

# Construct validity of the Functional Status Score for the Intensive Care Unit: a prospective observational study using actigraphy in mechanically-ventilated patients

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## Research

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# Abstract

**Background** The Functional Status Score for the Intensive Care Unit (FSS-ICU) is a widely used instrument, designed to measure the mobility of critically ill patients that is available in English, Portuguese, Turkish and Spanish. The lack of a gold standard for measuring mobility limits the validation of outcome measures. However, actigraphy, from which measures movement intensity can be derived, is a potential alternative in the intensive care unit (ICU). Thus, this study aimed to assess the construct validity (hypotheses testing) of the FSS-ICU using continuous actigraphy from ICU admission to ICU discharge.

**Methods** This prospective observational study included mechanically-ventilated patients selected from a 12-bed academic medical-surgical ICU. The Chilean-Spanish version of the FSS-ICU was used to evaluate its correlation with activity counts, activity time (>99 counts per minute) and inactivity time (0-99 counts per minute) measured by actigraphy (GT9X Link ActiGraph). The FSS-ICU was assessed on awakening and at ICU discharge, while actigraphy variables were recorded from ICU admission to ICU discharge.

**Results** Of 92 patients screened, 30 were analysed. The median FSS-ICU was 19 (IQR 10–26) points on awakening and 28.5 (IQR 22–32) at ICU discharge. There was no floor/ceiling effect of the FSS-ICU at awakening (0%/0%) and only a ceiling effect at ICU discharge that was acceptable (0%/10%). Less activity time was associated with better mobility on the FSS-ICU at both awakening ( $\rho = -0.62$ ,  $P < 0.001$ ) and ICU discharge ( $\rho = -0.79$ ,  $P < 0.001$ ). Activity counts and activity time were not correlated as expected with the FSS-ICU.

**Conclusions** The FSS-ICU had a strong correlation with inactivity time during the ICU stay. These findings enhance the available clinimetric properties of the FSS-ICU.

## Background

Decreasing mortality rates in the intensive care unit (ICU) have led to survivors who have functional disability even five years after hospital discharge[1]. Part of the challenge for clinicians and researchers is to design and use measurement instruments that could detect physical functioning issues early during the ICU stay[2]. In the ICU setting, 60 instruments focused on the measurement of physical functioning have been identified, of which 38 measure the mobility domain[3]. Based on their clinimetric properties, four instruments measuring mobility and designed for the ICU setting have been recommended[4, 5]: Chelsea Critical Care Physical Assessment Tool (CPAx)[6], Intensive Care Unit Mobility scale (IMS)[7], Physical Function in Intensive Care Unit Test-scored (PFIT-s)[8] and Functional Status Score for the Intensive Care Unit (FSS-ICU)[9, 10]. Of these four instruments, FSS-ICU is the only one that assesses the level of physical assistance required by the patient when performing functional activities on the bed, out of bed and walking.

The FSS-ICU is a widely used instrument because it is available in English[10], Portuguese[11], Turkish[12] and Spanish[13], and its reliability, validity, responsiveness and interpretability have been evaluated in

multiple studies[10, 14, 15], although not specifically for the Chilean-Spanish version. The validity of the FSS-ICU has been assessed through correlation analysis against other physical functioning measurement instruments, such as the Medical Research Council Sum Score (MRC-SS) ( $r^2 = 0.32$  to  $0.81$ ), the Activities of Daily Living ( $r^2 = 0.39$  to  $0.86$ ), the Instrumental Activities of Daily Living ( $r^2 = 0.48$  to  $0.57$ ), PFIT-s ( $\rho = 0.85$  to  $0.87$ ) and the IMS ( $\rho = 0.46$  to  $0.95$ )[10, 15]. However, physical functioning refers to a broad concept, including physiological functions, neuromuscular functions, and mobility[16]. The subjective nature of the assessment of mobility means there is no objective reference standard for its measurement. Therefore, using accelerometer-derived measures of human activity in the ICU could be an alternative to solve this issue[17, 18].

Actigraphy is a non-invasive alternative for quantifying movement continuously[19, 20] that has a good correlation with direct observation of human movement [21], providing that consideration is given to the type of device and wear location for the measurement variable [44]. Actigraphy uses accelerometers and has been validated in a wide variety of admitted and out-patient populations[22–24]. Its use in ICU patients is simple since it is a small instrument that does not interfere with clinical procedures and has been used in the ICU setting to measure human activity[25, 26].

The main aim of this study was to assess the FSS-ICU construct validity (hypotheses testing) using three variables measured through continuous actigraphy (activity counts, activity time and inactivity time) in mechanically-ventilated patients from their admission to ICU discharge. The secondary aim was to test the correlation of the FSS-ICU with MRC-SS, ICU length of stay (ICU LOS) and duration of mechanical ventilation.

## Methods

### Study design

A prospective observational study was conducted to assess the FSS-ICU clinimetric properties in a 12-bed academic medical-surgical ICU. The clinimetric properties were defined based on the COnsensus-based standards for the selection of health status measurement instruments (COSMIN)[27]. This manuscript followed the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) reporting guidelines[28]. This study was reviewed and approved by the research ethics committee of the faculty of medicine Clínica Alemana Universidad del Desarrollo (N° 2017 – 104).

### Participants

All patients admitted to the adult ICU were screened consecutively to determine eligibility for this study. The inclusion criteria were mechanically-ventilated adult patients older than 18 years old. The exclusion criteria were: limitation of life-sustaining care, plegia in one or more limbs, invasive mechanical ventilation in another centre for more than 24 hours, limb amputation, patient re-admitted to ICU who was already enrolled in this study, patients awakening in the first 24 hours since ICU admission (to ensure at least 24 hours of actigraphy recording between ICU admission and awakening), and previous functional

dependence (FSS-ICU score below 30 points based on a retrospective proxy interview). Once a patient was identified as eligible, their proxy was contacted at ICU admission to ask for their informed consent to participate. When patients achieved a maximum level of cooperation (defined as the ability to follow five simple commands as described below, and being delirium-free), they were asked for their consent to participate.

