Supplemental Appendix

Evaluating optimal rehabilitation strategies in ICU: study protocol for a multicentre cohort study to assess physical activity dosing, muscle mass, and physical outcomes (IPAMICS study)

Yasunari Morita, MD[1, 17], Shinichi Watanabe, PT, PhD[2, 17], Nobuto Nakanishi, MD, PhD[3], Akihito Tampo, MD, PhD[4], Kenzo Ishii, MD, PhD[5], Keisuke Suzuki, PT, PhD[2], Yoshie Hirota, PT, MA[6], Yuji Naito, PT[7], Naoya Sato, PT[8], Hiroyoshi Yano, PT[8,9], Tomohiro Yoshikawa, PT, MA[10], Atsushi Ishihara, PT, PhD[11], Hiroyasu Inoue, PT, PhD[12], Keibun Liu, MD, PhD[13], Shigeru Koba, MD[14], Kasumi Satoh, MD, PhD[15], Kensuke Nakamura, MD, PhD[16, 17]

1) Department of Emergency and Intensive Care Medicine, National Hospital Organization, Nagoya Medical Center, 4-1-1 Sannomaru, Naka-ku, Nagoya, Aichi, 460-0001, Japan.
2) Department of Physical Therapy, Faculty of Rehabilitation, Gifu University of Health science, 2-92 Higashiuzura, Gifu, 500-8281, Japan.
3) Department of Disaster and Emergency Medicine, Graduate School of Medicine, Kobe University, 7-5-2 Kusunoki-tyo, Chuo-ku, Kobe, Hyogo, 650-0017, Japan.
4) Department of Emergency Medicine, Asahikawa Medical University, 1-1-65, Kinboshi-tyo, Asahikawa, Hokkaido, 070-8610, Japan.
5) Department of Anesthesiology, Intensive Care Unit, Fukuyama City Hospital, 5-23-1, Zaou-tyo, Fukuyama, Hiroshima, 721-0971, Japan.
6) Department of Rehabilitation, National Hospital Organization, Beppu Medical Center, 1473 Uchikamado, Beppu, Oita, 874-0011, Japan.
7) Department of Rehabilitation, National Hospital Organization, Shizuoka Medical Center, 762-1 Nagasawa, Shimizu-tyo, Suntogun, Shizuoka, 411-0905, Japan
8) Department of Rehabilitation, National Hospital Organization, Saitama Hospital, 2-1 Suwa, Wako, Saitama, 351-0102, Japan.
9) Department of Rehabilitation, National Hospital Organization, Mito Medical Center, 280 Sakuranosato, Ibaraki-tyo, Higashiibaraki, Ibaraki, 311-3193, Japan
10) Department of Rehabilitation Medicine, National Hospital Organization, Hokkaido Medical Center, 7-1-1, Yamanote, Nishi-ku, Hokkaido, 063-0005, Japan.
11) Respiratory Support Center, Gifu Prefectural General Medical Center, 4-6-1 Noisshiki, Gifu, 500-8717, Japan.
12) Devision of Physical Therapy Course, Department of Rehabilitation, Showa University School of Nursing and Rehabilitation, 1865 Tokaichiba-tyo, Midori-ku, Yokohama, Kanagawa, 226-8555, Japan.
13) Non-Profit Organization ICU Collaboration Network (ICON), 2-15-13 Hongo, Bunkyo-Ku, Tokyo, 113-0033, Japan.
14) Department of General Internal Medicine, Nerima Hikarigaoka Hospital, 2-5-1, Hikarigaoka Nerima-ku, Tokyo, 179-0072, Japan.
15) Department of Emergency and Critical Care Medicine, Akita University Graduate School of Medicine, 1-1-1 Hondou, Akita City 010-8543 Akita, Japan.

