



medicina *intensiva*

<http://www.medintensiva.org/en/>



ORIGINAL ARTICLE

Safety and effects of early mobilization with in-bed cycloergometry versus conventional physiotherapy in critically ill patients: A randomized control trial

Gemma Rialp^{a,b,*}, Isabel Gil^c, Maria Romero^{a,b,d}, Catalina Morey^{a,e}, Fiorella Sarubbo^{f,g}, Catalina Forteza^{a,b}

^a Intensive Care Department, Son Llàtzer University Hospital, Palma, Spain

^b Institut d'Investigació Sanitària Illes Balears, IdISBa, Palma, Spain. Grup d'Investigació en Malalties Respiratòries i del Pacient Crític (RESPICRIT), Edificio S, Son Espases University Hospital, Palma, Spain

^c Department of Physical Medicine and Rehabilitation, Son Llàtzer University Hospital, Palma, Spain

^d Intensive Care Department, Comarcal Inca Hospital, Inca, Spain

^e Department of Rehabilitation, Centro de Salud Cintruénigo, Cintruénigo, Navarra, Spain

^f Neurophysiology, Behavioral Studies and Biomarkers Group, Health Research Institute of the Balearic Islands (IdISBa), University of the Balearic Islands, Palma, Spain

^g Department of Biology, Faculty of Science, University of the Balearic Islands, Palma, Spain

Received 5 December 2025; accepted 5 March 2026

KEYWORDS

Critical care;
Artificial Respiration;
Rehabilitation;
Muscle strength;
Treatment outcome;
Physical therapy modalities;
Exercise;
Patient safety;
Cycloergometer

Abstract

Objective: To compare the safety of conventional physiotherapy alone versus its combination with cycloergometry by analysing session interruptions and physiological tolerance in critically ill patients. Secondly, efficacy was assessed through strength and functional related outcomes.

Design: Single-centre, parallel, two-arm, randomized clinical trial.

Setting: Intensive Care Department.

Participants: Mechanically ventilated patients.

Intervention: Control group received 30-min of conventional physiotherapy; intervention group received 15-min of cycloergometry and 15-min of conventional physiotherapy.

Main variables of interest: Safety was evaluated by recording session interruptions and changes in blood pressure, heart rate, respiratory rate, SpO₂, FiO₂ and tidal volume before and after sessions. Muscle strength (modified Medical Research Council score, quadriceps and handgrip strength) was evaluated at first cooperation of participants, ICU discharge, 28-day and 6-month follow-up; Activities of Daily Living score and mobility scale at ICU discharge, 28 days and 6 months; and six-minute walking test and Short Form-36 at 28 days and 6 months.

* Corresponding author.

E-mail address: grialp@hssl.es (G. Rialp).

<https://doi.org/10.1016/j.medine.2026.502512>

2173-5727/Published by Elsevier España, S.L.U. This is an open access article under the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>).

Please cite this article as: G. Rialp, I. Gil, M. Romero et al., Safety and effects of early mobilization with in-bed cycloergometry versus conventional physiotherapy in critically ill patients: A randomized control trial, *Medicina Intensiva*, <https://doi.org/10.1016/j.medine.2026.502512>

Results: 46 participants completed 732 sessions. Both interventions produced significant but comparable physiological changes. Cycloergometry sessions were longer (30 vs. 25 min, $p < 0.001$) and had more interruptions (13% vs. 7%, $p = 0.008$), mainly due to fatigue and lack of cooperation. With the applied methodology no significant differences were observed in muscle strength or functional outcomes at any time point.

Conclusion: Partially replacing conventional physiotherapy with cycloergometry was safe and well tolerated in critically ill patients. However, due to methodological limitations and the small sample size, no firm conclusions regarding efficacy can be drawn.

Published by Elsevier España, S.L.U. This is an open access article under the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>).

PALABRAS CLAVE

Cuidados críticos;
Respiración artificial;
Rehabilitación;
Fuerza muscular;
Resultado del
tratamiento;
Modalidades de
fisioterapia;
Ejercicio;
Seguridad del
paciente;
Cicloergómetro

Seguridad y efectos de la movilización precoz con cicloergometría frente a fisioterapia convencional en el paciente crítico: un ensayo controlado aleatorizado

Resumen

Objetivo: Comparar la seguridad de la fisioterapia convencional frente a su combinación con cicloergometría analizando las interrupciones de sesiones y la tolerancia fisiológica en pacientes críticos. Adicionalmente se evaluó la eficacia mediante variables de fuerza muscular y resultados funcionales.

Diseño: Ensayo clínico unicéntrico aleatorizado con dos ramas.

Ámbito: Servicio de Medicina Intensiva.

Participantes: Pacientes con ventilación mecánica.

Intervención: Grupo control: 30-min de fisioterapia convencional. Grupo intervención: 15-min de cicloergometría y 15-min de fisioterapia convencional.

Variables principales: La seguridad se evaluó registrando las interrupciones de las sesiones y los cambios en presión arterial, frecuencia cardíaca, frecuencia respiratoria, SpO₂, FiO₂ y volumen corriente antes y después de cada sesión. La fuerza muscular (MRCm, cuádriceps y handgrip) se valoró el primer día evaluable, al alta de UCI, a los 28-días y a los 6-meses. Las escalas de Actividades de la Vida Diaria y de movilidad se evaluaron al alta de UCI, a los 28-días y a los 6-meses; la prueba de la marcha de 6-min y el Short Form-36 a los 28-días y a los 6-meses.

Resultados: 46 participantes completaron 732 sesiones. Ambas intervenciones produjeron cambios fisiológicos significativos pero comparables. Las sesiones con cicloergometría fueron más largas (30 vs. 25 minutos; $p < 0,001$) y presentaron más interrupciones (13% vs. 7%; $p = 0,008$), principalmente por fatiga o falta de cooperación. Con la metodología aplicada no se detectaron diferencias significativas en fuerza muscular ni en resultados funcionales.

Conclusión: La sustitución parcial de la fisioterapia convencional por cicloergometría fue segura y bien tolerada. Debido a limitaciones metodológicas no pueden extraerse conclusiones firmes sobre su eficacia.

Publicado por Elsevier España, S.L.U. Este es un artículo Open Access bajo la CC BY-NC-ND licencia (<http://creativecommons.org/licencias/by-nc-nd/4.0/>).