## Measurements

Measurements were conducted at three time points: 1) ICU admission, defined as within the first 12 hours from admission to the ICU; 2) awakening, defined as the first time a patient responded to five simple commands (as per De Jonghe[29] cooperation criteria a) open (close) your eyes; b) look at me; c) open your mouth and put out your tongue; d) nod your head; and e) raise your eyebrows when I have counted up to 5); and 3) ICU discharge, defined as the moment when a patient met medical criteria for discharge from the unit.

FSS-ICU. Mobility was measured with the FSS-ICU Chilean-Spanish version available at [www.improveLTO.com](http://www.improveLTO.com), which has been translated and adapted-culturally to Spanish in Chile[13]. The FSS-ICU was designed for the ICU setting to quantify the level of physical assistance required by the patient when performing five activities: rolling, transfer from supine to sit, sitting at the edge of the bed, transfer from sitting to stand, and walking. Each activity is scored using an 8-point ordinal scale ranging from 0 (not able to perform) to 7 (complete independence); therefore, the overall score ranges from 0 to 35 points with higher scores indicating greater functional independence[10].

Actigraphy. Gross motor activity was measured using triaxial accelerometers (GT9X Link ActiGraph, Pensacola, Florida)[30] daily for 24 hours from ICU admission to ICU discharge. Accelerometers were fitted to the patient's right ankle with an elastic Velcro strap as used elsewhere[31, 32], because it interferes less with clinical procedures, and is a valid recording method compared to placing it in the hip or wrist [33]. The time-sampling interval or epoch used was 5 seconds, and the sampling frequency was 90Hz[34]. The accelerometers were charged at 100% and initialised before being placed on the patient. The accelerometer was never removed from the patient; except for out-of-room clinical tests (i.e., magnetic resonance imaging, computed tomography, surgical procedures). Twice a day, the patient's skin condition, the battery level and functioning of the accelerometers were checked. To ensure continuous measurement, if the battery level fell below 10% the accelerometer was replaced by a fully-charged device. Additionally, an instructive for family members and staff members was left in each room providing care and maintenance instructions of the accelerometer. Once a patient was discharged from the ICU, actigraphy data were extracted using the "Low-frequency extension"[35] function available in the Actilife software (Version 6.13.3, Copyright 2009–2015, Actigraph, LLC). Data were filtered to include recordings from the first installation up to the final removal of the device. To achieve this, data were exported to an Excel® spreadsheet where the first and last hour of each device recordings were deleted. Data for activity counts, activity time and inactivity time were analysed. For the variable activity counts, the vector magnitude (i.e. three axes) was used and is reported in counts and counts per recording hour. The variables activity and inactivity time are reported in minutes and minutes per hour. Freedson et al.[36,

37] definition was used, where 0–99 counts per minute (CPM) are considered inactivity time, while 99 CPM or higher are considered activity time. The actigraphy variables reported on ICU awakening correspond to a cumulative measure of counts or minutes from ICU admission to awakening, while those reported at ICU discharge correspond to a cumulative measure of counts or minutes from admission to ICU discharge.

MRC-SS. The measurement of peripheral muscle strength was performed using the MRC-SS following the method described by Hermans et al.[38]. Six muscle groups were assessed bilaterally (i.e. shoulder abduction, elbow flexion, wrist extension, hip flexion, knee extension and ankle dorsiflexion). Every muscle group is scored between 0 and 5 points (0 = no palpable or visible contraction; 1 = visible/palpable contraction but no movement; 2 = active movement, gravity eliminated; 3 = active movement against gravity; 4 = active movement against resistance adjusted for age and sex; 5 = active movement against full resistance). The MRC-SS ranges from 0 to 60 points, with higher scores indicating greater strength, and < 48 points indicating ICU acquired weakness (ICU-AW)[29].

## Study protocol

Twelve physiotherapists were trained for the FSS-ICU measurement using the documentation available at [www.improveLTO.com](http://www.improveLTO.com) (i.e. training video, frequently asked questions, and the pocket card), obtaining an inter-observer agreement of ICC 0.96 (95% CI, 0.92 to 1.00)[39]. The medical-surgical ICU where data were collected has physiotherapy on-site 24 hours/seven days a week; therefore, patients can receive physiotherapy during weekends and out of usual business hours. This ICU performs standard ICU care with protocol-guided sedation, weaning and standard physiotherapy, including chest physiotherapy, passive/active mobilization, out and in-bed cycling, tilt-table, progressive mobility and neuromuscular electrical stimulation. The MRC-SS measurement was performed by one of three expert assessors that have used the scale routinely in their clinical practice for more than four years for assessing muscular strength[40].

Once the patient's proxy signed the informed consent, the patient's demographics, clinical and anthropometric data were registered in the Research Electronic Data Capture (REDCap®)[41] system and the accelerometer was fitted. The first measurement of the FSS-ICU and MRC-SS were performed within 24 hours of awakening. Before each measurement, clinical stability was assessed using cardiovascular, respiratory, neurological and orthopaedic safety criteria[42] so patients could sit on the edge of the bed and at least three FSS-ICU activities could be assessed, which are requirements for assessing the FSS-ICU total score. The FSS-ICU and MRC-SS were assessed again when ICU discharge was decided and within 24 hours of leaving the unit. The accelerometer was removed after these assessments.

## Statistical analysis

The sample size was calculated using QFAB Power Calculator web application[43]. For a power of 0.9, an expected correlation between the FSS-ICU and actigraphy of 0.7 [15], and a significance threshold of 0.01, the sample size calculated was 23 patients. An extra 15% was sampled to account for the potential loss

of accelerometer recordings; therefore, 27 patients were needed for this analysis. The statistical analysis was performed using Stata/IC 15.0 (Statacorp LLC, 2017, College Station, TX).

