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## Research paper

# The perceived barriers and facilitators to implementation of early mobilisation within a multicentre, phase 3 randomised controlled trial: A qualitative process evaluation study



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## ABSTRACT

**Background:** Process evaluation within clinical trials provides an assessment of the study implementation's accuracy and quality to explain causal mechanisms and highlight contextual factors associated with variation in outcomes.

**Objectives:** This study aimed to identify the barriers and facilitators of implementing early mobilisation (EM) within a trial.

**Methods:** This is a qualitative process evaluation study within the Trial of Early Activity and Mobilisation (TEAM) phase 3 randomised controlled trial. Semistructured interviews were conducted remotely with multiprofessional clinicians (physiotherapists, medical staff, and nursing staff) involved in the delivery of the TEAM intervention at Australian hospitals participating in the TEAM study. Inductive coding was used to establish themes which were categorised into the Behaviour system involving domains of Capability, Opportunity, and Motivation (COM-B), which allowed barriers and enablers affecting EM to be identified.

**Findings:** Semistructured interviews were conducted in three different states of Australia. There were 16 participants, including 10 physiotherapists, five physicians, and one nurse. The key themes that facilitated EM were mentoring, champions, additional staff, organisation of the environment, cultural changes, communication, and documented safety criteria. In contrast, the main factors that hindered EM were lack of expertise and confidence in delivering EM, heavy sedation, interdisciplinary conflicts, and perceived risks related to EM.

**Conclusion:** A wide range of barriers and facilitators that influenced EM within the TEAM study were identified using the COM-B framework. Many of these have been previously identified in the literature; however, participation in the study was viewed positively by multidisciplinary team members.

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## 1. Introduction

Rehabilitation is a complex intervention, and research in this area can be particularly challenging owing to the inherent heterogeneity of the research scenario.<sup>1</sup> Researchers need to consider multiple factors, including the interaction of the components within experimental and control interventions, the ability to measure the outcomes, the behaviour of the participants who deliver the intervention, the patients who receive the intervention, and how much flexibility is allowed to adapt a test intervention.<sup>2</sup> To ensure the effectiveness of complex interventions, it is necessary to understand whether, why, and how an intervention worked in a clinical context and to explain how research that has demonstrated effectiveness in one specific setting can or cannot be effective in others.<sup>3</sup> A process evaluation within a trial can be conducted to evaluate the fidelity and quality of implementation, explain causal mechanisms, and highlight contextual factors associated with variation in outcomes.<sup>4,5</sup>

Over the last few years, a multidisciplinary intervention called “early activity and mobilisation” has been developed and tested by the Trial of Early Activity and Mobilisation (TEAM) study investigators.<sup>6–8</sup> Currently, a multicentre, randomised controlled phase 3 study, the TEAM trial, has been conducted in patients expected to require prolonged mechanical ventilation to determine whether the early activity and mobilisation delivered during invasive mechanical ventilation increases the number of days patients spend alive and out of the hospital in the 180 days after randomisation.

To improve the delivery of this trial, understanding the nature of behavioural change is necessary. The Behavior Change Wheel is a systematic, theory-based guide to intervention design based on the principles of the Capability, Opportunity and Motivation.<sup>9</sup> This system suggests that for any behaviour to occur, there must be a change in one or more of the following: Capacity, Opportunity, or Motivation.<sup>9</sup> The COM-B system can be used to identify the barriers and facilitators of behaviour change and has been widely applied to the behaviour of health professionals.<sup>10–12</sup> With that in mind, this study aimed to systematically identify and exploit barriers and facilitators qualitatively to implement early EM) within a National Health and Medical Research Council (NHMRC) funded multicentre trial using the COM-B behaviour model.

## 2. Methods

### 2.1. Design

A qualitative process evaluation study was conducted using stakeholder interviews across seven Australian intensive care units (ICUs) from February 2020 to July 2020, participating in the TEAM phase 3 randomised controlled trial (RCT) – NCT03133377. Ethical approval was gained before study commencement, and written consent was obtained from all participants before the interview.

The participants' sites were chosen based on physiotherapists with education in both conducting and supervising patient mobilisation activity as well as an understanding of ventilation. Participants received education and training before starting the trial. The intervention arm comprises exercises based on a reproducible, physiological approach using both strength and functional activities. All efforts were made to mobilise patients out of bed. The control group received standard care from physiotherapy staff not involved in delivering the intervention whenever feasible. A previous study established that standard care in Australia for patients receiving prolonged invasive mechanical ventilation was minimal active exercises, and patients rarely mobilised out of bed.<sup>7</sup>

Physiotherapists assessed the patients daily for 7 days a week using the ICU Mobility Scale<sup>6</sup> to determine their highest level of mobility achieved. A multiprofessional (physiotherapists, nurses, and physicians) discussion was encouraged before the enrolment and the intervention. The intervention was performed by a mobility team comprising of a senior ICU physiotherapist (not the usual care physiotherapist in most instance), an allied health assistant, and the ICU bedside nurse.

