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A scoping review to determine the use of wearable devices to evaluate outcomes in survivors of critical illness

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Abstract:

Objective

Technology may be a cost-effective method to assess functional outcomes in survivors of critical illness. The primary objective of this review was to determine the extent to which wearable device technology, such as smartphones, pedometry, accelerometry and global positioning systems (GPS), have been used to evaluate outcomes in Intensive Care Unit (ICU) survivors.

<u>Design</u>

Studies were included if they were performed in patients surviving ICU admission and measured outcomes using wearable devices.

Data Sources and Review Method

A scoping review searching CINALH, EMBASE, MEDLINE and PUBMED was performed.

<u>Results</u>

The seven studies identified were published since 2012, and were predominately descriptive (n=6) with one randomised controlled trial. All studies described outcomes in cohorts of relatively few participants [range: 11–51]. Duration to follow-up was mostly short, at a median time of three months post-ICU discharge [range: in-hospital to 27 years]. All studies used accelerometers to monitor patient movement; specifically physical activity (n=5), sleep quality (n=1), and infant movement (n=1). The accelerometers were bi-axial (n=3), uni-axial

(n=2), combined uni-axial (n=1) and tri-axial (n=1). Common outcomes evaluated were the number of participants walking for < 30 min/day, mean daily step-counts and walking speed.

Conclusions

While wearable devices have been infrequently used to measure physical activity in survivors of critical illness, all identified studies were published recently, suggesting the use of wearable devices may be increasing. Thus far, only accelerometry has been reported, and the wide variation in methodologies used and the outcomes measured limits synthesis of these data.

Highlights: (3-5 bullet points of core findings, max 85 characters)

- Accelerometers have been used to quantify physical activity following critical illness.
- The heterogeneity between studies prevents extensive comparisons.

Abbreviations:

Intensive Care Unit (ICU), Global Positioning System (GPS)

Introduction

Physical activity and function is frequently impaired in survivors of critical illness [1-11]. While functional capacity after critical illness is an important outcome, to date, both researchers and clinicians have relied upon labour-intensive techniques, such as the six-minute walk test and subjective patient-reported questionnaires, to quantify quality of life (QOL) and physical function [1-10]. Given the logistical challenges and expense associated with these methods there is a need to be able to accurately, yet efficiently, assess physical recovery in survivors of critical illness in a way that is meaningful to patients and clinicians.

Technological advances provide the potential to quantify physical activity in a real-life setting, and in a cost-effective manner. It is possible that quantifying mobility, using daily step-counts, or measuring how much time individuals spend at home, may provide a holistic and patientcentric assessment of physical function.

A number of relatively inexpensive and seemingly accurate pedometers and accelerometers are now available [12]. A pedometer measures the number of steps taken by an individual and an accelerometer responds to acceleration in either one, two or three planes (uni-, bi-, and tri-axial accelerometers, respectively). With the use of differing body mounting and algorithms, accelerometers can be used to assess sleep, the intensity and duration of activity, body position, steps and energy expenditure. They record data continuously, providing a more representative measure of activity. Furthermore, ambulatory global positioning system (GPS) devices record movement through location data. A smartphone contains a tri-axial accelerometer, a gyroscope, a compass, and a barometer, combining these sensors with appropriate software applications (apps) and algorithms has the capacity to wirelessly transmit live data to researchers and clinicians. Such methodology is increasingly described in epidemiological studies, for example McConnell and colleagues recently report using a smartphone app to quantify physical activity from more than 20,000 healthy individuals [13].

Given the recent advances in technology of wearable devices that record physical activity, there has been growth in the number of researchers evaluating these devices across different healthcare settings. Accelerometers and pedometers have been used to assess physical activity in a variety of conditions including chronic obstructive pulmonary disease [14], cystic fibrosis [15], multiple sclerosis [16], diabetes [17] and joint replacement preoperative assessment [18]. To date, however, no review has summarised the current literature on wearable devices in survivors of critical illness.

