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ACCEPTABILITY, SAFETY, AND FEASIBILITY OF IN-BED CYCLING WITH CRITICALLY ILL PATIENTS

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Abstract

Background: In-bed cycling is a promising intervention that may assist critically ill patients to maintain muscle mass and improve their trajectory of recovery. The acceptability of in-bed cycling from the different perspectives of patients, clinicians, and families are unknown. In addition, the safety and feasibility of in-bed cycling in an Australian tertiary ICU is relatively unknown.

Objectives: The objective of this study was to examine the acceptability, safety, and feasibility of in-bed cycling in an Australian tertiary, adult, mixed medical, surgical, trauma ICU.

Methods: An observational process evaluation was embedded in one arm of a two-arm parallel Phase II randomised controlled trial that was conducted in an Australian tertiary ICU. The process evaluation was of the acceptability, safety, and feasibility of passive and active in-bed cycling for participants allocated to the trial intervention group. In-bed cycling acceptability questionnaires were designed through a three-step Delphi process. Questionnaire responses from patients, family members and clinicians who participated in or observed the intervention during the Critical Care Cycling Study (CYCLIST) were evaluated to determine the acceptability of in-bed cycling. The congruence of responses between respondents was also compared. Safety and feasibility of the in-bed cycling intervention were assessed against predetermined criteria.

Results: Acceptability questionnaire responses demonstrated that in-bed cycling was an acceptable intervention from the perspectives of patients, family members, and clinicians. Questionnaire responses were congruent across the respondent groups. Safety was demonstrated with two minor transient adverse events occurring during 276 in-bed cycling sessions (adverse event rate: 0.7%). In-bed cycling sessions were feasible, with 276 of 304 (90%) planned sessions conducted.

Conclusions: Acceptability questionnaire responses found that in-bed cycling was regarded as an acceptable intervention to patients, family members, and clinicians. The implementation of in-bed cycling was safe and feasible to complete with critically ill patients during the early stages of their critical illness in an Australian tertiary ICU setting.

Key Words:

Critical illness, Cycle ergometry, Early ambulation, Exercise, Intensive care units, Rehabilitation, Patient Acceptability of Health Care, Physical therapy (specialty).

Introduction

Patients who survive a period of critical illness often experience long-term physical and cognitive impairments that are reported to last for at least 8-years^{1,2}. Exercise interventions that aim to reduce the detrimental long-term effects of illness on patients' physical recovery can be implemented while patients are critically ill³. While clinicians agree on the rationales behind implementing exercise interventions with critically ill patients, the initiation of exercise interventions is often delayed^{4,5}. In-bed cycling may facilitate the early initiation of exercise interventions with critically ill patients, as in-bed cycling can be performed passively before patients can follow commands^{6,7}. Sessions can progress from passive to active-assisted and onto resisted exercise as patients' ability to participate in the intervention improves. In-bed cycling may assist in reducing sarcopenia and improving the trajectory of recovery for critically ill patients^{8,9}.

To date, only a single Scandinavian study has explored recollections and experiences of 11 critically ill participants who completed in-bed cycling while admitted to the ICU¹⁰. The acceptability of in-bed cycling with critically ill patients from the perspective of clinicians, families, and friends (hereafter referred to collectively as families) has not been explored. Patients are more likely to adhere to an intervention and potentially benefit from improved clinical outcomes if they consider the intervention to be acceptable¹¹. Acceptability is a multi-faceted construct that reflects the extent to which people are delivering or receiving a healthcare intervention consider it to be appropriate¹¹. Acceptability is based on anticipated or experienced cognitive and emotional responses to the intervention¹¹. Interventions are implemented by clinicians, often with the support and influence from family. However, if the delivery of an intervention is not perceived to be acceptable to clinicians as well as family, the intervention may not be delivered as intended (by intervention designers), reducing its

effectiveness¹¹⁻¹³. Consequently, it is important to determine the acceptability of exercise interventions with critically ill patients from the perspective of patients, family and clinicians. The Medical Research Council (MRC) framework suggests that acceptability should be assessed in the feasibility phase of studies¹⁴.

International studies have reported that in-bed cycling is safe^{8,9,15,16} and feasible^{6,7,10,17-20} with critically ill patients within the first week of their ICU admission. However, the safety and feasibility of in-bed cycling in an Australian ICU is yet to be confirmed. To date, only a single Australian pilot case-matched control study with eight participants completing in-bed cycling (and functional electrical stimulation) has been reported²⁰.

A pilot phase II feasibility randomised controlled trial (RCT) comparing usual care to usual care plus additional daily in-bed cycling, using a cycle ergometer, provided the optimal timing to investigate the acceptability of in-bed cycling from the perspectives of patients, clinicians, and families and to assess the safety and feasibility of in-bed cycling in an Australian tertiary ICU setting.

