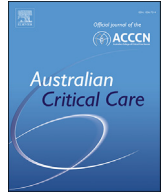




Contents lists available at ScienceDirect

Australian Critical Care

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

Research paper

Ventilator-tube holder for mobilising patients with a tracheostomy: A pilot usability study (TrachVest)

Paul Twose, MSc, BSc ^{a, d, *}, Susan Peirce, PhD, MSc, BSc ^b, John Maisey, BSc ^c, Laura Jones, MSc, BSc ^a, Jason Nunn, BSc ^a

^a Physiotherapy Department, University Hospital of Wales, Cardiff, CF14 4XW, UK; ^b Cedar, Cardiff Medicentre, Heath Park, CF14 4UJ, UK; ^c Mechanical Section, Clinical Engineering, Medical Physics Corridor, University Hospital of Wales, Heath Park, Cardiff, CF14 4XW, UK; ^d School of Healthcare Sciences, Cardiff University, Cardiff CF144XN, UK

ARTICLE INFORMATION

Article history:

Received 15 March 2024
Received in revised form
9 May 2024
Accepted 31 May 2024

Keywords:

Critical care
Physiotherapy
Tracheostomy
Mechanical ventilation
Mobilisation

ABSTRACT

Introduction: Patients in intensive care may have a tracheostomy and be dependent on a respiratory ventilator while yet conscious and able to mobilise. Early rehabilitation is known to be key to patient recovery. However, for these patients, therapy staff members are required to manage the ventilator tubing in addition to other patient-connected equipment whilst focussing on patient mobility and progress. A technical garment (TrachVest) was designed to hold the ventilator tubing securely during these therapeutic mobilisations.

Methods: We conducted a mixed-methods study to evaluate the use of this garment in an intensive care unit setting. The aim was to determine potential effects on patient safety, its potential benefits, and usability. Research methods included direct observations, user questionnaires (quantitative and qualitative), and staff focus groups.

Results: A total of 14 therapy sessions with the garment were observed, involving nine patients and 10 staff. Eleven staff members participated in two focus groups, including two previously involved in the therapy sessions. Therapy sessions consisted of a range of activities including sitting on the edge of the bed, transferring from bed to chair (including use of hoists), and mobilising with walking aids. Overall, staff members felt that the garment was easy to use and would likely improve patient safety during mobilisations. The main benefits were staff reassurance, allowing them to focus on therapy, and in potentially reducing the number of staff members needed for particular activities. Patient characteristics were found to be influential on the perceived utility, and TrachVest may have greater benefit for patients who have greater physical function (e.g., able to actively participate in rehabilitation) and can mobilise at least from bed to chair. Experience of using the TrachVest and of patient capabilities was thought to be key to knowing when it would be most useful.

Conclusion: Within this pilot usability study, participants, both staff and patients, reported that the TrachVest garment designed to support ventilator tubing during rehabilitation to be highly useable and beneficial to supporting rehabilitation in this patient group.

© 2024 Australian College of Critical Care Nurses Ltd. Published by Elsevier Ltd. This is an open access article under the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>).

1. Introduction

Early rehabilitation within critical care is now common practice, with literature supporting its safety^{1–3} and effectiveness in improving patient outcomes.^{4–6} Patients are supported to undergo rehabilitation by specialist staff including physiotherapists (PTs),

occupational therapists (OTs), nurses, and support workers. Part of this rehabilitation may include helping a patient to sit on the edge of the bed, stand, and mobilise.⁷ During rehabilitation sessions and other aspects of patient care, safety is paramount, and staff must take care to ensure that all lines and attachments are not dislodged.⁸ This includes tubing connecting the ventilator to the tracheostomy, excessive movement of which can cause damage to the airway, breakdown of skin, and partial or complete dislodgement, requiring immediate intervention.⁹

The number of staff members required to help mobilise a patient and maintain safety can be significant, especially when the patient

* Corresponding author.

E-mail addresses: TwosePW@cardiff.ac.uk (P. Twose), peirces@cardiff.ac.uk (S. Peirce), john.maisey@wales.nhs.uk (J. Maisey), Laura.Jones7@wales.nhs.uk (L. Jones), Jason.Nunn@wales.nhs.uk (J. Nunn).

