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Original citation:
McWilliams, D, Atkins, G, Hodson, J & Snelson, C 2017, 'The Sara Combilizer ® as an early mobilisation aid for critically ill patients: A prospective before and after study', Australian Critical Care, vol. 30, no. 4, pp. 189-195.
https://dx.doi.org/10.1016/j.aucc.2016.09.001

DOI 10.1016/j.aucc.2016.09.001
ISSN 1036-7314

Publisher: Elsevier

Australian Critical Care 30 (2017) 189–195

Contents lists available at ScienceDirect

Australian Critical Care

journal homepage: www.elsevier.com/locate/aucc

Research paper

The Sara Combilizer® as an early mobilisation aid for critically ill patients: A prospective before and after study

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At the conclusion of this article a Continuing Professional Development activity is attached

ARTICLE INFORMATION

Article history:
Received 3 June 2016
Received in revised form 26 July 2016
Accepted 1 September 2016

Keywords:
Critical care
ICU
Physiotherapy
Rehabilitation
Seating
Standing

ABSTRACT

Background: Early mobility within the ICU is associated with a number of positive outcomes including reductions in ICU and hospital length of stay and better functional recovery. The exact definition of 'early' mobility is still not defined, with the actual ability to mobilise limited by a number of perceived factors. The Sara Combilizer® is a combined tilt table and stretcher chair, which allows passive transfer of patients out of bed. This study aimed to assess whether the introduction of the Sara Combilizer® reduced time taken to first mobilise for patients mechanically ventilated for at least five days and at risk of ICU acquired weakness.

Methods: Patients admitted to a large UK critical care unit during the trial period and ventilated for ≥5 days were included in the study. Baseline data was collected prospectively for a period of four months. The Sara Combilizer® was then introduced for a one month training and familiarisation period, followed by a further four months prospective data collection. The primary outcome was time to first mobilisation, defined as a Manchester Mobility Score ≥2.

Results: Following the introduction of the Sara Combilizer®, time taken to mobilise reduced significantly from 13.6 to 10.6 days ($p = 0.028$). SOFA scores were significantly higher at the point of first mobilisation in the Combilizer group (mean: 2.9 ± 0.5 vs. 5.1 ± 2.4; $p = 0.005$). There was no statistical difference in therapy time between the groups, or ICU or hospital length of stay.

Conclusions: The introduction of the Sara Combilizer® was associated with a significant reduction in time to mobilise patients ventilated for ≥5 days, and patients were mobilised with a higher degree of organ failure. This was achieved without any increase in therapy time. The Sara Combilizer® may be a useful adjunct to an early mobility protocol within the ICU.

1. Background

Survivors of critical illness may experience significant physical and psychological morbidity. At least half of patients discharged are unable to return to premorbid levels of activity due primarily to weakness and lack of endurance.[1] These effects can last months to years after hospital discharge,[2–4] with a negative impact on employment and income in ICU survivors and their care-givers, as well as healthcare usage.[5] The weakness experienced by survivors of critical illness is thought to be multifactorial, including premorbid conditions, ICU acquired weakness (ICUAW) and prolonged bed

Abbreviations: HADS, Hospital Anxiety and Depression Scale; ICU, intensive care unit; ICUAW, intensive care unit acquired weakness; LOS, length of stay; MMS, Manchester Mobility Score; MRC, Medical Research Council; SOFA, Sequential Organ failure Assessment; UK, United Kingdom; US, United States.

