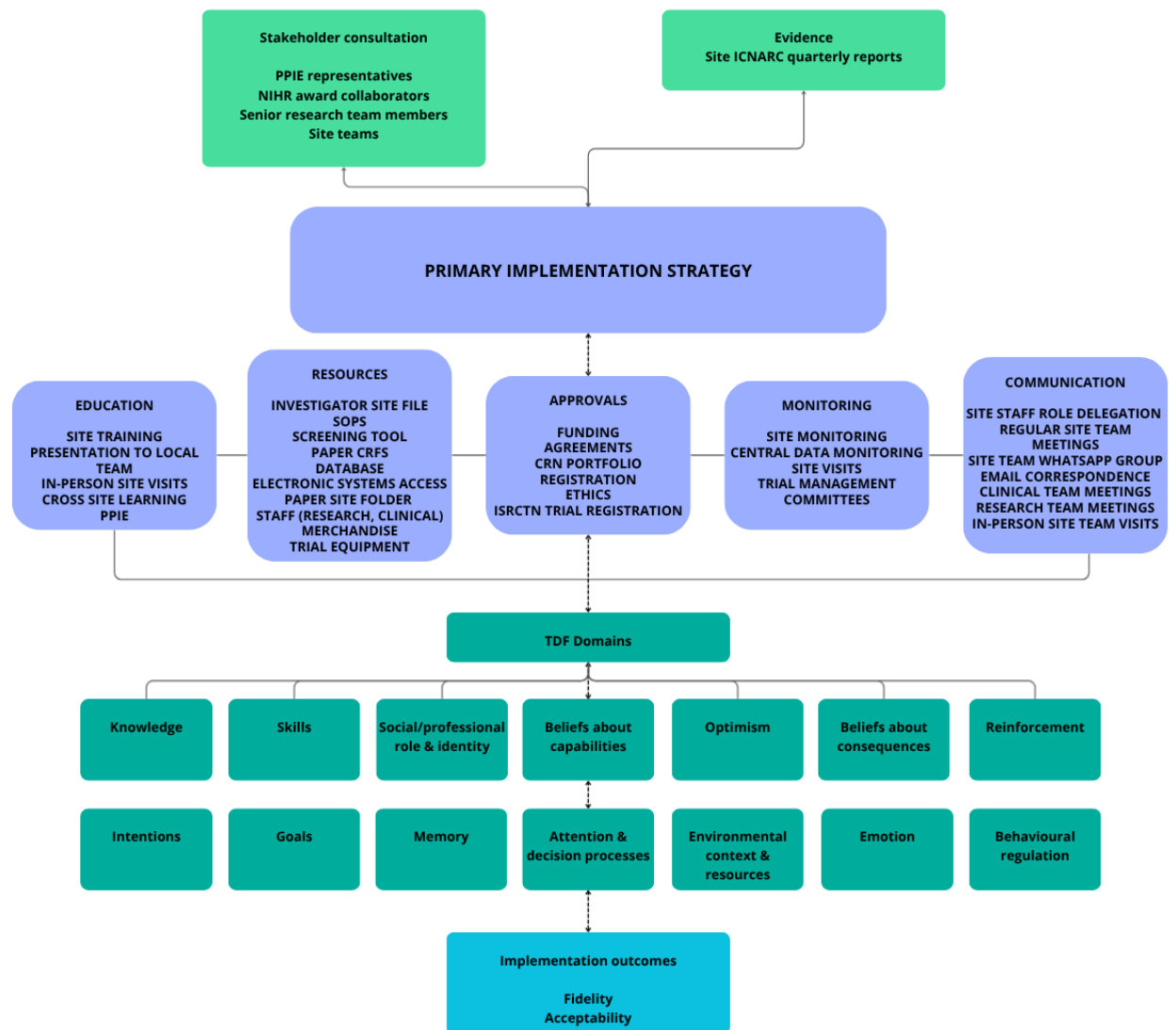


Does in-bed cycling, delivered within 48 hours of mechanical ventilation, reduce the occurrence of delirium in critically ill patients (FRECYcl-D): A protocol for a process evaluation.

Supplementary file

Figure sI. Trial implementation strategy



Patient and public involvement and engagement (PPIE), National institute for health and care research (NIHR), Intensive care national research and audit centre (INARC), standard operating procedures (SOPs), case report forms (CRFs), Theoretical domains framework (TDF). Figure made using [CANVA](#).