<https://doi.org/10.1016/j.aucc.2024.05.014>

1036-7314/© 2024 Australian College of Critical Care Nurses Ltd. Published by Elsevier Ltd. This is an open access article under the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>).

has multiple attachments. Time spent managing patient tubes/lines can account for up to 61.4% of the total time spent performing mobilisations.¹⁰ Unfortunately, this staffing burden may contribute to reduced levels of patient mobilisation and rehabilitation,¹¹ with workload and staffing constraints previously highlighted as the limiting barriers to mobility interventions.^{12,13} This is particularly relevant for patients with larger numbers of tubes/lines or those who are more at risk of missed rehabilitation opportunities and hence higher risk of the complications of immobilisation.¹⁰ However, it is possible that specially designed equipment may facilitate patient mobilisation with increased safety and reduce resource requirements.¹⁴

In 2016, a custom-designed 'TrachVest' garment was designed by the Medical Engineering Department for use within a Welsh NHS Health Board. The purpose of the garment was to support the ventilator tubing whilst walking a patient with a portable ventilator. This relieved pressure and pulling on the tracheostomy tube and allowed the patient greater freedom of movement without requiring additional staff to manage/handle the tubing. The apparent success of this custom-made garment could be repeated in other patients with similar conditions. Furthermore, it may help to reduce the number of staff members required when mobilising a patient and lower the handling burden.

Based on this, the aim of this study was to evaluate the 'TrachVest' garment in an intensive care unit setting, to determine the most appropriate mode of use, and improve the design of the garment.

1.1. Research question

To conduct a preliminary assessment of the potential safety issues, utility, and usability of the TrachVest garment for patients with a tracheostomy.

2. Method

2.1. Study design

A pilot mixed-methods study, providing formative evaluation of the garment.

2.2. Context

The host organisation was a tertiary 38-bed, mixed-dependency critical care unit, admitting 1600 patients per year, a 6-bed post anaesthetic care unit, and specialist services for ear, nose, and throat and oromaxillofacial surgery. Typically, across the specialities, 120–140 tracheostomies are performed each year. These may be for a variety of indications including prolonged mechanical ventilation or as part of head and neck surgery.

2.3. Participants

2.3.1. Patients

Purposeful sampling of patients was intended to ensure use of a range of garment sizes as well as patient conditions/pathologies. As a pilot study, a sample of 12 is considered sufficient.¹⁵

Patients meeting the following criteria were considered for inclusion:

- Inpatient in critical care unit for any admitting condition.
- Aged 18 or over.
- Any gender.
- A permanent or temporary tracheostomy.
- Dependent on a respiratory ventilator.

- Capable and expected to be out of bed and mobile in the critical care unit with the assistance of staff.
- Expected to remain in critical care unit for several days and to retain their tracheostomy during this time.
- Not currently Covid-positive (defined by local policy) and in area of reduced requirement for personal and protective equipment.
- Able to give written, informed consent or have an appropriate consultee who can be approached.

A limited exclusion criterion was utilised:

- Injuries or restricted movement of the arms and shoulders

2.3.2. Staff

Therapy staff (PTs and OTs) involved in patient mobilisations were recruited to provide feedback on the 'TrachVest' garment. Following in situ data collection, additional therapy staff (PT and OT) who had not used the garment were recruited to participate in focus groups. All staff provided informed consent for their inclusion in either patient-related activity or focus groups.

2.4. Intervention

The TrachVest was available in five sizes (extra-small to extra-large). The main component of the TrachVest is a single unit, which is applied to the back and secured across the upper torso by chest and shoulder straps. Three removable attachment loops can be applied to any part of the soft fabric sections to secure the tubing. Attachment to the soft fabric areas was achieved using sections of relatively hard plastic 'hook' material, in a 'hook-and-loop' style fastening. The fabric was designed for single-patient use only; however, it could be used multiple times with a single patient. The fabric was wiped clean only, and therefore, TrachVests would need to be replaced if they became soiled or if there were any concerns regarding infection risk.

Therapists working in the intensive care unit were shown how to use the TrachVest (see Fig. 1) by PTs in the research team. Training took approximately 30 min to complete and included staff applying the TrachVest to each other and responding to specific questions.

The TrachVest was applied to the patient in either a lying or sitting position, ensuring appropriate fit, and securing the ventilator tubing. The patient was then assisted to mobilise according to their ability and therapy goals.

