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The effects of short bouts of ergometric exercise for severely burned children in intensive care: a randomized controlled trial

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Abstract

Objective: To determine the effects of short bouts of ergometric exercises on the number of days in the burn intensive care unit (ICU), body mass, and functional ambulation.

Design: Multi-center, randomized controlled trial

Setting: Burn intensive care unit

Participants: Children ages 7 – 17 with severe burns covering over 30% total body surface area (TBSA).

Intervention: All patients received standard of care (Control) with the experimental group receiving additional exercise with a cycle ergometer (Exercise).

Main measures: The number of days in the ICU, total weight, lean body mass (LBM), and functional ambulation were taken shortly after randomization and again within one week of the scheduled hospital discharge. Results of outcomes are expressed as median ± interquartile range (IQR), unless otherwise noted (e.g., demographics).

Results: Fifty-four severely burned children (n=18 Control, n=36 Exercise) were included. The average ± standard deviation for age was 12 ± 3 years and TBSA was 48 ±16%. The median ±

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Declaration of conflicting interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

IQR ICU days for Control was 46 ± 51 days vs 31 ± 29 days for Exercise. The median total weight loss for Control was 2.2 ± 1.2 kg vs 1.8 ± 1.4 kg in Exercise. Control lost 0.75 ± 0.8 kg of LBM vs 0.46 ± 0.43 kg in Exercise. Both groups showed significant improvement in functional ambulation ($p<0.01$). However, exercise did not add additional benefits.

Conclusion.—Short bouts of ergometric exercises are feasible for severely burned patients while receiving care in the ICU but did not add additional benefits.

Keywords

Burns; intensive care; exercise; pediatric

Introduction

Severe burns covering over 30% of the total body surface area (TBSA) induce a profound and complicated hypermetabolic and hypercatabolic response that may persist up to one year after injury, leading to a significant loss of lean body mass and muscle wasting, and loss of function (1–3). To mitigate this, resistance and aerobic rehabilitative exercises were implemented to improve skeletal muscle accretion, increase muscle strength, increase cardiac work capacity, and restore metabolic functions during recovery from burn injury (4–7). Early rehabilitative therapies initiated immediately after hospital discharge showed greater benefits in increasing skeletal muscle mass and function than a delayed start (8). However, a recent study suggested that exercise initiated while the patient is hospitalized in the burn intensive care unit (BICU) may be beneficial to preserve body mass and function (9).

The average patient with severe burns spends approximately 31 days primarily bedridden in the BICU (10). About 50 – 70% of critically ill survivors experience ICU-acquired weakness after discharge. These burn survivors particularly present low functional status impacted by the profound loss of lean mass (11–13). The combination of these compounded effects of burn injury complications and prolonged immobilization with hospitalized bed-rest presents the need to develop a method to help these burn survivors preserve body mass and function while receiving burn care in the BICU. While specialized burn centers implement some form of exercise for their patients while in the BICU, there are no standard protocols, and its beneficial effects are largely unknown. Therefore, the purpose of this study was to determine the effects of short bouts of ergometric exercise on days spent in the BICU, total weight, lean body mass, and functional ambulation in severely burned pediatric patients.

Methods

This study was a randomized, multicenter trial that included severely burned children admitted for burn care to the Shriners Hospital for Children in Galveston, TX, and the Shriners Hospital for Children in Sacramento, CA, between September 2014 to September 2020. This study was approved by the Institutional Review Board at the University of Texas Medical Branch (IRB - #14-0432) and at the University of California Davis, Davis, CA (IRB # 734894-20) and registered in ClinicalTrials.gov (NCT02739464). The University of Texas Medical Branch served as the principal site responsible for the integrity and conduct of this

study. Funding support for this study were provided by the National Institutes of Health (NIH R01HD049471) and the Department of Defense (DOD W81XWH-15-1-0143, DOD W81XWH-14-2-0160).