Introduction

Intensive Care Unit (ICU) acquired weakness is a complication affecting approximately 25–50% of patients.^{1,2} This condition significantly prolongs the duration of mechanical ventilation and hospital stays,¹ as well as leading to a diminished quality of life, incomplete functional recovery, and notable sequelae upon hospital discharge.^{3–5} This entity is included within the so-called post-ICU syndrome (PICS). Physiotherapy plays a pivotal role in mitigating these issues and facilitating rehabilitation. The initiation of physiotherapy in the early phase of admission to the ICU is widely used^{6–9} and it is associated with better functional recovery at hospital discharge.^{10–12}

In recent years, there has been growing interest in the incorporation of cycloergometry as a therapeutic approach within critical care physiotherapy. This intervention is based on the use of a stationary bicycle while subjects are in supine position and can be adapted to suit the subject's level of fitness and functional capacity, even in sedated patients. This device provides a controlled environment for aerobic training, facilitating a range of passive, active, and resisted in-bed exercises, thereby contributing to the preservation of muscle architecture,^{13,14} and it can be easily integrated into conventional physiotherapy protocols in ICU. Patient acceptance of in-bed cycling sessions has been positive¹⁵ and it encourages subjects to engage in physical activity.¹⁶

Published meta-analyses suggest that cycloergometry could be safe in critically ill patients, though the certainty of evidence remains low.^{17,18} Given the physiological instability of these subjects, careful subject selection and close monitoring are essential. While the utilization of these devices for ICU mobilization has been suggested to lead to improved functional recovery,^{19,20} there is ongoing debate due to controversial findings in published studies.^{14,21–26} For this reason, ensuring the safety of cycloergometry in critically ill patients remains essential. Further high-quality studies are needed to assess safety and effectiveness.

The aim of this study was to evaluate the safety of adding early cycloergometry to conventional physiotherapy as a rehabilitation strategy in critically ill patients, compared with early conventional physiotherapy alone, by examining session interruptions, potential associated risks and changes in physiological variables. In addition, participants' functional status and muscle strength were assessed as secondary objective at different time points from the ICU stay throughout a 6-month follow-up for both treatment groups as measures of efficacy.

Patients and methods

Study design

This single-centre, parallel, open-label, two-arm, randomized-controlled trial with critically ill patients with invasive mechanical ventilation was conducted in the Intensive Care Medicine Department in collaboration with the Physical Medicine and Rehabilitation (RHB) Department of the University Hospital Son Llatzer in Palma, Spain.

Participants and settings

The study was conducted in a 16-bed, mixed medical and surgical ICU at a university hospital between June 2015 and February 2020. Patients of both sex were eligible if they were older than 18 years and were mechanically ventilated more than 48 h, regardless of sedation status, had functional independence prior to admission, and subjects or relatives had signed the informed consent. Patients were excluded if they met any of the following criteria: unable to adhere to follow-up (e.g., tourist), pregnancy, neuromuscular disease, an estimated fatal outcome within 48 h, inability to perform pedalling movements, active haemorrhage or a platelet count $<50 \times 10^9/L$, psychiatric disorders, severe agitation, hemodynamic instability despite requiring noradrenaline $> 0.5 \text{ mcg/kg/min}$, or admission due to cardiorespiratory arrest.

Randomization and treatment groups

Within the first 3 days after ICU admission subjects were randomly allocated in a 1:1 ratio in two groups based on the type of physiotherapy session administered by means of a computer-generated randomization list in block sizes of 6 subjects. Treatment allocation was concealed using opaque sealed and numbered envelopes. All sessions were delivered by licensed physiotherapists who had experience with

ICU environment and cycloergometric devices and were not blinded to the randomization group.

Control Group consisted of the application of conventional physiotherapy, as the usual care in our unit. Physiotherapists administered 30-minute session of physiotherapy (manual motor physiotherapy for the extremities and respiratory physiotherapy, if needed) on weekdays (5 sessions per week) that involved daily assessment of session intensity, which included phases of passive, passive/active, active, or active/resisted physiotherapy.

Intervention Group consisted of the application of 15-minute session of cycloergometric mobilization by physiotherapists with a motor-assisted bed-cycle (MOTomed® Letto 2, RECK-Technik GmbH & Co. KG, Betzenweiler, Germany) with individualized intensity adjustments, following the methodology used in randomized clinical trials.²⁶ This device allowed for active or passive leg pedalling exercises at six progressively challenging levels. Patients were positioned comfortably in a supine or reclining posture. Sedated patients engaged in passive leg pedalling for 15 min at a rate of 20 revolutions per minute.^{20,25} The remaining 15 min consisted of our standard care session involving arms and respiratory system, if needed.

Variables and measurements

Descriptive variables collected in the study included age, sex, weight, height, body mass index, comorbidities, Activities of Daily Living (ADL) score²⁷ one month before hospital admission, main diagnosis, type of patient (medical or surgical), SAPS3 score²⁸ and treatment received in ICU. For each session, a qualitative assessment of the intensity applied was recorded, classifying sessions as passive, passive/active, active, or active/resisted.

For the safety analysis, we documented the real-time duration of each session and prospectively recorded physiological variables immediately before and at the end of each session, regardless of whether it was completed or interrupted, without allowing for recovery time. Throughout all mobilization sessions, we continuously monitored blood pressure (BP), heart rate (HR), respiratory rate (RR) and pulse oximetry oxygen saturation (SpO₂). For the analysis, we defined poorly tolerated sessions as those exhibiting any of the following abnormal physiological responses: HR exceeding 140 bpm or falling below 40 bpm, systolic BP exceeding 180 mm Hg or decreasing by 20% from baseline, SpO₂ falling below 90% despite adjustment of FiO₂ or RR exceeding 35 bpm. Additionally, we noted any instances of session interruption and, when applicable, any disconnection of ventilator or devices dislodgement (catheters or tubes). A session was promptly halted if the patient had the presence of malignant arrhythmias or signs of myocardial ischemia. Physiotherapists also interrupted sessions when clinical derangement, agitation or at the patient's request due to poor cooperation or fatigue, in accordance with procedures used in other clinical trials.²⁹

Treatment effects on muscle strength were assessed with the Medical Research Council (MRC) score.³⁰ In addition, the maximum isometric strength of both quadriceps and the maximum handgrip force from the dominant hand were assessed using dynamometers, based on three

repeated measurements per limb. These measurements were performed as soon as patients were capable of active cooperation, at ICU discharge and at 28 days and 6 months after hospital discharge.