The study aims were to determine the following:

1. Acceptability of in-bed cycling with critically ill patients from the perspectives of patients, clinicians, and families,
2. Congruence of acceptability responses between patients, clinicians, and families,
3. Safety of in-bed cycling with critically ill patients within an Australian tertiary ICU setting, and
4. Feasibility of delivering the in-bed cycling intervention with critically ill patients in an Australian tertiary ICU setting.

Methods

Study Design

An observational process evaluation was embedded in one-arm of a two-arm parallel Phase II RCT that was conducted in an Australian tertiary ICU. The process evaluation was of the acceptability, safety and feasibility of passive and active in-bed cycling for participants allocated to the intervention group. Participants completed bilateral lower limb in-bed cycling (30-minutes, six out of seven-days/ week), using an in-bed cycle ergometer (MOTOmed Letto2, RECK-Technik GmbH & Co. KG, Betzenweiler, Germany). The principal investigator (MRN) delivered all the cycling sessions. The study protocol has been previously described ²¹, but methods relevant to determining acceptability, safety, and feasibility are summarised in the following section. The SQUIRE (Standards for Quality Improvement Reporting Excellence, version 2.0) and TIDieR (Template for Intervention Description and Replication) guidelines have been followed for better reporting of interventions ^{22,23}.

Participants and Setting

The study was conducted in a 26-bed tertiary, adult, mixed medical, surgical, and trauma ICU in Brisbane, Australia. Adult patients were eligible for the study if they were expected to be mechanically ventilated for greater than 48-hours and expected to remain in the ICU for more than 48-hours after study enrolment. Patients were excluded if they had pre-existing functional limitations, new neurological conditions or injuries, or conditions that would preclude in-bed cycling.

Patients randomised to the intervention group were eligible to complete the acceptability questionnaire if they were able to recall at least one in-bed cycling session. Similarly, family members must have observed at least one in-bed cycling session to be eligible to complete the acceptability questionnaire. As perspectives of different family members may differ, to maximise viewpoints, more than one family member per patient could complete the family acceptability questionnaire. Clinicians who cared for patients who performed in-bed cycling patients during the study period were eligible to complete the clinician acceptability questionnaire.

Outcomes

Assessment of acceptability and questionnaire development

Before study inception, there was no measure of acceptability for a similar intervention. Consequently, a Delphi panel was formed containing 11 members and new questionnaires were developed. Delphi panel members were asked to rate their support for each questionnaire item using a five-point Likert-type scale. The acceptability questionnaires developed through the three-step Delphi process had eight questions for the patient questionnaire, seven questions for the family questionnaire, and nine questions for the clinician questionnaire, including one question regarding clinician access to patients (three-point Likert scale). All versions of the questionnaires were designed to be completed within two to three minutes.

Median and interquartile range values were calculated from questionnaire responses. The acceptability of in-bed cycling from the different questionnaires was evaluated. A median rating of “agree” or “strongly agree” constituted acceptability for responses. The exceptions were questions evaluating pain, where median responses that indicated either no difference

or an improvement in pain perceptions were considered acceptable. A clinician's responses regarding access to the patient were considered acceptable if the median responses indicated either no or minimal impairment to the clinicians' ability to access the patient.

Assessment of safety

Pre-defined safety criteria were designed to check patients' suitability to complete the in-bed cycling intervention before the implementation of each session (Table 1). Patients' cardiovascular and respiratory observations were collected at baseline, then every ten-minutes during the intervention and ten-minutes after the intervention. Patients were verbally encouraged to cycle at a moderate intensity when they were following commands. Conscious patients were also asked to rate their perceived exertion²⁴. The number of pre-defined adverse events was recorded (Table 1). It was determined that in-bed cycling could be deemed to be as safe as other exercise interventions with critically ill patients if no major adverse events occurred and if the minor adverse event rate was less than 2.6%. This percentage is the current adverse event rate associated with exercise interventions performed with critically ill patients reported in a recent meta-analysis²⁵.