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http://dx.doi.org/10.1016/j.aucc.2016.09.001

rest.[6] Longer length of mechanical ventilation is a risk factor for ICUAW, with 55% of patients ventilated for more than eight days developing ICUAW in one study.[7] The presence of ICUAW worsens acute morbidity and one year mortality,[7] and is associated with significant long term physical impairments.[8]

The evidence base for rehabilitation within critical care is growing, demonstrating rehabilitation to be effective in improving short term outcomes and long term recovery in critical care patients. Early and structured rehabilitation programs have been shown to decrease both ICU and hospital length of stay (LOS),[9–11] as well as improve functional ability at critical care and hospital discharge.[12] This is particularly the case when led by physiotherapists.[13] Specifically, both Morris et al.[9] and McWilliams et al.[11] demonstrated reduced ICU LOS in response to earlier mobilisation, defined as sitting out of bed in a chair. However, the concept of 'early' rehabilitation is not a simple one and refers to a point in the patients' illness progression rather than a measure of a specific number of days. Previous research has demonstrated that patients with multi organ failure are most susceptible to muscle loss[14] and are most likely to suffer delays in mobilisation due to a need for ongoing organ support or lung protective ventilation strategies. As such, the key to 'early' mobility here would be to commence mobilisation in an earlier phase of the organ failure recovery than previously would occur.

A number of studies have explored the safety of mobilisation programs within critical care, suggesting a low incidence of adverse events. Recent evidence suggests mobilisation can be safely implemented for patients still mechanically ventilated via both tracheostomy and endotracheal tubes,[15] and for those receiving continuous hemofiltration.[16] In practice however, a number of perceived limitations to early mobilisation still exist with ongoing concerns regarding the safety of such interventions in the acute phase of critical illness.[16] With no clear definition or established protocols regarding the optimal time to start mobilisation, coupled with a lack of resources, large variations in practice have been demonstrated both nationally and internationally.[17–21]

The Sara Combilizer® (Arjo Huntleigh) is a combined chair and tilt table which can be taken completely flat to allow transfer via a sliding board (e.g. patslide), in addition to allowing standing positions to be achieved (see Figs. 1 and 2). The chair position also has a 'tilt in space' recline function which allows more supportive seating positions to be achieved in comparison to standard chairs used within the ICU. Although not as challenging as sitting on the edge of the bed, passive chair transfer does still elicit both a cardiovascular and respiratory exercise response.[22]

Fig. 1. Sara combiliser® sitting position.

The aim of this study was to investigate whether the Sara Combilizer® could facilitate safe and early mobilisation of critically ill patients at high risk of ICUAW who would otherwise be unable to get out of bed, thereby reducing time to first mobilisation.

2. Methods

The study was conducted after approval by the local ethics committee North West—Greater Manchester South (ref: 14/NW10180). As patients lacked mental capacity at the time of recruitment, written informed consent was gained from a personal consultee or Registered Medical Practitioner if no personal consultee was available. If the patient later regained mental capacity, written informed consent was gained directly for ongoing participation in the trial.

Fig. 2. Sara Combilizer® standing position.

Box 1: Contraindications to mobilisation.

- Significant dose of vasoactive agents (e.g. >0.2 mcg/kg/min noradrenaline or equivalent) for hemodynamic stability (Maintain Mean Arterial Pressure >60 mmHg)
- Mechanically ventilated with $Fi0_2$ >0.8 and/or PEEP >12 cmH_2O
- Active infusion of neuromuscular paralysing agent
- Acute neurological event
- Unstable spine or extremity fractures with contraindications to mobilise
- Active bleeding process

Box 2: Restrictions to edge sitting.

- Small dose of vasoactive agents (e.g. 01–0.2 mcg/kg/min noradrenaline or equivalent) for hemodynamic stability (Maintain Mean Arterial Pressure >60 mmHg)
- Mechanically ventilated with $Fi0_2$ >0.6 and/or PEEP >10 cmH_2O
- Poor tolerance of endotracheal tube
- Open abdomen or high risk for dehiscence—liaise with surgeons prior to mobilising
- Hemofiltration via a femoral line with significant flow restrictions on movement

Consecutive patients were recruited from the trauma, neurosciences and general ICU of Queen Elizabeth Hospital Birmingham, UK between July 2014 and March 2015. Physiotherapy staffing is provided at a ratio of one therapist to 10 patients. To be eligible, patients had to be ≥18 years of age and mechanically ventilated for five days or more. This duration was chosen to ensure a cohort of patients at significant risk of ICUAW and with limitations to sitting, transferring or standing by conventional methods.