### 2.2. Conceptual framework

The Behavior Change Wheel, which encompassed three major conditions (Capability, Motivation, and Opportunity), was used as a guide to structuring this study.<sup>9–12</sup> Capability was related to the individual's psychological and physical capacity to conduct an activity concerned. Motivation included the reflexive and automatic processes of an activity. Reflexive processes were defined as the brain processes that direct the person's decision and behaviour, involving evaluation and plans. Automatic processes imply the emotions and impulses that emerge from associative learning and/or innate dispositions. Finally, Opportunity referred to outer factors that make behaviour feasible or immediate. It was distinguished between physical opportunity (provided by the environment) and social opportunity (provided by the social setting that dictates the way people think about things.<sup>9</sup> This study used the consolidated criteria for reporting qualitative research.<sup>13</sup>

### 2.3. Participants

#### 2.3.1. Study population

Multiprofessional clinicians involved in the Trial of invasively ventilated adults with Early Activity and Mobilisation (TEAM) trial, a prospective multicentre phase 3 RCT at Australian hospitals.

#### 2.3.2. Inclusion criteria

Multiprofessional clinicians (physiotherapists, medical staff, and nursing staff) involved in the delivery of the TEAM intervention at Australian hospitals participating in the TEAM phase 3 RCT.

#### 2.3.3. Exclusion criteria

There were no exclusion criteria.

### 2.4. Data collection

Participants were identified by purposive sampling. Discussion guides for the interviews were developed based on the COM-B framework<sup>9</sup> and were designed to elicit the perceived barriers and facilitators to early mobilisation in the TEAM RCT (See [online supplement – Questions for interview](#)). Pilot testing of the interview occurred with two physiotherapists involved in the delivery of the TEAM intervention. Eligible staff members at each site were identified by the ICU research coordinators and invited by email to participate in the study. Semistructured interviews were conducted face-to-face or remotely (telephone, Zoom, or Teams) in a calm and quiet environment with the staff at each ICU between February and July 2020.

The interviews were audio recorded; detailed notes were written during and immediately after the interviews and transcribed by an independent evaluator (A.L.). Participants and sites were de-identified, and quotes used in the study remained confidential. No further interviews were conducted when thematic saturation was reached, as determined by two independent coders (A.L. and A.N.). This was determined to have occurred when no new major perceived facilitators or barriers were discussed within multiple interviews.

The interviewer (A.L.) was a female PhD student with clinical and research ICU experience and without previous contact with the participants or their workplace.

### 2.5. Analysis

Transcribed interviews were assessed independently by two investigators via open coding for the development of basic themes (A.L. and A.N.), before deductive axial coding was applied for the three COM-B domains using the process of framework analysis.<sup>9,12</sup> Emerging themes were explored and tested for applicability and consistency. Two researchers read the transcripts to familiarise themselves with the content (A.L. and A.N.). A framework matrix was developed for the domains of Capability, Opportunity, and Motivation. The two researchers independently coded and recoded transcripts using NVivo, version 11 (NVivo qualitative data analysis software; QSR International Pty Ltd), continually working back and forth between data sources in a process of open, axial, and thematic coding using the framework matrix developed to chart the codes into the relevant domains. Discrepancies were resolved by discussion and consultation with the research team as required. Any differences in themes between investigators were discussed and, if lack of consensus achieved, were resolved through a third independent investigator (C.H.). Major themes were identified if they were consistently identified in interviews at multiple sites. Minor themes were those that were mentioned once or twice only throughout the interviews. The interviewer provided feedback to participants on the transcription and on findings to validate the researcher's interpretations.

## 3. Findings

Semistructured interviews were conducted with multiprofessional intensive care staff involved in the TEAM trial from three different states in Australia. There were 16 participants, including 10 physiotherapists, five physicians, and one nurse. Participants' demographic data are outlined in Table 1.

Facilitators to implementing EM during the TEAM trial

The major themes that facilitated EM were mentoring, confidence and expertise, EM champions, additional staff to provide EM, desedation, organisation of the environment, cultural changes to promote EM, good communication to plan EM, and clear safety criteria. The minor themes were workload flexibility & time management, clear eligibility criteria, the environment, education and engagement, and clinicians' mindset changes in obtaining help from the team to achieve the EM intervention.

Barriers to implementing EM during the TEAM trial

The major themes considered barriers to EM were lack of expertise and confidence, ICUs without EM champions, insufficient staff, heavy sedation, environment and cultural factors, interdisciplinary conflicts, poor communication, and perceived risks related to EM. The minor themes that were barriers to EM

were increased workload, low recruitment rates, disengaged team and/or patient, and dosage and beliefs about EM, which made it a low priority.

The reported barriers and facilitators to early mobilisation for the TEAM trial using the COM-B framework are depicted in Fig. 1. The quotations to support each theme perceived by participants for the COM-B domains are described in Table 2, with the following examples.

### 3.1. Capabilities – psychological and physical capacity to implement EM

#### 3.1.1. Facilitator

**3.1.1.1. Mentoring.** Some participants reported that senior or more experienced professionals (mentors) acted as a guide to junior or nonexperienced staff, including cotreatment of patients in the ICU. Hence, these junior staff members were able to become more confident and competent in delivering EM (Table 2).