**Descriptive statistics.** Given that variables did not follow a normal distribution, medians and interquartile range [IQR] are used for numerical variables, while absolute and relative frequencies are used for categorical variables. The data captured through REDcap® was exported to an Excel® spreadsheet for their analysis. Floor and ceiling effects for the FSS-ICU were calculated as the percentage of patients obtaining the minimum (0 points) or maximum (35 points) score, respectively. These were interpreted as follows: excellent (no floor or ceiling effects), adequate (floor or ceiling effects < 20%) and poor (floor or ceiling effects > 20%)[44].

**Hypotheses testing.** As there is no gold standard for measuring mobility, the FSS-ICU construct validity was assessed by testing 12 hypotheses, including the correlation of the FSS-ICU with activity counts, activity time (minutes), inactivity time (minutes), MRC-SS (points), ICU LOS (days) and duration of mechanical ventilation (days). All correlations were performed for data on awakening and at ICU discharge. The correlation between the FSS-ICU and activity counts, activity time and MRC-SS were expected to be positive, and at least moderate (> 0.7). In the case of inactivity time, ICU LOS, and duration of mechanical ventilation, the correlations were expected to be negative. In addressing the secondary study objective, similar correlations to those reported for the English version of the FSS-ICU were expected for the MRC-SS, ICU LOS and duration of mechanical ventilation[10]; meaning correlation coefficients in the order of > 0.25 (Additional file 1: Table S1). The Spearman's rho correlation coefficient was used to test for the hypotheses. They were interpreted according to Domholdt et al. categories, where 0.00–0.25 was little if any, 0.26–0.49 weak, 0.50–0.69 moderate, 0.70–0.89 strong and 0.90–1.00 very strong correlation[45]. Given the number of hypotheses that were tested, the threshold for significance was modified using a Bonferroni correction ( $P < 0.003$ ). The trend line shown in the plots was constructed using a quantile regression model for the median.

## Results

Ninety-two mechanically-ventilated adult patients admitted to the ICU were consecutively screened from October 2018 to January 2019. The screening was completed when the number of patients with valid data reached the expected sample size for the analysis. The last enrolled patient was discharged from the ICU in March 2019. Forty-eight patients met the inclusion criteria, but due to loss to follow-up, data from 30 patients were analysed (Fig. 1). Baseline demographic and ICU admission characteristics of the study participants are available in Table 1.

Table 1  
Baseline characteristics of the study participants

	<b>n = 30</b>
Age, years	64.5 (55–74)
Body Mass Index, kg/m <sup>2</sup> <sup>a</sup>	25.7 (23.7–27.1)
APACHE II score <sup>a</sup>	16 (13–20)
Female gender	17 (59)
Diagnosis <sup>a</sup>	
Sepsis	9 (30)
Coma	6 (20)
Oncological	6 (20)
Hypovolemic shock	4 (13.3)
Respiratory	3 (10)
Transplant	1 (3.3)
Trauma	1 (3.3)
ICU admission to awakening, days	2.2 (1–4.2)
ICU LOS, days	5.7 (3.6–8.5)
Duration of mechanical ventilation, days	2.6 (1.6–5.2)
ICU-AW on awakening	11 (37)
ICU-AW at ICU discharge	6 (20)
Data are presented as median (25th–75th percentiles) or percentage (%)	
Abbreviations: APACHE Acute Physiology and Chronic Health Evaluation, ICU Intensive Care Unit, LOS length of stay, ICU-AW intensive care unit acquired weakness	
<sup>a</sup> at ICU admission	

The descriptive statistics for the FSS-ICU and the actigraphy variables on awakening and at ICU discharge are shown in Table 2. The distribution of the FSS-ICU score of the 30 patients showed a floor effect of 0% (0 of 30) on awakening and 0% (0 of 30) at ICU discharge. The ceiling effect observed was 0% (0 of 30) on awakening and 10% (3 of 30) at ICU discharge. The median of the total actigraphy recording time from admission to ICU discharge was 5.48 (IQR: 3.33–8.56) days. Of this recording time,

0.15 (IQR: 0.06–0.25) days corresponded to activity time and 5.33 (IQR: 3.26–8.37) days were inactivity time. This is equal to 2.5% of the time being active and 97.5% of inactive time during the whole ICU stay.

Table 2  
Descriptive results of the FSS-ICU and Actigraphy measures

<b>Variables</b>	<b>Awakening (n = 30)</b>	<b>ICU discharge (n = 30)</b>
FSS-ICU		
Rolling	5 (2–7)	7 (6–7)
Supine to sit transfer	3 (2–4)	6 (3–7)
Sitting at the edge of the bed	5 (4–7)	7 (7–7)
Sit to stand transfer	4 (1–5)	5 (3–6)
Walking	1 (0–5)	4 (2–5)
FSS-ICU Total score	19 (10–26)	28.5 (22–32)
Actigraphy <sup>a</sup>		
Activity counts (counts)	99396 (31707–193692)	309104 (133737–557149)
Activity counts (counts per day)	31590 (21275–52219)	50483 (38073–88649)
Activity time (min)	42.7 (19.5–97.1)	217.8 (92.6–356.3)
Activity time (min per day)	17.8 (11.5–26.9)	35.5 (25.5–57.1)
Inactivity time (min)	3621 (2062–5953)	7669 (4754.3–11769.1)
Inactivity time (min per day)	1422 (1413–1429)	1405 (1382.9–1414.5)
MRC-SS	50 (37–54)	56 (53–59)
Data are presented as median (25th–75th percentiles)		
Abbreviations: ICU Intensive Care Unit; FSS-ICU Functional Status Score for the Intensive Care Unit, MRC-SS Medical Research Council Sum Score, min minutes		
<sup>a</sup> For Actigraphy variables, the column "Awakening" corresponds to the cumulative values from ICU admission to awakening, and the column "ICU discharge" corresponds to the cumulative value from ICU admission to ICU discharge.		