Patients were excluded if they had contraindications to mobilisation (e.g. unstable pelvic fractures or spinal injuries), severe neurological injury or neuromuscular disease such as Guillain Barre or motor neurone disease. Due to possible unmeasurable confounding variables, patients were also excluded if they had received mechanical ventilation for >48 h at another facility immediately prior to admission or had a poor pre admission level of mobility (<10 yards reported by patient or proxy during admission assessment). Due to specific restrictions linked to the Sara Combilizer®, patients were excluded if they were over 6 ft 5 in. (1.96 m) tall or exceeded the weight limit of 440 lbs (200 kg).

3. Design

A single centre prospective before and after study was designed to evaluate the impact of the Sara Combilizer® device on early mobilisation within the ICU. Baseline data was collected for four months prior to the introduction of the product, representing current "standard of care". After this period, a one month training and orientation period was implemented to allow physiotherapy and nursing staff to become familiar with the Sara Combilizer® and gain experience using the device. This was then followed by a further four month data collection period, where four Sara Combilizers® were made freely available for use by staff. Our existing mobility protocol was adapted to incorporate the Sara Combilizer® to guide its use (see Fig. 3), alongside safety criteria adapted from previously published guidelines[23] for restrictions or contraindications for mobilisation (see Boxes 1 and 2). To summarise, this protocol recommended use of Sara Combilizer® for patients with restrictions to sitting on the edge of the bed, as a component of a seating program or for ongoing rehabilitation of patients unable to stand. If patients were able to sit on the edge of the bed this was chosen as the first line of treatment to allow assessment of sitting balance as well as exercise capacity and response.

Box 3: Manchester mobility score.

1. In bed interventions (passive movements, active exercise, chair position in bed)
2. Sit on edge of bed
3. Hoisted to chair (incl. standing hoist)
4. Standing practice
5. Step transfers with assistance
6. Mobilising with or without assistance
7. Mobilising >30 m

Demographic data, admission reason, APACHE II scores, Charlson co-morbidity indices and sedation days were obtained from hospital databases and the electronic prescribing system to assess homogeneity between groups. Sedation days was defined as greater than 1 h of sedative infusion in a 24 h period to account for any sedation given during procedures which may have impacted on rehabilitation. Physical function was assessed prospectively using the Manchester Mobility Score (MMS)[24] as a measure of daily rehabilitation status within ICU and at ICU discharge (see Box 3). Daily Sequential Organ Failure Assessment (SOFA) scores were calculated to allow comparisons of the degree of organ failure at the time of first mobilisation. The Barthel, Medical Research Council (MRC) sum score and Hospital Anxiety and Depression Scale (HADS) questionnaires were completed where possible at ICU and hospital discharge. Information regarding advanced respiratory support days defined as the delivery of positive pressure (including continuous positive airway pressure) via an endotracheal or tracheostomy tube, ICU LOS, mortality and functional status were collected from the ICU charts and local physiotherapy documentation. Pressure ulcer and falls incidence during critical care and hospital stay were collected from the hospitals electronic database.

The primary outcome was the time to first mobilisation, as defined as sitting on the edge of the bed or higher (MMS score of ≥2). Secondary outcomes were SOFA score at time of first mobilisation in order to assess organ failure at the point of mobilisation, MMS at critical care discharge, ICU length of stay (defined as time from point of admission to time declared medically fit for discharge by senior ICU clinician), duration of ventilation, ICU and hospital mortality, Barthel score at critical care and hospital discharge, MRC sum score and HADS score at ICU and hospital discharge, critical care readmission rate, pressure ulcer incidence and falls incidence.

