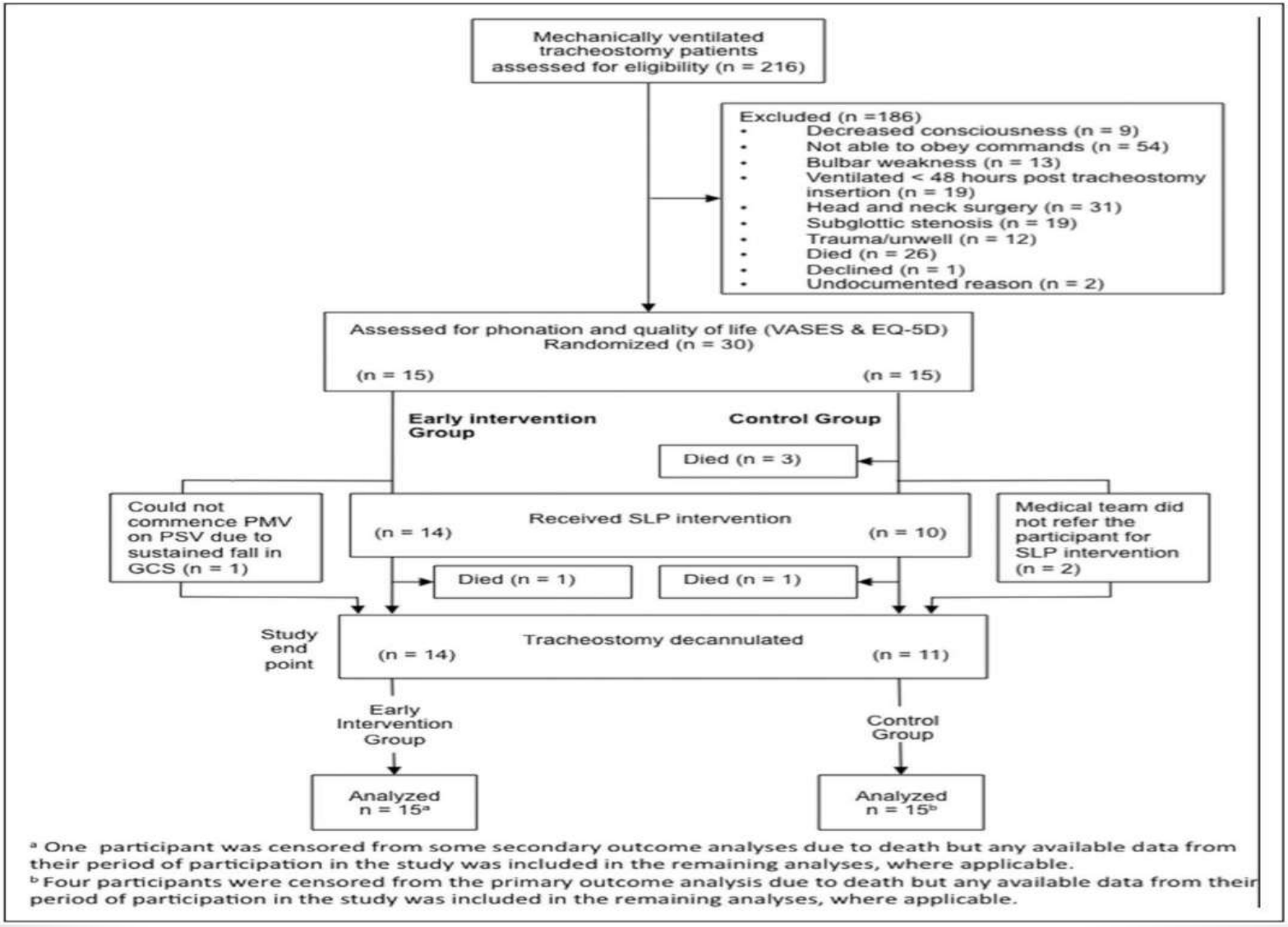
Other Care. All other usual care in the ICU was provided to participants in both groups including ventilator weaning, sedation protocols, management of pain, staff-to-patient ratios, and clinical monitoring.

YES

步驟 2: Validity（族群代表性合適、結果可靠、精確）？

YES

2-5.....是否有足夠的追蹤(Follow up)?說明: (P.1078 Figure 1)



步驟 2: Validity（族群代表性合適、結果可靠、精確）？

2-6.評估(Measurement)-受試者與評估者是否對治療方式及(或)評估目的維持盲法(Blind)? 說明：p1077 (部分Blind!)

Primary Outcome.
Time to phonation was the primary outcome.
It was measured from tracheostomy insertion to the ability to count from 1 to 10 using voice and reported in days.
The presence of phonation was assessed daily by an SLP or nurse who was not otherwise involved in the trial.

Secondary Outcomes.
The secondary outcomes were duration of tracheostomy cannulation, duration of mechanical ventilation, length of stay in ICU, length of stay in hospital, time to oral intake, safety, and quality of life

- There was no blinding of participants, the therapists who administered therapy, or the assessor of the primary outcome.
- However, blinding of most secondary outcomes was achieved.

