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Surgical Intensive Care Unit Optimal Mobilisation Score (SOMS) trial: a protocol for an international, multicentre, randomised controlled trial focused on goal-directed early mobilisation of surgical ICU patients

Matthew J Meyer,[1] Anne B Stanislaus,[1] Jarone Lee,[2] Karen Waak,[3] Cheryl Ryan,[4] Richa Saxena,[1] Stephanie Ball,[4] Ulrich Schmidt,[1] Trudy Poon,[1] Simone Piva,[5] Matthias Walz,[6] Daniel S Talmor,[7] Manfred Blobner,[8] Nicola Latronico,[5] Matthias Eikermann[1,9]

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For numbered affiliations see end of article.

Correspondence to
Dr Matthias Eikermann; meikermann@partners.org

ABSTRACT

Introduction: Immobilisation in the intensive care unit (ICU) leads to muscle weakness and is associated with increased costs and long-term functional disability. Previous studies showed early mobilisation of medical ICU patients improves clinical outcomes. The Surgical ICU Optimal Mobilisation Score (SOMS) trial aims to test whether a budget-neutral intervention to facilitate goal-directed early mobilisation in the surgical ICU improves participant mobilisation and associated clinical outcomes.

Methods and analysis: The SOMS trial is an international, multicentre, randomised clinical study being conducted in the USA and Europe. We are targeting 200 patients. The primary outcome is average daily SOMS level and key secondary outcomes are ICU length of stay until discharge readiness and 'mini' modified Functional Independence Measure (mmFIM) at hospital discharge. Additional secondary outcomes include quality of life assessed at 3 months after hospital discharge and global muscle strength at ICU discharge. Exploratory outcomes will include: ventilator-free days, ICU and hospital length of stay and 3-month mortality. We will explore genetic influences on the effectiveness of early mobilisation and centre-specific effects of early mobilisation on outcomes.

Ethics and dissemination: Following Institutional Review Board (IRB) approval in three institutions, we started study recruitment and plan to expand to additional centres in Germany and Italy. Safety monitoring will be the domain of the Data and Safety Monitoring Board (DSMB). The SOMS trial will also explore the feasibility of a transcontinental study on early mobilisation in the surgical ICU.

Results: The results of this study, along with those of ancillary studies, will be made available in the form of manuscripts and presentations at national and international meetings.

Registration: This study has been registered at clinicaltrials.gov (NCT01363102).

ARTICLE SUMMARY

Article focus

- Early mobilisation is important for critically ill patients who are at risk of developing intensive care unit (ICU) acquired weakness.
- ICU-acquired muscle weakness is associated with increase in duration of mechanical ventilation, ICU length of stay and mortality.
- In the surgical ICU, contraindications to early mobilisation exist in subsets of patients. We evaluate the value of the Surgical ICU Optimal Mobilisation Score (SOMS) guided algorithm for goal-directed early mobilisation.

Key messages

- This protocol presents an international, multicentre, randomised controlled clinical trial in the surgical ICU analysing the efficacy of goal-directed early mobilisation compared to standard of care on clinically important outcomes.
- The results of this trial should be broadly generalisable and provide a cornerstone for future early mobilisation research in surgical ICU.

Strengths and limitations of this study

- International, multicentre, randomised controlled clinical trial.
- Straightforward, intuitive and easily implementable algorithm designed by a multidisciplinary team interested in critical care medicine.
- No specific budget expenditure to implement the SOMS algorithm.
- Exploratory testing of genetic polymorphisms, which may explain parts of the variance in the effectiveness of early mobilisation.
- Contamination bias may occur when clinical experience with intervention activities affects mobilisation therapy in the standard of care group.

INTRODUCTION

Background

Previous studies have shown that early mobilisation improves outcomes in the medical intensive care unit (ICU).[1–3] Currently, there is little data on the effects of early mobilisation in the surgical ICU; however, there is some fear that surgical patients could be harmed by premature mobilisation following major surgery.[4] The risks of immobilising patients are well established,[4 5] especially ICU-acquired weakness.[6 7] ICU-acquired weakness is associated with increased risk of aspiration,[8] increased length of hospital stay (LOS)[9] and increased mortality.[9] Moreover, the consequences of ICU-acquired muscle weakness can result in persistent functional disability for at least 5 years,[10 11] which affects the quality of life of ICU survivors.[12]

Moderate exercise can mitigate the adverse consequences associated with immobility by improving muscle strength[13] and physical function[3] and it can translate into improved patient outcomes. Three prospective studies conducted in the medical ICU demonstrate improved outcomes when mobilisation was made a priority: patients have less exposure to benzodiazepines,[2] shorter durations of delirium,[2 3] less time on mechanical ventilation,[3] fewer ICU days,[1 2] fewer hospital days[1 2] and better functional independence at hospital discharge.[3]

Mobilising patients following surgery has been part of the surgical culture for over a century.[14 15] A variety of surgical procedures and conditions have been deemed safe for early mobilisation, including blunt trauma,[16] full thickness skin grafts,[17] left ventricular assist device placement[18] and lung surgery.[19] In elderly patients, early mobilisation following treatment for acetabular fractures has improved outcomes.[20] Establishing early mobilisation as safe following certain procedures, such as peripheral angioplasty,[21] has helped allocate hospital resources more efficiently.[22] However, there is evidence that early mobilisation may have negative effects in disease-specific subgroups, such as brain trauma.[23]

In surgical ICU, research on early mobilisation is limited. Barriers to mobilisation include surgical wound pain, musculoskeletal trauma, unstable fractures, open wounds, drains and other medical devices physically attached to the patient and the patient's proximity to or from surgery. Perceived difficulties to mobilisation also depend on the profession and training of the healthcare provider.[24] In surgical patients, optimally tailored mobilisation is desirable to avoid potential morbidity from excessive or inappropriate mobilisation.