This study investigated the efficacy of short bouts of ergometric exercise treatment in addition to the standard of burn care at the Shriners Hospital for Children in Sacramento, CA, and the Shriners Hospital for Children in Galveston, TX. Each burn center conducted a standard protocol to compare two parallel treatment groups. Patients who received only the standard of care served as the Control group, while the experimental group (Exercise) also received exercise treatment as described in detail in the following sections. Because exercise was the intervention, blinding the subject or the exercise physiologist performing the exercise bouts was not possible. However, the principal investigator and the exercise physiologist or research nurses who measured the outcomes were blinded to group allocation until the study was unblinded for data analysis. Our power calculation was based on previous studies where we found the average stay in the ICU was 3 weeks with standard deviation of 9.4 days in the ICU, which we expected to detect a one week decrease in ICU days with a power of 90%. Randomization was performed by a clinical biostatistician from the Office of Biostatistics at UTMB and based on the inclusion criteria. This study followed an asymmetric randomization format and was performed to offer potential benefit to a majority of patients of a 2:1 ratio (experimental exercise: control). In this manner, we also preserve the ability to extend randomization and enrollment numbers to account for mortality and dropouts as needed. The randomization list was stored on the biostatistician's computer and was referred to for allocation after patients were consented to the study.

Children between the ages of 7 and 17 who were admitted to the burn intensive care unit (BICU) at the Shriners Hospital for Children in Galveston, TX and Sacramento, CA who had severe burns that covered 30% of their total body surface area (TBSA) or higher were considered for this study. These patients were screened at admission and had no other known comorbidities other than their burn injury. After consenting to the study, they were randomized in a 1:2 study design to the Control or Exercise group, respectively, to maximize the potential benefit of exercise. Both, Control and Exercise groups began physical rehabilitation activities after the attending burn surgeon deemed it safe and appropriate. Patients in the Exercise group were under the supervision of a physical therapist, occupational therapist, or exercise physiologist for the experimental short bouts of ergometric exercises to ensure that the exercises were completed correctly. Patients were monitored for absolute and relative contraindications to exercise listed in Table 1. For patients showing absolute or relative contraindications to exercise, the attending physician supervised their safety and determined if they should continue or discontinue the study.

All patients with severe burns were treated with the individualized standard for burn care at the Shriners Hospital for Children in Galveston, TX and Sacramento, CA. Common standard of care at burn centers included surgical interventions for burn debridement, medications aimed at reducing the hypermetabolic effect of severe burns, early nutritional intervention, and physical and occupational therapy activities and exercises that aimed to improve range of motion, ambulation, mobilization, and stretching. Because this study was designed to investigate the efficacy of short bouts of ergometric exercises in addition to standard burn

care, there were no limitations on activities, treatment, or medications that were considered part of the standard of care.

The intervention consisted of short bouts of ergometric exercises utilizing a cycle ergometer (Monark Rehab Trainer 881-E) for the arms and legs. Each session was personalized to be performed at a moderate to hard effort that was measured by a rated perceived exertion (RPE) scale from 1 – 10, where “3” indicated moderate effort, and “5” indicated hard effort (14). RPE was measured for respiratory and muscle effort, indicating how difficult it was to breathe and how difficult their arms or legs were working, respectively.

An initial set-up was performed to determine the appropriate fit and the exercise load (in watts) for the training sessions. Each patient started at a 5-watt load for one minute, where RPE was recorded during the set-up. Following the first minute, the load was increased by five watts until an RPE of three and five were recorded for respiratory and muscle effort. This load was recorded and served as the starting intensity for subsequent ergometric exercise training sessions. The ergometric exercise training intervention began the day after the initial set-up session. The session started at the individualized load where the RPE of three was recorded. Time started when the patient made their first revolution on the ergometer and stopped after 10 minutes elapsed. In those 10 minutes, RPEs of respiration and muscles, revolutions per minute (RPM), total revolutions, brake knob levels, watts, and other notes were recorded at each minute. The reported RPE determined the intensity of all exercise sessions. When subjects reported an RPE below three or above five during the exercise session, the watts were adjusted to return the RPE to the three to five range. These exercises were performed twice daily from Monday to Friday in the mornings and afternoons, alternating between the arms and legs with rest days on Saturdays and Sundays until the patient was discharged from the BICU.

A research nurse or exercise specialist who did not participate in providing clinical care for patients, performed the assessments of outcome measures. The Pre-intervention measures were conducted after the patient was randomized to their group. When it was deemed safe by the attending physician, the post-intervention measures were performed either within one week of hospital discharge or three weeks after the scheduled hospital discharge if a surgery prevented the assessment of body composition or the six-minute walk test. The number of days spent in the BICU was determined from admission to discharge from the hospital. A calibrated scale measured the total weight, and the assessment of lean body mass was measured immediately afterwards by dual-energy x-ray absorptiometry (DEXA), which was performed by a trained and certified technician. Functional ambulation was assessed via a six-minute walk test, which was conducted in a standardized manner, as published by the American Thoracic Society Guidelines (15,16).