Of all hypotheses tested, 58% were confirmed (Table 3). Activity counts and activity time were not correlated as expected with the FSS-ICU score, while inactivity time was negatively correlated on awakening ( $\rho = -0.62$ ,  $P < 0.001$ ) and at ICU discharge ( $\rho = -0.79$ ,  $P < 0.001$ ) (Fig. 2).

Table 3  
Hypotheses and found correlations between the FSS-ICU and study variables

Variables	Hypotheses		Found correlation <sup>a</sup>	Hypotheses confirmed
	N <sup>o</sup>	Expected correlation		
Actigraphy: Activity counts	1	> 0.70 on awakening	-0.54 (P = 0.002)	No
	2	> 0.70 at ICU discharge	-0.05 (P = 0.79)	No
Actigraphy: Activity time	3	> 0.70 on awakening	-0.49 (P = 0.006)	No
	4	> 0.70 at ICU discharge	-0.51 (P = 0.004)	No
Actigraphy: Inactivity time	5	> -0.70 on awakening	-0.62 (P < 0.001)	No
	6	> -0.70 at ICU discharge	-0.79 (P < 0.001)	Yes
MRC-SS	7	> 0.44 on awakening <sup>b</sup>	0.67 (P < 0.001)	Yes
	8	> 0.60 at ICU discharge <sup>b</sup>	0.72 (P < 0.001)	Yes
ICU LOS	9	> -0.25 on awakening <sup>b</sup>	-0.70 (P < 0.001)	Yes
	10	> -0.25 at ICU discharge <sup>b</sup>	-0.77 (P < 0.001)	Yes
Duration of mechanical ventilation	11	> -0.25 on awakening <sup>b</sup>	-0.60 (P < 0.001)	Yes
	12	> -0.25 at ICU discharge <sup>b</sup>	-0.62 (P < 0.001)	Yes
Abbreviations: ICU Intensive Care Unit; FSS-ICU Functional Status Score for the Intensive Care Unit, MRC-SS Medical Research Council Sum Score, LOS length of stay				
<sup>a</sup> The correlation was calculated with Spearman rho.				
<sup>b</sup> Based on the combined results of previous data[10]				

## Discussion

This is the first study assessing the validity of a mobility measurement instrument designed for the ICU setting available in Spanish. The construct validity of the Chilean-Spanish FSS-ICU version was assessed through hypotheses testing, presenting a moderate to strong correlation with inactivity time, MRC-SS, ICU LOS, and duration of mechanical ventilation. There was no floor or ceiling effect for the FSS-ICU on awakening and similarly at ICU discharge there was no floor effect, while a ceiling effect was interpreted to be adequately acceptable. The findings of this study enhance the clinimetric properties already assessed of the FSS-ICU, such as reliability, validity, responsiveness and interpretability (Additional file 1: Table S1), and are similar to those reported for the versions in English[10], Portuguese[11] and Turkish[12].

The FSS-ICU, as other instruments measuring mobility such as PFIT-s, CPAx, and IMS, is an ordinal scale that allows classifying a patient's functional performance through a face-to-face assessment [5]. These assessments depend on the subjective perception of the assessor, which means there are only imperfect reference standards for measuring mobility. As a consequence, actigraphy was chosen as an objective method to assess the construct validity of the FSS-ICU. Previous studies have shown the feasibility and safety of using actigraphy for measuring movement in critically ill patients[20, 21, 36, 37], while others have reported the correlation between actigraphy with the gross motor activity: Comfort Scale ( $\rho = 0.48$  to  $0.62$ ,  $P < 0.001$ )[47], Richmond Agitation Sedation Scale ( $\rho = 0.58$  to  $0.98$ ,  $P < 0.001$ )[47, 48], and direct observation of activities (lying, rolling, sitting, standing and walking) ( $\rho = 0.36$  to  $0.98$ ,  $P < 0.001$ ) [26, 46].

Schweickert et al.[49] and Schaller et al.[50] have shown that critically ill patients participating in early mobilisation programmes that provide more activity time than usual care have lower mortality rates, fewer days with delirium, shorter duration of mechanical ventilation, and better functional performance. Additionally, actigraphy studies have shown that patients tend to increase their activity from their hospital stay up to the post-ICU follow-up[23, 51, 52]. Consequently, the main hypothesis for this study was that greater time or amount of movement during the ICU stay (actigraphy) would relate to better mobility (FSS-ICU), and also, that greater inactivity time would relate to worse scores in the FSS-ICU. However, only inactivity time measured with actigraphy was correlated with the FSS-ICU. Similarly to our findings, Estrup et al.[23] found little correlation ( $r^2 = 0.14$ – $0.25$ ,  $P < 0.017$ ) between the activity counts and the CPAx among ICU survivors who had low activity time. Our study found that activity time was equivalent to 2.5% of the whole ICU stay, which is similar to what Hussey et al. found (4%) in patients after surgery[52]. Possibly, the low correlation between the FSS-ICU and, activity counts and activity time could be explained by how little the activity time experienced by patients during the ICU stay is.

Additionally, a longer inactivity time during a hospital stay is associated with worse mobility[32, 37]. In this study, patients were inactive 98.8% of the time between ICU admission and awakening, and 97.5% between ICU admission and discharge. A recent randomised controlled trial reported high proportions of inactivity time during the ICU stay, with 95.7% for the control group and 92.3% for the group receiving early and progressive mobilisation[32]. Moreover, Baldwin et al. identified high levels of sedentary behaviour (defined as time spent lying/sitting) before awakening (98.1%) and at ICU discharge (95.7%),

which were correlated with mobility assessed with the PFIT-s and the Morton Mobility Index ( $\rho = -0.73$ ,  $P < 0.001$ )[51]. The present study also found a moderate to strong correlation between inactivity time (defined as low intensity movement) and mobility measured with the FSS-ICU on awakening ( $\rho = -0.62$ ,  $P < 0.001$ ) and at ICU discharge ( $\rho = -0.79$ ,  $P < 0.001$ ). These findings are consistent with population-based data, where it has been found that low-intensity movement and long periods of sitting/lying are risk factors for negative health outcomes[53–55].