Table 1. Pre-defined safety criteria to assess a patients' suitability to commence and cease in-bed cycling and adverse events

Safety Checklist (Pre-cycle ergometry)
Clinician opinion patient unstable
Evidence of coronary ischaemia, for example, chest pain or electrocardiogram changes
Resting heart rate < 40 or > 120 beats per minute
Mean arterial pressure < 60 or > 120mmHg
Peripheral capillary oxygen saturation < 90%
Significant Agitation (+2 to +4 Richmond Agitation and Sedation Score)
Wounds precluding cycle ergometry
Evidence of active bleeding (monitoring changes in haemoglobin value)

Coagulation disorder (International Normalised Ratio > 1.8, or platelets < 50,000 mCL)

Femoral access other than a femoral central line

Acute deep vein thrombosis or pulmonary embolism

Evidence of new/worsening rhabdomyolysis (monitoring creatine kinase level and changes)^a

Additional safety checklist (pre-active in-bed cycling)

> 20 units noradrenaline or comparable inotropic/ vasopressor support

Fraction of inspired oxygen > 0.55

Positive end expiratory pressure > 10cmH₂O

Respiratory rate > 30 breaths per minutes with adequate ventilatory support

Body temperature > 39° Celsius

Stopping criteria (Active or passive in-bed cycling)

Heart rate < 50 or > 140 beats per minute or new arrhythmia develops (including ventricular ectopic or new-onset atrial fibrillation)

Evidence of coronary ischaemia, e.g. chest pain or electrocardiogram changes

Systolic blood pressure > 200mmHg or > 80% of baseline

Mean arterial pressure < 60mmHg

Clinical signs of cardiorespiratory distress

Peripheral capillary oxygen saturation < 90% for more than 1 minute

Patient request to stop therapy

Adverse events (during or within 10 minutes after in-bed cycling):

Line or airway dislodgement

Increase in vasoactive medications > 5mcg/min

Increase in systolic blood pressure > 200mmHg for > 2 minutes

Decrease in mean arterial pressure < 60mmHg for > 2 minutes

Decrease in heart rate < 50 beats per minute for > 2 minutes

Increase in heart rate > 140 beats per minute for > 2 minutes

Change in ventilation parameters:

Increase in respiratory rate (sustained > 5 minutes after session)

Decrease in peripheral capillary oxygen saturation < 88% for > 1 minute requiring an increase in fraction of inspired oxygen > 0.1 sustained > 5minutes

^a Additional safety criteria implemented post-study commencement following a recommendation by the Data Safety and Monitoring Board.

mmHg, millimetres of mercury; mCL, microlitre; cmH₂O, centimetres of water; mcg, micrograms.

Assessment of feasibility

Feasibility of the study was recorded by the principal investigator who completed a diary of the intervention that included barriers, facilitators, clinician time-to-deliver the cycling intervention and session notes. The percentage of planned sessions commenced and the percentage of commenced sessions completed for the full 30-minute duration were considered to provide valuable intervention feasibility information. In-bed cycling would be deemed to be feasible if 80% of planned sessions were able to be commenced, and 80% of commenced sessions completed the full 30-minute duration. This is consistent with the definition of other feasibility definitions for in-bed cycling protocol delivery¹⁸.

Ethics approval and trial registration

Ethics approval for this project was received from Metro South Human Research Ethics Committee (HREC/12/QPAH/009) and Queensland University of Technology (1400000587). Initial approval included assessment of acceptability from the patient's perspective, while an assessment of acceptability from families and clinician's perspectives was included in a subsequent amendment. The CYCLIST study was prospectively registered on the Australian and New Zealand Clinical Trial Registry (ACTRN12616000948493).

Statistical analysis

Descriptive statistics were used to summarise the characteristics of the participants. Mean and standard deviation (SD) were calculated for approximately normally distributed data, and median and interquartile range (IQR) were calculated for data with large skewness or outliers. A range of minimum and maximum time was used to describe the range of time taken to set up the in-bed cycling intervention. Ordinal variables were used to record the number of in-

bed cycling sessions completed or observed, participants, family members, and clinicians, for example, “two to three sessions”. The mode was used to describe the most common response to the ordinal variables regarding the recall of in-bed cycling sessions.

Results

CYCLIST participant recruitment was conducted between July 2016 and May 2018, with 72 patients enrolled. Thirty-six patients were randomised into the in-bed cycling arm of the study, with a mean (SD) age of 56 (18) years, and 64% of patients being male (Table 2).

Table 2. Demographic clinical characteristics and outcomes

Variable	Intervention group, n= 36
Age in years, mean (SD)	56 (17.5)
Males, n (%)	23 (64%)
APACHE III score, median (IQR)	64 (49, 82)
SOFA (worst score), median (IQR)	9 (8, 12)
SOFA (most organs with dysfunction), median (IQR)	3 (3, 4)
BMI kg/m ² , mean (SD)	29 (5)
Length of MV, days, median (IQR)	6.3 (3.9, 9.5)
ICU length of stay a, days, median (IQR)	8.4 (5.0, 13.1)
Acute hospital stay b, days, median (IQR)	17.2 (10.5, 29.7)
Primary diagnosis on ICU admission	
Medical	12 (33%)
Trauma	8 (22%)
Sepsis	7 (19%)
Surgery	4 (11%)
Other	5 (14%)

^a Length of stay for patients who survived ICU admission

^b Length of stay for patients who survived acute hospital admission

n, number; SD, standard deviation; APACHE III, Acute Physiology and Chronic Health Evaluation III severity of illness score (0-299); SOFA, Sequential Organ Failure Assessment; BMI, body mass index, IQR, interquartile range; MV, mechanical ventilation; ICU, intensive care unit.