In response, our team, including critical care nurses, physical therapists and physicians, developed the Surgical ICU Optimal Mobilisation Score (SOMS)[24] and we apply it as an algorithm for goal-directed early mobilisation in the surgical ICU. SOMS is a simple '0' to '4' score ranging from 'No activity' to 'Ambulation.' The achieved SOMS on the first day of surgical ICU admission is an independent predictor of surgical ICU and hospital LOS, and in-hospital mortality.[25] SOMS facilitates the nominal classification of mobility in the surgical ICU and has adequate inter-rater reliability.[25]

Objectives

The primary objective is to

1. Evaluate the effectiveness of the SOMS-guided algorithm for goal-directed early mobilisation compared to standard of care on the primary outcome of average daily patient mobilisation, and the key secondary outcomes of surgical ICU LOS until discharge readiness and patient functional mobility at surgical ICU and hospital discharge.
2. Explore the effects of goal-directed early mobilisation compared to standard of care on quality of life after hospital discharge and global muscle strength at ICU discharge.

The secondary objectives are to

1. Generate data for hypotheses and power calculations for future trials.
2. Analyse relationships between polymorphisms in genes associated with circadian rhythm, sleep cycle and muscle homoeostasis and response to early mobilisation treatment.

Hypotheses for the primary outcome

1. Participants in the intervention group, receiving SOMS-guided goal-directed early mobilisation treatment, compared with standard care will have a higher average daily SOMS level, shorter length of surgical ICU stay and better functional mobility at discharge.
2. Participants in the intervention group, receiving SOMS-guided goal-directed early mobilisation treatment, compared with standard care will have better quality of life following hospital discharge and better muscle strength at surgical ICU discharge.

METHODS AND ANALYSIS

Trial design

The SOMS group has designed an international, multicentre, randomised controlled trial. An outline of the study design and daily work is provided in figure 1. We pledge to adhere to the CONSORT 2010 Statement[26] for reporting of our trial.

Subjects

All adult surgical ICU patients who have been ventilated for less than 48 h and are expected to continue ventilation for at least another 24 h at the time of screening, and who meet baseline criteria for functional independence (Barthel Index Score ≥70 2 weeks prior to admission[27]) are considered for the study. Table 1 contains the exclusion criteria.

Recruitment timeframe

This trial is occurring currently in the surgical ICU at three academic medical centres in the USA with expectations of expansion to one academic medical centre in

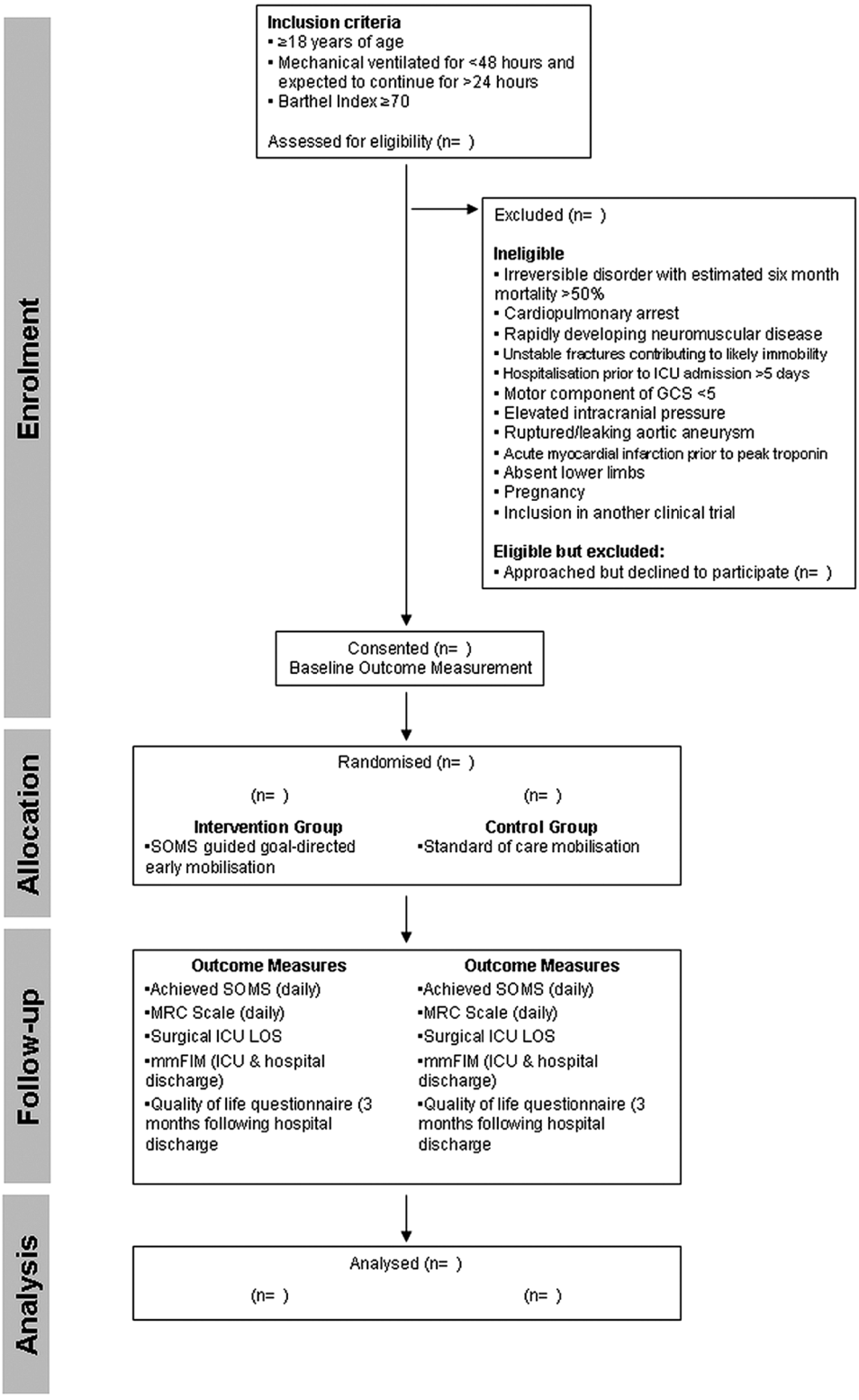


Figure 1 Participant progression through the study protocol. GCS, Glasgow Coma Scale; ICU, intensive care unit; LOS, length of stay; mmFIM, 'mini' modified Functional Independence Measure; MRC, Medical Research Council; SOMS, Surgical ICU Optimal Mobilisation Score.