Regarding the correlation between the FSS-ICU and other clinical variables, this study had different results to other studies assessing clinimetric properties, in which the FSS-ICU had a weak correlation with the MRC-SS on awakening ( $r^2 = 0.44$ ,  $P < 0.05$ ) and moderate at ICU discharge ( $r^2 = 0.60$ ,  $P < 0.05$ ), and little correlation of FSS-ICU at ICU discharge with the ICU LOS ( $r^2 = -0.25$ ,  $P < 0.05$ )[10]. Conversely, in this study the correlation between the FSS-ICU and the MRC-SS was moderate on awakening ( $\rho = 0.67$ ,  $P < 0.001$ ) and strong at ICU discharge ( $\rho = 0.72$ ,  $P < 0.001$ ), while the correlation of FSS-ICU with ICU LOS was strong on awakening ( $\rho = -0.70$ ,  $P < 0.001$ ) and at ICU discharge ( $\rho = -0.77$ ,  $P < 0.001$ ). These differences could be explained because Huang et al.[10] combined results of five datasets, where the datasets with larger sample sizes had weaker correlations than studies with smaller sample sizes. It would be plausible that studies with large sample sizes have greater variability, and therefore, the correlations are not as strong as the ones we found.

This study has some potential weaknesses worth mentioning. The findings of this work came from clinical measurements of patients receiving few days of mechanical ventilation (median = 2.6 days) and were performed in a single centre, which could limit the external validity of the results. A high number of patients ( $n = 23$ ) were screened but were not included in the analysis because the patient awoke before completing 24 hours of actigraphy recordings. This high rate of ineligible patients should be considered for the recruitment of participants in future actigraphy studies with sedated individuals. Another important weakness was that differentiating voluntary from involuntary movement was not possible, which could have modified the correlations found between the activity counts and the FSS-ICU scores. This is particularly relevant for sedated critically ill patients that receive passive mobilisation daily (e.g. passive range of motion, cycling, positioning).

Future research should study and report on the lack of movement of critically ill patients because, according to the current literature, patients are inactive for extended periods, which is associated with worse mobility[32, 51]. There is still the challenge to measure movement in real-time to guide and inform decision-making regarding dosage and strategies for preventing immobility of critically ill patients.

## Conclusions

In conclusion, the Chilean-Spanish FSS-ICU version has a strong correlation with inactivity time during the ICU stay in mechanically-ventilated patients. These findings enhance the available clinimetric properties of the FSS-ICU, which is a useful tool for clinical practice and research.

## Abbreviations

APACHE: Acute Physiology and Chronic Health Evaluation; ICU: Intensive Care Unit; ICU LOS: intensive care unit length of stay; ICU-AW: intensive care unit acquired weakness; FSS-ICU: Functional Status Score for the Intensive Care Unit; MRC-SS: Medical Research Council Sum Score; COSMIN: COnsensus-based standards for the selection of health status Measurement INstruments; STROBE: Strengthening the reporting of observational studies in epidemiology;

## Declarations

Ethics approval and consent to participate

The research ethics committee of the faculty of medicine Clínica Alemana Universidad del Desarrollo approved this study, and all patients provided informed consent.

Consent for publication

No individual participant data is reported that would require consent to publish from the participant

Availability of data and materials

Dataset used during the current study is available from the corresponding author on request

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

ACM and FGS were responsible for the conception and design of this study; collected, analysed and interpreted all data; and drafted the first version of this manuscript. JL and ACA supported the study design and data analysis. All authors contributed meaningfully to the final version of this manuscript.

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## References

1.

- Herridge MS, Tansey CM, Matté A, Tomlinson G, Diaz-Granados N, Cooper A, et al. Functional Disability 5 Years after Acute Respiratory Distress Syndrome. *N Engl J Med*. 2011;364:1293–304.
2.  
Parry SM, Granger CL, Berney S, Jones J, Beach L, El-Ansary D, et al. Assessment of impairment and activity limitations in the critically ill: a systematic review of measurement instruments and their clinimetric properties. *Intensive Care Med*. 2015;41:744–62.
3.  
González-Seguel F, Corner EJ, Merino-Osorio C. International Classification of Functioning, Disability, and Health Domains of 60 Physical Functioning Measurement Instruments Used During the Adult Intensive Care Unit Stay: A Scoping Review. *Phys Ther*. 2019;99:627–40.
4.  
Parry SM, Nydahl P, Needham DM. Implementing early physical rehabilitation and mobilisation in the ICU: institutional, clinician, and patient considerations. *Intensive Care Med*. 2018;44:470–3.
5.  
Parry SM, Huang M, Needham DM. Evaluating physical functioning in critical care: considerations for clinical practice and research. *Crit Care*. 2017;21:249.
6.  
Corner EJ, Wood H, Englebretsen C, Thomas A, Grant RL, Nikoietou D, et al. The Chelsea Critical Care Physical Assessment Tool (CPAx): validation of an innovative new tool to measure physical morbidity in the general adult critical care population; an observational proof-of-concept pilot study. *Physiotherapy*. 2013;99:33–41.
7.  
Hodgson C, Needham D, Haines K, Bailey M, Ward A, Harrold M, et al. Feasibility and inter-rater reliability of the ICU Mobility Scale. *Hear Lung J Acute Crit Care*. 2014;43:19–24.
8.  
Denehy L, de Morton NA, Skinner EH, Edbrooke L, Haines K, Warrillow S, et al. A physical function test for use in the intensive care unit: validity, responsiveness, and predictive utility of the physical function ICU test (scored). *Phys Ther*. 2013;93:1636–45.
9.  
Zanni JM, Korupolu R, Fan E, Pradhan P, Janjua K, Palmer JB, et al. Rehabilitation therapy and outcomes in acute respiratory failure: an observational pilot project. *J Crit Care*. 2010;25:254–62.
10.  
Huang M, Chan KS, Zanni JM, Parry SM, Neto S-CGB, Neto JAA, et al. Functional Status Score for the ICU. *Crit Care Med*. 2016;44:e1155–64.
11.  
Silva VZMda, Araújo Neto JA de, Cipriano Júnior G, Pinedo M, Needham DM, Zanni JM, et al. Brazilian version of the Functional Status Score for the ICU: translation and cross-cultural adaptation. *Rev Bras Ter Intensiva*. 2017;29:34–8.
- 12.