*"I think it is good for more junior staff to see that patients can actually do a lot more on the unit than previously that they thought they could."* (Physiotherapist)

**3.1.1.2. Expertise and confident staff.** A major theme that emerged about capability was confident, experienced staff. Higher levels of mobilisation were achieved in ICUs in which confident and experienced teams were part of the workforce.

*"I think EM has probably been changing our management .... I think with the TEAM study it is a little bit more than the routine to push these patients a bit more aggressively earlier. We are probably getting more comfortable in doing that, even to patients who are not in the TEAM trial."* (Physician)

*"Certainly, the staff have to be comfortable. They've got to ideally be experienced at least, have perhaps mobilised somebody before on the ventilator or even simulated it. I think that's another important thing to help with implementation."* (Physician)

*"I think particularly at the X Hospital, the physios who work in the ICU are highly skilled, so it was easy to adapt for this study."* (Physiotherapist)

**3.1.1.3. Encouraging champions for EM.** Several team members emphasised the importance of encouraging leadership or champions to ensure adequate communication and to minimise concerns related to EM. They also claimed that it was important to have champions for EM in each health discipline.

#### 3.1.2. Barriers

**3.1.2.1. Inexperienced and untrained staff.** Many participants raised the issue of inexperienced and untrained staff as a barrier. These factors were considered crucial to the implementation of EM.

**Table 1**  
Demographic data.

Characteristics	Physiotherapists	Physicians	Nurse
N	10	5	1
Age (years), mean (range)	34.3 (28–44)	41.25 (37–44)	31
Male n, %	1	5	1
Years of clinical experience, mean (range)	10.9 (5–15)	17 (14–20)	11
Year of ICU experience, mean (range)	7.7 (3–14)	10.75 (9–14)	6
Year of experience with early mobilisation, mean (range)	6.5 (1–15)	6.25 (2–10)	1
Interviews duration, mean (range)	25.1 (11–61)	14.2 (11–19)	21

ICU, intensive care unit.



**Fig. 1.** Application of the COM-B model to perceived facilitators to implementation of early mobilisation within the TEAM trial. ICU, intensive care unit; COM-B, Behaviour system involving domains of Capability, Opportunity, and Motivation; TEAM, Trial of Early Activity and Mobilisation.

*"I think it is very important because it is a scary thing for a physio that has not got experience and it is a scary thing for the nursing staff."* (Physiotherapist)

**3.1.2.2. ICU with no leadership.** A considerable barrier to the implementation of EM was units with no leadership in rehabilitation. The lack of someone to guide and motivate the staff hindered the conduct of EM.

## 3.2. Opportunity – social and environmental opportunity

### 3.2.1. Facilitators

**3.2.1.1. Additional staff.** Respondents reported that a facilitator to the implementation of EM would be additional staff (Table 2). A few participants related that some physiotherapists worked on their days off to guarantee that EM was performed.

*"They come in on their days off to make sure it happens, particularly over the weekend, when staffing and all the resources aren't as good."* (Nurse)

*"We should have an additional physiotherapist around to assist with the process because the demand for our nursing staff for a variety of other things is already pretty high. So I think having additional dedicated staff for the process of mobilisation would also be important."* (Physician)

**3.2.1.2. Sedation break.** Numerous interviewees stated that desedation was considered paramount to start EM. A sedation break was requested before intervention and throughout the study.

*"We can consult with bedside nurse and the consultant to try to reduce their sedation and inotropes because that's going to help*

*with us to be able to optimise the amount of early mobility we can implement."* (Physiotherapist)

**3.2.1.3. Organisation of the space, lines, attachments, and equipment.** The organisation of the ICU room space, lines, attachments, and equipment was raised as another facilitator to EM. This organisation was performed before the intervention, and it was deemed essential to avoid accidents.

*"... It is kind of like a Formula One pitstop, like when the car comes in, everyone needs to know what to do and where they need to be."* (Physician)

*"They also have to have all the necessary equipment in terms of mobility aids, ensuring that the infusions or the ventilator are capable of allowing the patient to mobilise."* (Physician)

**3.2.1.4. Cultural change.** Several participants reported that the implementation of the TEAM trial has changed the ICU culture in their hospitals. Once clinicians had become more aware of the potential benefits of EM and confident, physical activities with critically ill patients have been encouraged.

*"I knew that doing the study would raise the profile of early mobility within this unit. So I'm really glad that we are on board with it. It shows that it is a team-based on early mobility. It is not just about one discipline getting people up and doing the exercise and mobilising patients. It is everybody."* (Physiotherapist)

*"About early mobility, participating in this study helped that even with the nursing staff and the doctors, it also helped them to see the benefits for the patients and the benefits for the staff, thus boosting morale. It's good for families to know that their family member is able to do something. We can tell them, you know, they sat on the edge of the bed today, or they sat on a chair. They come in, and they see them sitting in the chair. It's very good for the staff and for the families to see that. So it's been very good."* (Physiotherapist)

**3.2.1.5. Workload flexibility & time planning.** Participants reported that owing to caseload flexibility and time planning, they were able to adhere to the protocol. Also, a few hospitals had extended hours of service to achieve the goal of treatment.