Germany and one in Italy. The trial began in June 2011 and is expected to be complete in 3 years.

Recruitment and randomisation

The local investigator will screen surgical ICU patients daily and patients will be included into the study according to locally dependent consenting standards. Participants will be immediately randomly allocated into the intervention or standard of care group by study staff. We stratify according to Glasgow Coma Scale (GCS; ≤8, >8) and Acute Physiology and Chronic Health Evaluation II (APACHE II; ≤12, >12) at each centre.

Table 1 Study exclusion criteria

Exclusion criteria	Justification
Irreversible disorders with 6-month mortality estimated at greater than 50%	Incomplete outcome data
Rapidly developing neuromuscular disease	Incomplete study procedures
Cardiopulmonary arrest	Unable to ensure future independent mobility
Brain injury with Glasgow Motor Score <5	Unable to ensure future independent mobility
Elevated intracranial pressure	Intervention contraindicated
Rupture/leaking aortic aneurysm	Intervention contraindicated
Acute myocardial infarction before peak troponin has been reached	Intervention contraindicated
Absent lower extremities	Incomplete study procedures
Unstable fractures	Intervention contraindicated
Prolonged hospitalisation >5 days at enrolment hospital or at an outside hospital	Potential confounding factors
Pregnancy (women 18–55 years old)	Intervention contraindicated
Enrolment in another clinical trial	Potential confounding factors

Participants are stratified into four groups: (1) GCS ≤8, APACHE II ≤12; (2) GCS ≤8, APACHE II >12; (3) GCS >8, APACHE II ≤12; and (4) GCS >8, APACHE II >12. Into each subgroup (1–4), the stratified randomisation is restricted to 50 : 50 (intervention : standard of care) initially.

Administrative structure

The clinical coordinating centre is at the Massachusetts General Hospital in Boston, Massachusetts, USA and is responsible for preparation of the protocol and revisions, managing communications and publishing study results. In each surgical ICU there is a clinical member of the unit (eg, a clinical nurse specialist or a nurse practitioner) who helps facilitate the implementation of SOMS-guided goal-directed early mobilisation (see box 1).

Surgical Optimal Mobilisation Score (SOMS) algorithm

The SOMS algorithm for goal-directed mobility ranges from '0—No mobility' to '4—Ambulation' (figure 2).

Box 1 The role of the Surgical Intensive Care Unit Optimal Mobilisation Score (SOMS) facilitator pertaining to intervention and standard of care participants

Roles of the SOMS facilitator

Standard of care

- Record activity level and SOMS achieved
- Identify adverse events and report them to study staff

Intervention

- Facilitate the discussion related to setting a daily SOMS goal with the rounding team, nurses, physical therapists and respiratory therapists
- Assist nurses with mobilisation strategies to achieve SOMS goal
- Give advice on how to address barriers to early mobilisation
- Present barriers to mobilisation to rounding team for solutions
- Identify adverse events and report them to study staff

The intermediate steps are '1—Passive Range of Motion,' '2—Sitting,' and '3—Standing.' A SOMS of '0' indicates that no mobilisation should be considered due to the clinical state of the participant. A SOMS of 1 indicates the nurse can perform passive range of motion exercises while the patient is in bed. The passive range of motion entails ankle dorsiflexion, knee and hip flexion, hip abduction, shoulder flexion, abduction and external rotation, wrist flexion and elbow flexion. The magnitude and frequency of passive range of motion is based on clinical discretion. A participant achieves a SOMS of 2 if able to sit either on the side of the bed or on a chair. A SOMS of 3 indicates that a patient is able to stand with or without assistance. The highest level a patient can achieve is a SOMS of 4, in which the patient is able to ambulate.

Standard of care

Surgical ICU nurses conduct daily neurological assessments using the Richmond Agitation Sedation Scale for arousal and the Confusion Assessment Method for ICU for delirium. Participants who are documented as positive for the Confusion Assessment Method for ICU will be considered delirious. Participants in the study as well as control groups are managed by goal-directed sedation and undergo daily decreases in sedatives and/or narcotics. Contraindications to daily attempts to decrease sedation are persistent neuromuscular blockade, sedative infusion for active seizures or alcohol withdrawal, persistent agitation, active myocardial ischaemia and elevated intracranial pressure. All patients receive early enteral feeding and patients with high glucose concentrations are treated with protocol-based insulin regiments.

