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Stepped wedge cluster randomised controlled trial to assess the impact of a decision support tool for physical restraint use in intensive care units (ARBOREa Study): a study protocol

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ABSTRACT

Introduction Intensive care units (ICUs) manage patients with or likely to have one or more life-threatening acute organ failures that might require the use of invasive supportive therapies. The use of physical restraint is frequent, with rates up to 50%, and usually initiated to maintain patient safety especially if the patient is agitated. Physical restraints have been associated with delirium, post-traumatic stress disorder and physical injuries while restricting patients' individual freedom. Moreover, the incidence of invasive therapeutic devices' self-removal by patients might not be decreased by physical restraint use. No recommendation is available concerning ICU patients and physical restraint management, despite being a daily practice. The main objective is to evaluate whether a strategy aimed at decreasing physical restraint use in ICU patients with that of a strategy based on routine and subjective caregivers' decision is safe and efficient.

Methods and analysis ARBOREa is a multicentre randomised, stepped-wedge trial testing an innovative, dedicated web-based, multiprofessionally developed, experts validated, nursing management strategy in comparison with standard care. The primary outcome is physical restraint use rate (effectiveness) measured at least every 8 hours and incidents' rate (tolerance) defined as the rate of incidents attributable to non-compliance, corresponding to the deterioration or self-removal of critical devices, a fall or self-aggressive or heteroaggressive behaviours. Planned enrolment is 4000 ICU adult participants at 20 French academic and non-academic centres. Safety and long-term outcomes will be evaluated.

Ethics and dissemination Trial results will be reported according to the Consolidated Standards of Reporting Trials 2010 guidelines. Findings will be published in peer-reviewed journals and presented at local, national and international meetings and conferences to publicise and explain the research to clinicians, commissioners and service users. The trial is funded by the French Ministry of Health and has been approved by the French local ethics committee (*Comité de Protection des Personnes Sud-Ouest et Outre-Mer 2*, Toulouse, France with registration number: 2020-A02904-35).

Trial registration number (ClinicalTrials.gov) NCT04957238 on 12 July 2021 before first inclusion in study.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The ARBOREa trial is the first large-scale interventional study on the impact of a novel, original, multiprofessionally designed web-based decision tool to guide physical restraint use in intensive care unit patients.
⇒ The multicentre design, broad inclusion criteria and large sample size will support external validity.
⇒ Rigorous stepped wedge randomised study design with participant centres as clusters is intended to avoid practices contamination.
⇒ Primary endpoint is defined according to well-defined and internationally validated criteria.
⇒ The unblinded design of the study may lead to a contamination bias during the control period, during which the investigators may seek to improve their performance, and to an information bias related to clinicians assessing outcomes by knowing the time period of the study.

INTRODUCTION

Intensive care units (ICUs) manage patients with or likely to have one or more acute organ failures that are life-threatening and might require the use of invasive supportive therapies. The use of physical restraint (PR) in these highly technical care settings is usually initiated to maintain patient safety.[1–5] '*Highly technical practices*' and the mission of resuscitation to '*restore life*' may tend to ignore patients' vulnerability and allow a certain amount of freedom restriction related to

physical constraint during hospitalisation.[1 6 7] A PR can be often defined as a device, whether or not in direct contact with the body, that the patient cannot remove by him/herself and that is intended to limit his/her mobility or freedom who, by his/her behaviour, endangers him/herself or those around. Despite several definitions having been proposed in the literature, most recent consensus defines PR 'as any action or procedure that prevents a person's free body movement to a position of choice and/or normal access to his/her body by the use of any method, attached or adjacent to a person's body that he/she cannot control or remove easily'.[8] It should be a temporary and exceptional measure that does not by itself constitute a therapeutic measure, bearing inherent physical side effects that can be serious.[3 6 9] Psychological and social issues might arise when PR is used.[10–13] PRs are regularly used in ICUs, with the main indication being patients' agitation and aiming at their safety.[14] This agitation may be caused by delirium,[15] pain, drug or non-drug therapies, systemic inflammation, nychthemeral cycle disturbance, noisy, bright and stressful environments or emergency care setting, among others.[16 17] Agitation and hyperactive delirium are serious events, associated with short-term complications such as self-extubation, catheter dislodgement and healthcare-associated infection. These events are acute or rapidly progressive and fluctuate during daytime. They combine fluctuating alertness, attention and judgmental issues, temporal and spatial disorientation, sleep-wake cycle disorders, hypoactive state and/or psychomotor agitation.[17] Long-term complications mainly include cognitive decline.[18] PR use has been strongly associated with delirium occurrence and emergence.[19] Challenges for caregivers are therefore to find the right conditions to ensure patient's safety while limiting the occurrence of delirium.