**3.2.1.6. Communication with team members.** Communication was one of the enablers most cited throughout the interviews. Many participants related that contact with staff was essential before starting the protocol and also to conduct EM. Discussing patients' clinical conditions, desedation and inotropic weaning, and scheduling a time to implement EM were paramount to start and conduct EM.

*"Quite a bit of implementation work done to ensure that people are comfortable because the last thing you would want would be someone to be mobilised and the nurse wasn't comfortable, the doctor wasn't happy and then that leads to whole lot of anxiety. Then that would derail the whole process. So, I think the key thing here is it can have lots of secondary gains, but the communication has to be robust."* (Physician)

*"I discuss EM with all the team in the room to ensure that they feel that it's still safe, that they're still happy to continue..."* (Physiotherapy).

**Table 2**

Perceived barriers and facilitators to implementation of EM in the TEAM trial using the COM-B framework.

COM-B Domain	Barrier	Interview quote	Facilitator	Interview quote
<i>Capability</i> The psychological and physical capability to implement EM throughout the TEAM trial	Inexperienced and untrained staff	"I think another negative point is that sometimes people assume it's an easy thing to do in ICU. I think to run the protocol you absolutely need a senior clinician doing the intervention. You need to be able to know when to stop." [Physiotherapist, interview 15]	Mentoring	"We do tutorials ... and competency for our junior staff. We do co-treats, and that's a big part of our grade one and grade two professional development plans. It's one of the things that you want them to be confident and competent." [Physiotherapist, interview 1]
	Lack of expertise and confidence	"We had initial issues when we did things that the nursing staff weren't familiar with, such as, sitting on the side of the bed with an endotracheal tube in place." [Physiotherapist, Interview 7]	Expertise and confident staff	"So you need a level of experience, and clinical reasoning to know when it is appropriated to push your patients more and to make sure that you're reassessing throughout the intervention and responding to any changing in their clinical condition. However, that comes with clinical experience rather than education specific to the TEAM study." [Physiotherapist, interview 3]
	ICU with no leadership/champion	"From a leadership point of view, I think it's difficult to have just the physiotherapist as a leader. The early mobility needs to be driven in every discipline." [Physiotherapist, Interview 15]	Encouraging ICU leadership/champion	"I think leadership is super important in this trial, ongoing teaching and training, which we have been doing and then communicating clinical reasoning and talking through all the concerns with all the stakeholders. Ensuring everyone has a chance to communicate their concerns." [Physiotherapist, interview 5]
<i>Opportunity</i> Factors outside the individual staff that influence the EM implementation during the TEAM trial	Insufficient number or unavailable staff	"The number one is the staff availability. So you have to have physiotherapists who have got time to do it, plus or minus one or two assistant. So that would be the main limiting factor for us." [Physician, Interview 8]	Additional staff	"We have been utilising nursing staff, wards staff and other physios to assist with those activities, particularly the functional-based exercises." [Physiotherapist, interview 6]
	Patients heavily sedated	"I think the biggest difficulty and barrier is actually sedation, often patients are too sedated or sedated for a long period of time. If they were recruited to the intervention group, maybe there was a long period of time where patients were an IMS 1 or were just doing usual care or the passive range of motion, bed exercises. So I think yes, the main difficulty was around sedation when the study is going." [Physiotherapist, interview 3]	Sedation break	If the patient is still sedated, we will then look at doing a sedation break to see whether we can wake them up to be able to actively participate in some therapy. [Physiotherapist, interview 1]
	Environment	"Definitely the lines, attachments part of the environment, and depending on how many machines the patient's attached to can make it seem more or less achievable." [Physiotherapist, interview 1] "Making sure it's appropriately resourced, so there's enough people, and enough equipment to actually do it safely. I think that is one of the major barriers" [Physician, interview 10]	Organisation of the space, lines, and attachments.	"In terms of environment, we always try to reduce lines and attachments, and things that could potentially be dislodged or moved. Hence, we will need fewer staff resources if these things can be optimised. We are always making sure that all staff and the patient are safe, organising everything, such as the ventilator, poles, lines, putting things onto the side of the bed next to the ventilator, rather than moving away from things that can be an issue" [Physiotherapist, interview 15]
	Cultural factors	The difficulties we have had have been due to probably cultural issues early on, like I was referring to before, we had a nurse who was risk-averse, who didn't want a patient sitting on the side of the bed because the patient was quite heavy in terms of body mass. This nurse thought that it was essentially a dangerous activity to complete. [Physiotherapist, interview 7]	Cultural change	"Secondly, to the evolving culture of our unit, that the nursing staff and medical team are thinking about early mobilisation not just as "rehab". Due to the trial we are exercising patients a lot earlier which has shown the medical team that it can actually help them get to that point of being well enough, in terms of strength, alertness, better respiratory status to be extubated. We've actually seen consultants now coming up to us and saying: -I'd love to see if this person can sit on the edge of the bed whilst they are intubated. Before I extubate them to see how they go." [Physiotherapist, interview 5]