Acceptability Questionnaire

Patients' responses regarding the acceptability of in-bed cycling

Thirty patients completed the acceptability of in-bed cycling intervention questionnaire. Of the six patients who did not complete the questionnaire, one patient passed away, and five patients were unable to recall the intervention. Half of the patients (n=15, 50%) who completed the questionnaire indicated that they were able to recall a median of between “two to three sessions” of in-bed cycling. Median responses demonstrated patients strongly agreed that in-bed cycling assisted their physical recovery and that they would be willing to continue to engage in the intervention if they were re-admitted to the ICU. Patients reported that in-bed cycling improved their feelings of well-being and made no difference or slightly improved their pain levels during and after the session (Figure 1B, Table 3). Patients strongly perceived that “in-bed cycling is beneficial for patients admitted to the ICU”. Overall, responses indicated that in-bed cycling is an acceptable intervention from a patient’s perspective (Figure 1A).

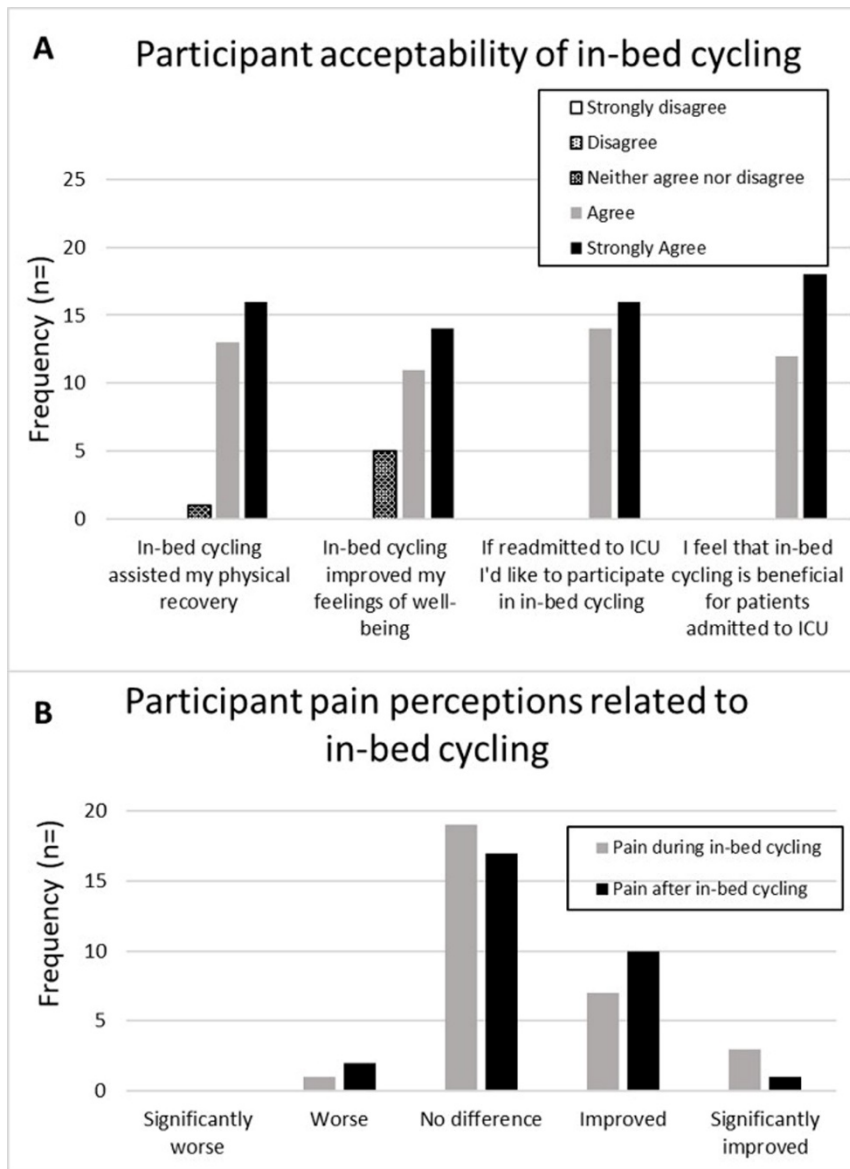


Figure 8.2 A: Participants acceptability of in-bed cycling, B: Participant pain perceptions related to in-bed cycling. n=, number; ICU, intensive care unit.