2.5. Data collection

2.5.1. Observational data

A researcher (SP) observed or video recorded the use of the TrachVest, including donning and doffing. Staff members were sometimes questioned during these manoeuvres to explain what they are trying to do and the usefulness of the garment. The researcher took ethnographic notes during the observations or used video recordings to produce these.



Fig. 1. TrachVest garment.

2.5.2. Staff opinions

Staff provided feedback immediately post mobilisation via a self-completed written questionnaire (see supplementary material 'TrachVest: Staff feedback questionnaire v1.0'). This included open-ended and quantitative (Likert scale) questions based on the three research questions and asked about improvements to the garment. Hand-written data forms were transcribed into electronic versions by the researcher.

2.5.3. Patient opinions

Patients who were able were also asked for verbal or written feedback, as appropriate. Handwritten data forms were transcribed as earlier.

2.5.4. Focus group

Two staff focus groups were convened following the analysis of the observational data and questionnaires. The focus groups were moderated by the researcher (SP), plus an additional note taker. Each session included a therapist who had used the TrachVest multiple times. The discussions were digitally recorded and transcribed. Initially, staff members naïve to the garment were asked to don it on a volunteer. Then results of the thematic analysis of the observations and staff surveys were presented to the focus groups, illustrated by use of images and videos from patient mobilisations (Fig. 2). Reflective discussions were directed around these themes.

2.6. Data analysis

A mixed-methods approach was utilised. Quantitative data were analysed descriptively, e.g., staff numbers, time to complete activities, Likert scales. The observational notes, and staff open-ended survey answers, were subject to thematic qualitative analysis (SP). This included both deductive coding (based on the research questions and improvements to the garment) and an inductive approach (allowing novel themes to arise from the data). Thematic analysis followed the method of Braun and Clarke.¹⁶ As the data set was relatively small and simple, manual coding and analysis was used.

2.7. Ethical considerations

Ethical approval for the completion of this study was provided by the Wales Research Ethics Committee REC 7 (21/WA/0302), with study sponsorship provided by Cardiff and Vale University Health Board. All staff participants and patients with capacity to consent provided informed written consent. For patients lacking capacity, a suitable consultee provided advice regarding the patient's participation. In instances where video recordings were completed, videos were stored on password-protected computers owned by the host organisation and were destroyed at study end. The completion of the recording was optional, with prior written consent from the patient or consultee advice.

2.8. Trial registration

ClinicalTrials.gov Identifier: NCT05281224.

3. Results

3.1. Demographics

Twelve patients were recruited (6 males, 50%), with a mean (\pm standard deviation) age of 51.7 (\pm 23.1) years and body mass index of 29.0 (\pm 8.0). Participant diagnoses included COVID pneumonia ($n = 3$), community-acquired pneumonia (3), sepsis (2),

upper gastrointestinal surgery (1), lower gastrointestinal surgery (3), stroke (1), and sepsis (2). Three patients did not proceed to data collection after recruitment, either because they improved quickly and came off ventilation (2) or because they deteriorated (1).

The TrachVest was used for the following activities: assisting patients to sit up on the edge of bed; assisted standing (with and without an aid), unassisted standing, using a standing aid or hoist to transfer patients to a chair, transfer to a tilt table using a Patslide, and walking with a wheeled walker and portable ventilator.

A total of 14 treatment sessions were completed and observed, involving nine patients and 10 therapy staff members (seven PTs and three nonregistered therapy support workers or physiotherapy students), with most staff involved in more than one treatment. The TrachVest was worn for 9–32 min and took between a few seconds and 2 min to don. A total of 35 postsession staff surveys were completed. Six patients were able to provide an indication of their opinion on at least one observation, of which four completed (or part-completed) patient-feedback surveys.

In addition, 12 staff participants were recruited to attend a focus group (two focus groups consisting of six staff members), with 11 attending. Each focus group included at least one person who had used the TrachVest during the clinical data collection and several who had seen or heard about it but not used it. This group included PTs, OTs, and therapy support workers.

The results are reported as a combination of the in-situ survey responses (staff and patients) and observations, followed by analysis of the focus-group material. In addition to safety, utility, usability, and garment improvements, an inductive theme relating to patient characteristics emerged from the data. Additional results are also reported in the supplementary material 'TrachVest evaluation—supplementary results'.

3.2. Safety

Staff members using it reported that they were confident that TrachVest held the tubing securely. Most staff were confident or very confident that the ventilator tubing was held securely and that the TrachVest would not cause problems with the tracheostomy tube (93.8%, 30/32). Furthermore, 87.5% (28/32) indicated that TrachVest would decrease the risk of the tracheostomy moving during mobilisation.