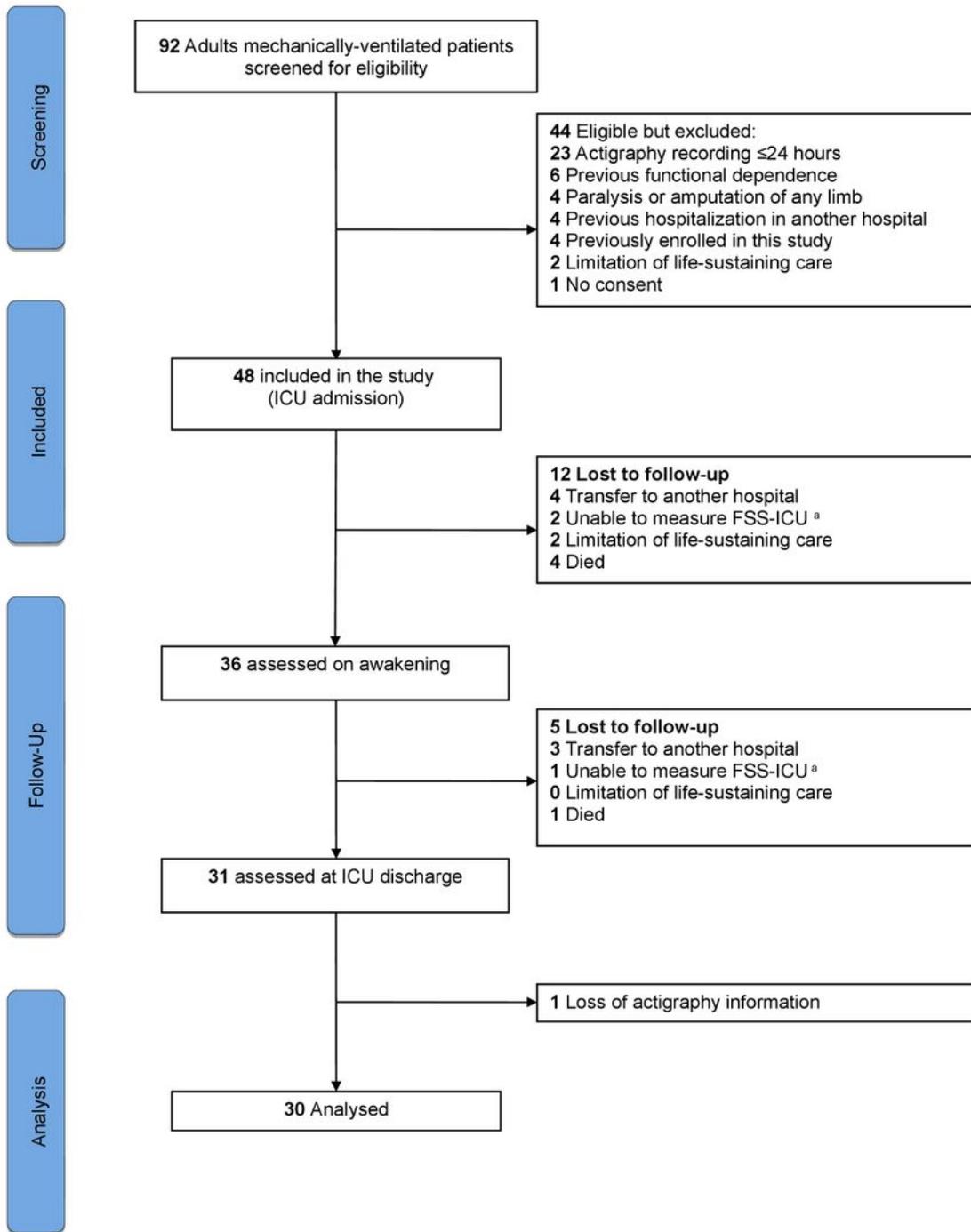
- Ozcan Kahraman B, Ozsoy I, Kahraman T, Tanriverdi A, Acar S, Ozpelit E, et al. Turkish translation, cross-cultural adaptation, and assessment of psychometric properties of the Functional Status Score for the Intensive Care Unit. *Disabil Rehabil.* 2019;8288:1–6.
13.  
González-Seguel F, Camus-Molina A, Leppe J, Hidalgo-Cabalín V, Gutiérrez-Panchana T, Needham DM, et al. Chilean version of the Functional Status Score for the Intensive Care Unit: a translation and cross-cultural adaptation. *Medwave.* 2019;19:e7439–9.
14.  
Hiser S, Toonstra A, Friedman LA, Colantuoni E, Connolly B, Needham DM. Interrater Reliability of the Functional Status Score for the Intensive Care Unit. *J Acute Care Phys Ther.* 2018;9:186–92.
15.  
Parry SM, Denehy L, Beach LJ, Berney S, Williamson HC, Granger CL. Functional outcomes in ICU – what should we be using? - an observational study. *Crit Care.* 2015;19:127.
16.  
World Health Organisation. Towards a common language for functioning, disability and health. Geneva WHO; 2002.
17.  
Schwab KE, To AQ, Chang J, Ronish B, Needham DM, Martin JL, et al. Actigraphy to Measure Physical Activity in the Intensive Care Unit: A Systematic Review. *J Intensive Care Med.* 2019;088506661986365.
18.  
Keadle SK, Lyden KA, Strath SJ, Staudenmayer JW, Freedson PS. A Framework to Evaluate Devices That Assess Physical Behavior. *Exerc Sport Sci Rev.* 2019;47:206–14.
19.  
Nichols JF, Morgan CG, Sarkin JA, Sallis JFCK. Validity, reliability, and calibration of the Tritrac accelerometer as a measure of physical activity. *Med Sci Sport Exerc.* 1999;31:908–12.
20.  
Meijer GAL, Westerterp KR, Verhoeven FMH, Koper HBM, ten Hoor F. Methods to assess physical activity with special reference to motion sensors and accelerometers. *IEEE Trans Biomed Eng.* 1991;38:221–9.
21.  
Mistraletti G, Taverna M, Sabbatini G, Carloni E, Bolgiaghi L, Pirrone M, et al. Actigraphic monitoring in critically ill patients: Preliminary results toward an “observation-guided sedation. *J Crit Care.* 2009;24:563–7.
22.  
Baldwin C, van Kessel G, Phillips A, Johnston K. Accelerometry Shows Inpatients With Acute Medical or Surgical Conditions Spend Little Time Upright and Are Highly Sedentary: Systematic Review. *Phys Ther.* 2017;97:1044–65.
23.  
Estrup S, Kjer CKW, Vilhelmsen F, Poulsen LM, Gøgenur I, Mathiesen O. Physical function and actigraphy in intensive care survivors—A prospective 3-month follow-up cohort study. *Acta Anaesthesiol Scand.* 2019;63:647–52.