(continued on next page)



Table 2 (continued)

COM-B Domain	Barrier	Interview quote	Facilitator	Interview quote
Motivation Automatic and reflective processes that influence the decisions made by a healthcare provider regarding the EM in the TEAM trial	Workload	"And I think that can be stressful for physiotherapy, nursing and potentially medical staff in the ICU, to manage the time requirements to perform early mobilisation, and do their other duties as well." [Physician, interview 4]	Workload flexibility & time management	I think it is a priority, often there is flexibility with the caseload to allow the intervention physio to deliver the full treatment for the patients." [Physiotherapist, interview 3] "I think daily care plans will be the most important factor ... Scheduling and timing become crucially important." [Physician, interview 12]
	Interdisciplinary conflicts	"Some consultants are very much on board, and some nursing staff are very much on board ... And if they are not on board, it is very hard for us. It is improving through the study, and we have had to change our culture a little bit." [Physiotherapist, interview 4]	Communication with team members	"We would reinforce that the physiotherapists have already had a discussion with the medical team .... Having the doctor onside seems to facilitate better early mobility." [Physiotherapist, interview 7]
	Low recruitment rate	"I completely understand why the inclusion-exclusion criteria are what they are. But I think they are so specific. I think that is why the rates in our unit are low ... the thing knocks out a lot of recruitment is the patient expected to be intubated the day after tomorrow. All of our consultants aim to extubate them on the next day in the morning." [Physiotherapist, interview 15]	Eligibility criteria	"However, the TEAM study gives us three days to enrol them. And usually by day three becomes a bit more obvious (whether patient will be extubated or not)." [Physician, interview 14].
	Poor communication	"I always talk about the first recruited patient because he was on the intervention arm ... I was too eager. I went in ready to go, so keen, my first patient, I didn't allow that communication from the nurse to discuss what her issues were. The communication from my end didn't allow for an open discussion ... I am glad this conflict happened because it made me re-evaluate my communication style within the trial." [Physiotherapist, interview 5]	Good communication	"I guess our learnings have been that communication is paramount. .... asking them: -What are their safety concerns? How can we do things to keep the patient as safe as possible?" [Physiotherapist, Interview 7]
	Disengaged team	"I also think that the consultants and the nursing staff that are on the day have an impact on whether we go ahead with mobilisation or not. There are some consultants that I feel they are very happy for us to continue with the physiotherapy. While, sometimes it is a little bit more difficult to engage and get on board physios, so that can be a barrier to mobilising patients." [Physiotherapist, Interview 16]	Education and engagement	"On the whole I think the nursing staff have been great in our unit. When we started, a lot of them were rolling their eyes, unfortunately. Even though they are very pro early mobility unit, the fact of having to do more anything, such as record it and have to be very pedantic about it (record the number of units, and have to mobilise a particular patient and not make the decision themselves about their patient), they were not so eager to do. They understand that we do a lot of research in our unit but not to that extent of recording it; they are not used to doing it – we have Research coordinators that record everything for our other research, but because TEAM is screened and performed by us as Physio's in our unit, we did rely on the bedside RN to obviously help us a little with some of it. But they got over it, and they are learning to do it. That is how we did it." [Physiotherapist, Interview 15]
	EM was not a priority	"I am speaking from the nursing side of things. It is not a priority for us, or for a lot of my colleagues. To them, it seems kind of just something else that takes up a lot of time, and they don't see a value in it. But certainly, when there are patients enrolled, and they are on the intervention arm, the physios are very engaged in making it a priority. They come in on their days off to make sure it happens, particularly over the weekend, when staffing and all the resources aren't as good." [Nurse, Interview 13]	Cultural changes	"I do think that it also has had a noticeable change in our physiotherapy culture that it's increasing our prioritisation of early mobilisation. Prior to this, chest treatments, have always been the priority in intensive care rather than mobilisation, or rehabilitation, we know this." [Physiotherapist, interview 5]
	Risks to EM	"I guess, from a safety point of view, sometimes we find nurses a little bit reluctant to mobilise the patients on high levels of PEEP. ... The level of alertness and ability to follow	Safety criteria compliance and daily assessment	"I think obviously if they meet the inclusion criteria, they've been deemed appropriated to be part of the