Staff felt the TrachVest decreased the risk of tube movement compared to a staff member holding it or other alternatives. The TrachVest was "Much better than taping vent tubing to patient top", and that initially "I was a bit worried the Velcro would come lose but it didn't and seemed strong when I checked", "[the patient] waved her arms a lot, and I was worried she might knock the trache[ostomy] tubing. The vest may be a good backup in that case."

One safety concern raised by participants was that staff may become complacent when using TrachVest and stop watching the ventilator tubing. In this case, they may not notice as quickly if an issue arose. However, this was not observed during the study, and there were no adverse events or disconnections of attachments. In one patient, one of the two attachment loops holding the ventilator tubing became detached from the shoulder strap whilst they were transferred in a hoist; however, as the 2nd loop remained attached, there was no impact.

3.3. Utility

Staff and patient feedback were generally positive regarding potential benefits, with 85.7% (24/28) of staff reporting that TrachVest would improve patient's ease of movement and 83.3% (25/30) that it would improve comfort. Most felt that the TrachVest would have benefits for the number of staff members needed to

Questions to direct focus group discussions:

- Safety
 - Does it hold the tubing securely? Could the tubing become detached during use?
 - What are the potential safety issues?
- Benefit
 - What activities might it be more beneficial for?
 - Does it save time or mean fewer staff are required?
 - Could it increase patient mobility or confidence?
 - Are there any patients for which it isn't suitable, or activities it would make harder?
- Usability
 - When should it be donned? Whilst lying or sitting?
 - Is it compatible with patient-connected equipment, or with the use of a hoist?
 - Could it be used at home?
- Patient characteristics
 - Does usability or benefit depend on patient mobility or ability?
 - Would it have benefit in other patient groups and settings?
- Improvements – what changes could improve the safety, benefits or usability?
- What would you like to know from a trial of TrachVest?

Videos and images presented to the focus group participants:

- TrachVest being donned and doffed in both sitting and supine positions
- Ventilator tubing being attached using the loops
- Different mobilisation activities: walking, using a PatSlide, assisted sitting.
- How the spare loops were used to attach additional equipment
- Tubing issues: swapping sides as the patient is moved, raising the tilt table
- Using the TV with a hoist – loop became detached

Fig. 2. Focus-group agenda.

mobilise a patient (78.1%, 25/32) and staff workload (81.3%, 26/32). However, fewer staff felt it would make the mobilisation process easier 55.5% (15/27), and 72.4% (21/29) were unsure whether the TrachVest would reduce the time needed to mobilise patients—although there was no suggestion it would take longer.

Staff commented that the TrachVest freed up a staff member or a 'pair of hands' and enabled them to focus on other things. "No support needed by staff, thus focus on mobility. Patient had the confidence to mobilise whilst ventilated". This view was supported by one of the patients who reported that "it kept tubing tidy and easy to manage" and "it's a very good aid".

Three responses highlighted staff concern for the tracheostomy during mobilisations, but using the TrachVest alleviated these concerns, allowing them to focus on the therapeutic activities. "It took a lot of anxiety away regarding securing the airway".

It was suggested that TrachVest could reduce the number of staff members needed under some circumstances. It held the tubing securely and could reduce the potential for movement of the tubing and disconnections from the ventilator. "Tubing is static compared to patient [the] tubing and patient move as one unit".

An unforeseen benefit was that some staff used spare attachments loops to secure additional patient connections during the movements (arterial lines, suction tubing). TrachVest "frees up my hands. It's very useful".

3.4. Usability

Most staff reported that the TrachVest was easy to use. The ventilator tubing could be attached in a variety of orientations

depending on the presence of additional attachments, e.g., heat moisture exchangers, speaking valves, or inhaler inlets.

Staff unanimously thought the TrachVest was easy or very easy to don and doff (32/32). Most reported it was easy/very easy to secure it on the patient (87.5%, 28/32), with only 9.3% (3/32) reporting it as hard to adjust. Of note, in one of these events, no difficulty with adjusting the TrachVest was observed, and the other two staff members rated this as 'very easy'. Additionally, 84.3% (27/32) of staff thought it was easy/very easy to secure the ventilator tubing to the TrachVest.