In 2003, Vance *et al* attempted to reduce PR use by developing a decision algorithm based on the systematic assessment of three elements: the patient's mental state, the imminent threat to the patient's life based on the treatments he or she is receiving and the technological equipment used to treat the patient.[5 20]

In the PRICE study conducted in 2010 in nine European countries, 39% of 566 included ICU patients were restrained.[21] This figure can increase to over 50% for mechanically ventilated patients.[3 9 22 23] However, there is a wide disparity in practices from one European country to another, and this might be related to various nurse-to-patient ratios[20] and certainly the healthcare culture of each country. Furthermore, main factors retrieved from the available literature for the use of PR are patient safety, need for mechanical ventilation and sedation, agitation and ward size (the more beds in the ward, the greater PR use).[2 4 6 21–23]

In 2013, De Jonghe *et al* drew up an inventory of practices in France based on a declarative survey including 130 ICUs.[22] This survey illustrated that PRs were widely used in French ICUs and were mostly used on intubated and ventilated patients. It also showed that in 30% of the responding ICUs, more than one out of two patients were restrained even though they were awake, calm and cooperative. Moreover, PR use was established on nurse initiative without any written medical order in the vast majority of cases, whereas physicians should be promptly notified and the use of PR must be entered into the medical record. Of note, it is the nurse's role to ensure their supervision.[24]

In 2015, Chanques *et al* discussed neuropsychological (post-traumatic stress disorder, delirium and agitation) and physical consequences of PR use. They stated that in the vast majority of cases, PR use did not prevent the risk of self-removal of devices. These data were published following a study by Mion *et al*, which found 44% of self-extubation cases were observed in restrained patients.[25]

In 2016, Hevener *et al* proposed a 'decision wheel' to reduce PR use.[5] This tool considered patient' behaviour, conditioning and level of independence and allowed the reduction of PR by 32% without increasing unplanned extubations or disruption of life-threatening therapeutic devices rates by unrestrained patients. Such a tool has also been developed in a study by Kang *et al* in the neurocritical care setting, in which the use of a decision tree by nurses effectively reduced PR use and adverse events.[26]

Recent study by Kang *et al* implemented a restraint decision tree for neurocritical patients to assist nurses in making PR decisions.[26] In a single centre, among 45 nurses, 237 patients have been included in a before-after fashion. Main results were that the total number of restrained patients significantly decreased from 20.7 to 16.3% (p=0.006), without any fall occurring during the study periods nor unplanned removal of devices during decision tree use (while there were 18.67 cases per 1000 patient-days in the high-risk group and 5.78 cases per 1000 patient-days in the moderate-risk group at baseline).

Finally, the 2018 international recommendations on pain, analgesia/sedation, delirium, immobility and sleep disruption in adult patients in the ICU report that, according to existing observational studies, incident rates were higher when patients were restrained.[27] Identified factors associated with increased PR use were: advanced age, delirium, sedation or invasive mechanical ventilation; while other factors, such as early mobilisation, appeared to reduce it.

Latest figures on PR practices in France date from 2013 and are based on a declarative survey.[22] PR use was in most cases 'caregiver dependent', depending on their representation of risk, seniority and clinical experience. PR might appear as a means of securing the patient while reassuring the caregiver. Environmental factors such as workload or the presence of family might influence PR decisions. In ICUs, families are increasingly integrated into care, notably through the introduction of 24-hour visiting hour policies.[28 29] Their presence can sometimes reassure and soothe the patient and might improve delirium incidence[27 30 31] and consequently have an impact on PR use.

The above studies showed that PR use for incident prevention is only partially effective, but agreed on the iatrogenic impact induced by PR in terms of neuropsychological and physical consequences,[32] while wide disparities in practices surrounding PR management exist.

The benefit-to-risk imbalance is essential in assessing the decision to restrain patients,[3 33 34] since PR could become a source of additional agitation.[35] Based on the available literature and observational prospective monocentric studies, our team developed a multiprofessional decision-making tool validated by two national experts to help caregivers to use or not use the PR in ICU patients. Main hypothesis of our study is that an objective and rationalised use of PR, via an algorithm, would decrease PR use without any increase in incident rates in case of PR absence. However, to date, data from large randomised clinical trials comparing subjective routine PR use and a strategy aiming at rationalising and decreasing their use are lacking.