Liberating patients from mechanical ventilation is performed via a protocol, with the decision to extubate made by the clinical team. Daily spontaneous breathing trials occur with all participants as long as there are no contraindications (critically elevated intracranial

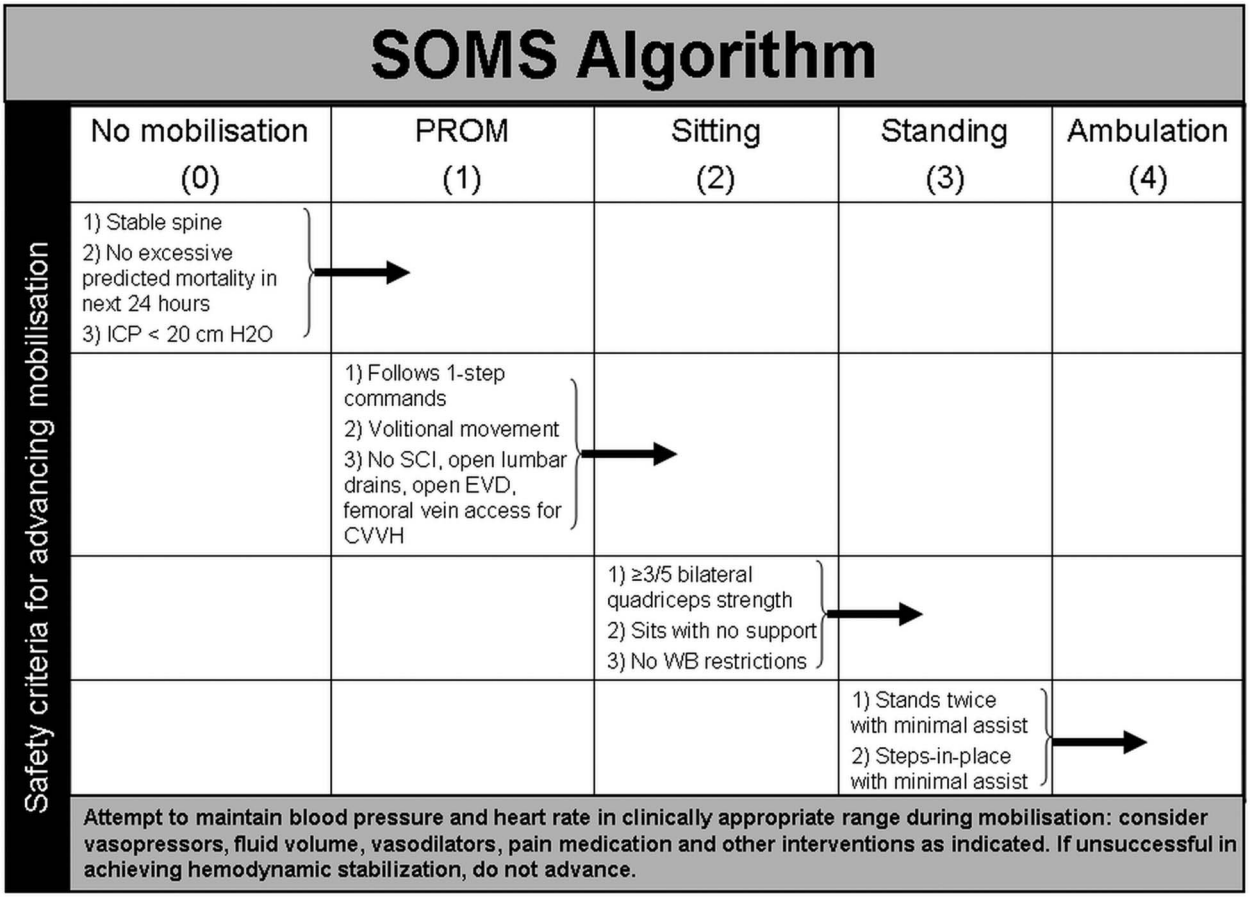


Figure 2 Surgical ICU Optimal Mobilisation Score (SOMS) algorithm for goal-directed early mobilisation.

pressure, neuromuscular blocker requirement, significant haemoptysis, haemodynamic instability, active myocardial infarction, an unstable airway, fraction of inspired oxygen >0.6, pressure control >20 cm H_2O, positive end-expiratory pressure ≥8 cm H_2O, expiratory volume ≥15 L/min or extracorporeal life support).

Intervention

The intervention (SOMS-guided goal-directed early mobilisation) will begin on the day following consent unless signed consent is received prior to the surgical ICU team conducting morning rounds. The SOMS algorithm (figure 2) will be discussed during morning rounds when the team defines a SOMS goal for the day with the assistance of the SOMS facilitator. The SOMS algorithm establishes a minimum standard for participant advancement to the next mobilisation level and contains polar (yes/no) and non-polar questions. Clinical staff member involved with mobilising the participant should be able to verify the polar questions (ie, intracranial pressure <20 cm H_2O). The non-polar questions which involve clinical judgment (ie, no excessive predicted mortality within the next 24 h) are discussed with the assistance of the SOMS facilitator.

Once the mobilisation goal has been determined, a sign will be posted at the participant's bedside with the goal for the day. The bedside nurse will work with the participant to achieve the goal. Prior to afternoon rounds, the nurse will document the highest achieved SOMS for the day. If the goal SOMS was neither met nor exceeded, the nurse documents barriers to mobilisation. These barriers will be discussed and attempts will be made to mitigate these barriers (ie, pain, anxiety, haemodynamic or respiratory concerns) in order to meet the SOMS goal for the following day.

Blinding

Given the design of the SOMS trial, blinding to the primary outcome is impossible. The assessors of the key secondary outcome of 'mini' modified Functional Independence Measure (mmFIM) and the secondary outcome of short form 36 (SF-36) 3 months after hospital discharge will be blinded to the study assignment. The data analyst will also be blinded to the study group assignments.

Outcome measures

The primary outcome is mean achieved SOMS level over the course of the ICU stay and this will be recorded daily until ICU discharge. The key secondary outcome of ICU LOS until discharge readiness will be recorded once determined by the clinical team. The key

secondary outcome of mmFIM, representing functional mobility, will be assessed at hospital discharge.

The secondary outcome of quality of life obtained through SF-36 survey will be completed at least 3 months following hospital discharge. The secondary outcome of Medical Research Council (MRC) Scale for testing global muscle strength will be administered daily while in ICU.