We conducted a scoping review with the primary objective to evaluate whether wearable devices have been used to measure outcomes in survivors of critical illness. For the purpose of this review wearable devices included smartphones, pedometry, accelerometry and GPS. Our secondary objectives were to compare outcomes evaluated using wearable devices to more conventional methodologies and to evaluate usability in study participants.

Scoping Review Question

Have smartphones, pedometry, accelerometry or GPS been used to assess outcomes in patients who have survived an ICU admission?

Methods

Data sources and searches

On 9 May 2016 we conducted a scoping review of the literature using four online databases (CINALH, EMBASE, MEDLINE and PUBMED). The search criteria are provided in Supplementary Table 1 (online at cicm.org.au/journal.php). All MeSH terms were expanded for further terms and included in the search of all four databases. Reference lists of all retrieved papers were reviewed to identify other eligible studies not captured in the primary search.

<u>Eligibility criteria</u>

We included studies that reported outcomes in survivors of critical illness using wearable devices. We defined wearable devices as smartphones, pedometers, accelerometers, and GPS devices, based on our understanding of current technologies that could be used to assess outcomes following critical illness, which we defined as any condition necessitating ICU admission regardless of the presenting problem. No date restrictions were applied. We excluded studies that did not specify whether they were conducted in ICU survivors, did not report on the use of an aforementioned devices, and were not published in English.

Study selection

Duplicate citations were removed and titles and abstracts were independently screened for inclusion by two reviewers (SG and LC). If it was not clear from the abstract if the citation could be excluded, then the full-text article was obtained. Full-text manuscripts were

independently evaluated for eligibility. Disagreements were resolved by consensus or consultation with a third reviewer (AD).

Data extraction

Two reviewers (SG and LC) independently extracted data from included studies using a modified version of a standardised data collection form [19]. Information extracted included study characteristics (author, publication year, country, design, sample size), type/s of technology used, outcomes from the technology used, conventional outcomes compared to wearable devices, and study results.

Quality assessment

Risk of bias for observational studies was assessed using the Newcastle-Ottawa Scale. The Newcastle-Ottawa scores studies on three domains relating to the: selection of study groups; comparability of groups; and ascertainment of either the exposure or outcome of interest for case-control or cohort studies, respectively [20].

Usability of wearable devices

We defined usability as whether the wearable device provided a data point. We measured usability as the number of incomplete records, due to either user or device failure, out of the total number of participant data points, with a lesser number signifying greater usability.

Results

Study selection

Our search returned 1317 references, of which 526 were duplicates. Of the 791 abstracts reviewed, 747 did not meet the defined inclusion criteria and were excluded. Forty-four full-text articles were obtained and assessed for eligibility. Of these, 37 were excluded due to: patients were not admitted to ICU (n=10); studies were conducted during ICU admission and not in survivors (n=10); duplicate data (n=9), outcomes not reported (n=5) and only published in abstract form (n=3). Accordingly, seven studies were included in our review [21-27] (Figure 1).

Study characteristics

There were five prospective observational cohort studies [22, 23, 25-27], one case control study [21], and one randomised controlled trial [24] (Table 1). Three studies were nested within larger studies: two within RCTs [23, 27] and one within a longitudinal study [25]. All studies were published since 2012. Using the Newcastle-Ottawa Scale the quality of all the observational studies were low with the major limitation to these studies being their single cohort and/or descriptive nature.

Cohort studied

One study was conducted in neonates who survived ICU admission [24] and one was conducted in adults who survived an earlier ICU admission as neonates [21]. The remainder were in survivors of adult ICU (Table 1), and included various enrolment criteria such as severe sepsis, mechanical ventilation, or ICU length of stay >5 days. All studies described outcomes

in cohorts of relatively few participants [range; n= 11–51]. Only one study [25] included a calculation to determine sample size. The majority of studies evaluated their outcomes within three months of ICU discharge, although one measured at 18 months post- ICU, and one at a mean of 26 years [21, 25]. Borges et al and Guyer et al were the only investigators to report on outcomes at more than one time point [24, 26].