Figure sII. Logic Model

FREcycl-D Trial Logic Model

Does in-bed **Cycling** within 48 hours of mechanical ventilation **r**educed the occurrence of **Delirium** in critically ill patients
A mixed-methods **F**easibility **R**andomised controlled trial

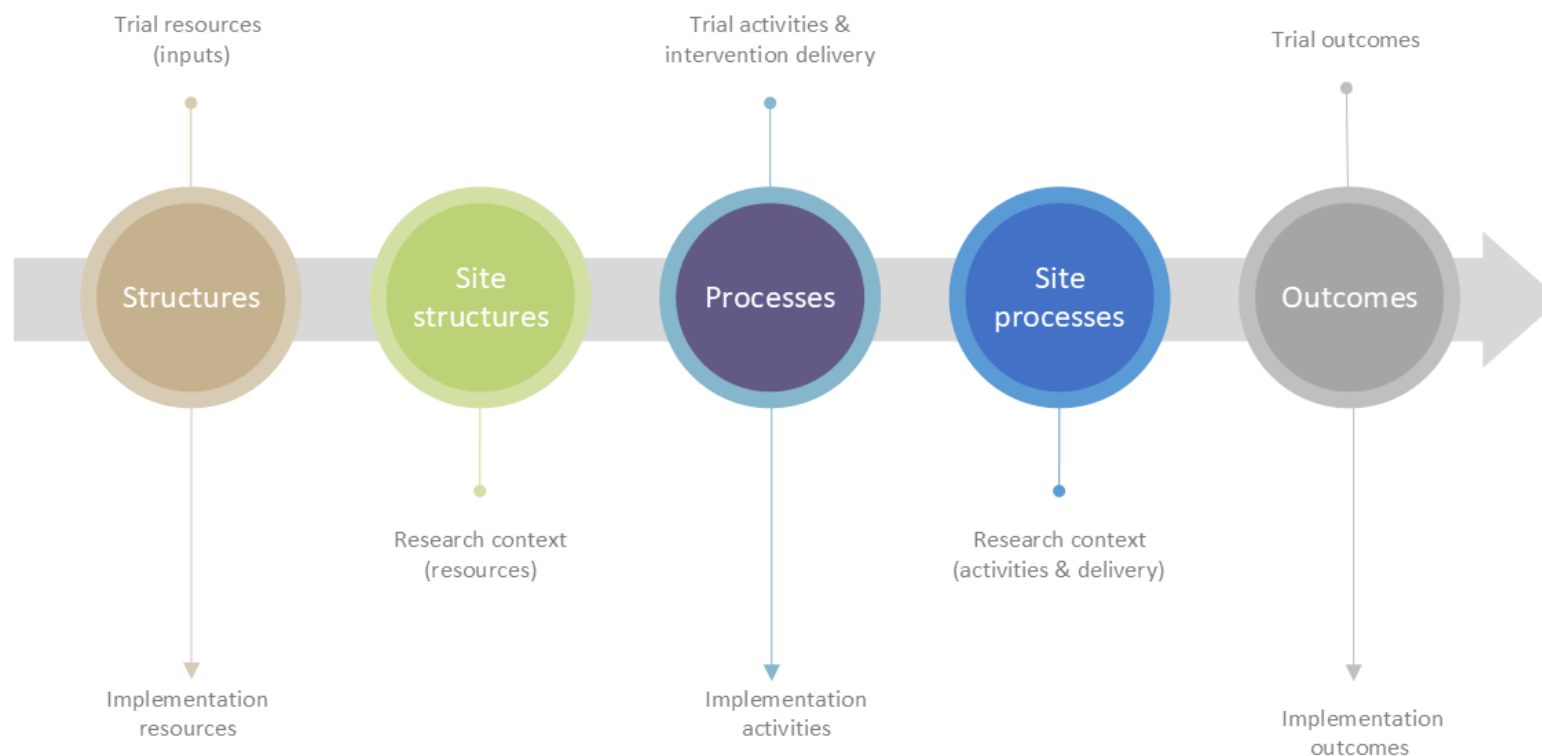


Figure made using [Microsoft365 Visio](#).