16) Department of Critical Care Medicine, Yokohama City University Hospital, 3-9 Hukuura, Kanazawa-ku, Yokohama, Kanagawa 236-0004, Japan.
17) The committee for the IPAMICS Study Group

*Corresponding author
Correspondence to Dr. Kensuke Nakamura, MD, PhD
Address: 3-9 Hukuura, Kanazawa-ku, Yokohama, Kanagawa 236-0004, Japan
Email: mamashockpapashock@yahoo.co.jp
Tel. 045-787-29

Contents

1. SPIRIT Checklist for *Trials*

Complete this checklist by entering the page and line numbers where each of the items listed below can be found in your manuscript.
Your manuscript may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please state "n/a" and provide a short explanation. **Leaving an item blank or stating "n/a" without an explanation will lead to your manuscript being returned before review.**
Upload your completed checklist as an additional file when you submit to *Trials*. You must reference this additional file in the main text of your protocol submission. The completed SPIRIT figure must be included within the main body of the protocol text and can be downloaded here: http://www.spirit-statement.org/schedule-of-enrolment-interventions-and-assessments/
In your methods section, please state that you used the SPIRIT reporting guidelines, and cite them as:
Chan A-W, Tetzlaff JM, Gøtzsche PC, Altman DG, Mann H, Berlin J, Dickersin K, Hróbjartsson A, Schulz KF, Parulekar WR, Krleža-Jerić K, Laupacis A, Moher D. SPIRIT 2013 Explanation and Elaboration: Guidance for protocols of clinical trials. BMJ. 2013;346:e7586

		Reporting Item	Page and Line Number	Reason if not applicable
Administrative information				
Title	#1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	P1. L2-3	
Trial registration	#2a	Trial identifier and registry name. If not yet registered, name of intended registry	P1. L2-3	
Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	P5. L84	
Protocol version	#3	Date and version identifier	P8. L143	
Funding	#4	Sources and types of financial, material, and other support	P19. L330	
Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	Cover letter	

Roles and responsibilities: sponsor contact information	#5b	Name and contact information for the trial sponsor	P2. L21	
Roles and responsibilities: sponsor and funder	#5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	P3. L57	
Roles and responsibilities: committees	#5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	P3. L53	
Introduction				
Background and rationale	#6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	P7. L118	
Background and rationale: choice of comparators	#6b	Explanation for choice of comparators	n/a	Because of this study design
Objectives	#7	Specific objectives or	P7. L127	

		hypotheses		
Trial design	#8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory)	P8. L135	
Methods: Participants, interventions, and outcomes				
Study setting	#9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	P9. L165 Supplemental file 2	
Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	P11. L185	
Interventions: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	n/a	Because of this study design
Interventions: modifications	#11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving / worsening disease)	n/a	Because of this study design

Interventions: adherance	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	n/a	Because of this study design
Interventions: concomitant care	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	n/a	Because of this study design
Outcomes	#12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	P12. L209	
Participant timeline	#13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	P10. L171, Fig. 2.	
Sample size	#14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions	P19. L330	

		supporting any sample size calculations		
Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	P19. L333	
Methods: Assignment of interventions (for controlled trials)				
Allocation: sequence generation	#16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	n/a	Because of this study design
Allocation concealment mechanism	#16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	n/a	Because of this study design
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	n/a	Because of this study design
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data	n/a	Because of this study design

		analysts), and how		
Blinding (masking): emergency unblinding	#17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	n/a	Because of this study design
Methods: Data collection, management, and analysis				
Data collection plan	#18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	P17. L293	
Data collection plan: retention	#18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	P17. L291	
Data management	#19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data	P17. L293	

		values). Reference to where details of data management procedures can be found, if not in the protocol		
Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	P20. L344	
Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	P20. L345	
Statistics: analysis population and missing data	#20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	P16. L287	
Methods: Monitoring				
Data monitoring: formal committee	#21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	P17. L293	
Data monitoring: interim analysis	#21b	Description of any interim analyses and stopping guidelines, including who will have access to these	P17. L295	

		interim results and make the final decision to terminate the trial		
Harms	#22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	P15. L266	
Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	n/a	Because of this study design, auditing is not necessary.
Ethics and dissemination				
Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	P8. L144	
Protocol amendments	#25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC / IRBs, trial participants, trial registries, journals, regulators)	n/a	Because of this study design, auditing is not necessary.
Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	P9. L148	
Consent or assent: ancillary	#26b	Additional consent provisions for collection and use of	P12. L209	

studies		participant data and biological specimens in ancillary studies, if applicable		
Confidentiality	#27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	P16. L278	
Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	Cover letter	
Data access	#29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	P17. L297	
Ancillary and post trial care	#30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	n/a	Because of this study design
Dissemination policy: trial results	#31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	P17. L302	
Dissemination policy:	#31b	Authorship eligibility guidelines and any	P17. L297	

authorship		intended use of professional writers		
Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	P17. L307	
Appendixes				
Informed consent materials	#32	Model consent form and other related documentation given to participants and authorised surrogates	n/a	Of course, there is. If it is needed, I will submit.
Biological specimens	#33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	P12. L209	