Exploratory outcomes for this study will include ICU LOS, hospital LOS, in-hospital mortality, 3-month mortality, discharge disposition, ICU delirium-free days, ventilator-free days, ICU sedation-free days, average daily morphine equivalent dose (mg), neuromuscular blocking agent-free days, vasopressor-free days, corticosteroid days, daily high serum glucose (mg/dL) and daily high serum sodium (mEq). All outcome measures will be monitored from study day 1 and stop with surgical ICU discharge unless otherwise indicated, such that a time-dependent analysis of positive and negative outcomes can be conducted in all patients. The predefined period for outcome-free days is 28 days and any participant who dies prior to day 28 will have all subsequent days counted as not outcome free. We will consider all days following surgical ICU discharge as outcome free.

'Mini' modified Functional Independence Measure

A trained and blinded member of the study staff will determine mmFIM. mmFIM is a shortened version of modified Functional Independence Measure (mFIM) and contains only two (locomotion and transfer) of the five components from mFIM to better reflect the functional activities of critically ill patients.[28] Like mFIM, mmFIM is scored from 1 to 4. A score of 1 indicates near or complete dependence for the aforementioned skill, 2 indicates partial independence, 3 indicates independence with activity setup or adaptive equipment and 4 indicates complete independence. Previously reported data have indicated a linear relationship between the standard FIM and the mFIM scales.[29] The mmFIM data will be analysed dichotomously, with a score of 4 indicating complete independence and scores of 1–3 indicating activity dependent on others or adaptive equipment.

Short form 36

SF-36 (SF-36v2; QualityMetric Inc, Lincoln, Rhode Island, USA) is a generic health status questionnaire validated for use across diverse populations.[30] It comprises 36 questions which provide summaries on physical, emotional and social function. Data are gathered using eight domains: physical function, social function, role limitations secondary to physical health, role limitations secondary to emotional well-being, bodily pain, vitality, general mental health and general health.[31] SF-36 is applied in our study to assess participant's quality of life 3 months following hospital discharge.

MRC manual muscle strength testing

MRC is a measure which reliably predicts in-hospital mortality, surgical ICU LOS and hospital LOS.[9] Study staff will aim to measure MRC daily. MRC manual muscle strength testing may only be assessed if a participant's level of sedation (Richmond Agitation Sedation Scale ≥ -1), attention span and ability to follow instructions are adequate. The ability to follow instructions will be gauged by asking the patient a series of 1-step and 2-step instructions, a modification of the De Jonghe *et al*[6] approach which we have previously reported.[9] If the patient is unable to complete the steps or deemed not alert, the test will not be conducted for that day. When appropriate, MRC will be conducted daily while the patient is in the surgical ICU. The MRC data will be analysed as a continuous variable.

Sample size estimation

The sample size calculation is informed by data from Kasotakis *et al*[25] and Schweickert *et al*.[3] From Kasotakis *et al*[25] we predict an intergroup SOMS difference of 1 ±1.5 and a correlation of SOMS to surgical ICU LOS of $r=-0.54$. From Schweickert *et al*[3] we predict an incidence of an mmFIM score of 4 (complete independence for the activity evaluated) of 59% in the intervention group and 35% in the standard of care group at hospital discharge.[3] Allowing for an expected 11% mortality rate and 11% attrition due to dropouts, enrolling 200 participants, 100 in each group, will provide us with a power of >80% to identify an intergroup difference with an α error of 0.05.

Enrolment goals will be 1–4 participants/site/month. Site enrolment will be evaluated every 3 months through communications relayed by site-lead investigators and designated representatives with the clinical coordinating centre. Any unexpected delays in enrolment will be discussed between the clinical coordinating centre and the respective site. If the delays in enrolment are due to limitations imposed by the inclusion and exclusion criteria, changes will then be considered. Any changes to these criteria will require the approval of the Data and Safety Monitoring Board (DSMB) and the institutional review board (IRB) of the respective institution. If enrolment is persistently below expectations and no changes to the inclusion or exclusion criteria are identified, additional clinical sites may be included.

Statistical methods

The study analysis will be by intention to treat. Summary statistics of mean and SD, frequency and percentage will be generated, respectively, for continuous and categorical/ordinal variables by the stratification based on GCS and APACHE II. The association between the outcome variables and stratification will be evaluated using ANOVA and χ^2 test, respectively.

The main outcomes of the study will be tested using a hierarchical sequence so the hypotheses, in an a priori specified order, can be tested with an α error of 0.05

without adjustment for multiple testing.[32–34] The outcomes will be tested in this predefined order: mean daily SOMS level, surgical ICU LOS until discharge readiness and mmFIM score at hospital discharge. If a p value is larger than 0.05, the procedure has to stop and no confirmatory conclusions can be based on outcomes at or after the outcome whose null hypothesis was the first that was not rejected.

The average SOMS level is calculated using the achieved mobility scores recorded daily during each participant's ICU stay. Trend tests will be used to assess the association between average ICU stay and other outcomes over levels of SOMS. For the key secondary outcomes, time-dependent survival analysis will be employed to assess relationships between the duration of admission and SOMS, with ventilator free and the like to be considered as time-dependent covariates. Statistical significance will be evaluated at α=0.05. All analyses will be conducted by a statistician blinded to the intervention.

Data collection

Baseline descriptive data collection will occur on the day of enrolment and include age, gender, race, ethnicity, height, weight, best preadmission SOMS, admission diagnosis, pre-existing comorbidities (diabetes mellitus, coronary artery disease, asthma, peripheral vascular disease, renal failure, psychiatric disease, musculoskeletal disease or other) and admitting surgical team.

Clinical data will be collected daily during the surgical ICU admission, including highest blood glucose level, highest sodium concentration, model Richmond Agitation Sedation Scale, Confusion Assessment Method for ICU and greatest pain score (1–10). Total daily dose will be collected for specific participant medications: neuromuscular blocking agents, narcotics, sedatives, antipsychotics, intravenous vasopressors and glucocorticoids. Physical therapy visits will be recorded. Discharge readiness is defined as the time when surgical ICU team requests a non-ICU room for the participant. Data will be uploaded to a secure database (REDCap). Data stored on REDCap are coded without protected information.