24. Martin JL, Hakim AD. Wrist Actigraphy Chest. 2011;139:1514–27.
25. Schwab KE, Ronish B, Needham DM, To AQ, Martin JL, Kamdar BB. Actigraphy to Evaluate Sleep in the Intensive Care Unit. A Systematic Review. *Ann Am Thorac Soc*. 2018;15:1075–82.
26. Verceles AC, Hager ER. Use of Accelerometry to Monitor Physical Activity in Critically Ill Subjects: A Systematic Review. *Respir Care*. 2015;60:1330–6.
27. Mokkink LB, Terwee CB, Patrick DL, Alonso J, Stratford PW, Knol DL, et al. The COSMIN study reached international consensus on taxonomy, terminology, and definitions of measurement properties for health-related patient-reported outcomes. *J Clin Epidemiol*. 2010;63:737–45.
28. von Elm E, Altman DG, Egger M, Pocock SJ, Gøtzsche PC, Vandenbroucke JP. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement: Guidelines for reporting observational studies. *Int J Surg*. 2014;12:1495–9.
29. De Jonghe B, Sharshar T, Lefaucheur J-P, Authier F-J, Durand-Zaleski I, Boussarsar M, et al. Paresis acquired in the intensive care unit: a prospective multicenter study. *JAMA*. 2002;288:2859–67.
30. Santos-Lozano A, Marín PJ, Torres-Luque G, Ruiz JR, Lucía A, Garatachea N. Technical variability of the GT3X accelerometer. *Med Eng Phys*. 2012;34:787–90.
31. Kamdar BB, Kadden DJ, Vangala S, Elashoff DA, Ong MK, Martin JL, et al. Feasibility of Continuous Actigraphy in Patients in a Medical Intensive Care Unit. *Am J Crit Care*. 2017;26:329–35.
32. Schujmann DS, Teixeira Gomes T, Lunardi AC, Zoccoler Lamano M, Fragoso A, Pimentel M, et al. Impact of a Progressive Mobility Program on the Functional Status, Respiratory and Muscular Systems of ICU Patients. *Crit Care Med*. 2019;1.
33. Ozemek C, Kirschner MM, Wilkerson BS, Byun W, Kaminsky LA. Intermonitor reliability of the GT3X + accelerometer at hip, wrist and ankle sites during activities of daily living. *Physiol Meas*. 2014;35:129–38.
34. Freedson P, Pober D, Janz KF. Calibration of accelerometer output for children. *Med Sci Sports Exerc*. 2005;37:523–30.
35. Anderson JL, Yoward LS, Green AJ. A study investigating the validity of an accelerometer in quantification of step count in adult hospital inpatients recovering from critical illness. *Clin Rehabil*. 2019;026921551982989.
- 36.

- Freedson PS, Melanson E, Sirard J. Calibration of the Computer Science and Applications, Inc. accelerometer. *Med Sci Sports Exerc.* 1998;30:777–81.
- 37.
- Moreno NA, de Aquino BG, Garcia IF, Tavares LS, Costa LF, Giacomassi IWS, et al. Physiotherapist advice to older inpatients about the importance of staying physically active during hospitalisation reduces sedentary time, increases daily steps and preserves mobility: a randomised trial. *J Physiother.* 2019;65:208–14.
- 38.
- Hermans G, Clerckx B, Vanhullebusch T, Segers J, Vanpee G, Robbeets C, et al. Interobserver agreement of medical research council sum-score and handgrip strength in the intensive care unit. *Muscle Nerve.* 2012;45:18–25.
- 39.
- González-Seguel F, Camus-Molina A, Cárcamo M, Hiser S, Needham D, Leppe J. Inter-observer reliability of trained physiotherapists on the Functional Status Score for the Intensive Care Unit (FSS-ICU) Chilean-Spanish version. *Physiother Theory Pract.* 2020;(in press).
- 40.
- Gutiérrez Panchana T, Hidalgo Cabalín V. Adherence to standardized assessments through a complexity-based model for categorizing rehabilitation©: design and implementation in an acute hospital. *BMC Med Inform Decis Mak.* 2018;18:21.
- 41.
- Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research electronic data capture (REDCap) –A metadata-driven methodology and workflow process for providing translational research informatics support. *J Biomed Inform.* 2009;42:377–81.
- 42.
- Conceição TMA da, Gonzáles AI, Figueiredo FCXS de, Vieira DSR, Bündchen DC. Safety criteria to start early mobilization in intensive care units. Systematic review. *Rev Bras Ter Intensiva.* 2017;29:509–519.
- 43.
- QFAB. ANZMTG Statistical Decision Tree [Internet]. 2019. Available from: <https://www.anzmtg.org/stats/PowerCalculator/PowerCorrelation>.
- 44.
- Andresen EM. Criteria for assessing the tools of disability outcomes research. *Arch Phys Med Rehabil.* 2000;81:15–20.
- 45.
- Domholdt E. *Physical therapy research, principles and applications.* 2nd ed. Philadelphia: WB Saunders; 2000.
- 46.
- Anderson JL, Green AJ, Yoward LS, Hall HK. Validity and reliability of accelerometry in identification of lying, sitting, standing or purposeful activity in adult hospital inpatients recovering from acute or critical illness: a systematic review. *Clin Rehabil.* 2018;32:233–42.
- 47.