Dosage (difficulty to achieve their target minutes)	commands and RASS levels, definitely impact on our ability to implement the protocol." [Physiotherapist, Interview 6] "I'm very proud of the study, and we love it. However, getting a certain number of minutes is a barrier, as well. For instance, we might be there with the patient doing this many minutes of standing, and then this many minutes of sitting, and this many minutes of sitting balance, but actually it is 2 min of standing and a minute and a half of this and a minute, and you feel like you've actually been in there for an hour and you actually end up only doing 30 min" [Physiotherapist, Interview 15]	Obtain help from the team to achieve their target minutes	study. However, daily you would still assess the patient fully." [Physiotherapist, Interview 3] "Although I said at the beginning, we tried to have our senior staff to do the intervention for the intervention arm patients. However, we have junior staff in our evening service (4.30 pm–9 pm). Sometimes, we can not finish our intervention-arm treatment during our shift. Then we say to the junior physiotherapists that we need a few more minutes. We ask them to do the specific activities that we could not do, just to make up those few more minutes." [Physiotherapist, Interview 15] "The trial I think challenges the mindset of clinicians to rehabilitate people from the moment they come in the door. EM forces us to think about what can we do to get them functionally better from the start of admission ... I think the early mobilisation just changes the mindset from sick patients in a bed to how do we get these people home in the best shape possible. I see that as very positive." [Nurse, interview13] "Sometimes we walk to the veranda, we set up the ventilators and the oxygen outside, everyone is amazed at the difference that makes to our patients in improving their natural sleep/wake cycle." [Physiotherapist, interview 15]
Team beliefs on early mobilisation	"Probably the biggest thing has been the perceived degree of illness. The clinicians' perception of the patient's abilities. The medical staff also have said yes, but the nursing staff have said: - No, I have concerns. I don't think that the patient can do this. The staff perception of patient ability and illness is the biggest barrier." [Nurse, interview13]	Changes in clinicians' mindset	
Disengaged patients	"The patient mental attitude is another factor. If the patient is sad, upset, suffering in pain, that will affect the conduct of early mobilisation for the staff." [Physician, interview 12]	Changes in the ICU environment	

COM-B, Behaviour system involving domains of Capability, Opportunity, and Motivation; TEAM, Trial of Early Activity and Mobilisation; EM, early mobilisation.

### 3.3. Eligibility criteria

Patients meeting the inclusion criteria should be intubated and expected to continue to be mechanically invasively ventilated the day after tomorrow. This criterion was considered a facilitator because clinicians had 72 h to predict whether patients would be kept intubated or not.

#### 3.3.1. Barriers

**3.3.1.1. Insufficient number or unavailable staff.** A recurring theme for many hospitals was the insufficient numbers of staff or unavailable staff to implement EM throughout the TEAM trial. Resources were considered an issue, particularly in the complex, longer term patient and on weekends.

*"On the weekend, it could be a little bit different depending on staffing and what level the patient needs to do. So, in the afternoon would not probably be able to happen as well, or we often don't get a chance to meet the required minutes on the weekend. Like I said, patients need to do 30 min of active exercises, for various reasons like staffing and timing, and on the weekend, we might not be able to achieve that. We try to if we can." (Physiotherapist)*

*"We sometimes might not get to do the same thing on a weekend that we would do in the week." (Physiotherapist).*

**3.3.1.2. Patients heavily sedated.** Most participants reported that an important barrier was when patients were deeply sedated, which made the implementation of the proposed EM harder to achieve.

*"In terms of implementing early mobility, particularly with the intervention group, we had a few patients who were really slow to wake up from their sedation. So we had a really hard time meeting our mobility time targets because they couldn't be interactive and follow commands or an appropriate RASS to do active therapy. We had one patient who was not following commands for 10 days, so all we could do was transfer them out of bed. There was very little else we could do with them, so it was very difficult to try and increase that time." (Physiotherapist)*

**3.3.1.3. Environment.** Critically ill patients were often on mechanical ventilation, on haemodialysis, and with several lines, catheters, and attachments. All these accessories likely hinder patients' ability to get out of bed.

*"I think when you've got lots of lines and attachments, and all four limbs are attached to things, it can seem quite overwhelming and quite daunting as to how we're going to move that". (Physiotherapist)*

*"We certainly haven't had any equipment issues. However, bariatric patients are often more difficult to mobilise in general-they often are not able to use the cycle ergometer due to their size. They are also more difficult to do those activities related to higher ICU Mobility Scale level because we do not have easy access to the appropriate equipment for bariatric patients" (Physiotherapist)*

**3.3.1.4. Cultural factors.** Some participants identified several barriers related to the culture of the unit. Despite acknowledging that EM is beneficial to the patients, many professionals, especially those who were risk-averse, were not prepared to adhere to the protocol to provide EM, especially out-of-bed exercises.

*"Whereas the nursing staff is probably more worried about making sure that an adverse event doesn't happen under their watch. So it's more of a safety short term goal, physiotherapists have got more*

physical rehabilitation long term goals. So I understand that we're coming from different perspectives." (Physiotherapist)

**3.3.1.5. Workload.** Barriers related to the workload were a frequent issue discussed by participants. Many struggled to reconcile their usual workload with the time spent with TEAM trial patients.

*"I think the busyness and the stress on the medical departments are factors that could influence it. If they are rushed, or time-pressured or inundated with other requirements to deliver care to other patients, and other problems, that can impede them agreeing to provide EM."* (Physician).

**3.3.1.6. Interdisciplinary conflicts.** Interdisciplinary conflict was another main barrier manifested by professionals from different areas. Many of them had divergent opinions and were concerned about having patients enrolled and implementing the EM.

*"There are a couple of doctors who may present more barriers than others in regards to recruiting and mobilising patients."* (Physiotherapist).