Safety guidelines for mobilisation

Oxygen saturation, ECG, blood pressure and heart rate will be monitored throughout the study as indicated by clinical staff. The healthcare provider will be responsible for determining whether the study intervention should be stopped in each participant. In the situation of severe and/or persistent hypoventilation, or when blood pressure or heart rate changes substantially to a threshold defined during morning rounds by the surgical ICU care team, mobilisation therapy will be terminated. Additionally, the SOMS algorithm has been designed by a multidisciplinary team to ensure the safety of the participant. Participants are not to be advanced to greater mobilisation levels unless they fulfil specific safety-focused criteria (figure 2).

Adverse events

Adverse events will be recorded daily. Nursing charts and documentation, as well as physicians' notes will be reviewed daily to identify potential adverse events.

All adverse events will be recorded and are defined as any unfavourable and unintended signs, symptom or disease chronologically associated with mobilisation therapy. The relationship of any adverse event to mobilisation therapy will be assessed by the investigator and qualified by association (not related, unlikely, possibly, probably or definitely related) and intensity of the effect (mild, moderate or severe). All adverse events will be summarised by the treatment group and reported to DSMB at the time of review.

Adverse events will be monitored daily, and, when appropriate, reported to the local human research committee. Severe adverse events include fall to knees, endotracheal tube removal and oxygen desaturation to less than 80%.[3] Severe adverse events related to arterial blood pressure will be defined individually by the clinical team since this condition is greatly dependent on pathology, treatment and the overall clinical milieu.

Role of DSMB

DSMB has been created and comprises physicians with relevant critical care and medical experience. The members are not involved in the study and will be completely independent of any study-related patient recruitment and data collection. One interim review focused on safety data will be completed when data are available at 3-month follow-up on 100 participants.

ETHICS AND DISSEMINATION

Consent

As this is an international trial, the process of informed consent may be different between sites and will be dependent on cultural and national standards.[35] For the majority of participants in our study written consent will be provided by a healthcare proxy. Informed consent will be obtained from each potential participant's healthcare proxy by study staff. The study staff receiving the consent will give a copy of the IRB approved informed consent form to the healthcare proxy and/or potential participant. The healthcare proxy and/or potential participant will have adequate time to read the informed consent form, evaluate the risks of the study, consult with any family members or clinicians requested and ask questions to the study staff. If the healthcare proxy and/or patient decides to participate then the informed consent form will be signed. Participants will be informed of their participation in the study following resolution of their critical illness and any residual delirium.

Ancillary studies

The SOMS trial will be conducted in the USA and in Europe. A validation trial of the SOMS has been conducted in English in the USA.[25] Additional validation

studies of the Italian and German SOMS translations in Italy and Germany, respectively, are planned. This study lends itself to a qualitative assessment of culture change in the surgical ICU from a unit with predominantly immobilised patients to one with a focus on early mobilisation. We have the opportunity to assess the manner in which patients are mobilised internationally and discuss and share any best practices that are identified.

Alongside of our primary trial, participants will be able to opt in to a related, hypothesis-generating exploratory genetic study. We anticipate wide variability in the effectiveness of early mobilisation and speculate that some of the variability are related to circadian dysregulation. In ICU patients, decreased total sleep time, decreased deep (restorative) sleep, fragmented sleep as well as altered circadian patterns have been reported.[36 37] Other preliminary data suggest that treatments to improve circadian disruption such as intermittent light therapy may facilitate early ambulation in critically ill patients.[38] We also believe some of the variability in the effectiveness of early mobilisation is related to inherent qualities of the muscles. Therefore, with an exploratory intention, we will evaluate whether the existence of single-nucleotide polymorphisms in genes associated with sleep, circadian rhythm and muscle function explain some variance in the effectiveness of early mobilisation in ICU patients (figure 3).

We will conduct genetic tests to find associations between known polymorphisms related to sleep quality, circadian rhythm and muscle homoeostasis, and muscle strength, mobility and surgical ICU outcomes. Specifically, we will focus on polymorphisms in CLOCK,[39] NPAS2,[40] PER2,[41] PER3,[42] PDE4D,[43] MUC1,[44] ATP2B1,[44 45] DCDC5,[44] TRPM6,[44] SHROOM3[44 46] and MDS1[44] genes, which are associated with sleepiness, sleep phase and potentially respiratory muscle weakness. If consent is received for the genetic study, blood is drawn and stored prior to transport to the Center for Human Genetic Research at Massachusetts General Hospital where blood samples will be processed and genetic analysis performed. All laboratory specimens will be stored with a coded identification to maintain privacy.