Additional file 1. SPIRIT Checklist for Trials

It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license. This checklist can be completed online using https://www.goodreports.org/, a tool made by the EQUATOR Network in collaboration with Penelope.ai

2. Participating ICUs and the patients

Information	The participating ICUs (n =)
Type of hospital, n (%)	
Tertiary care hospital	15 (65)
Secondary care hospital	8 (35)
Type of ICU, n (%)	
Mixed medical-surgical ICU	23 (100)

System of ICU, n (%)	
Closed ICU: intensivists have the primary responsibility of treatment to the patients	4 (17)
Mandatory consultant to intensivists at all ICU admission	11 (48)
Elective: ICU physician is mainly involved as a consultant	8 (35)
The presence of dedicated physiotherapist	
Staffing ratio, mean (SD)	
Physician to patients	0.4 (0.3)
Nurse to patients	3.8 (1.3)

Additional file 2. The background information of the participating ICUs and the patients

The data in this table are number (percentage), mean (SD).
ICU = Intensive care unit; SD = Standard deviation

3. Terms definitions

1) End-of-life: In clinical medicine, the ‘end of life’ can be thought of as the period preceding an individual's natural death from a process that is unlikely to be arrested by medical care, and in terms of insurance, the ‘end of life’ has been operationalized to represent the last 6 months of a patient's life.

2) Terminal care cases: A condition caused by injury, disease, or illness , which includes irreversible coma and/or a persistent vegetative state. Without artificial life-prolonging procedures, will lead to natural death or a persons whose physicians attest that the patient has ‘a terminal illness with a life expectancy of six months or less.'

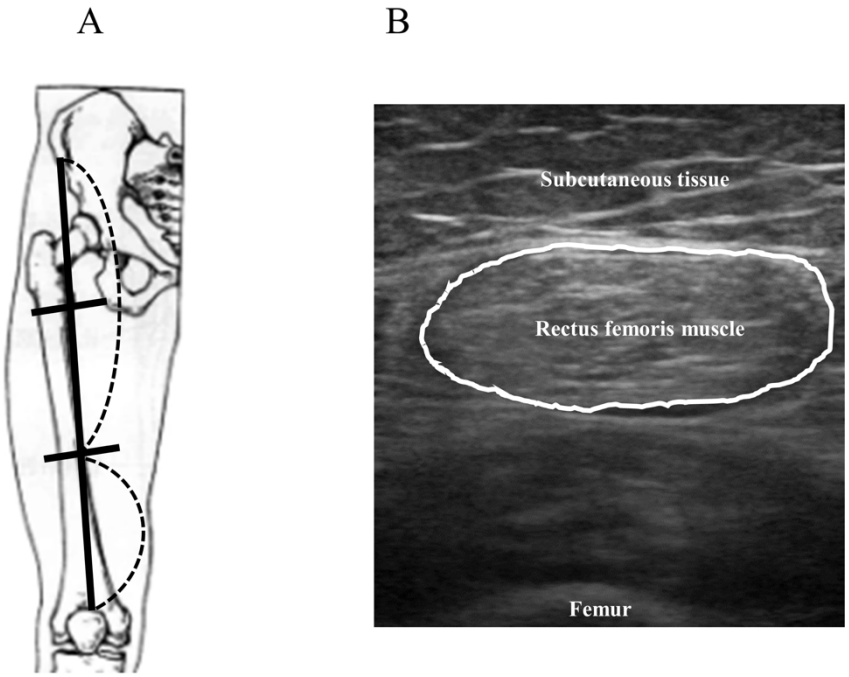
Additional file 3. Terms definitions

4. Ultrasonography assessment

We will use a linear transducer in B-mode. The ultrasound devices are not uniform because differences in the devices will not affect the measurement data. The measurements will be performed with knees extended in the supine position. The bed angle will be adjusted to a flat position because the measurements of the rectus femoris cross-sectional area increase with increasing bed angles. Most often, we will evaluate the right side of the thigh, unless it is paralyzed. Measurements will be conducted distal 2/3 point between the anterior superior iliac spine and proximal end of the patella. For consistency, the measurement location will be marked and used for subsequent measurements. We will evaluate the cross-sectional area and muscle thickness of the rectus femoris muscle by outlining the muscle area shown in the transverse plane (Additional file 4.). When ultrasonography cannot capture the muscle in one image, the image will be divided into two parts by identifying the intramuscular tendon or another landmark, and measurements will be combined. Generous amounts of contact gel will be applied to avoid muscle compression by the transducer. To avoid measurement errors, the transducer will be placed perpendicular to the long axes of the limbs. The measurement will be conducted three times, and the median value will be used for the evaluation.