The Office of Biostatistics performed statistical analyses at the University of Texas Medical Branch in Galveston, TX. All data were first assessed for normality, and appropriate tests were run based on those results. A student’s t-test was performed for demographic measures such as age, total body surface area burned, and 3rd-degree burns. A non-parametric Mann-Whitney test analyzed the number of days in the BICU. Total body weight, lean mass, and the six-minute walk performance were analyzed using linear models relating

the outcomes to relevant predictors such as age, treatment (Control vs. Exercise), and the number of days in the BICU. Multiple linear regression models were first created with all interaction terms. In all cases, the interaction terms were found to be not significant, so new models were created with just the three independent variables of age, number of days in the BICU, and treatment. Data were evaluated for linearity of the data, normality of residuals, homoscedasticity, and independence of residuals error terms, and all were found to be appropriate. All analyses were performed using R software v 4.0.4, and $p < 0.05$ was determined as significant.

Results

This study enrolled 70 subjects and included 54 in this analysis following eight withdrawals, two expired patients, and six subjects removed because no data was able to be collected. The subject retention tree is shown in Figure 1. Patient demographics are presented as means ± standard deviations (+/−SD) in Table 2. Days in the BICU, lean body mass, total weight, and distanced walked in during the six-minute walk test are presented as the median ± interquartile range (Table 3). Weight and the multiple linear regression analyses for these outcome measures are shown in Tables 4 – 6. There were 18 subjects randomized to Control and 36 to Exercise, with an average age of 12 ± 3 years with 48 ± 16% TBSA, and 37 ± 20% 3rd-degree burns. There were no significant differences between groups for age or severity of injury. The Exercise group performed exercises at a median of 22% of their total number of days spent in the BICU.

The median number of days in the BICU for Control was 46 ± 51 days ranging from 8 – 91 days, while the Exercise group stayed at a median of 31 ± 29 days, ranging from 14 – 100 days. The median length of BICU days with Exercise was approximately 15 days less than the median of Control length of stay. However, they were not significantly different, and we noted large ranges within both groups.

The median and IQR for total weight for Control at Pre was 44.5 ± 4.6 kg and 41.9 ± 4.4 at Post with an average weight loss of 2.2 ± 1.2 kg. The median and IQR for total weight for Exercise at Pre was 52.9 ± 3.6 kg and 48.6 ± 3.2 kg at Post with a weight loss of 1.8 ± 1.4 kg. The linear model with primary variables (age, days in BICU, and treatment) as well as all potential interactions between the variables indicated that the number of days in the BICU was predictive for determining weight differences when controlling for age and treatment group ($p<0.05$) (Table 4).

The median and IQR for lean body mass for Control at Pre was 29.2 ± 2.7 kg ending with 27.3 ± 2.5 kg at Post with a lean body mass loss of 0.75 ± 0.8 kg (approx. 2.56%). The median and IQR for lean body mass for Exercise at Pre was 34.9 ± 2.2 kg and 33.2 ± 2.2 kg at Post with a lean body mass loss of 0.46 ± 0.43 kg (approx. 1.32%). The linear model for the primary variables of age, days in BICU, and treatment indicated that none of the three variables are informative at predicting the lean body mass difference (Table 5). All p-values were larger than 0.05.

The six-minute walk test was performed with the physician's clearance for the Pre time-point at the earliest possible time. When the patient was physically unable to ambulate, a value of zero was designated. The median and IQR results for pre six-minute walk for Control was 162.0 ± 47.1 ft and 867.1 ± 128.8 ft at the post time point, with an improvement of 705.1 ± 124.7 ft. The pre six-min walk for Exercise was 178.7 ± 30.8 ft and 871.4 ± 66.0 ft at the post time point, with a gain of 698.6 ± 72.4 ft. Both groups showed significant improvement from Pre to Post ($p<0.01$). However, the linear models for age, days in the BICU, or treatment were not predictive of a walk difference in the distance with p-values greater than 0.05 (Table 6).

Discussion

This study investigated the effects of short bouts of ergometric exercises on the number of days spent in the BICU, total weight, lean body mass, and functional ambulation in severely burned children. Our results found that all patients improved their functional ambulation from their early admission until discharge. However, there were no additional benefits of ergometric exercises on any of our outcome measures.