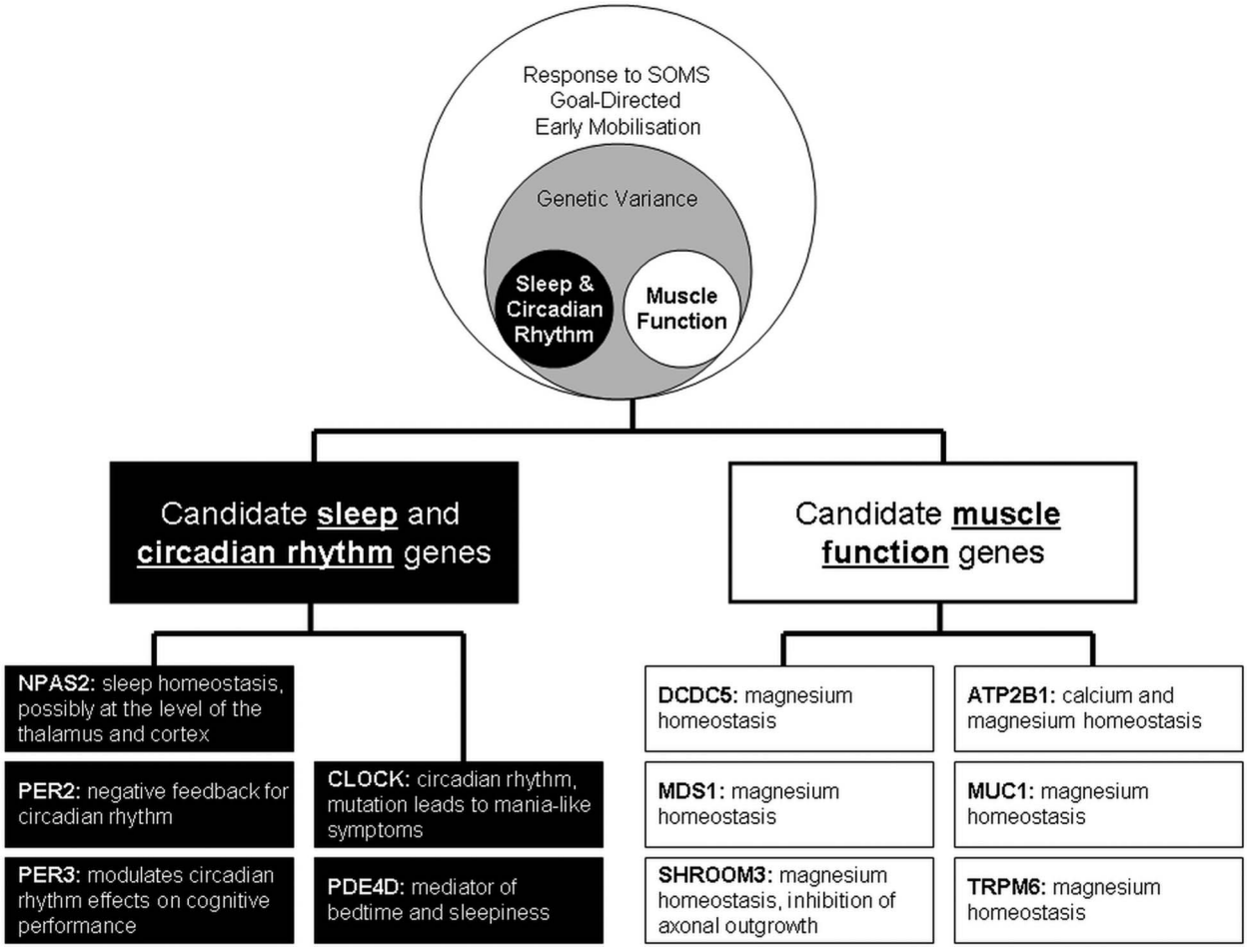


Figure 3 An ancillary study to explore genetic mechanisms contributing to the effectiveness of early mobilisation in the surgical intensive care unit (ICU). We target a subset of genes linked to either sleep and circadian rhythm or muscle function. These candidate genes are part of a greater set of genes and polymorphisms that may be responsible for some of the variance of response to goal-directed early mobilisation. Genetic tests will be performed as an ancillary study linked to the Surgical ICU Optimal Mobilisation Score (SOMS) protocol.

Publication and dissemination

The results of this study along with those of ancillary studies will be publicised in the form of presentations at national and international meetings. The complete study and conclusions regarding the primary objectives will be presented in manuscript form.

DISCUSSION

This article presents the protocol and data analysis plan for the SOMS trial; an international, multicentre, randomised controlled clinical study evaluating SOMS-guided goal-directed early mobilisation and its capacity to improve patient mobilisation, reduce surgical ICU LOS and improve other surgical ICU outcomes. Research associated with mobilisation in the medical ICU is robust and the associations with improved clinical outcomes strong.[1–3] We believe that the SOMS algorithm will help surgical ICU clinicians avoid many of the risks of immobilisation, including atrophy and decreased contractile function of skeletal muscles[5 47] and the diaphragm,[48] motor and sensory neuropathy[49] and persistent functional deficits[10 11] likely due to ICU acquired weakness,[6 7] We also believe the structure of the SOMS algorithm will help surgical ICU clinicians minimise the hazards of mobilising patients: dislodgement of medical devices, mechanical trauma, haemodynamic instability[24] or hypoxia secondary to respiratory failure[50] (figure 4).

The strength of the SOMS trial comes from three fundamental characteristics embedded in the design: (1) simplicity, (2) clinical team focus and (3) utilisation of resources already available. SOMS-guided goal-directed early mobilisation is straightforward, progressive and intuitive. It was created with input from the fields of nursing, physical therapy, physiatry and critical care to ensure safety and function. It is written in clinically precise and mutually comprehensible language. The process of setting a mobilisation goal should add minimal time to morning rounds. The role of the SOMS facilitator to assist in goal setting and assess the participant's progress will require a few minutes spread throughout the day. The results of this study will be generalisable to the broader clinical community such that the study finding will be externally valid and should guide clinical standards for early mobilisation, or 'prehabilitation,' in the surgical ICU.

The SOMS algorithm allows nurses to readily contribute to goal setting on rounds and it provides structure for the nurses to mobilise the participants. The act of delivering the intervention, mobilising participants from the bed to sitting and so forth, takes time. While we believe the SOMS algorithm makes efficient use of existing resources, we acknowledge that shifting resources towards mobilisation may be associated with opportunity costs under certain circumstances.

SOMS is a thoughtful and uncomplicated intervention. However, owing to the nature of the research, there are notable limitations. One limitation in the study is the inability to blind the assessor of a participant's achieved SOMS. For study participants, the achieved SOMS is obtained daily from the participant's nurse who is unblinded and part of the intervention. The achieved SOMS is checked against the nursing documentation. For control participants, the achieved SOMS is obtained by the clinical SOMS facilitator during regular afternoon rounds. The numbers obtained by the nurses and the SOMS facilitator are again checked against the nursing chart.