METHOD AND ANALYSIS

Trial design and setting

The ARBOREa study is an investigator-initiated, prospective, multicentre, randomised, parallel-group clinical trial with stratified clusters, stepped-wedge allocation of patients admitted in ICUs to a strategy of PR use based on a web-based algorithm (figure 1).

The study protocol adheres to the Standard Protocol Items: Recommendations for Interventional Trials reporting guidelines.[36] The trial will take place at 20 academic and non-academic hospitals.

The ARBOREa study involves a total of 19 mixed medical and surgical ICUs in France (Aurillac, Avignon, Belfort, Clermont-Ferrand (two centres), Dijon, Le-Puy-en-Velay, Lyon, Marseille, Montpellier, Moulins, Nice, Paris, Saint-Etienne, Saint-Malo, Salon de Provence, Strasbourg (two centres) and Vichy).

Participant eligibility and consent

All patients admitted to a participating clinical trial site will be considered for participation. Patients will be eligible for randomisation if they fulfil all the inclusion criteria and none of the exclusion criteria (table 1). After the patient's informed consent has been obtained (or proxy consent has been obtained by the patient's next of kin or legally authorised surrogates), study inclusion will be performed after 48 hours of ICU length of stay. Since in non-communicant patients, obtaining informed consent prior to participation may not be feasible, the study protocol also provides for a waiver of informed consent from the patient's next of kin if he or she is not

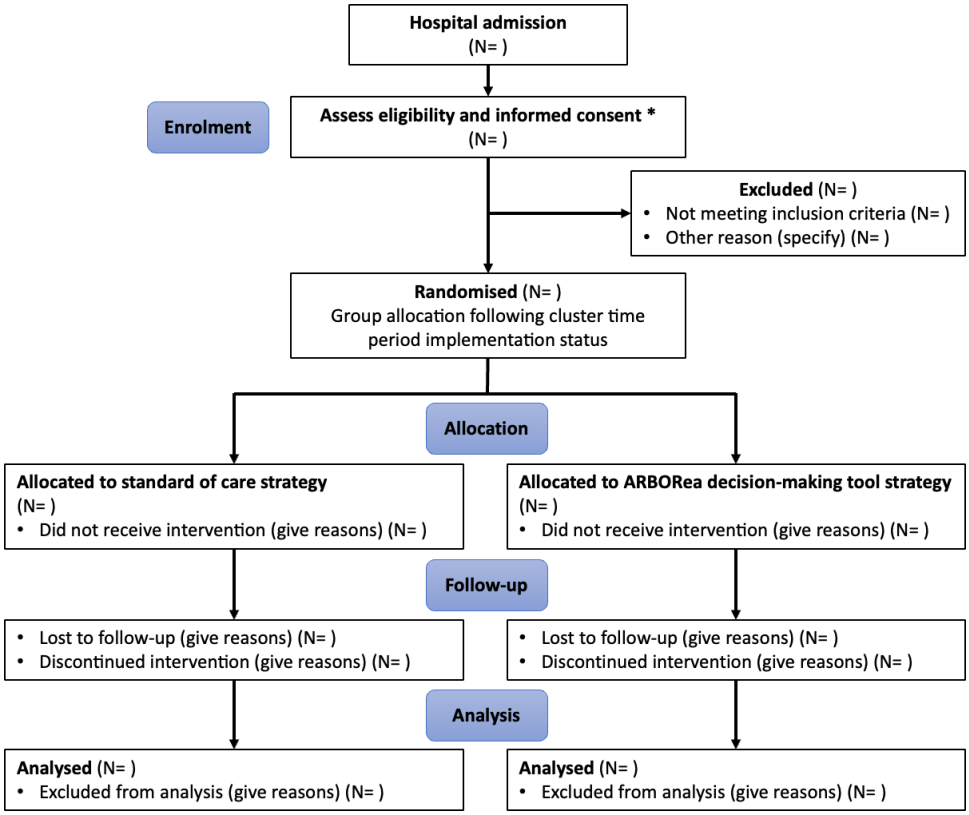

Figure 1 Consolidated Standards of Reporting Trials flow diagram of the ARBOREa trial. Flow chart (N=) will be filled during or at the end of the trial. * Because, in some cases, patients' condition interferes with effective communication, the study protocol provides for a waiver of informed consent from the patient. The consent from the patient's next of kin will therefore be sought actively. In case the patient's next of kin cannot be reached in a timely manner, the investigator will decide to include the patient in the study using an emergent consent procedure. Deferred informed consent will be obtained from participants for potential continuation of the research.