While our results tend to show a lower number of days spent in the BICU with patients who participated in the ergometric exercises, they were not significantly different. Recovery from a severe burn injury is complicated and multi-factorial regarding the response to surgical and drug interventions. The individualized needs and care of the patient would explain the large variability in the number of days spent in BICU found in both the Control and the Exercise groups, requiring a greater sample size than what this study provided to reach statistical significance. However, considering the economic impact of burn care, each day is meaningful to the family of severe burn survivors. The average cost of burn care in the United States was $88,218, with the median cost of $44,024 (17), approximately $1,330 in a university setting (18). Any reduction in the number of days spent in the ICU would be impactful, particularly for low-income families in rural areas are at higher risk of incidence of burn injury (19).

The Control group lost approximately 5.0% of their total weight and 2.6% lean body mass, while the Exercise group lost about 3.3% of their total weight and 1.3% of lean body mass. Differences between treatment groups in total weight or lean body mass loss were not significantly different. However, our results indicate that the number of days spent in the BICU was a predictor of a loss of total body weight, suggesting that a greater length of stay would predict a greater loss of total weight but not lean mass loss. A significant loss in total weight without a significant loss of lean mass suggests that there are other factors such as total body water that may contribute to their total weight, and total body weight may not be a reliable method to measure lean mass retention.

Rehabilitation programs following discharge showed improved lean body mass of severe burn survivors included resistance training (6,8,20,21). Our exercise protocol only included an aerobic type of exercise. The absence of resistance exercise in this intervention may explain the lack of lean mass retention or accretion in the exercising subjects. Considering

the specificity of exercise training, the inclusion of resistance training such as using exercise bands may induce lean body mass accretion and preservation while in the BICU.

Burn injured children showed a substantial reduction in the six-minute walk test compared to the results of healthy age-matched children (22). However, both groups showed significant improvement in the six-minute walk test from the time of admission until they were discharged. The Control group showed an improved performance by approximately 705 ft., and the Exercise group improved by about 698 ft. Although normative standards have not been established for the pediatric burn population, the analysis for gait speed has been utilized in other adult populations as a predictor of prognosis, mortality, frailty, and functional status (23–26). Because the six-minute walk test shows a similar prognostic capability to gait speed (25), we can extrapolate our results to determine their average gait speed. The Control and the Exercise group improved their gait speed by about 0.59 m/s. Previous studies indicated that a substantial, meaningful change of 0.10 m/s (27,28) were attained by both groups.

There were limitations to this study. The number of days spent in the ICU, the clearance to exercise, and the ability to perform and collect outcome measures were impacted by the patient's clinical status and surgical procedures. Thus, we were unable to standardize the total number of exercise sessions and when they were performed. Though not included as part of our outcome measures, patients who had a longer stay in the ICU participated in more exercise sessions than those patients with a shorter number of days spent hospitalized. This could reflect a larger benefit of exercise over those with a shorter stay in the ICU who participated in fewer exercise sessions.

Secondly, patients at times were unable to exercise due to surgical and drug interventions, thereby reducing the number of exercise sessions and possibly minimizing the treatment effect. As this is a small study, we are only able to detect large differences between the two treatments. This does not mean that smaller differences between the groups are not significant. It just means that we may not have enough subjects to be able to rule out the possibility of a type II error. However, our study does strongly support the safety of aerobic exercise during ICU stay.

Thirdly, while standardized care was carefully followed, there were individual variability related to the nature of the injuries. For example, severe burns on the legs and feet would impact functional ambulation more than injury to the arms and hands. The number of surgeries required impacts the clearance and ability of patients to perform certain exercises. Severely burned patients require multiple medications during recovery, and the variability of the type of drugs, the amount they receive, and the potential adverse effects will impact their ability to perform exercises. In our study, location of burn using retrospective medical chart extraction was not possible. Thus, more burns in the lower body in one group relative to the other group is possible. However, this is unlikely due to the large TBSA % burned, and due to the randomization process in which each participant meeting the TBSA inclusion criteria had an equal chance of being in one group or the other group. In addition, we individualized the exercise regime to diminish the impact of % burn and location of burn (i.e., training regime included upper body and/or lower body as applicable).

Despite these limitations, this study is the first attempt to quantify the benefits of early exercise in the ICU in severely burned children. While our study did not show that short bouts of ergometric exercise in the ICU significantly improved lean body mass, shorten the days spent in the ICU, or improve functional ambulation, we were able to show the feasibility of an early exercise intervention in the ICU and the potential economic impact on families of severe burn survivors. Additionally, no adverse events, including hypotension, arrhythmia, or cardiac ischemia (29), were directly linked to the aerobic exercise intervention supporting the safety and practicality of early exercise in the ICU. While our outcomes did not reach statistical significance, there are other outcome measures that should be investigated such as the psychosocial and analgesic effect of exercise.