A second limitation is that we do not add any additional personnel resources to accomplish the daily SOMS goal and this is an environment which occasionally has difficulty meeting its current mobilisation goals.[51] We believe the SOMS algorithm for goal-directed early mobilisation is complementary to the philosophy of nursing and will be fluidly incorporated into their systems with limited effect on their workload. Foremost, the SOMS algorithm should improve mobility-related communication between providers, and thus lead to more frequent mobilsation of patients and a change in mobilisation culture in the surgical ICU. However, there is the possibility that this budget-neutral intervention may not improve mobilisation adequately to draw conclusions, and a dedicated mobilisation specialist

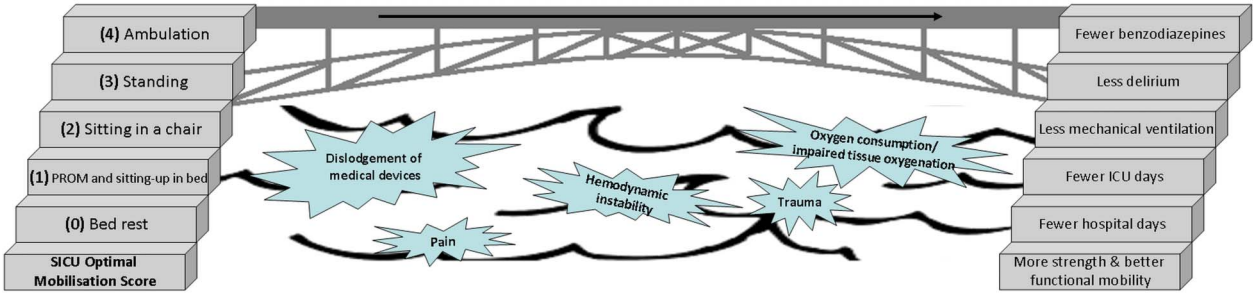


Figure 4 Potential benefits and adverse effects of SOMS-guided early mobilisation. The SOMS algorithm is designed to carefully and incrementally advance mobilisation. On the basis of the knowledge gathered in the medical ICU, early mobilisation leads to improved clinical outcomes such as fewer days in the ICU and better functional mobility at discharge. However, while using the bridge of goal-directed early mobilisation, possible complications and side effects of mobilisation must be considered like pain and increased oxygen consumption. ICU, intensive care unit; PROM, passive range of motion; SICU, surgical intensive care unit; SOMS, Surgical ICU Optimal Mobilisation Score.

or team, as applied in other medical ICU studies,[1–3] may be necessary.

The adoption of patient mobilisation into the surgical ICU prompts a third limitation: culture shift from immobilised patients[52] to mobilised patients. As nurses gain more experience mobilising critically ill patients due to their patients' participation in our study, they will become more comfortable applying this same concept to all of their patients: intervention, control and other. Consequently, we expect mobilisation in the standard of care group to increase with time, which may lead to a type II error. The multicentric trial design with a high sample size utilising individual randomisation may help minimise contamination.[53]

Furthermore, throughout the world and even in the most affluent nations, mobilising patients in the surgical ICU is performed by a variety of different healthcare providers with different training backgrounds[24]: nurses, nursing assistants, students, respiratory therapists, physical therapists and physicians of different specialties. Additionally, the availability of resources, both assistive equipment[52] and personnel, differs between a tertiary care hospital in Europe and in the USA. Accordingly, a specific algorithm with decision points explicitly requiring 'yes' and 'no' answers to advance, stall or regress the mobilisation goal must accommodate cultural, linguistic and resource-based variation. Therefore, our goal-directed early mobilisation algorithm will be identical across all centres relative to the stages of mobilisation and the focus on promoting early and clinically appropriate mobilisation, but the algorithm will have minor, local adaptations.

Finally, in consideration of the minor effect that genetic differences in sleep, circadian rhythm and muscle homoeostasis may have on variance in surgical ICU outcomes, our study may be underpowered to identify genetic influence on surgical ICU outcomes.

CONCLUSION

This manuscript provides a description of our study protocol and analysis plans for the SOMS multicentre randomised control trial. Beyond evaluating the effects of goal-directed early mobilisation on clinical outcomes and patient mobility, this study is designed to maximise the efficiency of existing resources without requiring any new personnel or funding. Furthermore, the design of this study lends itself to ancillary studies related to the cultural issues associated with mobilisation of surgical ICU patients. This trial is an opportunity to use goal-directed early mobilisation to improve surgical ICU clinical outcomes safely without adding to the hospital expenses.

Author affiliations
[1]Department of Anesthesia, Critical Care, and Pain Medicine, Massachusetts General Hospital and Harvard Medical School, Boston, Massachusetts, USA
[2]Department of Surgery, Trauma, Emergency Surgery, Surgical Critical Care, Massachusetts General Hospital and Harvard Medical School, Boston, Massachusetts, USA
[3]Department of Physical and Occupational Therapy, Massachusetts General Hospital, Boston, Massachusetts, USA
[4]Department of Clinical Nursing Services, Massachusetts General Hospital, Boston, Massachusetts, USA
[5]Department of Anesthesia, Intensive Care and Perioperative Medicine, University of Brescia at Spedali Civili, Brescia, Italy
[6]UMass Memorial Medical Center and UMass Medical School, Worcester, Massachusetts, USA
[7]Department of Anesthesia, Critical Care and Pain Medicine, Beth Israel Deaconess Medical Center, Harvard Medical School, Boston, Massachusetts, USA
[8]Klinik für Anaesthesiologie, Klinikum rechts der Isar der Technischen Universität München, Munich, Germany
[9]Universitaet Duisburg-Essen, Germany

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