*"There have been some incidents where the nursing staff did not feel that it was safe and that the patient was capable. The nursing staff refused to participate, which might make the job of mobilising the patient more difficult."* (Nurse)

**3.3.1.7. Low recruitment rate.** Several interviewees linked the low recruitment rate at their site to the inability to predict whether a patient would be extubated the day after tomorrow. Many of them also linked the low rates to patient severity and COVID-19 pandemic.

*"Sometimes I feel as though our patient population does not meet the criteria to participate in the trial, just because they are either quite medically unwell or extubated quite quickly."* (Physiotherapist)

*"... but during COVID, we are not enrolling suspected cases because of the risks to staff."* (Physician)

**3.4. Motivation – the brain processes that direct reasoning and decision-making to conduct specific practice**

**3.4.1. Facilitators**

**3.4.1.1. Education sessions for staff and having people aware of the benefits of EM.** A crucial factor that was a facilitator to EM during the TEAM trial was to have education sessions to inform the staff what the TEAM trial is, the potential benefits of EM, and how to conduct the intervention.

*"I think good education programmes and training resources are always a good idea concerning any change in practice"* (Physician)

**3.4.1.2. Safety criteria, compliance, and daily assessment.** Many professionals reported a daily assessment routine and the safety criteria compliance according to TEAM protocol. That evaluation was conducted to avoid risks related to EM.

*"I think that the other things that really come into play are the kind of the trajectory of stability for the patient. How they have looked over a 24 h period, not just how they are at that one point in time. That can give you a lot of information as to whether they're more stable or less stable than they have been."* (Physiotherapist)

**3.4.1.3. Obtain help from the team to achieve the target minutes.** Obtaining extra support from other staff members to reach the protocolised minutes was a facilitator to implement EM during the TEAM trial.

*"Even if our workloads have been busy, there's been enough physiotherapists that are familiar with the study to achieve the intervention time that was targeted."* (Physiotherapist)

**3.4.1.4. Changes in the ICU environment.** A few participants reported that environmental changes were used in the ICU to encourage patients to do the EM, such as natural light and exercises on the veranda or outdoors.

**3.4.2. Barriers**

**3.4.2.1. Poor communication.** Poor communication may be a factor that interferes with the success of the implementation of EM.

*"Obviously, if that communication doesn't happen, it can have negative impacts. I think that it's clearly part of the process for delivering the TEAM intervention"* (Physician).

**3.4.2.2. Disengaged team.** EM is a task that needs to be carried out as a team. Often the participants had to face an unmotivated team to assist the patients. For this reason, the disengaged team was considered another barrier to the implementation of EM.

*"The worst thing is as soon as you get one nurse offside, that translates to having issues down the track when we're trying to recruit and do exercise for other patients."* (Physiotherapist)

**3.4.2.3. EM as nonpriority.** Each profession had different priorities in the ICU. Participants recounted that occasionally EM was not considered a priority for the other teams, and only one group was responsible for EM, which makes this task more complicated.

**3.4.2.4. Risks to EM.** Several participants faced difficulties with implementing EM in critically ill patients owing to risks related to EM. Some patients were deemed high risk of an adverse event, and EM was not recommended.

*"If patients are on high doses of vasopressors or large fractions of oxygen, these patients are often deemed too 'unstable' to be mobilised. I think that seems to be a major barrier to deliver the intervention, illness severity and sedation."* (Physician)

**3.4.2.5. Dosage.** Some participants expressed difficulties achieving the target dose in minutes to deliver the patients' mobilisation.

*"...but to get the number of minutes that are required, it's sometimes difficult. Due to different patient activities or patient visitors and things like that, you may not get all the duration that we're aiming to get for that patient in the morning session."* (Physiotherapist)

**3.4.2.6. Team beliefs on EM.** Another barrier that was raised was team beliefs on EM. Divergent EM beliefs were reported, and this might complicate the EM negotiation with the interdisciplinary team.

*"Beliefs/benefits versus risks influence our team culture. I think that's just very nurse dependent. Subjectively, Twenty to 25% of nurses in our unit that still no matter how much education we give them even would rather just not get that patient out of bed and still don't understand that – although they still are getting them up according to our audit."* (Physiotherapist)



**3.4.2.7. Patients were not engaged.** A few participants reported the patients' attitude might influence the delivery of EM. Patients being less engaged with the exercises was considered a barrier.

#### 4. Discussion

This process evaluation study examined multiprofessional clinical staff perceptions of barriers and facilitators to implementation of EM within the TEAM phase 3 trial using the COM-B framework. Mentoring, confidence and expertise, EM champions, additional staff to provide EM, desedation, organisation of the environment, cultural changes to promote EM, good communication to plan EM, and clear safety criteria were considered the main themes related to EM facilitation. On the other hand, lack of expertise and confidence, ICUs without EM champions, insufficient staff, heavy sedation, environment and cultural factors, interdisciplinary conflicts, poor communication, and perceived safety risks related to EM were the main themes that were deemed barriers to EM.