Table 3. Patient responses regarding the acceptability of in-bed cycling, n=30

	n=	Median (IQR)	Median word response
Recall of in-bed cycling sessions	35*	3 (2, 4)	2 to 3 times
In-bed cycling assisted my physical recovery	30	5 (4, 5)	Strongly agree
In-bed cycling assisted my feelings of well-being	30	4 (4, 5)	Agree
My pain during in-bed cycling	30	3 (3, 4)	No difference
My pain after in-bed cycling	30	3 (3, 4)	No difference
I would participate in in-bed cycling if I was admitted to ICU again	30	5 (4, 5)	Strongly agree
In-bed cycling is beneficial for ICU patients	30	5 (4, 5)	Strongly agree

* 5 participants unable to recall in-bed cycling and therefore were not asked further questions. IQR, interquartile response; ICU, intensive care unit

Families' responses regarding the acceptability of in-bed cycling

Twenty-two family members or friends of 18 patients completed the acceptability of intervention questionnaire from the families' perspective. Families were encouraged to be present during the intervention. Families who completed the questionnaire recalled a mode of "two to three sessions" and strongly agreed that "in-bed cycling for patients admitted to the ICU is beneficial". Overall, median families' responses indicated that in-bed cycling is an acceptable intervention to conduct with critically ill patients (Table 4).

Table 4. Family and friends' responses regarding the acceptability of in-bed cycling, n=22

	n=	Median (IQR)	Median word response
Recall of in-bed cycling sessions	22*	3 (3, 4)	2 to 3 times
In-bed cycling assisted patients' physical recovery	22	5 (4, 5)	Strongly agree
In-bed cycling assisted patients' feelings of well-being	22	3.5 (3, 4.75)	Neither agree nor disagree - improved
Patients' pain during in-bed cycling	22	3 (3, 3)	No difference
I would want the patient to participate in in-bed cycling if they were admitted to ICU again	22	5 (4.25, 5)	Strongly agree
In-bed cycling is beneficial for ICU patients	22	5 (4, 5)	Strongly agree

* Responses relating to 18 patients. IQR, interquartile response; ICU, intensive care unit.

Clinicians' responses regarding the acceptability of in-bed cycling

The acceptability of intervention questionnaire was completed by 124 clinicians. Professional groups represented were nurses (n=94), medical officers (n=21) and physiotherapists (n=9). Clinicians were eligible to complete the questionnaire if they had observed patients participate in the in-bed cycling intervention during the study. Approximately 221 nurses, 36 medical officers, and 14 physiotherapists were employed in the intensive care unit during the study. Owing to the variable rostering pattern (e.g., night shift, part-time, leave) and variable roles (e.g., management, research, educator, clinician), the exact number of clinicians who observed the intervention and were eligible to complete the questionnaire cannot be determined. Consequently, a conservative response rate of 52% was estimated (Table 5).

Table 5. Acceptability questionnaires response rate

Respondents	Responses	Response Rate	Notes
Patient	30/36	83%	5 unable to recall, 1 passed away
Family/ friends	18/25	72%	22 responses related to 18 patients
Medical Officers	21/36	58%	Denominator from staff roster ^a
Nursing	94/221	43%	Denominator from staff roster ^a
Physiotherapy	9/14	64%	Denominator from staff roster ^a
Total	172/332	52%	

^a Due to the variable rostering pattern the exact number of clinicians who observed the intervention and were eligible to complete the questionnaire cannot be determined. Consequently, the estimated response rate is likely to be conservative.

Clinicians recalled a mode of “two to three sessions” of in-bed cycling with critically ill patients. Clinicians felt that in-bed cycling assisted their patients’ physical recovery while making no change to their patients’ pain during or after the sessions. Overall, median responses demonstrated that clinicians agreed that “in-bed cycling for patients admitted to the ICU is beneficial”. Clinicians reported that in-bed cycling minimally affected their ability to access a patient (Table 6). Overall, clinician responses (regardless of profession) indicated that in-bed cycling is an acceptable intervention to implement with suitable critically ill patients within the ICU.

Table 6. Clinicians responses regarding the acceptability of in-bed cycling,

n=124

	n=	Median (IQR)	Median response word
Recall of in-bed cycling sessions	124*	3 (3, 5)	2 to 3 times
In-bed cycling assisted patients' physical recovery	124	4 (3, 4)	Strongly agree
In-bed cycling assisted patients' feelings of well-being	124	3.5 (3, 4.75)	Neither agree nor disagree
Patients' pain during in-bed cycling	124	3 (3, 3)	No difference
Patients' pain after in-bed cycling	124	3 (3, 3)	No difference
In-bed cycling affected my ability to access the patient	124	2 (1, 2)	Minimally affected
In-bed cycling is beneficial for ICU patients	124	4 (4, 5)	Strongly agree

IQR, interquartile response; ICU, intensive care unit.