Before the study, measurement reproducibility will be secured by confirming a 3% intra- or inter-observation differences in each facility. We also intend to perform diaphragmatic ultrasonography as part of the ICU-AW assessments, but only at experienced facilities, as this is a slightly difficult technique for inexperienced facilities.

5. Figure of ultrasonography measurement site and cross-sectional area



Additional file 5. Figure of ultrasonography measurement site and cross-sectional area

A. Rectus femoris muscle mass is measured at midway between the anterior superior iliac spine and the proximal end of the patella.

B. Image of rectus femoris cross-sectional area.

6. Early Mobilization Protocol

Level 1 Respiratory RASS−5 ～ −3	**Level 2 HOB** RASS ≥ −3	**Level 3 Sitting** RASS ≥ −1	**Level 4 Standing** RASS ≥ 0	**Level 5 Walking** RASS ≥ 0
Physical therapy Passive ROM exercise Respiratory physical therapy	**Physical therapy** Positioning Passive ROM exercise Active ROM exercise Respiratory physical therapy continuous lateral rotation therapy	**Physical therapy** Positioning Passive ROM exercise Active ROM exercise Sitting on the edge of bed Rising from the supine position	**Physical therapy** Positioning Passive ROM exercise Active ROM exercise Standing at side of bed Stand and pivot to a chair	**Physical therapy** Positioning Passive ROM exercise Active ROM exercise Walk with assistance Walk independently
Positioning Posture change HOB ≤45 degrees	**Positioning** Posture change HOB ≥60	**Positioning** Posture change HOB ≥60	**Positioning** Posture change HOB ≥60	**Positioning** Posture change HOB ≥60
Step up criterion Oxygenation/ hemodynamic stability Can withstand posture change Can withstand HOB ≤45 degrees	**Step up criterion** Can withstand supplementary motion of physical therapy Can withstand HOB ≤60 degrees Anti-gravity movement possible	**Step up criterion** Can endure the active movement of physical therapy Can withstand HOB ≤60 degrees Can withstand sitting on the edge bed	**Step up criterion** All exercise can be carried out Can withstand partial weight standing	**Step up criterion** Increase walking distance gradually
Step up criterion to level 3 or higher are defined as RASS: -2 to +1, BPS ≤ 3 or NRS ≤ 5, SpO_2 ≥ 90%, FIO_2 < 0.6, PEEP < 10 cmH_2O, respiratory rate: <35 times / min, mean blood pressure ≥				

65 mmHg, heart rate: 50 to 120 times / min, there were no new arrhythmias, no additional administration of vasopressors, no bleeding, no wound with the possibility of separation, no unstable fracture.

Additional file 6. Early Mobilization Protocol

RASS = Richmond agitation sedation scale; ROM = Range of motion; HOB = Head of bed; BPS = Behavioral pain scale; NRS = Numeric rating scale; FIO_2 = Fraction of inspiratory oxygen; PEEP = Positive end-expiratory pressure; EM = Early mobilization.

7. Criteria for physiological stability

Physiological stability variable	Variable range
Medical stability	
Bleeding tendency	May get worse by mobilization
Fever	38.5 or less
Bed rest order	When the attending physician determines that the condition requires rest
Cardiovascular stability	
Heart rate	50-130 beats per minute
Mean arterial blood pressure	65-110 mmHg
Vasoactive medication infusions	No increase in vasoactive medications within 24 hours
Respiratory stability	
Fraction of inspired oxygen	0.6 or less
Respiratory rate	30 breaths per minute or less
Saturations of percutaneous oxygen	90% or greater
Neurological stability	
Richmond Agitation-Sedation Score	-2 to 1
Delirium	M6 (able to follow commands)
Glasgow Coma Scale	M6 (able to follow commands)

