The ICU-Recover Box: using smart technology for monitoring health status after ICU admission Pilot study 2.0

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This study aims to determine feasibility of providing and following ICU discharged patient with smart technology for 3 months after hospital discharge from a general ward of the Leiden UniversityMedical Centre. If proven successful, home monitoring...

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON57282

Source
ToetsingOnline

Brief title
The ICU-Recover Box 2.0

Condition

- Other condition

Synonym
post ICU monitoring

Health condition

aandoeningen na IC ontslag, het gaat om monitoren van de post IC gezondheidstoestand

Research involving
Human

Sponsors and support

Primary sponsor: Intensive Care
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: health status, home monitoring, post-ICU patients, smart technology

Outcome measures

Primary outcome

Primary endpoint of this study is the feasibility of providing patients with the ICU-Recover Box after ICU discharge and before hospital discharge, including the collection of measurement/questionnaire data after hospital discharge. This study will be used to identify the issues when implementing such a system. Feasibility is defined as:

• 50 post-ICU patients, who gave informed consent and who were discharged from hospital with the ICU-Recover Box, were able to use the devices within its intended use.

• We were able to acquire data from the devices in the ICU-Recover Box.

• We were able to store the acquired data in a safe manner.

• We were able to analyse the acquired data.

• > 80 % of the persons that were discharged with an ICU-Recover Box contributed for 3 months to post-ICU data.

Secondary outcome

Secundary study parameters/outcome of the study (if applicable):

• Users, i.e. post-ICU patients, have been asked, by short interviews, for

feedback and suggested adjustments and improvements of the ICU-Recover Box. And when deemed relevant, adjustments and improvements to the ICU-Recover Box or procedures for adequate use will be made.

• By means of PDCA cycli, the lessons learned and feedback will have led to adjustment and improvement of the ICU-Recover Box, from it*s content and it*s use to data acquisition and data analysis.

Study description

Background summary

Approximately 80.000 critically ill patients are admitted to an intensive care unit (ICU) in the Netherlands yearly (NICE) and this number is increasing. Due to improved treatment techniques on surgical wards and critical care facilities, the survival rate of critically ill patients admitted to the ICU also rises rapidly. The standardized mortality ratio was 0.92 in 2007 and 0.79 in 2020 (Stichting Nationale Intensive Care Evaluatie, NICE). This progress in ICU medicine with respect to increased survival comes at a cost as many ICU survivors are vulnerable and experience new and long lasting physical, cognitive and mental health sequelae (e.g. PTSD, depression, anxiety, acquired weakness), increased health care needs, increased risk for hospital readmission and death (Prescott et al. Crit Care Clin 2018; Shankar-Hari et al. Curr Infect Dis Rep 2016). This impaired quality of life is summarized as the post intensive care syndrome (PICS) by the Society of Critical Care Medicine. (Capuzzo & Bianconi, 2015; Elliott et al., 2014; Herridge & Cameron, 2013; Myers, Smith, Allen, & Kaplan, 2016; Needham et al., 2012; Torgersen, Hole, Kvale, Wentzel-Larsen, & Flaatten, 2011; Turnbull et al., 2016).
Around 30-63% of ICU survivors go on to experience high rates of health care utilization and have to be readmitted to the hospital in the following year after ICU and hospital discharge (DeMerle et al. CCM 2017; Prescott et al. Crit Care Clin 2018; Prescott et al. JAMA 2015, Shankar-Hari et al. Curr Inf Dis Rep 2016). Furthermore, many of these readmissions, approximately 40% according to Prescott (Prescott et al. JAMA 2015), are for diagnoses that could potentially be prevented or treated early to avoid hospitalization potentially. These preventable causes, most

commonly included infection, heart failure exacerbation, acute renal failure, chronic obstructive pulmonary disease exacerbation, and aspiration pneumonia. Thus, to improve quality of care during ICU and hospital stay and after hospital discharge, more knowledge of risk factors is needed to be able to take preventive measures. And in addition to addressing new disabilities, early outpatient care should focus on active screening for and mitigating risk of common post-discharge problems (Prescott et al. Crit Care Clin 2018; Prescott et alJAMA 2015). Also we need to know more precisely the different trajectories that a post-ICU patient can experience, because that also contributes to the ability to take preventive measures, early recognition and treatment, all to prevent hospital readmissions and improve quality of life and shift from unplanned to planable care. And knowledge of the different trajectories has to include multiple facets of patient-centered outcomes (i.e. physical, functional, mental, cognitive) and their time course. And most importantly, we need to add the above specificity to our prognostication and should use detailed post-ICU information and should focus on patient-centered outcomes when trying to prognosticate the future for post-ICU patients.