Regarding functional status, the ADL score²⁷ and the ICU Mobility Scale³¹ were assessed at ICU discharge and at 28 days and 6 months after hospital discharge. The 6-minute walk test (6MWT)³² and the SF-36³³ questionnaire were assessed at 28 days and 6 months after hospital discharge.

Sample size calculation

The primary objective of this study was to evaluate safety. For the safety analysis, the sample size calculation assumed a 2% prevalence of interrupted physiotherapy sessions,²⁹ considering a prevalence above 4% as relevant increase. Assuming a type I error of 5% and a statistical power of 80%, and a loss percentage of 5%, a total of 687 physiotherapy sessions were needed.

For the secondary objective based on efficacy of cycloergometry, 36 subjects were required in each treatment group to demonstrate a minimally clinically significant difference in the 6MWT (50 m),^{20,34} with a statistical power of 80% and a type I error of 5%.

Statistical analysis

Categorical variables are expressed as frequency and percentages. Continuous variables are expressed as mean and standard deviation (SD), or as median and interquartile range (IQR), depending on whether they present normal distribution or not. Normality was assessed using the Shapiro–Wilk test. Categorical variables were compared using the χ^2 test. For continuous variables, the independent samples were analyzed using the Student's *t*-test or the non-parametric Mann–Whitney *U*-test, according to normality. For paired samples, comparisons were performed using the paired Student's *t*-test or the Friedman test, depending on data distribution. A difference with a significance level equal to or less than 0.05 was considered significant.

Ethics

The study has been approved by the institutional research ethics committee prior to its initiation with the protocol number IB 2565/15 of the Balearic Ethical Committee and is registered on clinicaltrials.gov under the identifier NCT02478411. The study has been conducted in accordance with the principles of the Declaration of Helsinki. The signed informed consents from all participants or participant relatives were obtained.

Results

Participants characteristics

The flowchart of the participants enrolment is shown in Fig. 1a. Among the 634 patients screened for eligibility, 388 did not meet the inclusion criteria, 18 declined par-

ticipation and 157 were not included for unavailability of resources or recruitment oversight. In total, 71 participants were randomized, and 68 (68% women) received the allocated treatment, 34 participants in control group and 34 participants in intervention group, with a median age of 66 (56–77) years. Ultimately, 24 subjects in the control group and 22 in the intervention group were included in the efficacy analysis.

Eight-hundred six physiotherapy sessions were scheduled for the 68 randomized subjects, 394 (49%) allocated in the control group and 412 (51%) in the intervention group. Thirty-one sessions (8%) in the control group and 43 (10%) in the cycloergometric group were not initiated ($p = 0.22$) due to clinical reasons before the start of the session as prone position, fever, hemodynamic instability, need for medical procedures (e.g., pleural drainage, tracheostomy, CT scan...), agitation, or physiotherapist workload, as shown in Fig. 1b. Subjects received a median of 7 (5–16) sessions during the ICU stay, with a median duration of sessions of 27 (20–30) min. Sessions were started at a median of 3 (2–5) days from ICU admission. Baseline characteristics according to treatment group are summarized in Table 1.

Characteristics of physiotherapy sessions

Regarding the clinical condition of participants before the start of each session, no significant differences were observed between the two groups in FiO₂ levels, the need for vasopressors, or the requirement for invasive mechanical ventilation. Continuous renal replacement therapy was more frequently used in the control group sessions ($p < 0.001$), whereas tracheostomy was more common in the intervention group sessions ($p = 0.009$). There were no significant differences between groups in the qualitative classification of session intensity. Session duration was significantly shorter in the control group compared to the cycloergometry group [25 (20–28) min vs. 30 (25–33) min, $p < 0.001$] (Table 2).