4. Statistical methods

A power calculation was performed from pilot data using an online power calculation tool recommended by the Trusts' statistician (http://www.stat.ubc.ca/~rollin/stats/ssize/n2.html). This was based on a 2 tailed t-test, with significance level of 0.05 and an 80% power. Baseline mean time to mobilise for patients mechanically ventilated for greater than 5 days was 10.6 days, with a sample standard deviation of 4.1. Based on these figures, the minimal detectable difference was 3 days, for a sample size of 30 patients in each phase (before & after introduction of Sara Combilizer®). Therefore, we planned recruitment of 40 patients in each phase of the study, to allow for ICU mortality and withdrawals from the trial.

All analyses were performed using IBM SPSS Statistics 22 (IBM Corp. Armonk, NY), with $p < 0.05$ deemed to be indicative of statistical significance throughout. Prior to the analysis, the distributions

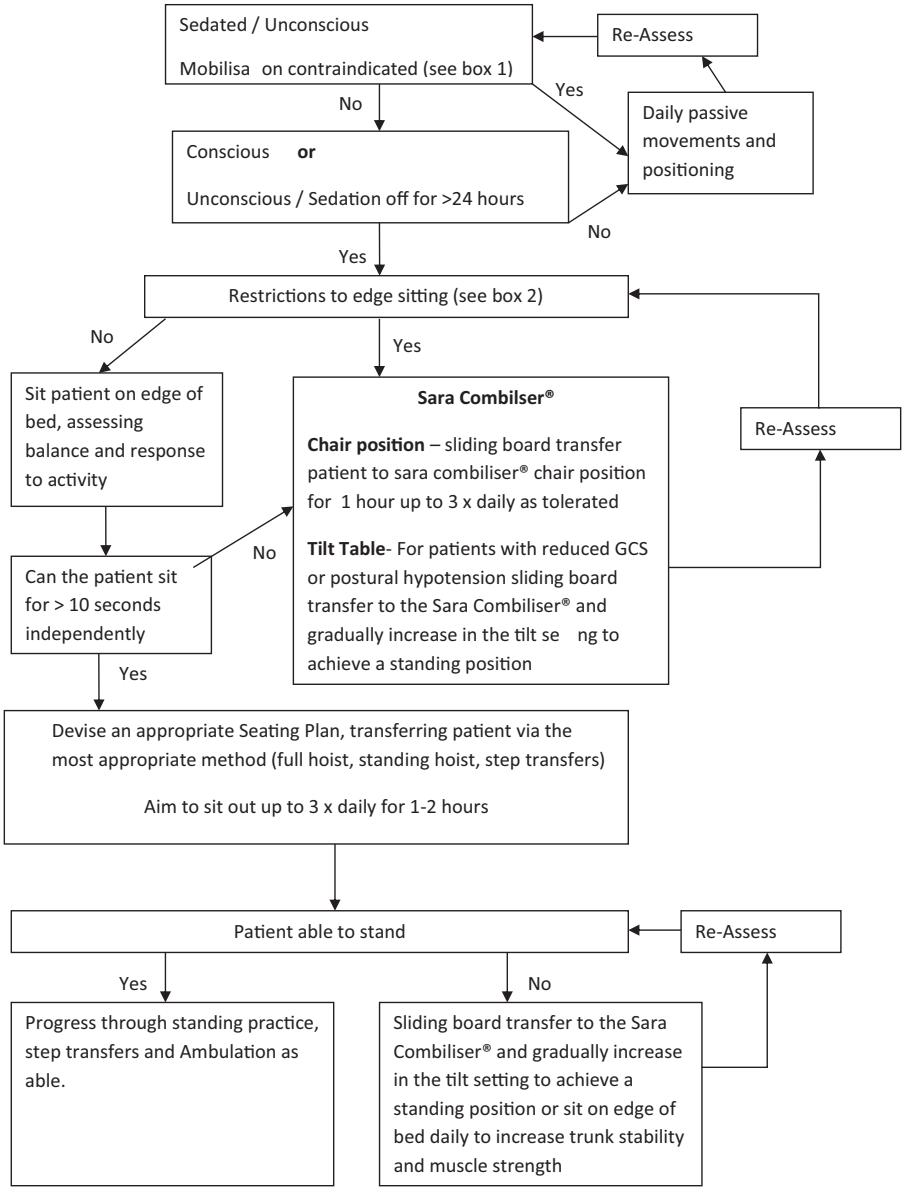

Fig. 3. Sara Combiliser® early and structured mobility protocol.