Many studies have previously evaluated the barriers and enablers to EM in the ICU.<sup>7,14–20</sup> The use of sedation has been reported as an essential initial factor in providing EM in both context clinical trial and clinical practice.<sup>14,16–20</sup> During the interviews, participants reported that before conducting the intervention, they usually discussed a sedation break with physicians and nurses to allow active mobilisation. Although sedation was considered a barrier, team members tried to mitigate it by liaising with ICU staff. On occasions, they reported that this could delay the start of the mobilisation as some patients were awake and alert at the time of assessment.

Several barriers and facilitators found in this process evaluation study have been reported in other studies.<sup>7,14–20</sup> Team members faced similar difficulties experienced in clinical practice and were able to overcome them with facilitators that would also be used in clinical practice (e.g., good communication, mentoring).

Despite these similarities, different factors were related to the additional staff and workload that was required to deliver the TEAM intervention. Additional staffing appeared to be needed to facilitate the intervention, with staff reporting that TEAM physiotherapists used the study budget to pay for additional staff on weekends to mobilise the TEAM patients in the ICU. Staff also reported that when TEAM physiotherapists in charge of EM were overloaded, a redistribution of patients' caseload was required, and other physiotherapists, i.e., not part of the TEAM RCT, increased their workload to treat additional patients in the ICU.

Another unique theme to the TEAM trial was the ability to complete the dosage (minutes) of intervention during the day. If the EM dosage duration had not been completed as per the protocol, a discussion with the ICU bed nurse was held to complete the full dosage as required.

The nurses' role was crucial during the trial. A bedside round was performed during the morning. Nurses informed physiotherapists about the patients' conditions, sedation, and daily care plans and determined the best time to deliver EM. At the time of the intervention, each member of staff had a role. For instance, nurses were asked to protect the airway (endotracheal or tracheostomy tube) and the ventilator and another staff member protected the lines and attachments. Physiotherapists led the intervention, clearly explaining each role and the expectation of the team member before EM.

Resistance to EM, particularly from nursing staff, was described. However, participation in the TEAM study in some cases did appear to facilitate cultural changes, with physiotherapists recognising the importance of communication in preparation for EM interventions and engagement by the nursing staff in the process. Most of the interviewees reported that these interprofessional conflicts were mitigated with good communication, explaining the benefits of EM during critical illness.

Over several months of EM during the TEAM trial, some participants reported that as the TEAM protocol was an easy way to guide EM safely, the ICU clinicians' mindset about EM changed. Many cotreatments occurred at the bedside during the intervention. Although EM was led by senior physiotherapists (in most cases) for the TEAM trial, other staff members were reported to be more engaged. Hence, ICU staff became more confident, realised that EM was safe and feasible, and started to deliver EM in other patients not participating in the trial.

There were several strengths of our process evaluation. We included multiprofessional participants involved in the TEAM study from seven ICUs. This allowed an understanding of the clinical context in which the intervention took place. The second strength was that the COM-B provided a detailed understanding of barriers and enablers to implementing the EM within an ongoing clinical trial, allowing us to examine the contextual factors that influence individual behaviour. There were also several limitations to this study. First, although the TEAM trial has been conducted internationally, this process evaluation study only included staff in Australian ICUs. It would be interesting to include a broader evaluation involving other countries and cultures. Second, only one nurse was assessed, although several were invited to participate in the study. This is an important area for future research, as EM is a multiprofessional intervention with buy-in required from all of the ICU team. For example, if it was found that the nursing staff members do not feel engaged with the intervention within the context of a clinical trial, this may need to be addressed as an important barrier to delivery of the intervention.

#### 5. Conclusion

Within the context of an international clinical trial, this process evaluation study identified the relevant barriers and facilitators to the implementation of EM using the COM-B framework. A wide range of barriers and facilitators that influenced EM within the TEAM study using the COM-B framework were identified. Many of these have been previously identified in the literature; however, participation in the study was viewed positively by multidisciplinary team members. Participation in clinical research may positively influence changes in ICU culture and clinical practice.

#### CRediT authorship contribution statement

**Alessandra F Lago:** Formal analysis, Investigation, Data curation, Writing – original draft, Visualisation. **Angus J. Nicholson:** Validation, Investigation, Writing – review & editing. **Janani Sivasuthan:** Methodology, Validation, Resources, Writing – review & editing. **Ada Clarice Gastaldi:** Validation, Resources, Supervision. **Alicia Bowen:** Validation, Resources, Writing – review & editing. **Anne Stratton:** Validation, Resources, Writing – review & editing. **Claire Tipping:** Validation, Resources, Writing – review & editing. **Courtney Campbell:** Validation, Resources, Writing – review & editing. **Gemma Pound:** Validation, Resources, Writing – review & editing. **Kate McCleary:** Validation, Resources, Writing – review & editing. **Lauren Thomas:** Validation, Resources, Writing – review & editing. **Marc Nickels:** Validation, Resources, Writing – review & editing. **Melanie Paykel:** Validation, Resources, Writing – review & editing. **Morag Shealy:** Validation, Resources, Writing – review & editing. **Carol Hodgson:** Conceptualisation, Methodology, Validation, Formal, Investigation, Analysis, Resources, Data curation, Writing – review & editing, Supervision and Project administration.

#### Data sharing

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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## Conflict of Interest

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## Appendix A. Supplementary data

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