Usability of wearable devices

There were 8/301 records across all studies that failed to complete activity monitoring; four in Denehy's [27] study, three in McNelly's [25] study, and one in Edbrooke's [23] study, suggesting the devices were usable.

Technology reported

All studies used accelerometers to monitor activity. The bi-axial AMP331 was the most commonly used accelerometer, with bi-axial accelerometers being used by three groups of investigators [23, 25, 27], uni-axial accelerometers by two groups [22, 24], and combined uni-axial accelerometers [21] and tri-axial accelerometers were used by one group each [26].

Outcomes measured

Studies evaluated physical activity (n=5) [21, 23, 25-27], sleep quality (n=1) [22], and infant movement (n=1) [24]. Reported outcome measures are summarised in Table 1. Several studies reported multiple accelerometer outcomes. The physical activity outcomes measured varied and included simple assessments of body position [26], walking speed [23, 26], duration in dynamic activities [21], distance walked [23, 27], time spent walking [26], time spent inactive [26, 27] and steps [23, 25, 27]. Only daily step-count [25, 27], walking speed

[23, 26] and number of participants walking <30 minutes a day [26, 27] were reported in more than one study.

Associations with traditional outcome measures

Two studies reported direct correlations between outcomes measured using wearable devices and more 'traditional' outcomes, such as global reported QOL measures. There was a modest association between the total Physical Activity Scale for the Elderly (PASE) score and mean daily step-count (Spearman's rank coefficient (rho)=0.332 p=0.05) or distance walked (rho=0.313 p=0.05) [27]. Stronger correlations were shown between mean daily step-count and both the Physical Component Summary score (r^2 =0.25, p<0.01) and Physical Function score (r^2 =0.51 p<0.01) of the SF-36 and with the Clinical Frailty Scale (CFS) (r^2 =0.55 p<0.01) [25]. McNelly [25] and Denehy [27] both reported that patients with chronic disease who survived ICU had reduced step-count compared to those without chronic disease.

Discussion

Our scoping review revealed that seven studies have reported on the use of wearable devices to measure outcomes in survivors of critical illness. However, as all identified studies were published within the last five years it appears that the use of wearable devices may be an emerging field of research. The use of wearable devices permits a high degree of 'usability' with only a small number of failed readings/absent data points.

Our review also revealed that the majority of studies in this field have been exploratory in nature, and conducted in small, often single, cohorts of patients, with short-term follow-up. Additionally, the quality of study design was modest. Only one RCT was identified, and three studies were nested in other studies. This would be consistent with an emerging field of research where exploratory studies frequently do not have the methodological rigor of large-scale RCTs [28].

Variety in outcomes reported

While the studies all utilised accelerometry to quantify outcomes, a wide variety of outcomes were measured and reported, such as sleep actigraphy [22] and movement assessment [24]. The outcome most frequently reported was locomotion. Even with this outcome, there was a lack of consensus between investigators on how this should be quantified. While locomotion was recorded in four studies [23, 25-27], the only commonly reported outcomes were mean daily step-count, distance walked, and the number of participants that walked for <30 minutes/day. This variation is expected during the initial phases of a methodology but over time it is important that consistency in core domains is established [29]. The findings of this

review highlight the need for the development of core outcome sets for measurement of physical activity in ICU survivors using technology.

We were surprised there was no utilisation of GPS data to create life-spaces [30], activityspaces [31] or to quantify percentage time spent at home [32], as such measures have been used in other populations e.g. after surgery for peripheral vascular disease [33], spinal disorders [34], and in those with mental health issues [35]. The activity space is a geographic information systems construct that represents the environment an individual interacts with. Such measurements may provide an assessment of recovery from critical illness. We were also surprised that smartphones, with their associated apps, had not been used in any relevant study.