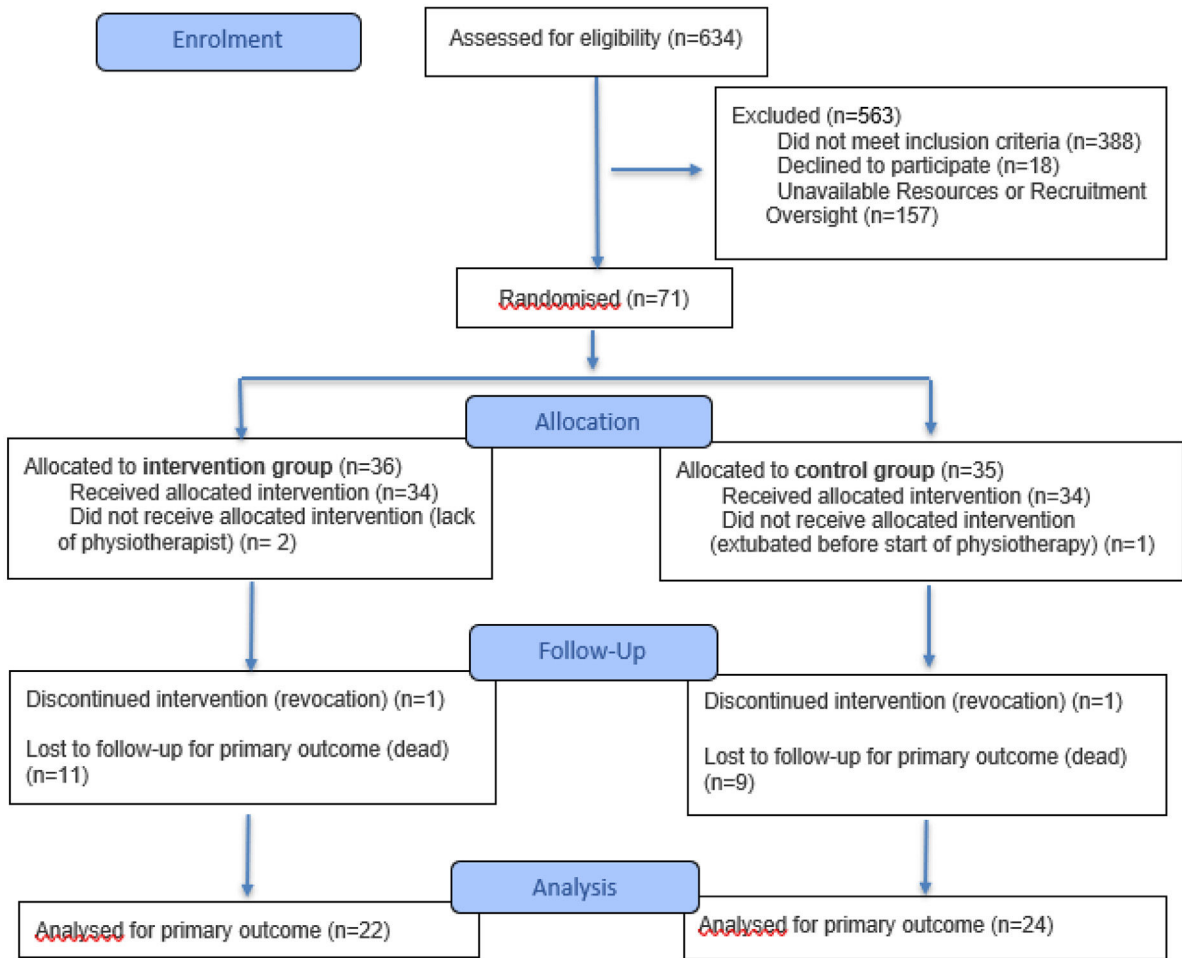
Safety of physiotherapy sessions

Overall, at least one sign of poor physiological tolerance was detected in 37 sessions (10%) in the control group and 53 sessions (14%) in the cycloergometry group ($p = 0.07$) (Table 2), affecting 16 subjects (47%) in the control group and 19 subjects (56%) in the cycloergometry group ($p = 0.47$). However, the presence of poor tolerance signs did not necessarily lead to session discontinuation. Of the 90 sessions in which at least one sign of poor tolerance was recorded, only 8 sessions (22%) in the control group and 21 sessions (40%) in the cycloergometry group were interrupted ($p = 0.07$).

Globally, session interruptions were more frequent in the intervention group, occurring in 13% of cases (47 sessions) compared to 7% (25 sessions) in the control group ($p = 0.008$) (Table 3). The primary reasons for session interruptions, detailed in Table 3, were patient fatigue and lack of cooperation.

In terms of the physiological impact of physiotherapy sessions, both groups resulted in significant changes in heart rate, respiratory rate, and tidal volume during sessions in

a



b

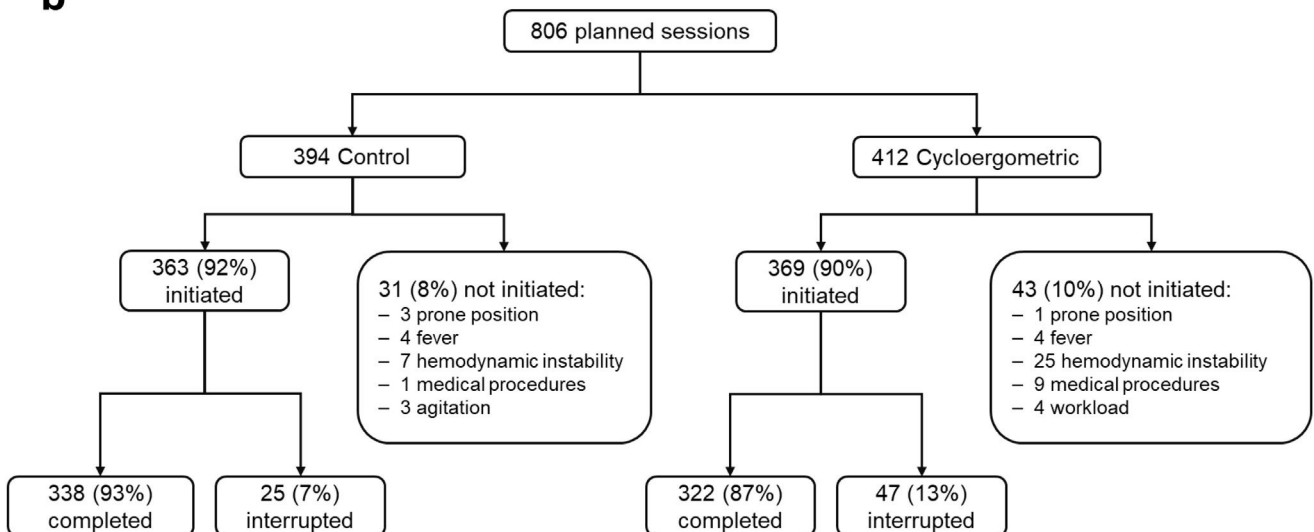


Figure 1 Flowchart of patients according to CONSORT diagram (a) and flowchart of physiotherapy sessions (b).

Table 1 Demographic and clinical characteristics of subjects according to treatment group allocation.

	Control group (n = 34 patients)	Intervention group (n = 34 patients)	p
At ICU admission:			
Age (years), median (IQR)	71 (55–79)	64 (57–76)	0.67
Female sex, n (%)	24 (71)	22 (65)	0.80
BMI (kg/m ²), mean (SD)	29.5 (4.5)	28.4 (6.7)	0.41
SAPS 3 score (points), mean (SD)	61 (13)	61 (13)	0.83
ADL score (points), median (IQR)	6 (6–6)	6 (6–6)	0.78
Type of patient:			
Medical, n (%)	31 (91)	29 (85)	0.71
Surgical, n (%)	3 (9)	5 (15)	
Main diagnosis:			
Pneumonia, n (%)	22 (65)	16 (47)	
Septic shock, n (%)	7 (21)	6 (18)	
Encephalopathy, n (%)	3 (9)	2 (6)	
Abdominal sepsis, n (%)	2 (6)	4 (12)	
COPD exacerbation, n (%)	0	4 (12)	
Polytrauma, n (%)	0	1 (3)	
Retropharyngeal hematoma, n (%)	0	1 (3)	
During hospital admission:			
Tracheostomy, n (%)	11 (32)	13 (38)	0.80
Number of sessions per patient, median (IQR)	8 (4–13)	7 (6–17)	0.87
Days between ICU admission and 1 st session, days, median (IQR)	3 (2–4)	3 (2–5)	0.52
Days of IMV, median (IQR)	10 (7–20)	11 (7–23)	0.94
ICU LOS (days), median (IQR)	17 (12–37)	16 (11–37)	0.97
Hospital LOS (days), median (IQR)	36 (18–50)	26 (18–51)	0.65
Hospital mortality, n (%)	10 (31)	11 (32)	0.92

ADL: Activity Daily Life score²⁷; BMI: body mass index; COPD: Chronic Obstructive Pulmonary Disease; ICU: Intensive Care Unit; IMV: Invasive mechanical ventilation; IQR: Interquartile range; LOS: length of stay; SAPS 3: Simplified Acute Physiology Score 3²⁸; SD: standard deviation.