of the continuous variables were assessed for normality using histograms. Normally distributed variables were reported as means and standard deviations, with comparisons between treatment groups performed using independent samples t-tests. Skewed variables were $\log_{10}$-transformed, after adding one to remove zeros, in order to normalise their distributions. The resulting variables were then compared between groups using independent samples t-tests, and summarised with geometric means and 95% confidence intervals. Where normality could not be achieved by transformation, a non-parametric approach was employed, with data reported as medians and interquartile ranges (IQR), and comparisons between groups made using Mann–Whitney tests. For categorical variables, Fisher's exact tests were used.

5. Results

A total of 80 patients were recruited, of whom 14 died and 3 were transferred to another ICU, leaving 63 patients included in the final analysis; 31 for the baseline period and 32 in the group following the introduction of the Sara Combilizer® (see Fig. 4). Subjects were well matched in terms of age, gender, pre admission functional level and preexisting comorbidities, although patients in the Sara Combilizer® phase had significantly higher illness severity scores on admission to critical care. There were also significant differences noted regarding admission speciality (see Table 1). Five patients in each group only commenced mobilisation after discharge from the ICU. There was no statistical difference in the total duration of physiotherapy received by each group. When the Sara Combilizer® was made available, it was used in 47% of the total patient cohort, a mean of 2.6 times per patient.

The differences in all measured outcomes are shown in Table 2. There was a significant reduction in time to mobilise following introduction of the Sara Combilizer® (geometric mean (95% CI): 10.6 (9.1–12.4) vs. 13.6 (11.7–15.8) days, $p = 0.028$), with SOFA scores also significantly higher at the point of mobilisation in the Sara Combilizer® group (mean (SD): 5.1 (2.4) vs. 2.9 (1.2), $p = 0.005$). No significant differences were observed in the duration of mechanical ventilation, ICU length of stay, or any additional outcomes in the Sara Combilizer® phase (Table 3).