Accelerometer methodologies

Four identified studies reported on locomotion using algorithms to access raw accelerometer data to determine step data. Step data are increasingly reported in other healthcare settings [36-39]. It has been shown that uni-axial accelerometers are adequate for detecting heal strike [40] to calculate physical activity from walking, but this may under-estimate when assessing gait in slower walkers, particularly those with a shuffling gait [41]. It does, however, produce data that are patient-centered and easily interpreted by clinicians.

While using locomotion data may have its advantages, the accelerometer literature suggests that using centrally mounted tri-axial accelerometers to count activity frequency and intensity would provide the best estimate of total physical activity [40], and raises the suggestion of

using advanced modeling techniques combining accelerometer outputs to produce estimates of activity counts and energy expenditure [42].

Although less patient-focused, the use of total activity counts to estimate energy expenditure, taking into account intensity and frequency of all movements, rather than just energy expenditure, and hence physical activity, related to walking would, perhaps, provide a better assessment of physical activity. Notwithstanding the limitations of each methodology, the use of a single research methodology is ideal.

<u>Relationships between outcomes obtained from wearable devices compared to other</u> <u>methodologies</u>

It appears that there are fair associations between outcomes after critical illness measured using wearable devices compared with more 'traditional' methodologies, such as selfreported QOL questionnaires. In this review, we found stronger associations between subjective measures than between subjective and objective measures, the subjective assessment of sleep (Pittsburgh sleep quality index) had stronger correlations with the subjective assessments of health-related QOL (EQ-5D and SF-36), than with objective actigraphy measures [22], as did the subjective assessments of physical function (SF-36) with frailty (CFS) than with daily step-counts [25]. It is important, prior to the widespread implementation of step data into critical care research, to establish that measurement of physical activity after critical illness is both clinically important and related to functional outcomes of importance to patients, their care-givers, and the community.

Usability as an outcome for large trials

Although two studies [21, 22] reported that only a subset of patients used the wearable devices due to availability, potentially implying a cost limitation, the cost of follow-up using accelerometers has not been explicitly stated in any study. An AMP331 costs \$1200 (and is no longer produced), a Sensewear accelerometer \$120 and an Actiwatch 2 (4 is discontinued) \$1500. This is likely to be prohibitively expensive for researchers conducting trials involving large numbers of patients and/or sites. Fortunately, however, this cost is likely to reduce over time. An example of the dynamic nature of the technology landscape is that two of the accelerometers used in the identified studies, which were conducted within the last five years, have already been discontinued. The rapid evolution of these technologies and dynamic pricing structures is evident in that 'market leaders' in the commercial space, such as the FitBit One (\$130) and Flex (\$89) are comparatively inexpensive, and have been shown to be accurate [12]. Therefore, these dynamic changes may reduce costs however, the rapid evolution in makes, models and function could hinder attempts to develop core outcomes and methodologies using these technologies.

Strengths and limitations

Our review is, to the best of our knowledge, the first to appraise the use of wearable devices in ICU survivors. The strengths are: our search technique was relatively comprehensive; we evaluated studies for bias and quality and we used a standardised data extraction tool. However, we only accessed English language literature and moreover, there may be other wearable devices we are not aware of, and were not included in our search terms. Finally, the considerable heterogeneity of differing populations, wearable device outcomes, and timepoint to follow-up between studies limits any firm conclusions.

Conclusions

Currently, wearable devices are infrequently used to report outcomes from survivors of critical illness. While accelerometry was the only technology reported, there was considerable variation as to the type of accelerometer used, the specific outcome reported, and the time point that observations were made.

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STRING 2			
Mobile phone\$			
Cell\$ phone\$			
Smartphone\$			
Smart phone\$			
Pedomet\$			
Step count\$			
Acceleromet\$			
Actigraph\$			
GPS			
Global positioning system\$			
Cell\$ telephone\$			
Life space\$			
Activity space\$			

Supplemental Table 1: Search terms used in each database. \$ corresponds to the appropriate truncation command in each

database.