The 'hook' fastenings of the TrachVest could get stuck to the rest of the fabric when not in use, resulting in the staff needing to spend time separating and orienting the TrachVest before use. Additionally, the all-black colouring made it harder to identify if the TrachVest was inside out, with staff voicing concerns that family or carers may don the TrachVest incorrectly.

The test design did not fit all patients equally well. The upper back strap was sometimes seen to be against the patient's neck, although this did not seem to cause any irritation or distress, and no patients reported any discomfort. As single-patient use, the garment could not be tried on to determine the fit, and staff needed to estimate the most appropriate size for a patient.

3.5. Patient characteristics

Whilst it was more effort to don the TrachVest on supine patients, it was still beneficial in holding the tubing secure, allowing staff to better assist the patient. *"Put it on lying if able, so lying to sitting is easier with the tubes secure"*. Others suggested that the TrachVest may be more useful for those more functionally able, *"[the TrachVest] makes it more work initially to roll [the patient] to put on. Will be useful for more mobile patients/further on with recovery"*. Application was easier for patients with more upper-body strength/control; *"[the] patient was able to lift torso forward therefore increased ease of application"*. For one patient, who was able to walk unassisted with a walker and mobile ventilator, the staff stated that the *"TrachVest is working really well for her"*.

One-way valves extend the tubing length slightly, and in some cases made finding a good position for the attachment loops more difficult. *"We're dragging the trache[ostomy] around a bit, aren't we?"*

One patient had a relatively large laryngeal prominence, with a lower tracheostomy stoma. This resulted in the tracheostomy tube projecting further out than in others. This made for a tighter bend in the ventilator tubing, with the tracheostomy pulled slightly towards the side on which it was secured. Staff commented that they had the greatest difficulty in finding a suitable fixation of the tubing for this patient, and half (6/12) of the negative survey comments related to this single patient. *"We put the vest on in lying, and I felt we did not find an optimal position for the tubing. Once we were up, the fastening had come away by approx[imately] 75% and we had to re-adjust"*.

3.6. Future modifications

Staff provided suggestions on improvements to the TrachVest design. This included use of colour to allow easier recognition of the correct orientation of the TrachVest and easier location of the fixing loops. Staff also suggested several times that wider attachment areas for the shoulder straps would be more accommodating for variable patient body shapes and enable the ventilator tubing to be secured further away from the patient's head.

3.7. Focus groups

3.7.1. Safety

Staff in the focus groups agreed that the TrachVest looked secure on the videos and may be safer than a person holding the tube. However, some participants agreed that there may be a danger of complacency. It was recognised that the use of the TrachVest *"doesn't take away the responsibility for the airway"*, and they advocated continuing to allocate an individual to care for the airway during mobilisation (as per local practice).

Staff did not believe the TrachVest would cause any additional harm to the patient, particularly regarding wound dehiscence or tracheostomy displacement. Indeed, some staff identified the TrachVest as a 'strain-relief' device, acting as additional protection from accidental disconnection. *"If we were pulling it too tight, you'd get a warning because this [attachment loop] is harder to detach than the tubing from the trache"*. *"If it starts to pull, it's going to pull from the TrachVest first rather than straight from the trache(ostomy)"*.

There were minor concerns that any lines or tubing under the TrachVest may result in pressure damage if worn for a long time. This did not occur during the observations, which were of short duration. Some staff thought that the videos showed the tracheostomy tube being pulled down and to one side by the TrachVest and suggested that there was a risk of damage over the long term. A change in design or instructions was suggested, or the use of some padding to keep the tracheostomy tubing horizontal. This was not identified during any of the mobilisations.

3.7.2. Utility

Staff in focus groups reiterated the idea that the TrachVest freed up one set of hands and foregrounded the value of being reassured about the tracheostomy and able to focus on the patient. *"I could have my hands elsewhere to improve the quality of the therapy they're getting. It's hard work to keep changing your hands all the time and worry about the trache[ostomy] or the tubing"*. *"I didn't have to think about it. Not in a way that I'd forgotten about it, in a way that I definitely knew it was secure"*.

Staff debated the value of using the TrachVest for relatively short mobilisation procedures (such as lying to sitting) in highly dependent patients with low neurological tone. Whilst some staff felt that *"It's an extra fuff isn't it?"*, others repeated previous comments that the TrachVest could potentially *"free up a pair of hands"*. This was particularly true where a staff member's sole responsibility is to support the tubing, including when the patient is relatively static. *"I'd have to have a second pair of hands to hold the tubing if we're ... washing face or shaving. You could just pop that on, and then the other person could go"*.