RCT Appraisal sheets(RAMbo)

Appraisal Tool [RCT]

步驟1:研究探討的問題為何?

步驟2: 研究的品質有多好? (內在效度)

步驟3: 研究結果的意義為何? (效果)

步驟3：研究結果的意義為何?

Measurements and Main Results: The primary outcome measure was time from tracheostomy insertion to phonation. Early intervention significantly hastened return to phonation (median difference = 11 d; hazard ratio = 3.66; 95% CI, 1.54–8.68) with no significant effect on duration of tracheostomy cannulation (hazard ratio = 1.40; 95% CI, 0.65–3.03), duration of mechanical ventilation in days from tracheostomy insertion (hazard ratio = 1.19; 95% CI, 0.58–2.51), length of stay in ICU (hazard ratio = 1.16; 95% CI, 0.54–2.52), or time to return to oral intake (hazard ratio = 2.35; 95% CI, 0.79–6.98). Adverse events were low and equal in both groups. There was no significant change in measures of quality of life.

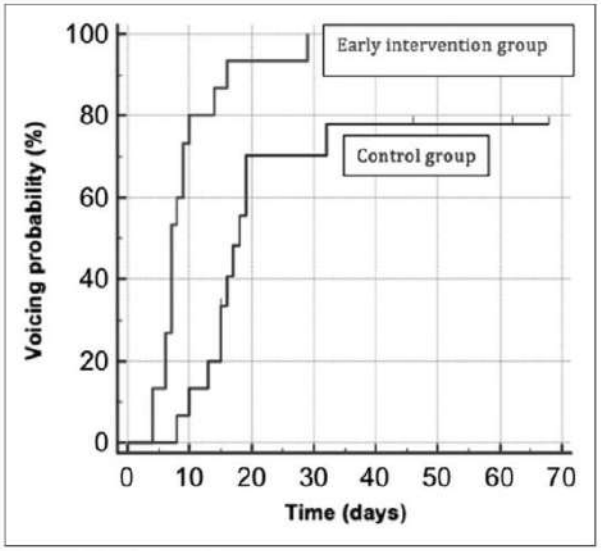


Figure 2. Time to phonation.

TABLE 3. Number of Clinical Events Associated With Tracheostomy Cuff Deflation

Clinical Event	Early Intervention	Standard Care
Oxygen desaturation < 88%	1	1
Respiratory rate > 35 breaths/min	2	2
Increased upper respiratory tract secretions	0	2
Excessive coughing	1	0
Systolic blood pressure > 160 mm Hg	1	0
Total events	5	5

步驟3：研究結果的意義為何?

Quality of Life. None of the eight domains of the VASES that we measured showed a statistically significant benefit from the early intervention.