In conclusion, our study provided insight of the feasibility of implementing an early exercise intervention for severely burned children while in the BICU. Future studies should consider both aerobic and resistance training conjunctive with an anabolic agent to determine its effects on skeletal muscle mass and function, which may improve the standard of burn care, allowing patients to restore their function and enhance their independence and safety to discharge home.

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Clinical Message

- Short 10 min bouts of arm and leg cycle ergometry is a feasible therapeutic strategy for children recovering from severe burn injury in the ICU.
- The addition of resistance exercise such as exercise bands may provide additional benefits in preserving body mass and function while receiving care in the burn ICU.

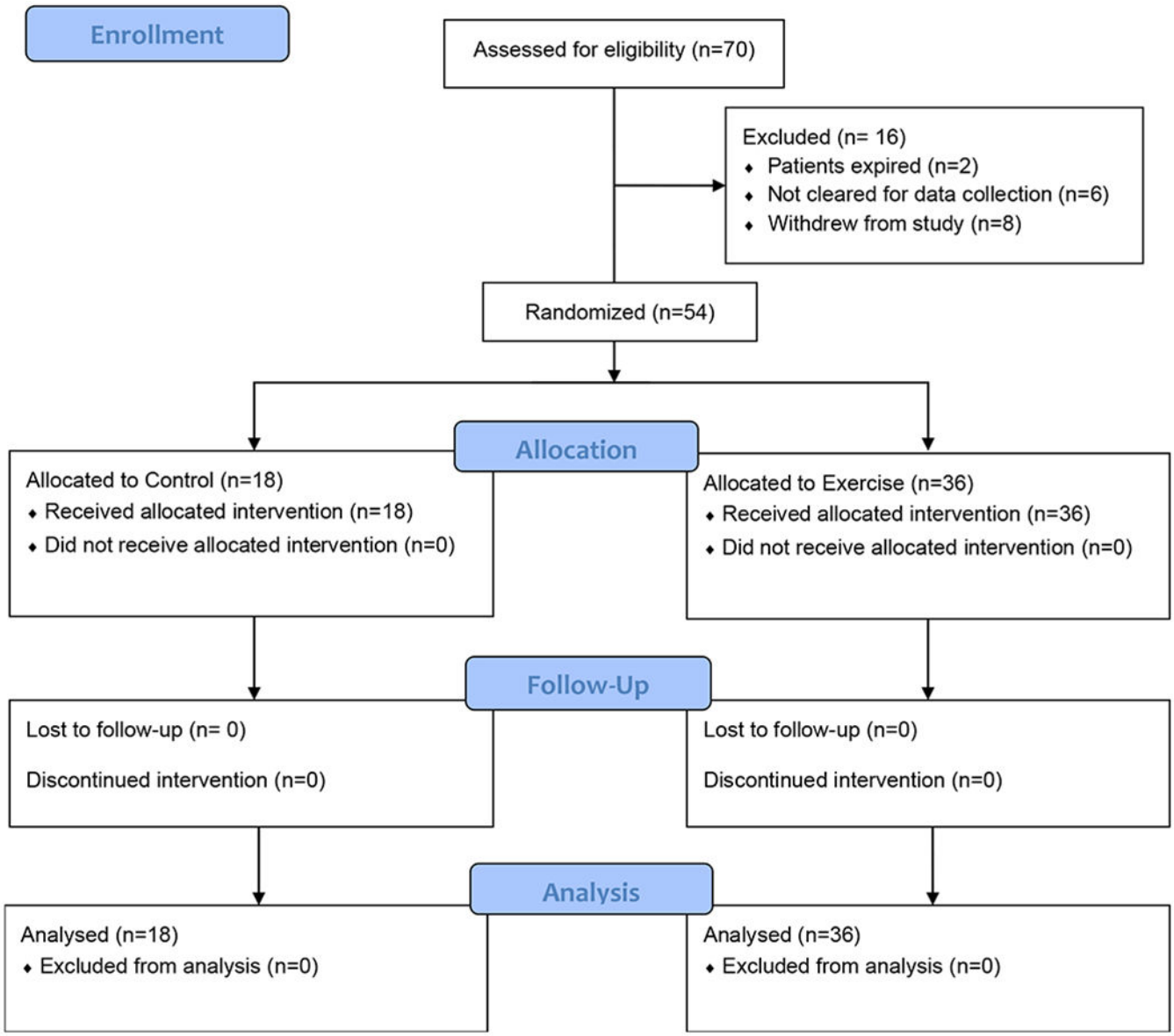

Figure 1.
Patient enrollment and retention.