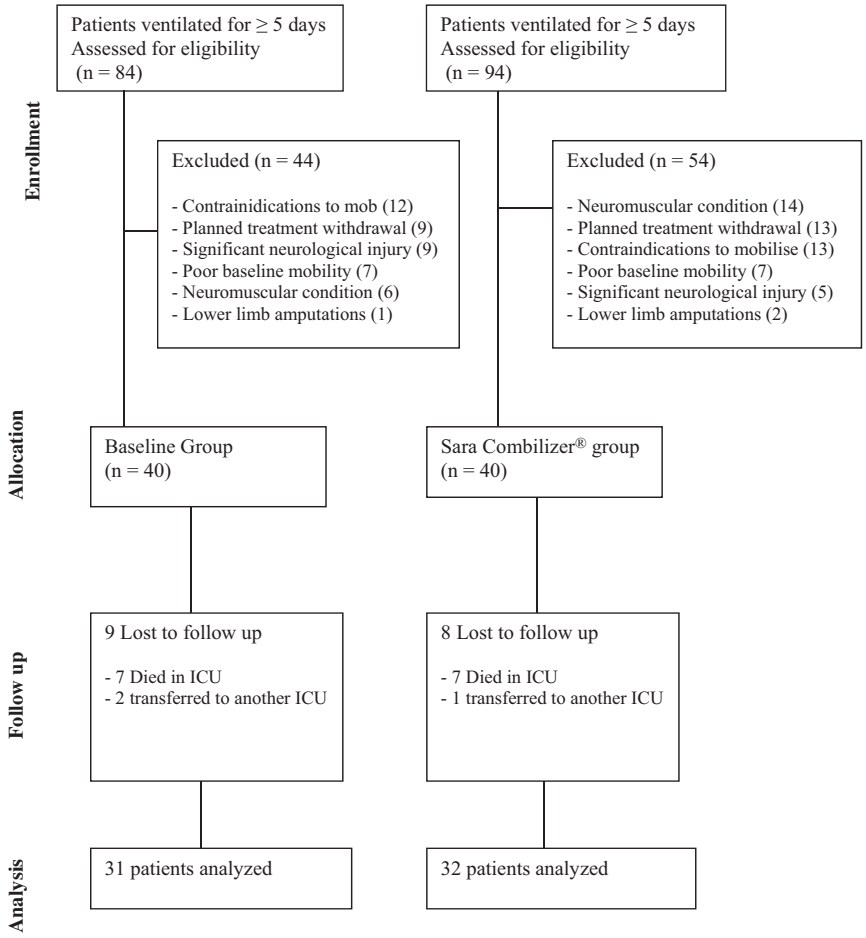

Fig. 4. Participant flow diagram.

Table 1
Patient demographics and physiotherapy treatment time.

	Baseline group (n = 31)	Sara Combilizer® group (N = 32)	p-Value
Age	49.6 (15.8)	48.9 (17.7)	0.868
Gender (% male)	21 (68%)	20 (63%)	0.793
Charlson Comorbidity Index[#]	1 (0, 1)	1 (0, 2)	0.410
SOFA score at recruitment	6.7 (2.8)	7.3 (2.9)	0.430
Apache II score	12.7 (5.0)	16.0 (6.9)	0.037[*]
Pre admission Barthel (% with score of 20)	29 (94%)	31 (97%)	0.613
Admission speciality			0.039[*]
Burns/trauma	7 (23%)	3 (9%)	
General surgery	2 (6%)	4 (13%)	
Medical	2 (6%)	10 (31%)	
Neurological	20 (65%)	15 (47%)	
Chronic respiratory disease	3 (10%)	1 (3%)	0.355
Previous significant cardiac disease	0 (0%)	2 (6%)	0.492
End stage renal failure	0 (0%)	1 (3%)	1.000
Chronic liver disease	0 (0%)	1 (3%)	1.000

Reported as mean (SD), with p-values from t-tests or N (%), with p-values from Fisher's exact test, unless stated otherwise.
[#] Medians and IQR, with p-values from Mann–Whitney tests.
[*] Significant at $p < 0.05$.

Table 2
Time to first mobilisation and other outcome measures.

	Baseline group (n = 31)	Sara Combilizer® group (n = 32)	p-Value
Sara Combilizer® used	0 (0%)	15 (47%)	–
Mean total duration of physiotherapy (min)	503 (142)	348 (210)	0.103
Time to first mobilisation (days)	13.6 (11.7–15.8)	10.6 (9.1–12.4)	0.028[*]
SOFA score at 1st mobilisation[#]	2.9 (0.5)	5.1 (2.4)	0.005[*]
Sedation days	7.2 (5.9–8.7)	5.6 (4.7–6.6)	0.066
Ventilation days[†]	11 (6, 15)	8 (6, 12)	0.104
ICU dependency days	15.6 (12.9–19.0)	13.3 (11.4–15.5)	0.201
ICU length of stay (days)	17.1 (14.3–20.5)	15.3 (13.3–17.5)	0.331

All variables completed for all patients and reported as geometric mean (95% CI), with p-values from t-tests on logged values, unless stated otherwise.
[#] Reported as mean (SD), with p-value from a t-test. SOFA scores calculated for patients mobilising within the ICU only.
[†] Reported as median (IQR), with p-value from a Mann–Whitney test.
[*] Significant at $p < 0.05$.