Congruence of acceptability responses

Acceptability questionnaire responses were almost identical for patients', clinicians', and families' responses (Appendix 1). A slight difference was apparent for median responses regarding well-being; clinicians responded that in-bed cycling did not make any difference to patients' feelings of well-being. Whereas patients and families perceived that in-bed cycling improved patients' feelings of well-being.

Patients' and families' responses had identical medians and interquartile ranges for questions related to in-bed cycling, assisting patients' physical recovery, pain, and well-being. In the event of an ICU readmission, patients and families indicated they would be willing to complete or have their family member participate in the intervention again. All clinical professions, patients, and families agreed that participants experienced or showed either no difference or slightly improved pain levels during and after the intervention. All groups agreed or strongly agreed that "in-bed cycling is likely to be beneficial for ICU patients" (Appendix 1).

Safety events

In-bed cycling with critically ill patients was safe during this study. Two minor transient adverse events, without long-term consequence, occurred on two separate occasions affecting the same participant with pancreatitis during the 276 sessions (adverse event rate: 0.7%). The two separate minor events were oxygen desaturation and increased respiratory rate. The participant's peripheral capillary oxygen saturation (SpO₂) decreased from 95% to 87% after 18-minutes of passive cycling; ventilator settings were adjusted to increase the positive end-expiratory pressure from 8cmH₂O to 10cmH₂O and fraction of inspired oxygen from 0.35 to 0.40. The participant's SpO₂ returned to pre-exercise baseline value within a minute, and the in-bed cycling session was able to be continued and completed. During a different session, the same participant's respiratory rate increased during a passive cycling session. Baseline respiratory rate was already elevated at 35 breaths per minute, and the treating clinicians were consulted and agreeable for the participant to commence passive in-bed cycling. After the passive cycling session, the participant's respiratory rate increased to 45 breaths per minute and remained elevated for more than five-minutes after the cycling session. The participant's ventilation parameters returned to the baseline respiratory rate after nine-minutes; no adjustments to the ventilator settings were required. This same patient experienced similar spontaneous variations in their respiratory parameters at other times without any physical stimulus.

After an in-bed cycling session, a participant's creatine kinase (CK) levels were noted to have become acutely elevated. This participant was the second participant in the study to be randomised to the in-bed cycling group. Clinician concerns about the potential for in-bed cycling to cause rhabdomyolysis were raised. The Data Safety and Monitoring Board (DSMB) was notified, and it was recommended that routine monitoring of CK levels for both

intervention and usual care group patients should be incorporated in the study. Bi-monthly monitoring reports of CK levels were provided to the DSMB. The DSMB concluded that patients in both arms of the study experienced large fluctuations in CK levels, and hence, it did not appear that the participants' CK elevation was directly related to the in-bed cycling intervention. Non-traumatic elevation in CK levels could be due to various causes including influenza, sepsis, side effects of medications, and raised body temperature ^{26,27}.

Feasibility

Delivery of in-bed cycling sessions was found to be feasible. More than 90% of planned in-bed cycling sessions were completed. Patients completed their first in-bed cycling session a median (IQR) of 2.3 (1.8, 3.1) days after ICU admission and completed the session a median (IQR) of 6 (4, 8) sessions in total. Sessions lasted a mean (SD) of 27 (5) minutes, during which patients cycled a mean (SD) of 3.2 (1.6) kilometres (Table 7). Fifty-three percent of sessions (146 of 276 sessions) were passive exercise sessions (Table 7). Participants actively cycled for at least 100 metres during 130 of 276 sessions (47%) for a mean (SD) duration of 12.7 (10.7) minutes (Table 7). Once in-bed cycling sessions were commenced, most sessions, 222 of 276 (80%), were conducted for the full 30-minutes planned. The sessions that were ceased early were primarily due to patient fatigue (n=33), patient factors (n=18) (toileting, insufficient motivation, confusion, ventilation concerns, and discomfort), and hospital factors (n=3).