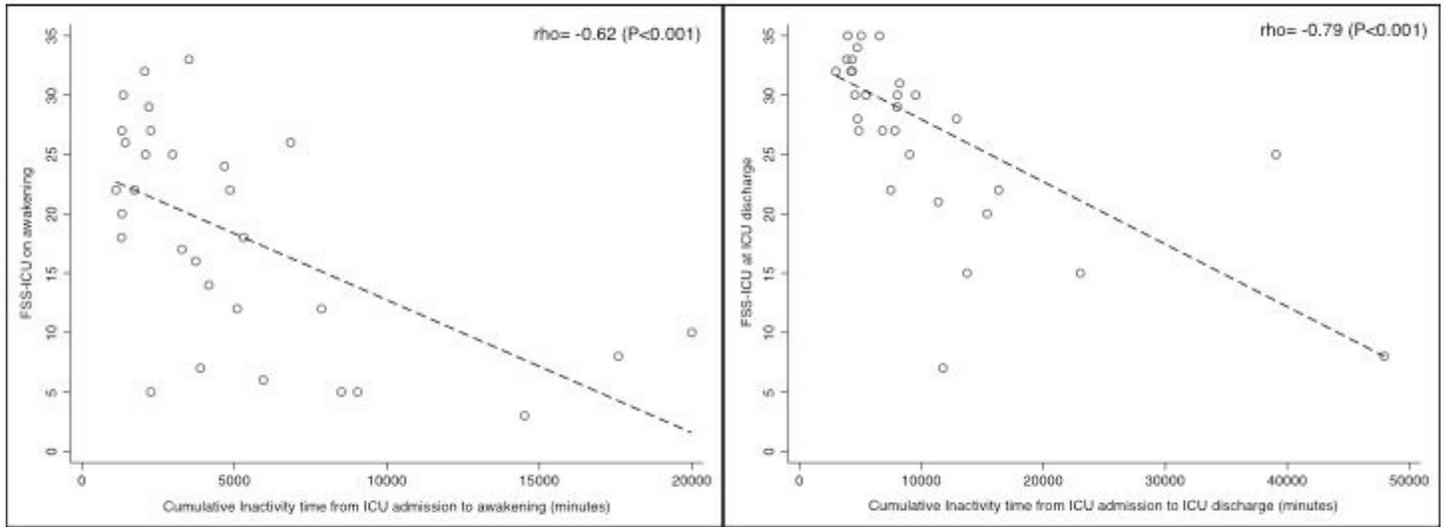
- Grap MJ, Borchers CT, Munro CL, Elswick RK, Sessler CN. Actigraphy in the Critically Ill: Correlation With Activity, Agitation, and Sedation. *Am J Crit Care*. 2005;14:52–60.
- 48.
- Raj R, Ussavarungsi K, Nugent K. Accelerometer-based devices can be used to monitor sedation/agitation in the intensive care unit. *J Crit Care*. 2014;29:748–52.
- 49.
- 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 Elsevier Ltd*. 2009;373:1874–82.
- 50.
- Schaller SJ, Anstey M, Blobner M, Edrich T, Grabitz SD, Gradwohl-Matis I, et al. Early, goal-directed mobilisation in the surgical intensive care unit: a randomised controlled trial. *Lancet*. 2016;388:1377–88.
- 51.
- Baldwin CE, Rowlands AV, Fraysse F, Johnston KN. The sedentary behaviour and physical activity patterns of survivors of a critical illness over their acute hospitalisation: An observational study. *Aust Crit Care*. 2019;in press.
- 52.
- Hussey JM, Yang T, Dowds J, O'Connor L, Reynolds JV, Guinan EM. Quantifying postoperative mobilisation following oesophagectomy. *Physiotherapy*. 2019;105:126–33.
- 53.
- Bankoski A, Harris TB, McClain JJ, Brychta RJ, Caserotti P, Chen KY, et al. Sedentary activity associated with metabolic syndrome independent of physical activity. *Diabetes Care*. 2011;34:497–503.
- 54.
- Zhao R, Bu W, Chen Y, Chen X. The Dose-Response Associations of Sedentary Time with Chronic Diseases and the Risk for All-Cause Mortality Affected by Different Health Status: A Systematic Review and Meta-Analysis. *J Nutr Health Aging*. 2020;24:63–70.
- 55.
- Ekelund U, Brown WJ, Steene-Johannessen J, Fagerland MW, Owen N, Powell KE, et al. Do the associations of sedentary behaviour with cardiovascular disease mortality and cancer mortality differ by physical activity level? A systematic review and harmonised meta-analysis of data from 850 060 participants. *Br J Sports Med*. 2019;53:886–94.

## Figures



**Figure 1**

Study flow diagram (STROBE) Abbreviations: ICU Intensive Care Unit, FSS-ICU Functional Status Score for the Intensive Care Unit a Include: pain, discomfort, hemodynamic or respiratory instability preventing evaluation



**Figure 2**

Relationship between the Functional Status Score for the Intensive Care Unit and inactivity time on awakening and at ICU discharge

## Supplementary Files

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- [TableS1.docx](#)