Table 1 Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
Adult (18 years or older)	Predictable and uninterrupted maintenance of deep sedation throughout the duration of the stay, due to the severity of diseases, from the moment the patient is admitted to the ICU.
Hospitalisation in ICU for at least 48 hours.	Lack of predictable remission of a severe coma present on admission to ICU.
Consent to participate in the patient's study or authorisation to carry out the research collected from the designated trustworthy person.	Refusal to participate by the patient or by the trusted person contacted by default.
Patient covered by a social security system.	Patient with do not resuscitate orders.
	Patient's or relative's refusal to participate.
	Guardianship or trusteeship patient.
	Patients already enrolled in the ARBORea trial.

ICU, intensive care unit.

present at the time of the patient's inclusion. Deferred informed consent will be obtained as soon as possible from participants or legally authorised surrogates for potential continuation of the research.

Randomisation, allocation concealment and blinding

Enrolled patients will be randomised by local investigators using a dedicated, password-protected, Secure Sockets Layer-encrypted website specifically developed for the study (https://arborea.chu-clermontferrand.fr) accessible 24 hours, around-the-clock, to allow immediate inclusion. Each patient is identified by a unique patient number. Randomisation of participating centres will be carried out according to the cluster method using a table of random numbers and considering stratification according to the recruitment capacity of each centre and centre characteristics (university and non-university).

Because of study design, PR use will not be blinded to clinicians in charge of included patients. During the first period of the stepped-wedge design, clinicians will use PR following their habits; mandatory data for decision-making aid following the web-based algorithm will be collected (but results will not be communicated to clinicians). After the washout period, further PR use decisions will be suggested by a web-based algorithm, and clinicians will be encouraged to follow it. Although the allocation group will not be blinded to clinicians (nurses and physicians) in charge of patients due to stepped-wedge design, much attention will be given to ensuring strict blinding during data analysis. At each participating centre, data will be collected and entered into the electronic web-based case report form (eCRF) by the trained clinician in charge of the patient. Outcome assessors will be blinded to patient records throughout the study.

Study interventions

Patients eligible for inclusion will be enrolled in one of the two periods of stepped-wedge design study:

1. In the first period (control stage), patients included will be restrained or not restrained, following habits of clinicians in charge. Data needed to run the web-based algorithm to help with decision-making of PR use will be collected at least every 8 hours, but results will not be disclosed.
   Algorithm is based on five items:
   - Delirium presence (assessed by trained research staff using the Confusion Assessment Method for the ICU (CAM-ICU)).[37 38]
   - Sedation and agitation level (assessed with Richmond Agitation and Sedation Scale (RASS)).[39]
   - Recent change in use or level of sedation and analgesics medications infusion rates.
   - Presence of close relatives or family members involved in patients' care.
   - Type of tubes or lines classified (class 0–3) following the severity of consequences for the patient, in case of dislodgement.

   These items have been implemented in a dedicated and investigator-initiated algorithm intended to be a decision-making aid to guide PR use in ICU patients. As the study is ongoing and some centres include patients in the first step period of the trial, divulgation of the algorithm would create potential bias. Complete ARBORea decision-making tool has been registered and protected by French *institut national de la propriété industrielle* (e-Soleau). Figure 2 presents an example of the ARBORea algorithm. The implemented decision tree has been developed to guide and rationalise PR use as well as to encourage reassessment of their appropriateness. The present tool has been validated by two independent experts (Jean-Michel Constantin, MD-PhD, Professor of anaesthesiology and critical care, Sorbonne University, Pitié-Salpêtrière Hospital, Paris, France and Gérald Chanques, MD-PhD, Professor of anaesthesiology and critical care, Montpellier University, University Hospitals of Montpellier, Montpellier, France).