Staff supported using the TrachVest to secure other equipment/attachments, including arterial-line transducers and nasogastric drainage bags. They indicated that this should not be included in the instructions for use but left to the judgement of experienced therapists.

The value and suitability of TrachVest was thought to be dependent on its cost. As a single-patient-use product (able to use multiple times with one patient), staff would be more likely to try it out with a patient only if it was inexpensive and easily available. Staff recognised that although simple to use, there would be a learning curve with respect to working out when it was most beneficial to use and for what patients. *"It's about trying different things and seeing what's going to work for that patient and that treatment, isn't it? It's going to be different under different circumstances"*. Experience with the TrachVest and each patient would enable staff to judge whether the effort to use the TrachVest was

outweighed by the benefit during the mobilisation (dependent on the nature and duration)—“*Not for the first sit*”.

3.7.3. Usability

Staff in the focus groups who were untrained in using TrachVest had some difficulty in donning the garment, including which way round it went and how to secure the straps. However, after watching the videos they agreed it was easy to use. It was suggested that ‘formal’ training was unnecessary. The versatility of the attachment loops was commented on; “*I like that you can literally stick this [loop] anywhere*”.

Staff felt that they would probably not leave the TrachVest fastened around the patient once they were sat out in the chair. This was based on concerns around pressure areas and the potential that “*Patients can get hypersensitive if it's around the chest. One patient [in the study] said that she felt it was quite restrictive. I don't think it was physically, I think it was more the psychological ... of having something around her chest and fixing something to her*”.

3.7.4. Patient characteristics

Both focus groups agreed that the TrachVest may have greater benefit for more mobile patients. For a highly dependent patient “*depending on their sitting balance, if they're quite heavy (low toned), it could be a challenging to put that on*”. Additionally, patients have different tolerance for the number of attachments, but for others who are quite agitated and may move around a lot, the TrachVest may be more appropriate than looping the tubing over a rigid support arm.

3.7.5. Future studies

Focus group participants were asked about the design of future studies on TrachVest. It was felt that this should be in longer-term ventilated patients, particularly in paediatric patients (who are very mobile and energetic) and in adults cared for at home. The only objective outcomes were thought to be disconnections (common) and decannulations (rare), although patient-reported outcome measure would be difficult due to the large proportion of such patients who lack capacity.

4. Discussion

The use of the TrachVest during mobilisation of patients requiring mechanical ventilation via a tracheostomy appears to be safe and has additional benefits for staff efficiency and workload and for patient comfort. In this study, staff felt the TrachVest reduced the potential for adverse events during mobilisation and that it was easy to use and was beneficial in providing additional support for the ventilator tubing, allowing staff to focus more on the patient and rehabilitation activity. To our knowledge, this is the first such study exploring the use of a support garment to aid the provision of rehabilitation of those requiring mechanical ventilation via a tracheostomy, and hence comparison with existing literature is not possible.

The adverse-event rate during mobilisation within critical care is low,¹ but there remains a significant safety risk, especially in the case of tracheostomy displacement or accidental decannulation via excessive forces on ventilator tubing.² Perhaps unsurprisingly point prevalence studies continue to show relatively low overall rates of active mobility.^{17,18,19} A recent UK research has shown that ‘staffing’ remains a significant barrier to providing out-of-bed rehabilitation, with nearly 20% of the nonphysiological reasons (or 3% of the entire critical care cohort) for not completing a rehabilitation session, being due to staffing alone.¹⁷ The presence of patient attachments, or their increasing number, has significant impact on the delivery of rehabilitation sessions.²⁰ Benjamin et al.¹⁰ determined that staff

spend large proportions of time purely focussed on attachment management (up to 61.4% of overall time), with positive correlations between the number of attachments and the amount of time needed to manage them ($p = 0.014$) and the overall number of staff required to complete the rehabilitation session ($p = 0.002$).

Identifying strategies to reduce the burden of attachment management, e.g., tubes and lines, whilst maintaining patient safety are paramount to increasing rehabilitation activity. Especially given the provision of such activity has been shown to improve patient outcomes^{4,21} and reduce length of stay.²² The TrachVest may have the potential to achieve these aims. Based on our findings, there is suggestion that the use of the TrachVest may reduce the workload involved in mobilising a patient receiving mechanical ventilation via a tracheostomy, adding reassurance to staff and patients that the ventilator tubing is secure, potentially allowing increased focus on supporting the patient to mobilise, or increasing the patient's independence to mobilise alone if able.