Table 2 Clinical characteristics of physiotherapy sessions based on treatment group.

	Control group (n = 363 sessions)	Intervention group (n = 369 sessions)	p
FiO ₂ at start of session, median (IQR)	28 (24–35)	30 (24–35)	0.45
Need of vasopressors, n (%)	149 (41)	127 (34)	0.07
Connected to CRRT, n (%)	38 (11)	7 (2)	<0.001
Invasive mechanical ventilation, n (%)	186 (65)	214 (59)	0.19
Tracheostomy, n (%)	108 (52)	154 (65)	0.009
Session Intensity, ^a median (IQR)	2 (1–2)	1 (1–2)	0.175
Duration of sessions, minutes, median (IQR)	25 (20–28)	30 (25–33)	<0.001
Presence of at least one poor tolerance criteria, ^b n (%)	37 (10)	53 (14)	0.07

CRRT: continuous renal replacement therapy; IQR: Interquartile range; FiO₂: fraction of inspired oxygen.

^a Session intensity: 1 = passive, 2 = passive/active, 3 = active and 4 = active/resisted.

^b Poorly tolerated session criteria: heart rate exceeding 140 bpm or falling below 40 bpm; systolic blood pressure exceeding 180 mm Hg or decreasing by 20% from baseline; SpO₂ falling below 90% despite adjustment of FiO₂; or respiratory rate exceeding 35 bpm.

each studied group (Table 4). Moreover, significant variations in SpO₂ were observed during conventional physiotherapy (p = 0.01), whereas intervention group sessions resulted in changes in mean blood pressure (p = 0.007). Despite these

differences, the overall percentage change in physiological parameters at the end of the sessions was similar between groups (Table 4). No episodes of malignant arrhythmias or signs of myocardial ischemia were recorded.

Table 3 Characteristics of interrupted sessions.

	Control group (n = 363 sessions)	Intervention group (n = 369 sessions)	p
Number of interrupted sessions, n (%)	25 (7)	47 (13)	0.008
Duration of interrupted sessions, median (IQR)	15 (12–17)	15 (12–20)	0.61
Main reason of session interruption:			
Poor-cooperation, n (%)	11 (44)	12 (26)	
Fatigue, n (%)	7 (28)	16 (34)	
SpO ₂ < 90%, n (%)	3 (12)	7 (15)	
Pain, n (%)	1 (4)	7 (15)	
Hypotension, n (%)	3 (12)	3 (6)	
Hypertension, n (%)	0	1 (2)	
Removal rectal tube, n (%)	0	1 (2)	

IQR: interquartile range.

Table 4 Physiologic variables at the start and at the end of all physiotherapy session according to treatment group.

	Control group (n = 363 sessions)			Intervention group (n = 369 sessions)		
	Start of session	End of session	p	Start of session	End of session	p
MBP (mm Hg), median, (IQR)	92 (79–101)	91 (78–102)	0.44	86 (77–97)	88 (77–99)	0.007
HR (bpm), median, (IQR)	89 (78–105)	92 (79–103)	0.002	91 (81–102)	94 (82–105)	0.001
RR (rpm), median (IQR)	22 (17–28)	23 (18–29)	0.01	25 (19–30)	25 (20–31)	0.006
SpO ₂ (%), median (IQR)	97 (95–99)	97(95–99)	0.01	97 (95–99)	97 (95–98)	0.06
FiO ₂ (%), median (IQR)	28 (24–35)	28 (24–35)	0.38	30 (24–35)	30 (24–35)	0.80
Tidal volume (mL), median (IQR)	489 (395–624)	513 (411–625)	0.003	495 (402–609)	507 (405–650)	0.01
Percentage of change at end of session:		Control group		Intervention group		p
ΔMBP (%), median, (IQR)		0 (-5.5–5.9)		1.9 (-5.9–9.4)		0.06
ΔHR (%), median, (IQR)		1 (-2.4–4.4)		1.2 (-3.4–6.4)		0.50
ΔRR (%), median (IQR)		0 (-8.5–15.8)		0 (-7.6–16.7)		0.97
ΔSpO ₂ (%), median (IQR)		0 (-1.1 – 1.0)		0 (-1.0–1.0)		0.52
ΔFiO ₂ (%), median (IQR)		0 (0 – 0)		0 (0 – 0)		0.45
ΔTidal volume (%), median (IQR)		1.5 (-4.3–11.5)		1.3 (-6.3–13.7)		0.88

MBP: mean blood pressure; HR: heart rate; RR: Respiratory rate; SpO₂: O₂ saturation by pulse oximetry; FiO₂: oxygen inspired fraction; Δ: change of variables from the start to the end of sessions measured as: (end value – initial value)/initial value) × 100. IQR: Interquartile range.

Effects of cycloergometric treatment

With the methodology employed in our study no significant differences between the groups were observed with respect to weakness (as assessed by the MRC scoring system, quadriceps strength and handgrip strength) and functional recovery (as measured by the ADL score, 6MWT, mobility scale and SF-36 score) in each follow-up point (Table 5).

Analysing the evolution within each group using repeated-measures analyses, it was found that control and intervention groups showed a progressive improvement over time in ADL (p < 0.001 and p < 0.0001, respectively), mobility scale (p < 0.0001 and p = 0.015, respectively), SF-36 score (p = 0.035 and p = 0.034, respectively), and handgrip strength (p = 0.017 and p = 0.006, respectively). However, for MRC score, 6MWT, and quadriceps strength, although improving over time in both groups, only the control group

exhibited significant gains (p = 0.002, p = 0.007, p = 0.047, respectively) (Table 5).

Discussion

This study evaluated the safety and physiological tolerance of early rehabilitation using either conventional physiotherapy alone or a combination of conventional physiotherapy and cycloergometry in critically ill patients. When delivered for similar total duration, both interventions showed comparable safety profiles, with no serious adverse events and similar physiological changes after sessions, although sessions in the cycloergometry group were interrupted more frequently. Although no statistically significant differences in efficacy outcomes were identified, these findings must be interpreted with caution given the methodological constraints of the trial.