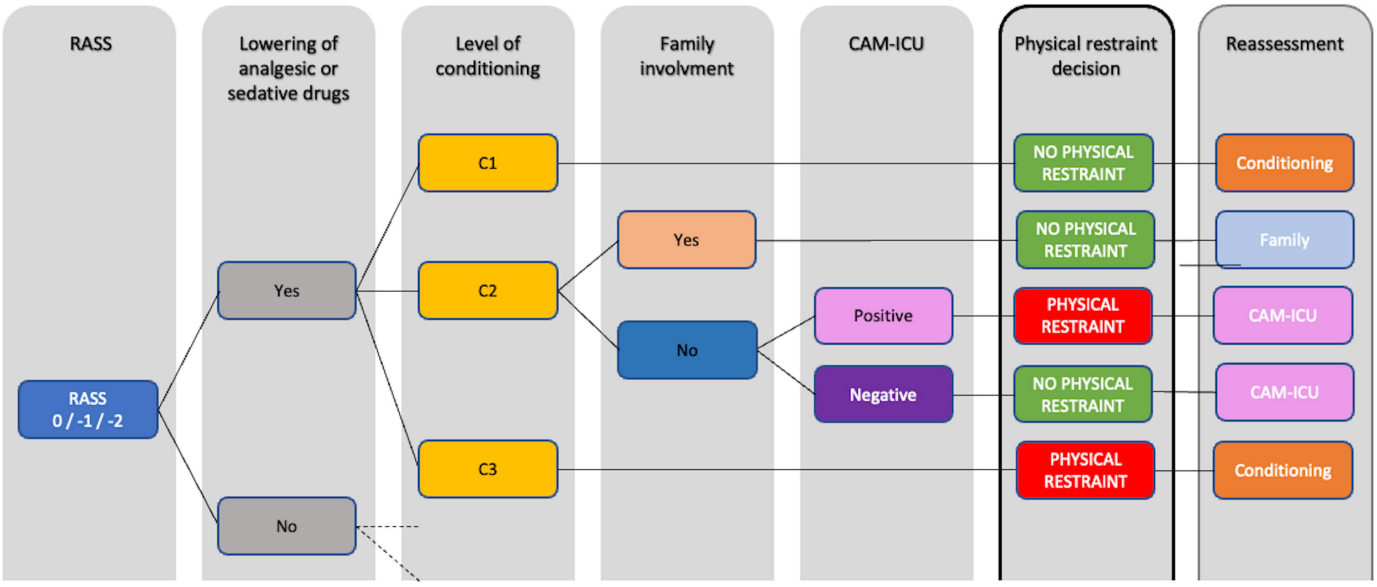

Figure 2 Example of decision-making algorithm to guide physical restraint use in ICU patients. Each item entered in the electronic web-based case report form to be used in the algorithm is depicted in grey rectangles (with identification in the top part of the rectangle). Each possible option for individual items is presented within grey rectangles. Example of algorithm, results concerning physical restraint use and item reassessment are presented and must be constructed from left to right side. CAM-ICU: confusion assessment method for the intensive care unit; RASS: Richmond Agitation Sedation Scale. Levels of conditioning: C1 (Class 1): peripheral venous catheter, nasogastric tube, Foley and subcutaneous drains; C2 (Class 2): central venous access, Swan-Ganz catheter, continuous renal replacement therapy catheter, peripherally inserted central catheter (peripherally inserted central catheter and midline), arterial line, intracranial pressure sensor, endotracheal tube, chest tube and surgically inserted drains; C3 (Class 3): veno-venous and veno-arterial extracorporeal membrane oxygenation, intra-aortic counterpulsion balloon and external pacemaker probe.

2. During the washout period, study teams and clinicians at each participating centre will receive a 30-day training phase with face to face or videoconference course on the use of dedicated algorithm and website implementation. Training phase will last longer than maximum follow-up of 28 days to avoid contamination bias. No inclusion will take place.
3. During the intervention phase (third period), clinicians will complete dedicated eCRF at least every 8 hours, and the implemented algorithm will suggest whether to use PR or not. Clinicians will be encouraged to follow it. If the nurse does not follow the suggestion of the decision tree, a protocol deviation will be collected, including the reason for this non-respect of the restraint proposal. Intervention phase will end 2 years after the first inclusion in each participating centre.

During each phase, decisions about all other aspects of patient care will follow usual practice and the expertise of involved centres staff to minimise interference with the trial intervention. Clinicians at each participating centre will be strongly encouraged to manage analgesia and sedation using a multimodal approach targeting numeric rating scale pain scores <3 (or behavioural pain score <4) and light sedation (targeting RASS level: −1 to 0, whenever possible). Delirium prevention will be encouraged using published bundles of care as stated in recommendations on pain, agitation/sedation, delirium, immobility and sleep disruption in adult ICU patients.[17 27]

The end of inclusions for all centres is anticipated to be in October 2025. With follow-up at 90-day, the end of the study is therefore scheduled for January 2026.