Table sI: Trial context (Programme theory)

• Description of the context of the trial e.g., processes and systems in place.									
Structures				Processes			Outcomes (All sites)		
Material resources	Human resources	Organisational structure	Resources for implementation strategy	Actions to implement intervention (with resources)	Actions to deliver intervention (with resources)	Implementation strategies	Feasibility outcomes at 6 months (short-term)	Feasibility outcomes at 9 months (medium-term)	Feasibility outcomes at 18 months (long-term)
							Recruitment: Retention: Fidelity: Intervention sessions: Available Delivered Delivered in full CAM-ICU Available Completed RASS -4/-5 Not assessed CAM-ICU-7 (excl. weekends) Available Completed RASS -4/-5 Not assessed Weekend	Recruitment: Retention: Fidelity: Intervention sessions: Available Delivered Delivered in full CAM-ICU Available Completed RASS -4/-5 Not assessed CAM-ICU-7 (excl. weekends) Available Completed RASS -4/-5 Not assessed Weekend	Recruitment: Retention: Fidelity: Intervention sessions: Available Delivered Delivered in full CAM-ICU Available Completed RASS -4/-5 Not assessed CAM-ICU-7 (excl. weekends) Available Completed RASS -4/-5 Not assessed Weekend

Table sII Site context (Programme theory)

<ul style="list-style-type: none"> • Description of the context of the individual site e.g., processes and systems in place. • Description the implementation of the trial within the individual site contexts 									
Structures				Processes			Outcomes (individual site)		
Material resources	Human resources	Organisational structure	Resources for implementation strategies	Actions to implement intervention (with resources)	Actions to deliver intervention (with resources)	Implementation strategies	Effect on service users & service 6 months (short-term) Fidelity	Effect on service users & service 9 months (medium-term) Fidelity	Effect on service users & service 18 months (long-term) Fidelity
							Intervention (<i>excl. clinical decision to stop</i>) Delivered Delivered as intended CAM-ICU Available Completed RASS -4/-5 Not assessed CAM-ICU-7 (excl. weekends) Available Completed RASS -4/-5 Not assessed Weekend	Intervention (<i>excl. clinical decision to stop</i>) Delivered Delivered as intended CAM-ICU Available Completed RASS -4/-5 Not assessed CAM-ICU-7 (excl. weekends) Available Completed RASS -4/-5 Not assessed Weekend	Intervention (<i>excl. clinical decision to stop</i>) Delivered Delivered as intended CAM-ICU Available Completed RASS -4/-5 Not assessed CAM-ICU-7 (excl. weekends) Available Completed RASS -4/-5 Not assessed Weekend

Table sIII Sample Matrix

Primary criteria			Secondary criteria			Monitoring		
Exposure	Participant type	Site	Sex at birth	Age (years)	Ethnicity	Interview method	No interview	Description
Screening	Intervention Participant	01	Male	18-30		In-person	Did not meet criteria	
Consent	Relative	02	Female	31-45		Telephone	Declined interview	
Intervention (integrated criterion)	Carer (integrated criterion)	03		46-59		Virtual	Control group	
<ul style="list-style-type: none"> • ≥ 1 Intervention (sedated) 	<ul style="list-style-type: none"> • Social carer 			60-75				
<ul style="list-style-type: none"> • ≥ 1 Intervention (alert) 	<ul style="list-style-type: none"> • ICU treating consultant/medical professional 			76+				
<ul style="list-style-type: none"> • ≥ 1 Intervention (sedated & alert) 	<ul style="list-style-type: none"> • Bedside nurse 							
Delirium OCMs (integrated criterion)								
<ul style="list-style-type: none"> • CAM-ICU 								
<ul style="list-style-type: none"> • CAM-ICU-7 								

Outcome measures (OCMs), Confusion Assessment Method for the ICU (CAM-ICU/CAM-ICU-7), Intensive care unit (ICU),

Table sIV Interview guide (trial intervention participants)

Ice breaker	Can you tell me about why you were admitted to the ICU?
Transition question	What can you remember about physical activity in the ICU?
I	Can you describe your experience of in-bed cycling?
II	Is there anything about in-bed cycling that was difficult?
III	Is there anything about in-bed cycling that was beneficial?
IV	What was your experience of in-bed cycling and delirium?
V	Do you remember the ways that were used to assess different aspects of your health? E.g., CAM-ICU
VI	What would you say are the most important issues about in-bed cycling in the ICU for patients?

Table sV Interview guide (relatives and carers)

Ice breaker	Can you tell me about why [patient's name] was admitted to the ICU?
Transition question	What can you remember about [patient's name] physical activity that they received in the ICU?
I	Can you describe your experience of [patient's name] cycling in-bed?
II	Is there anything about in-bed cycling that you felt was difficult?
III	Is there anything about in-bed cycling that you felt was beneficial?
IV	What was your perspective of in-bed cycling if [patient's name] was delirious? (e.g., when agitated, withdrawn, restless).
V	What did you think about the ways used to assess [the patient's] health e.g., CAM-ICU?
VI	What would you say are the most important issues about in-bed cycling in the ICU for patients?