Table 1.

Relative and absolute contraindications to exercise in the Burn ICU related to this study.

Relative contraindications	Absolute contraindications
	Factors deemed by the surgeon in charge to exclude the patient from ergometric exercises (arm or leg crank)
Left main coronary stenosis	Acute thrombotic myocardial infarction (within 6 months)
Moderate stenotic valvular heart disease	Uncontrolled cardiac arrhythmias causing symptoms or hemodynamic compromise
Known electrolyte abnormalities (hypokalemia, hypomagnesemia)	Uncontrolled symptomatic heart failure
Severe arterial hypertension; resting diastolic	Aortic dissection
BP >110 mmHg and/or resting systolic BP >200 mmHg	Acute myocarditis or pericarditis
Tachyarrhythmias or bradyarrhythmias	Acute pulmonary embolus or pulmonary infarction
Hypertrophic cardiomyopathy and other forms of outflow tract obstruction	Unstable blood pressure or inability to remain upright
High-degree atrioventricular block	Lines in arms or legs that prevent rotating motion
Mental impairment leading to inability to exercise adequately	Sepsis
	Acute Respiratory Distress Syndrome
	Deep sedation that interferes with mobility or cooperation

Table 2.

Patient Demographics

	Control	Exercise	p-value
n	18	36	NA
Age (years)	11.9 ± 3.2	12.2 ± 3.5	0.76
Burn severity (%TBSA)	51 ± 17	46 ± 15	0.67
3rd degree burns (%TBSA)	39 ± 24	36 ± 19	0.41
Exercise Sessions	0	9 ± 10	<0.001

Values are mean ± SD; TBSA: total body surface area; NA: not applicable. P <0.05 considered a significant difference between groups. P values determined via Mann-Whitney Tests.

Table 3.

Outcome measures

	Control		Exercise		P-value
	Pre	Post	Pre	Post	
Days in ICU	-	46 ± 51	-	31 ± 29	0.56
Total body weight (kg)	44.5 ± 4.6	41.9 ± 4.4	52.9 ± 3.6	48.6 ± 3.2	0.94
Lean Body Mass (kg)	29.2 ± 2.7	27.3 ± 2.5	34.9 ± 2.2	33.2 ± 2.2	0.69
6 min walk test (ft)	162.0 ± 47.1	876.1 ± 128.8	178.7 ± 30.8	871.4 ± 66.0	0.98

Values are median ± interquartile range; P <0.05 considered a significant difference between groups. P values determined via Mann-Whitney Tests

Table 4.

Statistical results for multiple linear regression predicting weight

Coefficients	**Estimate**	**Std. error**	**t-value**	**Pr(>|t|)**
Age	−0.3463	0.3428	−1.01	0.3197
Days in ICU	−0.1014	0.0465	−2.179	**0.0366**
Treatment	−0.1672	2.5637	−0.065	0.9484
Multiple R-squared	0.1658			
Adjusted R-squared	0.09			
F-statistics	2.187 on 3 and 33 DF			
p-value	0.1082			

DF = degrees of freedom.

Table 5.

Statistical results for multiple linear regression predicting lean body mass

Coefficients	**Estimate**	**Std. error**	**t-value**	**Pr(>|t|)**
Age	−0.0857	0.1609	−0.533	0.599
Days in ICU	0.0269	0.027	0.996	0.33
Treatment	0.4749	1.189	0.399	0.693
Multiple R-squared	0.0497			
Adjusted R-squared	−0.0743			
F-statistics	0.401 on 3 and 23 DF			
p-value	0.7536			

DF = degrees of freedom

Table 6.

Statistical results for multiple linear regression predicting 6MWT

Coefficients	**Estimate**	**Std. error**	**t-value**	**Pr(>|t|)**
Age	−7.771	20.643	−0.376	0.7084
Days in ICU	3.224	2.768	1.165	0.2502
Treatment	3.588	147.438	0.024	0.9807
Multiple R-squared	0.031			
Adjusted R-squared	−0.0337			
F-statistics	0.479 on 3 and 45 DF			
p-value	0.6985			

6MWT = 6-min walk test, DF = degrees of freedom