Outcome measures

Details on trial endpoints definitions are given in online supplemental file 1.

Primary outcome measure

The primary outcome jointly evaluates the effectiveness and tolerance of the use of a PR decision support tool during maximum follow-up of 28 days or ICU discharge:

- Effectiveness: defined as the rate of observations with PR use; the statistical unit will not be the patient by themselves but all the observations measured per patient over the entire duration of ICU stay (at least once every 8 hours).
- Tolerance: described as the rate of incidents attributable to non-compliance, corresponding to the deterioration, dislodgment or self-removal of C2 or C3 devices or self-aggressive or heteroaggressive behaviour or fall. Incidents are determined as soon as an incident occurs, measured every day during ICU stay.

Secondary outcome measures

Key secondary endpoints (within 28 days following inclusion).

- Effectiveness.
- Tolerance.

- All-cause mortality.

Secondary endpoints (within 28 days following inclusion otherwise noted).

- Rate of incidents attributable to PR use.
- Rate of incidents without PR use.
- Characteristics of PR.
- Indications of PR.
- Rate of medically prescribed PR.
- Characteristics of recorded incidents.
- Rate of recorded incidents.
- Short Form Health Survey-36 (SF-36) 90 days following ICU discharge.[40]
- Impact of Event Scale-Revised (IES-R) 90 days following ICU discharge.[41]
- Delirium-free days (DFDs) to 28 days following inclusion. A DFD is defined as the absence of delirium (absence of CAM-ICU positive) within a 24-hour period.
- ICU-free days (censored at 28 days following inclusion).
- Duration of ICU and hospital stay (patients who will be outside the hospital but in other types of healthcare facilities at day 28 will be considered to have been discharged home).
- Time to death (or censoring).
- All-cause mortality to day 90 following ICU discharge.

Statistics

Sample size estimation

Concerning PR use rate (effectiveness), 2175 measurements per arm will be necessary to highlight an absolute difference of around 5% (X=30% vs 25%), for a two-sided alpha level of 5%, a 90% statistical power, a median value of Z=7 measurements per patient and an intraindividual correlation coefficient of around 5%.

Concerning the rate of incidents attributable to non-restraint (tolerance), 5012 measurements per arm will be necessary in order to highlight a non-inferiority margin of 2% for expected rate in usual care group of Y=10% of measurements with an incident with PR with a two-sided alpha level of 5%, a 90% statistical power, a median value of Z=7 measurements per patient and an intraindividual correlation coefficient of around 5%.

In order to take into account the correction due to: (1) the experimental design of the cluster randomised trial (intracentre correlation coefficient set at 0.01, more precisely between 0.001 and 0.05 with regard to data from the literature[42]) and (2) more particularly to the sequential permutation aspect, it would be necessary to include 13 783 measurements per arm (stepped-wedge programme developed by Hemming and Girling in Stata[43]).

Considering a median value of Z=7 measurements per patient, 1969 patients per arm would be necessary (n=13 783/7), that is, 3938 patients in total. Finally, it was proposed to include 4000 patients (2000 per arm).

The hypotheses (X=30%, Y=10%, Z=7 measurements) were set with regard to the results of a pilot study carried out on 275 patients (more than 3000 measurements) at our institution.

Statistical analysis

All analyses will be performed with the use of Stata software (V.15, StataCorp, College Station, Texas, USA) before the breaking of the randomisation code, in line with the International Conference on Harmonization Good Clinical Practice guidelines. Analyses are detailed in a separate statistical analysis plan (see online supplemental file 2).

Data registration

Data are collected and entered into a web-based eCRF (https://arborea.chu-clermontferrand.fr) by previously trained trial or clinical personnel, under the supervision of the trial site investigators at each participating centre. Trial database will be established based on eCRF. Paper CRF will be used in case of technical difficulties with the eCRF. Data collection will be monitored by trained research coordinators.

The following data will be registered:

Pre-randomisation and baseline characteristics

Date and time of hospital admission; source of admission (emergency department, surgical ward, medical ward, other ICU); demographic data (age, sex, weight, height, body mass index); comorbidities (arterial hypertension: Y/N, diabetes: Y/N, active smoking: Y/N, alcohol abuse: Y/N, chronic pulmonary disease: Y/N, cancer: Y/N); values for Simplified Acute Physiology Score[44].