Table 7. Characteristics of cycling sessions, n = 36

Variable	n	Intervention group
ICU admission to first session, days, median (IQR)	36	2.3 (1.8, 3.1)
Sessions per participant, median (IQR)	36	6 (4, 8)
Sessions planned, n	304	
Sessions completed, n (%)	276	91%

Session total duration, minutes, mean (SD)	276	27.6 (5.2)
Total distance cycled in a session, km, mean (SD)	276	3.23 (1.63)
Passive cycling sessions ^a , n (%)	146	53%
Passive cycling duration ^a , minutes, mean (SD)	253	22.2 (10.8)
Passive cycling distance ^a , km, mean (SD)	253	2.0 (1.1)
Active cycling sessions ^b , greater than 100m, n (%)	130	47%
Active cycling session duration ^b , minutes, mean (SD)	130	12.7 (10.7)
Active cycling session distance ^b , km, mean (SD)	130	2.7 (2.6)

^a Passive cycling defined as less than 100m active cycling during a session

^b Active cycling defined as greater than 100m active cycling during a session

n, number; ICU, intensive care unit; IQR, interquartile range; SD, standard deviation; km, kilometres.

Sessions were set-up, conducted, and completed, including cleaning, by a single clinician (experienced ICU physiotherapist) (MRN). It took a minimum of five-minutes and a maximum of 12-minutes for a single operator to establish the in-bed cycling session and typically ten-minutes to remove the patient from the cycle ergometer and clean and store the device. The usual total clinician time required was 50-minutes including set-up, delivery of the intervention, and clean up.

Barriers

Twenty-eight of 304 (9%) planned in-bed cycling sessions were not initiated. Barriers to the implementation of in-bed cycling sessions were infrequent and primarily related to patient factors such as fatigue (n=9), delirium (n=5), haemodynamic instability (n=4), airway concerns (n=2), pain from pre-admission injury (n=2), and other reasons (all n=1) including investigation scheduling, family concerns, pulmonary haemorrhage, lumbar puncture, sore knee (likely gout), and seizures.

Discussion

This observational process evaluation found that in-bed cycling was an acceptable intervention to complete with critically ill patients from the perspectives of patients, their families, and clinicians. In addition, the responses of patients, their families, and clinicians were congruent with each other. In-bed cycling interventions were safe and feasible with critically ill patients in an Australian tertiary ICU setting, with over 90% of planned sessions being commenced, and an adverse event rate of less than one percent. In addition, the target 30-minute cycling duration was completed in 80% of the sessions that were commenced. Patient fatigue was the main barrier to both the commencement of in-bed cycling sessions and the reason for sessions being ceased before the maximum planned duration. It took approximately 50-minutes for a single clinician to set-up, implement, and clean-up after the in-bed cycling session.

Implications and comparison with previous research

This is the second study to measure the acceptability of an exercise intervention from the perspective of critically ill patients¹⁰ and the first study to assess acceptability from the perspectives of clinicians and families. Engaging with family members could provide a psychological benefit to families that can assist patients by encouraging them to participate and complete exercise sessions²⁸. Open responses that were recorded on the acceptability questionnaire indicated that family members understood the aims of the intervention and were positive about their family member participating in in-bed cycling while they were critically ill. Acceptability ratings from patients, families, and clinicians were congruent with each other and demonstrated that the in-bed cycling intervention was highly acceptable from different perspectives. All groups agreed that in-bed cycling did not change patients' pain levels.

International studies have reported that in-bed cycling is safe with critically ill patients^{6-10,15-20}. The very low rate of adverse events and sessions ceased early due to safety concerns in the present Australian study was consistent with those reported by others^{6-10,15-20}, and is comparable with the adverse event rate for exercise interventions within the ICU^{25,29}. Most in-bed cycling adverse events are minor and transient such as desaturation and hypotension and are usually without long-term consequence^{6-10,15-20}. Adverse events reported in other in-bed cycling studies include one accidental airway extubation¹⁶, one arterial catheter dislodgement (pre-identified requiring re-securement)¹⁷ and a single episode of arrhythmia¹⁸. The use of pre-determined study inclusion and exclusion criteria and safety guidelines to guide session commencement and cessation²¹ may have contributed to the safe implementation of the in-bed cycling intervention in the present study.

The present study adds to the evidence supporting the feasibility of early in-bed cycling, with critically ill patients completing more than 90% of planned sessions that commenced just over two-days from ICU admission. Each participant completed approximately six sessions of just under 30-minutes which took approximately 50-minutes for one clinician to set up, deliver, and takedown. In-bed cycling has been reported to be feasible by several international in-bed cycling studies^{8,10,17,18,20}. In-bed cycling sessions have been initiated in-between 73% to 90% of times when a session was planned^{8,18,20}. Previous studies have reported a comparable time taken to set-up, remove and clean the equipment which ranges, between 15 to 22-minutes, plus 20 to 30-minutes to deliver the intervention^{8,17,18,20}.