Table 5 Effects on muscle strength and functional recovery over time according to treatment group.

	At first patient cooperation		p	UCI discharge		p	28 days after hospital discharge		p	6 months after hospital discharge		p
	Control (n = 16)	Intervention (n = 18)		Control (n = 12)	Intervention (n = 16)		Control (n = 18)	Intervention (n = 17)		Control (n = 12)	Intervention (n = 8)	
MRC score, median (IQR)	40.5 (33–51)	43.5 (39.0–53.3)	0.30	48 (46–56)	53.0 (46.5–56)	0.64	58 (53–60)	56 (48–60)	0.77	60 (58–60)	55 (53–60)	0.06
Quadriceps strength (Kg), median (IQR)	9.8 (6.0–14.9)	11.0 (8.1–17.1)	0.52	10.1 (8.2–12.6)	9.3 (7.7–13.1)	0.87	15.5 (12.7–20.9)	16.6 (14.9–19.3)	0.66	16.3 (11.8–19.4)	18.5 (15.4–21.3)	0.57
Handgrip strength (Kg) median (IQR)	11.6 (4.8–22.2)	13.9 (8.0–23.1)	0.30	13.3 (12.7–19.3)	13.8 (8.9–23.9)	0.77	27.9 (15.6–35.3)	24.1 (15.8–31.8)	0.48	29.9 (17.5–42.6)	33.1 (23.9–44.0)	0.43
ADL, median (IQR)	-	-		1 (0–4)	2 (1–4)	0.08	6 (5–6)	5 (4–6)	0.22	6 (6–6)	6 (6–6)	0.65
Mobility scale, median (IQR)	-	-		5 (4.25–7)	5 (4–8)	0.92	10 (10–10)	10 (9.3–10)	0.46	10 (10–10)	10 (9–10)	0.22
6MWT (minutes), median (IQR)	-	-		-	-		296.5 (227.5–419.5)	330.0 (132.5–428.3)	0.75	416.5 (344.3–470.25)	360.0 (195–437.5)	0.25
SF-36, median (IQR)	-	-		-	-		53.4 (26.4–73.3)	38.64 (15.9–75.0)	0.19	86.4 (78.4–93.2)	72.7 (45.5–86.4)	0.06

MRC: Medical Research Council score²⁹; ADL: Activity Daily Life score²⁷; 6MWT: 6-minute walking test³¹; Mobility scale³⁰; SF-36: Short Form-36.³²

Safety remains a central concern in early rehabilitation given the vulnerability of participants as the TEAM study³⁵ reported a higher incidence of adverse events in participants receiving early physiotherapy compared with usual care physiotherapy in critically ill patients. In that trial, longer sessions duration and sedation minimization in the intervention group may have contributed to these results, acting as potential confounders. Additionally, although cycloergometry has been associated with high subject satisfaction and increased motivation,^{15,16} its safety profile must be further evaluated and closely monitored given the frailty of this population.

In our study, the systematic assessment of physiological variables immediately before and after every session in both study groups enabled a rigorous and detailed characterization of safety events. This approach likely explains the higher overall incidence of safety events observed compared to previous reports that have used broader definitions or less intensive monitoring approaches.^{15,18,21,24,25,29} Importantly, most events were mild and did not require session interruptions.

In this context, the addition of cycloergometry to conventional physiotherapy was associated with a higher rate of session interruptions than conventional physiotherapy alone, resulting in an overall discontinuation frequency greater than previously described.²⁹ However, no serious adverse events occurred, supporting the feasibility and safety of both interventions when implemented with strict physiological monitoring, as fatigue or lack of cooperation were main reasons for session discontinuation, in line with previous reports.²⁹

Regarding efficacy, although previous randomized trials have reported potential benefits of cycloergometry such as reduced muscle autophagy¹⁴ or improvements in physical function in terms of better walking capacity,^{20,36} greater quadriceps strength²⁰ or higher MRC scores,^{36,37} these findings have not been consistently replicated,^{21,24–26} leaving the overall evidence inconclusive. A recent meta-analysis¹⁸ including 33 randomized controlled trials and 3274 critically ill patients concluded that cycloergometry may improve physical function and reduce ICU and hospital length of stay, but it showed no significant effects on other clinically relevant outcomes, including mortality. Despite these apparently beneficial findings, the overall quality of evidence remains low or very low limiting the strength and generalizability of these findings.

Although our study aimed to strengthen the existing evidence regarding efficacy with cycloergometry and included a relatively high number of sessions per patient compared with previous reports,^{21,24–26} methodological aspects may have limited the ability to detect clinically meaningful differences. Consequently, the absence of statistically significant effects should be interpreted with caution.

First, the modest sample size represents an important limitation, as it may have resulted in insufficient statistical power to identify clinically relevant differences in efficacy between groups. This limitation arises from several practical and methodological challenges encountered during the study. Subject recruitment was slow due to the limited availability of a single cycloergometer in our department and the small number of physiotherapists trained in

cycloergometry. Additionally, loss of subjects during follow-up primarily due to mortality, but also to non-attendance at outpatient assessments, further limits the robustness of our long-term findings regarding the efficacy of physiotherapy. Second, cycloergometry sessions were shorter than in comparable studies^{20,24,37} due to feasibility constraints. We cannot rule out that 15 min may represent a suboptimal dose of physiotherapy to induce measurable functional or strength enhancements, and that this limitation restricts the conclusions that can be drawn regarding efficacy. In many randomized trials, physiotherapy intensity has been imbalanced between groups, as patients allocated to cycloergometry often also receive conventional physiotherapy,^{14,21,24–26,37} increasing total intervention time and potentially confounding the results. In contrast, our trial maintained comparable session durations between groups, allowing for a clearer assessment of the independent effect of cycloergometry but the duration of the intervention was likely insufficient. Third, both interventions were delivered at low intensity, with median levels ranging from passive to passive–active. Although trials comparing different intensities of the same physiotherapy modality have not found significant differences in long-term functional outcomes,^{38,39} given that low workloads in our study may be insufficient to stimulate functional recovery or prevent muscle atrophy, the intervention dose may have been inadequate. Moreover, assessing session intensity is inherently challenging, and the lack of detailed workload metrics in our study may have introduced some heterogeneity between groups, further limiting the interpretation of the negative efficacy results. Finally, frequent session interruptions in the cycloergometry group reduced the effective intervention time and may have attenuated any potential benefit. The relatively brief stimulus,^{21,24–26,40} combined with frequent session interruptions, may have limited the intervention's impact on muscle preservation and functional outcomes. Furthermore, subjects with limited tolerance may not have completed enough effective sessions to experience the theoretical advantages of cycle ergometry. Together, these factors restrict conclusions about efficacy and highlight the need for caution when interpreting the absence of significant differences.