Lead	Year	Study Design	Cohort studied	Number of	Wearable Device	Time to follow-up	Duration of	Observations from wearable device	Other outcomes	Associations
author				patients			observation			
Solverson	2016	Prospective	Adults, >4 day ICU LoS.	55 (11 sleep	Sleep actigraphy	3 mo post-hospital	3 nights	Sleep/Awake cycles	Sleep Quality - PSQI,	No association between total sleep
		observational	Excluded TBI,	actigraphy)		discharge		-Mean total sleep time – 6.15hrs	ESS.	time, sleep efficiency or sleep
		cohort study	neurocognitive disorders,					- Sleep efficiency 78%	HRQOL; EQ-5D, SF-36.	disruptions and PSQI or PSQI
			acute strokes, patients					- Number of awakenings (duration) 11	Depression/anxiety;	component scores. Significant
			living a distance from the					(7mins)	HADS.	association with APACHE II score. Total
			hospital					- Sleep onset latency – 12 mins.		sleep time had no association with
										HADS, ED-5D individual domains or
										MCS or PSC.
Edbrook	2012	Prospective	Adults, sourced from a	20	AMP331 biaxial	Post-ICU hospital	Point in time, in	Reported distance walked, steps taken and	Direct observation	Slight underestimations of walking
		observational	concurrent RCT, able to		accelerometer	ward	hospital	walking speed.		distance (2.79 (walk 1) – 3.11 (walk 2)
		cohort study	walk >5m without				assessment			m over a total of 90m) and walking
		(nested in	assistance							speed (28.87 cm/s) and a slight
		RCT)								overestimation of step-count (0.92,
										95% CI -3.27 – 5.11)
Guyer	2012	Randomised	Neonates <32 weeks	37	Actiwatch mini and	5 and 11 wks post-	10 days at each	Reduced activity count per 24 hrs in the DL	Sleep and crying	No correlations with wearable devices
		control trial	gestational age		Actiwatch AW4	term corrected	time point.	group at 5 and 11 wks. No between group	behavior every 5 mins in	were reported.
						age		difference for activity count/night or day.	an auditory diary (3	
								Age-effect noted with increased activity	days), Weight	
								between 5 and 11 wks		

Van Der	2014	Retrospective	Adult survivors of neonatal	57 (28 activity	4 uni-axial	Unplanned follow-	2 days	Reduced duration of dynamic activities in	Lung Function -	No correlations with wearable devices
Cammen-		case control	resp distress,(27 with CDH,	monitoring)	accelerometers	up of PICU		the CDH group. No difference for mean	Spirometry	were reported
van Zijp		study	30 without)			survivors in		motility and motility during walking. No	Exercise testing – CPET	
						adulthood (Mean		significant differences between groups	Fatigue – FSS	
						26.7 years)			HRQOL - LIFE-H 3.0 and	
									SF36	
McNelly	2016	Prospective	Adult, >48 hrs ventilation,	30 pts (27	SenseWear bi-axial	18 mo post-ICU	>5 days, including	Daily step-count was half that of healthy	HRQOL - SF-36,	Steps/d vs SF-36 PF r ² =0.51, vs SF36
		observational	>7 d ICU LoS. Excluded;-	provided	accelerometer,	discharge	one weekend day.	controls. Pre-existing chronic disease was	Frailty - CFS	PCS r ² =0.25, vs CFS r ² =0.55. Variation
		cohort study	pregnant; lower limb	data) and 30				associated with lower step-counts		in steps vs SF-36 PF r ² =0.24 vs CFS –
		(nested in	amputees; disseminated	age and						r ² =0.32.
		longitudinal	cancer, neuromuscular	gender						
		outcomes	pathology	matched						
		study)		controls						
Borges	2015	Prospective	Adult, severe sepsis or	72 at hospital	Dynaport tri-axial	Prior to hospital	2 consecutive days	Septic patients had a lower walking time in	Muscle strength:	No associations between
		observational	septic shock, able to walk	D/C	accelerometer	discharge and 3	at both time	at both time points compared to healthy	inspiratory muscles -	accelerometer data and any other
		cohort study	without assistance pre-	51 at 3mo		mo post discharge	points.	individuals. Patients were more inactive	MIP, handgrip	variable during hospital admission or
			admission, able to	follow-up and				(sitting or lying) on the ward, than at 3-	(dominant hand	at 3-mo
			complete 2 assessments at	50 healthy				months. Walking intensity was lower after	dynamometry) and	
			ICU D/C Excluded;-	controls.				hospital discharge than healthy individuals.	quadriceps	
			previous stroke,					40% of septic patients walked <30	(dynamometry)	
			neurological disease, TBI,					mins/day vs 15% of healthy individuals	Exercise capacity -	
			SAH, SCI, fractured limbs						6MWT	
			or amputation, terminal							
			illness							