No other significant differences were observed for any of the physical or psychological outcomes. Barthel scores indicated a significant loss of function as a result of critical illness, with subjects in both groups almost completely dependent at the point of critical care discharge. Although improvement was seen by the point of hospital discharge, this had still not returned to baseline levels and no significant differences were seen in the level of functional recovery between groups at either critical care or hospital discharge. There was no difference in HADS between groups, although less than 50% of patients were able to complete this due to confusion or reduced consciousness. Completion of the MRC sum scores was similarly limited.

Table 3
Additional outcomes.

	Baseline group (n = 31)	Sara Combilizer® group (n = 32)	p-Value
Barthel score at ICU discharge	1 (0, 3)	2 (0, 7)	0.267
Barthel score at hospital discharge	13 (2, 19)	15 (2, 18)	0.850
Anxiety score at ICU discharge	11 (7, 12) [n = 12]	4 (2, 8) [n = 11]	0.103
Anxiety score at hospital discharge	8 (3, 11) [n = 16]	3 (2, 6) [n = 15]	0.321
Depression score at ICU discharge	7 (3, 13) [n = 12]	3 (2, 7) [n = 11]	0.282
Depression score at hospital discharge	5 (2, 11) [n = 16]	6 (3, 10) [n = 15]	0.843
MRC sum score at ICU discharge	51 (41, 54) [n = 16]	47 (34, 56) [n = 22]	0.579
MRC sum score at hospital discharge	58 (48, 60) [n = 19]	54 (50, 60) [n = 27]	0.855
Readmission to ICU—n (%)	3 (10%)	1 (3%)	0.355
Falls on ward—n (%)	4 (13%)	4 (13%)	1.000

Reported as median (IQR), with p-values from Mann–Whitney tests, or as N (%), with p-values from Fisher's exact test, as applicable.

6. Discussion

The introduction of the Sara Combilizer® was associated with a significant reduction in the time to first mobilisation for patients mechanically ventilated for greater than five days within critical care. This was achieved despite the therapy time remaining similar. Patients' SOFA scores were higher at the time of first mobilisation in the Sara Combilizer® group, suggesting they were in a greater degree of organ failure whilst mobilising.

Advances in rehabilitation practice within critical care have demonstrated significant benefit. Improvements in strength, function and mobility serve to reduce the impact of a period of critical illness, whilst the reductions in LOS results in both costs savings and more efficient utilisation of resource within critical care units.[25] The key message from national guidance in this area is to start rehabilitation as early as clinically possible,[26] although no exact definition currently exists on what 'early' really means. Previous research has attempted to identify specific barriers to early mobilisation, finding factors such as the presence of an endotracheal tube, reduced conscious levels and hemofiltration lines as common barriers. Organisational factors also play a part, with limitations reported due to reduced staffing levels and concerns regarding patient and caregiver safety.[19,20,27] We specifically assessed the impact of a device designed to facilitate mobility of patients who would otherwise be confined to bed, in a cohort at high risk of ICUAW. We have demonstrated the introduction of this mode of transfer to be an effective method of reducing the time taken to first mobilise within critical care. Importantly, SOFA scores confirm this occurred during a more acute stage of the patients' illness.

The strengths of this study are that it was appropriately powered to detect the primary outcome of time to mobilise and that recruitment targets were achieved in the specified time frame. The one month training and familiarisation period allowed training to be delivered to the nursing and physiotherapy teams working within critical care. The development of a protocol also provided some guidance on use of the device. Although the reduced time taken to mobilise (10.6 days) for the Sara Combilizer® group may appear slower than previously published studies, the specific population studied were those still sedated and mechanically ventilated at recruitment with more potential restrictions to mobilise. The Sara Combilizer® allowed mobilisation of patients at a time when SOFA scores were significantly higher, potentially supporting mobilisation at an earlier time point in their illness and recovery than would otherwise have been possible.