In summary, both conventional and cycloergometric early physiotherapy were safe and physiologically well tolerated. Because of the uncertainty introduced by the methodological limitations of this trial, including restricted intervention duration, concerns on intensity quantification and insufficient statistical power, the reliability of the observed efficacy results cannot be ensured.

Conclusions

Partially replacing conventional physiotherapy with cycle ergometry proved safe and physiologically well tolerated in critically ill patients. Given the methodological limitations related to intervention dose, intensity quantification, and the restricted sample size, efficacy outcomes cannot be interpreted with confidence, and no reliable conclusions about the effects on treatment efficacy can be drawn.

Author's contributions

Gemma Rialp and Catalina Forteza have made a substantial contribution to the study design, data acquisition, analysis and interpretation, as well as to the drafting of the manuscript.

Isabel Gil contributed to patient management, data acquisition, and the revising of the manuscript.

Maria Romero contributed to data acquisition, data analysis and interpretation, and the revising of the manuscript.

Catalina Morey has made a substantial contribution to the study design and the revising of the manuscript.

Fiorella Sarubbo has made a substantial contribution to data analysis and interpretation, as well as to the drafting of the manuscript.

All authors read and approved the final version of the manuscript.

Declaration of Generative AI and AI-assisted technologies in the writing process

Artificial intelligence tools were employed exclusively to refine the language and improve the clarity of expression in the manuscript. No AI-generated content was used for data analysis, interpretation, or substantive scientific contributions.

Funding source

The authors received a Research Grant for Pilot Projects from Son Llatzer University Hospital in 2019. This grant had no implications in the study design, data collection, analysis or interpretation, in the writing of the report, or in the decision to submit the article for publication.

Declaration of competing interest

The authors certify that there is no conflict of interest with any financial organization regarding the material discussed in the manuscript. The authors declare that RECK-Technik provided an unconditional loan of the cycle ergometer. The company had no role in the design, conduct, analysis, or reporting of the study.

Acknowledgments

The authors sincerely thank Carmen Buen and Petra Vidal, Chief and Lead Physiotherapist of the Department of Physical Medicine and Rehabilitation of the Son Llatzer University Hospital in Palma, respectively, for their valuable contribution to the implementation of the study. Authors gratefully acknowledge RECK-Technik for their unconditional loan of the cycloergometer used in this study.

References

1. De Jonghe B, Sharshar T, Lefaucheur JP, Authier FJ, Durand-Zaleski I, Boussarsar M, et al. Paresis acquired in the intensive care unit: a prospective multicenter study. *JAMA*. 2002;288:2859–67.
2. Hodgson C, Bellomo R, Berney S, Bailey M, Buhr H, Denehy L, et al. Early mobilization and recovery in mechanically ventilated patients in the ICU: a bi-national, multi-centre, prospective cohort study. *Crit Care*. 2015; 19:81.
3. Herridge MS, Cheung AM, Tansey CM, Matte-Martyn A, Diaz-Granados N, Al-Saidi F, et al. One-year outcomes in survivors of the acute respiratory distress syndrome. *N Engl J Med*. 2003;348:683–93.
4. Tipping CJ, Harrold M, Holland A, Romero L, Nisbet T, Hodgson CL. The effects of active mobilisation and rehabilitation in ICU on mortality and function: a systematic review. *Intensive Care Med*. 2017;43:171–83.
5. Hodgson CL, Udy AA, Bailey M, Barrett J, Bellomo R, Bucknall T, et al. The impact of disability in survivors of critical illness. *Intensive Care Med*. 2017;43:992–1001.
6. Truong AD, Fan E, Brower RG, Needham DM. Bench-to bedside review: mobilizing patients in the intensive care unit—from pathophysiology to clinical trials. *Crit Care*. 2009;13: 216.
7. Hodgson CL, Stiller K, Needham DM, Tipping CJ, Harrold M, Baldwin CE, et al. Expert consensus and recommendations on safety criteria for active mobilization of mechanically ventilated critically ill adults. *Crit Care*. 2014;18:658.
8. Schweickert WD, Kress JP. Implementing early mobilization interventions in mechanically ventilated patients in the ICU. *Chest*. 2011;140:1612–7.
9. Gosselink R, Bott J, Johnson M, Dean E, Nava S, Norrenberg M, et al. Physiotherapy for adult patients with critical illness: recommendations of the European Respiratory Society and European Society of Intensive Care Medicine Task Force on Physiotherapy for Critically Ill Patients. *Intensive Care Med*. 2008;34:1188–99.
10. Schweickert WD, Pohlman MC, Pohlman AS, Nigos C, Pawlik AJ, Esbrook CL, et al. Early physical and occupational therapy in mechanically ventilated, critically ill patients: a randomised controlled trial. *Lancet*. 2009;373:1874–82.
11. Needham DM, Korupolu R, Zanni JM, Pradhan P, Colantuoni E, Palmer JB, et al. Early physical medicine and rehabilitation for patients with acute respiratory failure: a quality improvement project. *Arch Phys Med Rehabil*. 2010;91:536–42.
12. Dinglas VD, Parker AM, Reddy DRS, Colantuoni E, Zanni JM, Turnbull AE, et al. A quality improvement project sustainably decreased time to onset of active physical therapy intervention in patients with acute lung injury. *Ann Am Thorac Soc*. 2014;11:1230–8.
13. Griffiths RD, Palmer TE, Helliwell T, MacLennan P, MacMillan RR. Effect of passive stretching on the wasting of muscle in the critically ill. *Nutrition*. 1995;11:428–32.
14. Hickmann CE, Castanares-Zapatero D, Deldicque L, Van Den Bergh P, Caty G, Robert A, et al. Impact of very early physical therapy during septic shock on skeletal muscle: a randomized controlled trial. *Crit Care Med*. 2018;46:1436–43.
15. Nickels MR, Aitken LM, Barnett AG, Walsham J, McPhail SM. Acceptability, safety, and feasibility of in-bed cycling with critically ill patients. *Aust Crit Care*. 2020;33:236–43.
16. Ringdal M, Warren Stomberg M, Egnell K, Wennberg E, Zätterman R, Rylander C. In-bed cycling in the ICU; patient safety and recollections with motivational effects. *Acta Anaesthesiol Scand*. 2018;62:658–65.
17. Takaoka A, Utgikar R, Rochweg B, Cook DJ, Kho ME. The efficacy and safety of in-intensive care unit leg-cycle ergometry in critically ill adults a systematic review and meta-analysis. *Ann Am Thorac Soc*. 2020;17:1289–307.
18. O'Grady HK, Hasan H, Rochweg B, Cook DJ, Takaoka A, Utgikar R, et al. Leg cycle ergometry in critically ill patients — an updated systematic review and meta-analysis. *NEJM Evid*. 2024;3. EVIDoa2400194.