And with increasing numbers of elderly, chronically ill patients we will only be able to deliver affordable, high-quality and patient-centered care if we adopt new ways of acquiring patient-specific knowledge and new ways of delivering care. To obtain this level of insight we need a smart and connected health care system. Today there are many examples of applications that illustrate connected health*s potential for improving access, quality and efficiency in health care. They all involve the implementation of new technologies, including remotely over the telephone and with electronic interfaces, i.e. telemedicine and telehealth (Kvedar et al. Healtth Affairs 2014, Wysham et al. Curr Opin Crit Care 2014).

Over the past (ten) years, smartphone compatible detectors of cardiovascular, respirator and other parameters have been released on the consumers market. Examples of these include heart rate monitors, ECG monitors, blood pressure monitors, activity trackers, weight and fat percentages monitors. These monitors have often been validated and are CE-marked for use in the European Union within their intended use (Whithings, https://www.withings.com/nl/en/for-professionals/devices).

Recent publications implicate that home monitoring with such consumer devices might improve quality of care. A study by Bosworth et al. in patients with hypertension showed that increased monitoring and subsequent treatment led to a better controlled blood pressure in patients who were treated for hypertension (Bosworth et al. Arch Intern Med 2011). Another study, carried out at the LUMC, showed smart technology was feasible and yielded similar percentages of patients with regulated BP compared with the standard of care after they had

a myocardial infarction
(Treskes et al JAMA 2020). For heart failure patients studies reported a decrease in hospital readmission (Clark et al. BMJ 2007; Kulshreshtha et al. Int J Telemed Appl. 2010) as well as no
difference in outcomes with home telemonitoring (Kulshreshtha et al. NEJM 2020). These results indicate the importance of a thorough independent evaluation of telehealth strategies, for
different patient groups, in different phases of their illness, before their adoption.
Currently, patients who have been admitted to the ICU are not seen in a post-ICU outpatient clinic and there exists no other pathway of structured care for ICU patients after their discharge, other
than extramural care initiated by patient themselves or scheduled visits to the outpatient clinic. What we do know is that regularly post-ICU patients are involved in a rehabilitation trajectory in
collaboration with rehabilitation specialists. Smart technology is hypothesized to increase the chances of diagnosing physical (i.e. cardiovascular, respiratory, neuromuscular), mental and
neurocognitive deterioration and may show a declining trend before a patient visits the general practitioner or outpatient clinic, which can lead to early detection and treatment before a patient
deteriorates and has to be readmitted to the hospital.

Study objective

This study aims to determine feasibility of providing and following ICU discharged patient with smart technology for 3 months after hospital discharge from a general ward of the Leiden University
Medical Centre. If proven successful, home monitoring via smart technology will be used in future studies.

Study design

• This is a single center cohort study.
• The duration of the study is four months: approximately one month for the inclusion of the 15 patients, and three months follow-up.

Study burden and risks

The 2 smart devices used in this study for personal management are non-invasive, easy to use, and electrically safe. Using the devices is without risks. This study has some potential benefits for patients:
- first, patients can monitor their own recovery based on the measurements. This can reassure patients and give them more insight into their own health (the so-called 'patient empowerment'). A test subject is always responsible for his/her health and will have to contact his/her GP or medical specialist at the

outpatient clinic if necessary, or with an emergency service.

There are several helplines for patients if they have questions about the measurements, both technically and regarding interpretation of the measurements. If outliers are identified in the data, the patient will be called and advised to contact his/her GP or medical specialist.

A disadvantage of this study is that patients must perform one measurement per day and a calibration of the blood pressure measurement once a month. In addition, there is a half hour time commitment per month in the first 3 months and then once every 3 months for a telephone interview using: a number of questionnaires.
In addition, psychological strain can be caused by continuously measuring health parameters, especially when the values **are irregular or not within the normal range. We will record the frequency of the latter problem and hope to resolve any mental health issues with all safety nets in place and will adjust our future main protocol accordingly.
In summary, we believe this is a valuable study for post-ICU patients, with almost no risks and some potential benefits for both participating patients and future patients. We therefore believe that this research is ethically responsible.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Discharged from ICU.

Exclusion criteria

ICU admission shorter than 24 hours.
Not intubated and ventilated.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2025
Enrollment:	50
Type:	Anticipated

Medical products/devices used

Generic name:	The ICU-Recover Box containing Corsano CardioWatch 287-2;non-invasive bloodpressure monitor.
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	29-01-2025
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL86464.058.24