Limitations

The acceptability of the intervention component of this study has some limitations. At the time of the questionnaire design, there was no consensus regarding the definition of acceptability, although this questionnaire is consistent with the framework that has recently

been published ¹¹. At present, no measure has been validated to assess the acceptability of interventions ³⁰. This study was conducted at a single-centre tertiary ICU, and hence, findings may not be generalised to dissimilar settings. The principal investigator administered acceptability questionnaires with patients and their families; consequently, a social desirability bias may have occurred whereby patients and families may have provided responses that they perceived to be desirable ^{31,32}. It is difficult to assess the accuracy of patients' self-reported ratings of pain provided during the acceptability questionnaire as patients may have difficulty recalling their experiences of pain sometime after the in-bed cycling intervention. Current clinical guidelines for the management of pain, agitation and delirium do not provide any recommendations for using exercise as a non-pharmacological method of pain relief within the ICU ³³. However, these guidelines recommend early mobility as a non-pharmacological method to reduce the incidence and duration of delirium ³³. The relationship between early activity, acute pain and the subsequent development of chronic pain in critically ill patients remains poorly understood and is a priority for future research.

Future research

Future research could evaluate the acceptability of in-bed cycling and other exercise interventions at other ICUs. To be compliant with MRC recommendations, future research should incorporate assessment of the acceptability of different interventions from the perspectives of patients, family members, and clinicians. Further research is required to establish the efficacy of in-bed cycling, including research to examine the efficacy of passive versus active (or combined passive and active) cycling sessions to determine what is the optimal intervention dose for improving critically ill patients' outcomes.

Conclusion

Acceptability questionnaire responses established that in-bed cycling was an intervention that was acceptable to patients, family members, and clinicians. The implementation of in-bed cycling was safe and feasible to complete with critically ill patients during the early stages of their critical illness in an Australian tertiary ICU setting. Further research is required to establish the efficacy of in-bed cycling before it can be incorporated into the usual care of critically ill patients.

Ethics approval: Human research ethics approvals for this study have been gained from Metro South Human Research Ethics Committee (EC00167) on 28 April 2016 (HREC/16/QPAC/193), and subsequent approval following an administrative review from Queensland University of Technology Human Research Ethics Committee (QUT reference number: 160000441). Ethics approval has been granted until 28 April 2019. Site-specific approval (SSA) has been granted by Metro South Centres for Health Research, Research Governance (SSA/16/QPAH/195) on 1 June 2016. CYCLIST Study Protocol Version 2.1 dated 30 March 2017 was approved on 13 April 2017.

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Trial Registration: Australian and New Zealand Clinical Trials Registry (ACTRN 12616000948493)

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Authors' contributions

Marc Nickels: Study design, participant screening and recruitment, intervention implementation, data collection, safety monitoring, analysis, manuscript preparation, critical review and approval of the manuscript.

Leanne Aitken: Study design, safety monitoring, analysis, manuscript preparation, critical review and approval of the manuscript.

Adrian Barnett: Study design, analysis, manuscript preparation, critical review and approval of the manuscript.

James Walsham: Study design (safety measures), safety monitoring, manuscript preparation, critical review and approval of the manuscript.

Steven McPhail: Study design, study oversight, safety monitoring, analysis, manuscript preparation, critical review and approval of the manuscript.

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Appendix 1.

Comparison of acceptability responses regarding the acceptability of in-bed cycling expressed as median (IQR) and median word response, n=176

Respondent	n=	In-bed cycling assisted patients' physical recovery	In-bed cycling assisted patients' feelings of well-being	Patients' pain during in-bed cycling	Patients' pain after in-bed cycling	If readmitted to ICU I would like to complete in-bed cycling again	In-bed cycling affected my ability to access the patient	In-bed cycling is beneficial for ICU patients
Patients	30	5 (4, 5) Strongly agree	4 (4, 5) Agree	3 (3, 4) No difference	3 (3, 4) No difference	5 (4, 5) Strongly agree	Not applicable	5 (4, 5) Strongly agree
Family	22	5 (4, 5) Strongly agree	4 (4, 5) Agree	3 (3, 4) No difference	Not enquired	5 (4, 5) Strongly agree	Not applicable	5 (4, 5) Strongly agree
Medical officers	21	4 (3, 4) Agree	3 (3, 4) Neither agree nor disagree	3 (3, 3) No difference	3 (3, 3) No difference	Not applicable	1 (1, 2) No change	4 (4, 4) Agree
Nurses	94	4 (4, 5) Agree	4 (3, 4) Agree	3 (3, 3) No difference	3(3, 3) No difference	Not applicable	2 (1, 2) Minimally affected	4 (4, 5) Agree
Physiotherapists	9	5 (4, 5) Strongly agree	4 (4, 5) Agree	3 (3, 3) No difference	3(3, 4) No difference	Not applicable	1 (1, 1) No change	5 (4, 5) Strongly agree