The pilot nature of this study resulted in several limitations. Purposive sampling was intended but was not possible due to recruitment issues, partly related to the Covid pandemic. However, a reasonable range of body habitus, physical capability, conditions, and mental capacity were achieved for a small study. This study only recruited adult patients within an inpatient setting. Future studies should consider paediatric populations and similar patients in community settings. This may affect the findings, particularly as staff highlighted the potential for the TrachVest to have greater benefit in those more physically able. These future studies would also help determine clearer indications, precautions, and contraindications for use of the TrachVest.

This study only involved PTs (including nonregistered staff) in the rehabilitation sessions, which reflected common practice within the host organisation. Future studies using the TrachVest must involve a wider range of healthcare professions including nursing staff. The TrachVest was only tried with one type of ventilator, tubing, and accessories, and the outcomes may differ for other equipment. It was removed from each patient after the therapy session was completed, despite the original device being used for longer durations. This was because it could not be guaranteed that trained staff participants would be available when the patient was returned to bed. This limited our ability to assess the comfort and safety of TrachVest over longer durations.

5. Conclusions

Within this pilot usability study, participants, both staff and patients, reported that the TrachVest garment designed to support ventilator tubing during rehabilitation, to be highly useable and beneficial to supporting rehabilitation in this patient group. Further studies are now needed to explore its use in a wider patient population and with a range of healthcare professionals to determine its impact on adverse events and staff workload.

Funding

This was a European Regional Development Fund funded ACCELERATE (Welsh Health Innovation Technology Accelerator) project, led by the Life Sciences Hub Wales. In kind contributions were provided by industry and Cardiff and Vale University Health Board.

Credit authorship contribution statement

PT: Conceptualisation, methodology, funding acquisition, investigation, formal analysis, supervision, project administration, visualisation and writing original draft. SP: Methodology, funding

acquisition, investigation, formal analysis, visualisation and writing original draft. JM: Conceptualisation, Review and editing. LJ: Methodology, investigation, writing review and editing. JN: Methodology, investigation, writing review and editing.

Conflict of interest

None of the authors have any conflicts of interest to declare.

Data availability

The data that support the findings of this study are available on request from the corresponding author [PT]. The data are not publicly available due to containing information that could compromise the privacy of research participants.

Acknowledgements

We acknowledge the contribution from Michael Beddard (senior researcher, CEDAR), assisting with focus-group management and data collection, and Dafydd Roberts (CEO, Brodwaith Cyf) for designing and creating the TrachVest and providing garments for the completion of this trial.

Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.aucc.2024.05.014>.