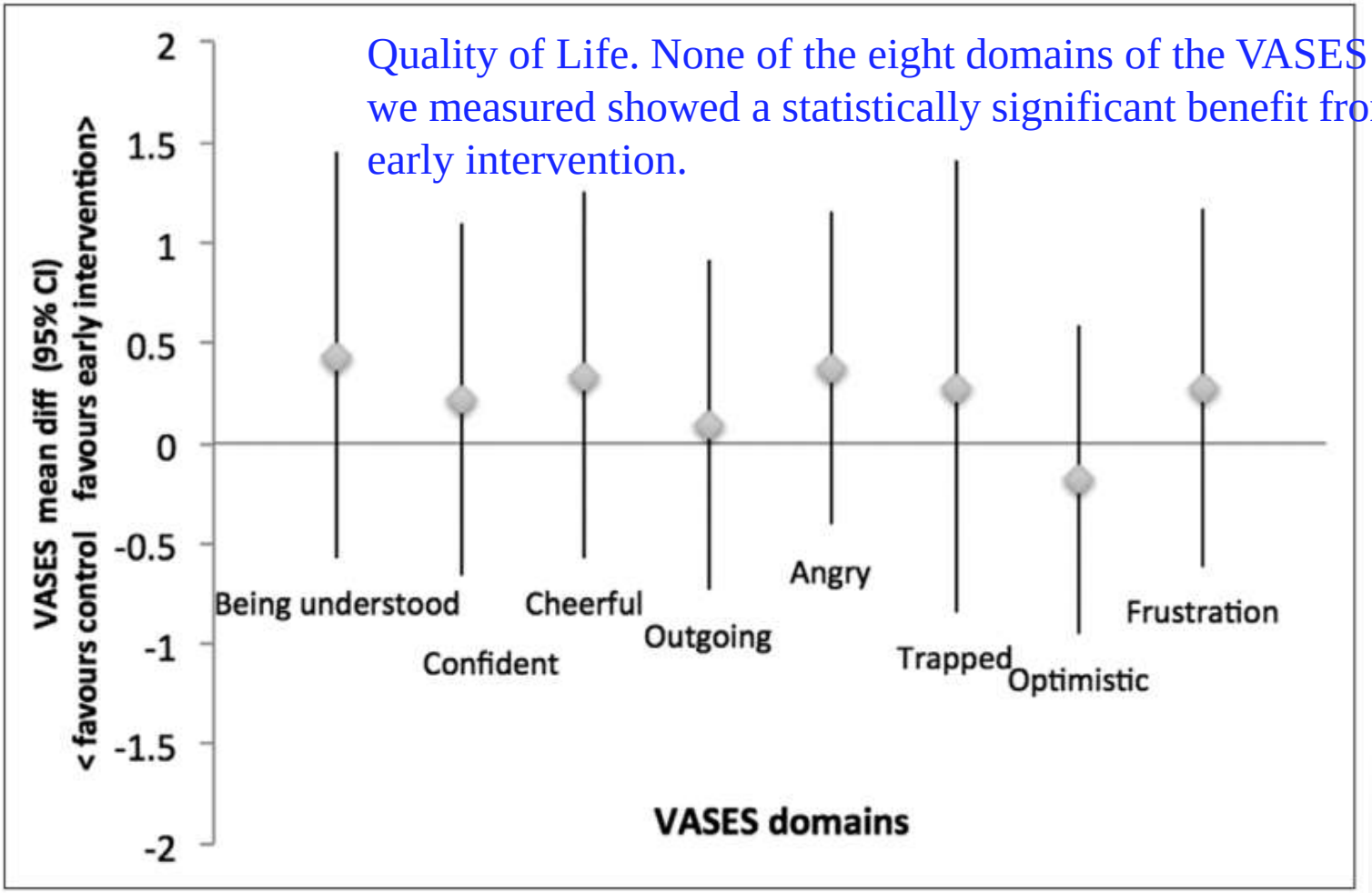


Figure 3. Time-weighted average scores for communication quality of life.

RCT Appraisal sheets(RAMbo)

RESEARCH Open Access

A randomized clinical trial for the timing of tracheotomy in critically ill patients: factors precluding inclusion in a single center study

Appraisal [RCT]-結論

（內在效度 & 結果 ）

1.招募(Recruitment)-受試者是否具有代表性？	YES
2. 分派(Allocation)-分派方式是否隨機且隱匿性？	YES
3. ….每個組別，在研究開始時的情況是否相同？	YES
4. 維持(Maintenance)-各組是否給予相同的治療?	YES
5…..是否有足夠的追蹤(Follow up)?	YES
6. 評估(Measurement)-受試者與評估者是否對治療方式及(或)評估目的維持盲法(Blind)?	No
7. 使用何種評估方式，療效有多大?	
8. 這個研究結果是否可能隨機(巧合)發生?	

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Clinical Investigations

Return of Voice for Ventilated Tracheostomy Patients in ICU: A Randomized Controlled Trial of Early-Targeted Intervention*

Freeman-Sanderson, Amy L. BachApplSc; Togher, Leanne PhD; Elkins, Mark R. PhD; Phipps, Paul R. PhD

Limitations

1. In asking participants to count to 10, the measure used for the primary outcome failed to capture the complexity of their communication
2. It was an objective measure of their ability to phonate
3. There was no blinding of participants, the therapists who administered therapy, or the assessor of the primary outcome
4. The study sample was small

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CONCLUSIONS

- In conclusion, **targeted early treatment during mechanical ventilation hastened return to phonation for patients with a tracheostomy tube**.
- Earlier return of voice facilitates effective communication that is beneficial for improved patient care in the ICU that may include **improved reporting of medical symptoms and assessment and management of pain, delirium, and emotional distress experienced in ICU.**
- In the study cohort, there were **no adverse impacts** on other facets of care including time to tracheostomy weaning milestones
  - additional studies with larger participant numbers need to be conducted to replicate these findings, monitor safety, and confirm secondary clinical benefits with this particular treatment.
- Early treatment by an SLP to promote the return of phonation may therefore be considered for selected ventilated tracheostomy patients in the ICU.

- 個案

討論

證據與實證照護(Evidence)

本篇研究在意識清楚且呼吸器使用病人早期介入speaking valves能提早發聲具有顯著意義，對ICU使用也能促進醫病溝通。

臨床專家意見(Expertise)

- 胸腔內科醫師:臨床團隊互相配合，對於病人能成功使用speaking valves相當重要，每一個環節都是重要。
- 呼吸治療師:依病人狀況開始練習發聲，採漸進式發聲，通常第一次較困難，speaking valves可以使用在有無呼吸器的病人，也不會影響平時活動。
- 物理治療師:此類病人呼吸肌，使用speaking valves能幫助肺擴張，橫膈膜運動等介入措施也可幫助肺部擴張，。

病人及家屬的期望(Expectation)

家屬會比較關心病人的感受性問題如：

(1)Quality of Life (2) Prolong time (3)價格

[Shared Decision Making need EBM& EBM need Shared Decision Making]
Learn from *3rd International Society for Evidence-Based Health Care Conference (ISEHC) 2014*

- 對意識清楚/有氣切病人，建議使用 speaking valve?

THANKS FOR YOUR ATTENTION~