At inclusion (± 1 hour)

RASS score; analgesia; recent change (within previous hour) of sedative medications infusion rate: Y/N; CAM-ICU positive: Y/N; close relatives or family members presence involved in patient's care: Y/N; type of tubes or lines classified following the severity of consequences for the patient in case of dislodgement.

Every 8 hours following inclusion within ICU stay or 28 days following inclusion

Date and time of evaluation; nurse to patient ratio; nurse's workload (admission, emergency, imagery, invasive technical procedures, patient death, at least two events, no event); RASS score; pain assessment and treatment; recent change (within previous hour) of sedative medications infusion rate (increased sedation, reduced sedation, no change in sedation dosage, unsedated patient, stop sedation); CAM-ICU positive: Y/N; close relatives or family members presence involved in patient's care: Y/N; type of tubes or lines classified following the severity of consequences for patient in case of dislodgment; PR use: Y/N; type of PR use; PR medical prescription: Y/N.

Whenever an incident occurs during ICU stay or 28 days following inclusion

Date, time and type of incident; narrative description of incident.

Every day during ICU stay or 28 days following inclusion

Patient location (ICU: Y/N, high dependency unit (HDU): Y/N, surgical ward: Y/N; medical ward: Y/N); discharge from hospital: Y/N (if yes, date and time of discharge); survival status (date of death).

Ninety days after inclusion

Survival status (and date of death); discharge from hospital: Y/N (if yes, date and time of discharge); discharge from ICU/HDU: Y/N (if yes, date and time of discharge); SF-36 score; IES-R score.

Study discontinuation and patient withdrawal

A participant or a patient's relative who no longer agrees to participate in the clinical trial may withdraw their consent at any time without need of further explanation. In order to conduct intention-to-treat analyses with as little missing data as possible, it is in the interest of the trial to collect as much data from each participant as possible. In accordance with French law, data already collected prior to and up to the date of consent withdrawal will be retained and analysed. If data for the primary endpoint are not yet available, the investigator may ask the participant and/or relatives, whenever possible, for permission to obtain data for the primary outcome measure. If this person declines, all data from that patient will be destroyed and a new patient will be randomised to obtain the full sample size. All randomised patients will be reported, and all data available with consent will be used in the analyses. If appropriate, missing data will be handled in accordance with multiple imputation procedures if missing data are greater than 5%. Patients will be excluded from the study in case of withdrawal of care decision.

Data handling and retention

Data will be entered into a dedicated web-based eCRF by trial and clinical staff. Each site will only have access to site-specific data. Each patient will receive a unique trial identification number. Only investigators and the research team will have access to any protected health information of study participants and any study data. Data will be handled according to French law. All original records (including consent forms, reports of serious adverse events and relevant correspondences) will be archived at trial sites for 15 years. The clean trial database file will be anonymised and maintained for 15 years. Only the principal investigators and the statistician will have access to the final data set.

Trial status

The current protocol is V.6.0. The trial began in May 2022. At the time of manuscript submission, over 2500 patients had been recruited (more than 42 000 measurements), with a 2-year recruitment period per study site planned.

Data statement

The data generated and/or analysed during the trial are not yet publicly available as the trial is ongoing. When the trial is complete, data sets will be available from the principal investigators (PV, AB and TG) on reasonable request and after ethics and publication agreements (see online supplemental file 5).

Patient and public involvement

There is no patient and public involvement in the design and execution of this study.

DISCUSSION

The ARBOREa trial is to allow us to evaluate whether a dedicated decision support tool to guide PR use in ICU patients is associated with a significantly lower incidence of PR use (effectiveness) without rate increase of incidents attributable to non-compliance (tolerance) during maximum follow-up of 28 days or ICU discharge.

PR use is a common practice for caregivers in ICUs and affects several thousands of patients worldwide each year. Carried out on medical prescription, it requires the attention of paramedical and medical teams for its implementation, monitoring and removal. However, PR represents a major restriction of patients' individual freedom. No recent recommendation based on the literature with a high level of evidence is available, to date and to our knowledge, concerning ICU patients, despite being a daily practice.[7 24] The main criterion for PR introduction reported by caregivers is patients' safety. The non-medical team guarantees their safety and physical integrity at bedside. However, PR use decision is often left to the sole discretion of nurses and varies according to their safety representation and depends on several factors such as seniority in ICU, nurse to patient ratio and workload. PR use has been associated with increased incidents such as delirium occurrence, dislodgement of invasive devices by patients or self-aggressive or heteroaggressive behaviours.