References

- [1] Bailey PP, Miller RR 3rd, Clemmer TP. Culture of early mobility in mechanically ventilated patients. *Crit Care Med* 2009;37:S429–35. <https://doi.org/10.1097/CCM.0b013e3181b6e227>.
- [2] Nydahl P, Sricharoenchai T, Chandra S, Kundt FS, Huang M, Fischill M, et al. Safety of patient mobilization and rehabilitation in the intensive care unit. Systematic review with meta-analysis. *Ann Am Thorac Soc* May 2017;14(5):766–77. <https://doi.org/10.1513/AnnalsATS.201611-843SR>.
- [3] Lang JK, Paykel MS, Haines KJ, Hodgson CL. Clinical practice guidelines for early mobilization in the ICU: a systematic review. *Crit Care Med* 2020;48(11):e1121–8.
- [4] McWilliams D, Snelson C, Goddard H, Attwood B. Introducing early and structured rehabilitation in critical care: a quality improvement project. *Intensive Crit Care Nurs* 2019;53:79–83. <https://doi.org/10.1016/j.iccn.2019.04.006>.
- [5] McWilliams D, Weblin J, Atkins G, Bion J, Williams J, Elliott C, et al. Enhancing rehabilitation of mechanically ventilated patients in the intensive care unit: a quality improvement project. *J Crit Care* Feb 2015;30(1):13–8. <https://doi.org/10.1016/j.jccr.2014.09.018>.
- [6] Hodgson CL, Bailey M, Bellomo R, Bricklell K, Broadley T, Buhr H, et al. Early active mobilization during mechanical ventilation in the ICU. *N Engl J Med* 2022;387(19):1747–58. <https://doi.org/10.1056/NEJMoa2209083>.
- [7] Connolly B, O'Neill B, Salisbury L, Blackwood B. Physical rehabilitation interventions for adult patients during critical illness: an overview of systematic reviews. *Thorax* 2016;71(10):881–90. <https://doi.org/10.1136/thoraxjnl-2015-208273>.
- [8] Stiller K, Phillips A. Safety aspects of mobilising acutely ill inpatients. *2003/01/01 Physiother Theory Pract* 2003;19(4):239–57. <https://doi.org/10.1080/09593980390246751>.
- [9] Morris LL, Whitmer A, McIntosh E. Tracheostomy care and complications in the intensive care unit. *Crit Care Nurse* 2013;33(5):18–31. <https://doi.org/10.4037/ccn2013518>.
- [10] Benjamin E, Roddy L, Giuliano KK. Management of patient tubes and lines during early mobility in the intensive care unit. *2022/12/01/ Human Factors Healthcare* 2022;2:100017. <https://doi.org/10.1016/j.hfh.2022.100017>.
- [11] Twose P, Newey V, Jones U. The role and staffing of physiotherapy in critical care: a scoping review. *J Assoc Chartered Physiotherap Respirat Care* 2022;54(2):92–120.
- [12] Lewis M, Cumming L, Twose P. Comparison of perceptions and barriers to mobilization in critical care: a comparison of nursing staff and physiotherapists—a single-site service evaluation. *Nurs Crit Care* 2021. <https://doi.org/10.1111/nicc.12625>. n/a(n/a).
- [13] Boehm LM, Lauderdale J, Garrett AN, Piras SE. A multisite study of multidisciplinary ICU team member beliefs toward early mobility. *2021/01/01/ Heart Lung* 2021;50(1):214–9. <https://doi.org/10.1016/j.hrtlng.2020.09.021>.
- [14] Needham DM, Truong AD, Fan E. Technology to enhance physical rehabilitation of critically ill patients. *Crit Care Med* 2009;37:S436–41. <https://doi.org/10.1097/CCM.0b013e3181b6fa29>.
- [15] Julious SA. Sample size of 12 per group rule of thumb for a pilot study. *Pharmaceut Stat* 2005;4(4):287–91. <https://doi.org/10.1002/pst.185>.
- [16] Braun V, Clarke V. Using thematic analysis in psychology. *2006/01/01 Qual Res Psychol* 2006;3(2):77–101. <https://doi.org/10.1191/1478088706qp063oa>.
- [17] Black C, Sanger H, Battle C, Eden A, Corner E. Feasibility of mobilisation in ICU: a multi-centre point prevalence study of mobility practices in the UK. *Crit Care* 2023/06/01 2023;27(1):217. <https://doi.org/10.1186/s13054-023-04508-4>.
- [18] Berney SC, Harrold M, Webb SA, Seppelt I, Patman S, Thomas PJ, et al. Intensive care unit mobility practices in Australia and New Zealand: a point prevalence study. *Crit Care Resusc* Dec 2013;15(4):260–5.
- [19] Jolley SE, Moss M, Needham DM, Caldwell E, Morris PE, Miller RR, et al. Point prevalence study of mobilization practices for acute respiratory failure patients in the United States. *Crit Care Med* 2017;45(2):205–15. <https://doi.org/10.1097/CCM.0000000000002058>.
- [20] Hodgson CL, Capell E, Tipping CJ. Early mobilization of patients in intensive care: organization, communication and safety factors that influence translation into clinical practice. *Crit Care* 2018;22:1–7. <https://doi.org/10.1186/s13054-018-1998-9>.
- [21] McWilliams DJ, King EB, Nydahl P, Darbyshire JL, Gallie L, Barghouthy D, et al. Mobilisation in the EveNing to prevent and TreAt deLirium (MENTAL): a mixed-methods, randomised controlled feasibility trial. *eClinicalMedicine* 2023;62. <https://doi.org/10.1016/j.eclinm.2023.102101>.
- [22] Waldauf P, Jiroutková K, Krajčová A, Puthuchery Z, Duška F. Effects of rehabilitation interventions on clinical outcomes in critically ill patients: systematic review and meta-analysis of randomized controlled trials. *Crit Care Med* 2020;48(7):1055–65.