19. Needham DM, Truong AD, Fan E. Technology to enhance physical rehabilitation of critically ill patients. *Crit Care Med.* 2009;37:S436–41.
20. Burtin C, Clerckx B, Robbeets C, Ferdinande P, Langer D, Troosters T, et al. Early exercise in critically ill patients enhances short-term functional recovery. *Crit Care Med.* 2009;37:2499–505.
21. Kho ME, Molloy AJ, Clarke FJ, Reid JC, Herridge MS, Karachi T, et al. Multicentre pilot randomised clinical trial of early in-bed cycle ergometry with ventilated patients. *BMJ Open Respir Res.* 2019;6:1–9.
22. França EETde, Ribeiro LC, Lamenha GG, Magalhães IKF, Figueiredo T de G, Costa MJC, et al. Oxidative stress and immune system analysis after cycle ergometer use in critical patients. *Clinics (Sao Paulo, Brazil).* 2017;72:143–9.
23. Kayambu G, Boots R, Paratz J. Early physical rehabilitation in intensive care patients with sepsis syndromes: a pilot randomised controlled trial. *Intensive Care Med.* 2015;41:865–74.
24. Kho ME, Berney S, Pastva AM, Kelly L, Reid JC, Burns KEA, et al. Early in-bed cycle ergometry in mechanically ventilated patients. *NEJM Evid.* 2024;3. EVIDoa2400137.
25. Eggmann S, Verra ML, Luder G, Takala J, Jakob SM. Effects of early, combined endurance and resistance training in mechanically ventilated, critically ill patients: a randomised controlled trial. *PLoS One.* 2018;13:e0207428.
26. Fossat G, Baudin F, Courtes L, Bobet S, Dupont A, Bretagnol A, et al. Effect of in-bed leg cycling and electrical stimulation of the quadriceps on global muscle strength in critically ill adults: a randomized clinical trial. *JAMA.* 2018;320:368–78.
27. Katz S, Ford AB, Moskowitz RW, Jackson BA, Jaffe MW. Studies of illness in the aged: the index of ADL: a standardized measure of biological and psychosocial function. *JAMA.* 1963;185:914–9.
28. Moreno RP, Metnitz PGH, Almeida E, Jordan B, Bauer P, Campos RA, et al. O R I G I N A L S A P S 3-From evaluation of the patient to evaluation of the intensive care unit. Part 2: development of a prognostic model for hospital mortality at ICU admission. *Intensive Care Med.* 2005;31:1345–55.
29. Kho ME, Molloy AJ, Clarke FJ, Ajami D, McCaughan M, Obrovac K, et al. TryCYCLE: a prospective study of the safety and feasibility of early in-bed cycling in mechanically ventilated patients. *PLoS One.* 2016;11:e0167561.
30. Kleyweg RP, Van Der Meché FGA, Schmitz PIM. Interobserver agreement in the assessment of muscle strength and functional abilities in Guillain-Barré syndrome. *Muscle Nerve.* 1991;14:1103–9.
31. Hodgson C, Needham D, Haines K, Bailey M, Ward A, Harrold M, et al. Feasibility and inter-rater reliability of the ICU Mobility Scale. *Heart Lung.* 2014;43:19–24.
32. Guyatt GH, Sullivan MJ, Thompson PJ, Fallen EL, Pugsley SO, Taylor DW, et al. The 6-minute walk: a new measure of exercise capacity in patients with chronic heart failure. *Can Med Assoc J.* 1985;132:919–23.
33. Ware JE Jr, Gandek B. Overview of the SF-36 Health Survey and the International Quality of Life Assessment (IQOLA) Project. *J Clin Epidemiol.* 1998;51:903–12.
34. Redelmeier DA, Bayoumi AM, Goldstein RS, Guyatt GH. Interpreting small differences in functional status: the Six Minute Walk test in chronic lung disease patients. *Am J Respir Crit Care Med.* 1997;155:1278–82.
35. TEAM Study Investigators and the ANZICS Clinical Trials GroupHodgson CL, Bailey M, Bellomo R, Brickell K, Broadley T, et al. Early active mobilization during mechanical ventilation in the ICU. *N Engl J Med.* 2022;387:1747–58.
36. Veldema J, Bösl K, Kugler P, Ponfick M, Gdynia H-J, Nowak DA. Cycle ergometer training vs resistance training in ICU-acquired weakness. *Acta Neurol Scand.* 2019;140:62–71.
37. Machado A dos S, Pires-Neto RC, Carvalho MTX, Soares JC, Cardoso DM, Albuquerque IM de. Effects that passive cycling exercise have on muscle strength, duration of mechanical ventilation, and length of hospital stay in critically ill patients: a randomized clinical trial. *Jornal Brasileiro de Pneumologia.* 2017;43:134–9.
38. Moss M, Nordon-Craft A, Malone D, Van Pelt D, Frankel SK, Warner ML, et al. A randomized trial of an intensive physical therapy program for patients with acute respiratory failure. *Am J Respir Crit Care Med.* 2016;193:1101–10.
39. Denehy L, Skinner EH, Edbrooke L, Haines K, Warrillow S, Hawthorne G, et al. Exercise rehabilitation for patients with critical illness: a randomized controlled trial with 12 months of follow-up. *Critical Care.* 2013;17:R156.
40. Yu T, Cai F, Jiang R. Effects of early bedside cycle exercise on gastrointestinal function in intensive care unit patients receiving mechanical ventilation. *Front Med (Lausanne).* 2022;9:823067.