Denehy	2012	Prospective	Adult, >5 d ICU LoS, English	49	AMP 331	2 mo post ICU	7 days	Participants took 4,894 (SD – 3,070)	Lifestyle - PASE	Fair correlation between total PASE
		observational	speaker, live within 50km,	accelerometer	Accelerometer	discharge		steps/day, 80% took <7500 and only 6%	questionnaire	and mean steps/day rho=0.332 and
		cohort study,	Participation agreed by the	data				>10,000 steps/day. Only 54% of steps were	Exercise capacity -	mean distance walked rho=0.313 at
		(nested in a	attending intensivist.	45 PASE data				taken in the locomotion category. Median	6MWD Manual Muscle	p=0.05. Fair correlation between PASE
		RCT)	Excluded neurological,					distance walked was 1.69km. 90% of their	strength - Timed up and	occupation sub-score and daily steps
			spinal or musculoskeletal					time was spent inactive, 3% of the time	go test (TUG)	rho=0.332. Fair correlation between
			dysfunction.					was spent in the locative category. 63% of		walking <30 mins/day from PASE and
								the cohort spent <30 mins/d in the		steps (rho=0.345) and distance
								locomotive category.		(rho=0.344). 6MWD and SF-36 PF
										was associated with walking time and
										steps/da in a univariate analysis, in the
										multi-variant analysis this was
										confounded by the presence of chronic
										disease.
		1		1						

Table 1 - Details of the peer reviewed articles included in our scoping review – AA – Age Adjusted, 6MWD – Six-Minute Walk Distance, CDH – Congenital Diaphragmatic Hernia, d – Day, D/C - Discharge, CFS –

Clinical Frailty scale, CL – Cycled Light, CPET – Cardo-Pulmonary Exercise Testing, DL – Dim Light, DLco – Diffusion capacity of the lung for carbon monoxide, EQ-5D – EurolQol-5D, ESS – Epworth Sleepiness Scale, FEV1 –

Forced expiratory volume in 1 sec, FSS – Fatigue Severity Score, FVC – Forced Vital Capacity, HADS – Hospital Anxiety and Depression Scale, MIP – Maximal Inspiratory Pressure, MCS – Mental Composite Score of SF-

36, PADL – Physical Activities of Daily Life, PASE – Physical activity scale for the elderly questionnaire, PCS – Physical Composite Score of SF-36, PSQI – Pittsburg Sleep Quality Index, SCI – Spinal Cord Injury, SDS –

Standard Deviation Scores, SF-36 – Short-Form 36, TBI – Traumatic Brain Injury, TPDA – Time Post-Discharge Adjusted, TUG – Timed Up and Go Test, VA – Alveolar volume, VAT – Ventilatory anaerobic threshold.



Figure 1 Flow diagram for selection of studies. ICU - Intensive Care Unit.