One major limitation to our findings is the before and after nature of the study. As the devices were made freely available to all staff, a randomised design within a single centre would have led to high risk of contamination. Population variations may have impacted on results. The baseline data collection occurred during the summer months and included a higher proportion of trauma and neurological patients, who may have different recovery trajectories to the more medical population seen in the Sara Combilizer® group. Patients with specific exclusions to mobilise such as lower limb fractures or spinal injuries were however excluded from the study which should have limited the impact of this. Subjects were otherwise well matched at baseline, although the intervention group did present with a higher illness severity on admission. No formal change in sedation practice occurred, but there was a non-significant reduction in the number of sedation days in the intervention group in comparison to baseline. This may have meant patients were more alert and therefore able to commence mobilisation at an earlier time point. Certainly previous research has demonstrated the link between reductions in duration of sedation and improved outcomes.[28]

Use of the Sara Combilizer® was supported by a mobility protocol, and was utilised in 47% of the patients for whom it was made available. It was impossible and may have been counterproductive to mandate use, as some patients were ready to progress with mobilising through the protocol at a faster rate, and therefore use may paradoxically have held progress back. As such, the Sara Combilizer® protocol specifically recommended its use for patients with a delayed ability to mobilise or restrictions which may have previously deemed mobilisation unsafe. Only 23 of the 63 patients in the 2 groups were able to complete all of the outcome measures of Barthel, HADS and MRC sum score, demonstrating the difficulties in using such scoring systems as outcome measures in critical care trials.

Despite the reduced time to mobilise no changes were seen in either physical or psychological outcomes from use of the device, although it is acknowledged the study was not specifically powered to detect such changes. Further research is required to confirm these findings and future evaluations of this and similar devices should be conducted as a multi-site cluster randomised trial due to the high potential for contamination between groups. It would be useful to explore the impact of the device for specific populations with significant restrictions to early mobilisation (e.g. neurosurgical or trauma patients) who may have been excluded from previous trials in this area. A lack of impact of early mobility has been seen in a number of recently published studies.[29–31] This may in some part be due to the inclusion of patients with shorter ICU lengths of stay or lower illness severity scores. thus meaning they may be less likely to require or show benefit from the intervention. Future studies should carefully consider inclusion and exclusion criteria in more detail to ensure rehabilitation is evaluated for specific populations most at need. More information regarding the specific barriers to mobilisation may also help to provide greater insight into the lack of translation seen into clinical practice.

7. Conclusions

The introduction of the Sara Combilizer® was associated with a significant reduction in time to mobilise in patients mechanically ventilated for $\geq$5 days and at high risk of the long term sequelae from critical illness. The degree of organ failure, assessed using SOFA scores, was significantly higher during mobilisation in the Combilizer group suggesting patients were being mobilised at a more acute stage of their critical illness. The Sara Combilizer® may be a useful adjunct to early mobilisation protocols for patients within the ICU.

Funding

Funding support for a research physiotherapist and the four Sara Combilizer® devices was provided by Arjo-Huntleigh. The physiotherapist delivered no clinical care to the patients in the trial and was solely involved in data collection and staff training regarding use of the device. Arjo-Huntleigh had no input into the design, conduct, analysis of results or manuscript and have not paid the open access fees.

Authors contribution

DM: conception and design, introduction and training sessions for the Sara Combilizer®, data collection and analysis, manuscript writing and final approval of the manuscript. GA: introduction and training sessions for the Sara Combilizer®, data collection and final approval of the manuscript. JH: statistical analysis, manuscript writing and final approval of the manuscript. CS: conception and design, data analysis, manuscript writing and final approval of the manuscript. All authors read and approved the final manuscript.

Acknowledgements

We are grateful to the support of University Hospitals Birmingham Research and Development department for help in protocol development and research governance oversight, and the patients and staff of the critical care unit.

To answer the Continuing Professional Development Questions – go to page 196 http://dx.doi.org/10.1016/S1036-7314(17)30234-5

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