The rigorous rationalisation and prevention of PR use among ICU patients is lacking. In the absence of issued guidelines, providing evidence-based recommendations for PR use becomes a priority since significant controversy remains as well as a gap in knowledge in the context of ICU stay.

However, one must keep in mind that the implementation of novel tools such as decision trees in daily practice remains a huge challenge even in the case of proven benefits supported by the scientific literature. Indeed, implementation requires education and tool acceptance while performing challenging daily practices, when tradition on restraining, among other examples of clinical cares, passes down generation after generation.[45 46]

Among the strengths of the present trial are the multicentre design and the use of a robust and pragmatic primary endpoint that is pertinent to the development and evaluation of a novel web-based tool in the general ICU population. Primary endpoint consists of two components: effectiveness and tolerance of a decision support tool dedicated to rationalisation of PR use. Combined, these components may provide a clinically

meaningful measure of efficacy in improving outcome during ICU stay. Additionally, the patient group is easily identified in daily clinical practice, combined with limited exclusion criteria lessening the chance of selection bias.

One limitation of the study is that clinicians (nurses and physicians) are aware of PR use. However, given the characteristics of the two strategies under evaluation, a double-blind trial is not feasible. The ARBORea trial, however, aims at minimising detection bias by blinding of the outcome assessor and using a stepped-wedge design limiting learning and contamination bias. Additionally, adjustments will be made after multivariate logistic regression by including variables independently associated with the primary outcome and anticipated relationship with PR use. Finally, the study is not aimed at collecting data on all potential covariates that may influence the association between the intervention and outcome measures. However, stratified random allocation of patients to study groups will help minimise potential confounding. Another limitation could arise from the underdeclaration of incidents related (or not) to PR use (or not). This point will be balanced by the data monitoring team that will review clinical files of included patients at each centre. Finally, the main limitation of the study design is based on the choice of items included in the decision tool provided by the algorithm. This tool has been developed upon extensive discussions within the research team and international experts and has been tested in a local pilot trial for feasibility. This point will be discussed in the final manuscript prior to publication.

CONCLUSION

In conclusion, the ARBORea trial is an investigator-initiated pragmatic randomised clinical trial empowered to test the hypothesis that a dedicated decision support tool aimed at guiding PR use, in comparison to clinical decision, would help at reducing PR use in ICU patients without increasing incidents attributable to non-compliance. PR use is common in general ICU patients and rationalisation holds a markedly clinical potential to improve outcomes.

ETHICS AND DISSEMINATION

The ARBORea trial is an investigator-initiated trial supported by funding from the French Ministry of Health obtained in 2019 from a national hospital clinical research program in nursing (*Programme Hospitalier de Recherche Infirmière et Paramédicale* 2019).

Study protocol and statistical analysis plan have been approved for all centres from a central ethics committee (*Comité de Protection des Personnes Sud-Ouest et Outre-Mer 2*, Toulouse, France; registration number: 2020-A02904-35). The trial is registered at ClinicalTrials.gov (NCT04957238).

Three methods of consent will be used, as required by the Institutional Review Board in accordance with the Declaration of Helsinki. Whenever possible, the patient will be included after written informed consent. However, the patient may be unable to provide informed consent because of the severity of illness (eg, altered mental status, use of sedation). These patients will be included after written informed consent is provided by the next of kin or using an emergency procedure (investigator signature, countersigned by an independent physician) if the next of kin is not present. When available, and as soon as possible after recovery, patients will be retrospectively asked for written consent to continue the trial (online supplemental file 3).

A scientific committee, including PV, IG, TG and AB, conceived, drafted and wrote the project.

An independent data monitoring and safety committee will review unblinded data and serious adverse events every 6 months to advise on any recruitment and safety issues they identify and to investigate whether the conduct of the trial may compromise patient safety (a between-group difference in mortality).

Trial results will be reported according to the Consolidated Standards of Reporting Trials 2010 guidelines. Findings will be published in peer-reviewed journals and presented at local, national and international meetings and conferences to publicise and explain the research to clinicians, commissioners and service users. Authorship rules are described in online supplemental file 4.

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