Additional file 7. Criteria for physiological stability

8. Adverse events list

1) Cardiovascular event; Cardiac arrest / Tachycardia >150 bpm newly onset / Ventricular tachycardia / Other dangerous arrhythmias / Hypotension that falls by more than 20 mmHg below the original level for 3 min or more persists

2) Respiratory event; Tachypnea > 35/min / Desaturations < 80% for 3 min or more persists

3) Neurological event; Lack of consciousness / Dizziness / Vomit

4) Other event; Falls / Unplanned extubation / Other device removal

Additional file 8. Adverse events list

9. Japanese version of Mobilization quantification score

SOMS	IMS	離床レベル	内 容	単位	計算式 （動きのレベルx単位）	1セッション あたりのMQSスコア
1	0	他動での関節運動	スタッフにより他動的な寝返りや運動は行えるが、能動的な動きはない。（例：他動による床上自転車エルゴメータの使用）	60分＝1単位	1 x 単位	
1	1	ベッド上での自動運動	寝返り、腰上げ（ブリッジ）、自動運動、床上自転車エルゴメータ、自動他動運動など、ベッド上でのあらゆる活動。（ベッドまたは椅子の外へ出たり端座位にはならない）	15分＝1単位	1 x 単位	
2	2	椅子座位	抱きかかえやスライド手技、他動リフトを使っての移乗。または椅子に座っている状態。	30分＝1単位	2 x 単位	
2	3	端座位	スタッフによる介助を含み、ある程度体幹コントロールを伴った能動的な端座位。	5分＝1単位	3 x 単位	
3	4	立位	介助の有無にかかわらず、立位になって体重を足で支えられる。 立位リフト装置、ティルトテーブル、または体重をサポートする歩行トレーニング機器の使用を含む。	5分＝1単位	4 x 単位	
3	5	能動的なステップを伴った移乗動作（すり足を含む）	椅子への移乗時に立位姿勢で足の踏み出しや、すり足が可能。この動作は、椅子へ移動するために、一方の下肢から他方へ体重を能動的に移動させることを含む。患者が医療機器の補助により立っている場合、椅子に向かって足をあげ踏み出せなければならない。（患者が立位介助用リフトを使用し、足を踏み出さずにすり足等で移動した場合を含まない）	5分＝1単位	5 x 単位	
3	6	5m未満の歩行 または足踏み4歩以上	介助の有無にかかわらず、1足を交互に上げることによってその場で足踏みが可能（少なくとも4回、各足2回ずつの足踏みができなければならない）	5分＝1単位	6 x 単位	
4	7	2名以上の介助による 5m以上の歩行	2名以上の介助で、ベッドや椅子から離れて少なくとも5メートル歩く。	5分＝1単位	7 x 単位	
4	8	1名の介助による 5m以上の歩行	1名の介助で、ベッドや椅子から離れて少なくとも5メートル歩く。	5分＝1単位	8 x 単位	
4	9	歩行補助具を使用した 5m以上の自立歩行	人による介助はなく、歩行補助具を用いて、ベッドや椅子から離れて少なくとも5メートル歩く。車椅子患者の場合は、ベッドや椅子から5メートル自力で車椅子を操作して離れられる。	5分＝1単位	9 x 単位	
4	10	歩行補助具なしで 5m以上の自立歩行	人による介助はなく、歩行補助具も用いないで、ベッドや椅子から少なくとも5メートル歩く。	5分＝1単位	10 x 単位	
					トータルスコア	

Additional file 9. Japanese version of Mobilization quantification score

SOMS = Surgical ICU Optimal Mobilization Score; IMS = ICU mobility scale

10. Collaborators

IPAMICS STUDY COMMITTEE INFORMATION

Office address: National Hospital Organization Nagoya Medical Center, 4-1-1, Sannomaru, Naka-ku Nagoya-Shi, Aichi-ken, Japan 460-0001

Office TEL: +81- 052-951-1111

Office members: Yasunari Morita, Mika Ono, Shinichi Watanabe

ELECTRICAL DATA CAPTURE CREATION-

DATA SECURITY, REVISION AND MANAGEMENT:

Tomohiro Sonoo: Hitachi General Hospital, Hitachi, Ibaraki, Japan, TXP Medical Co. Ltd., Tokyo, Japan,

Shoko Hayashi: TXP Medical Co. Ltd., Tokyo

10. List of Collaborators

HOSPITAL/FACILITIES	COLLABORATORS
National Hospital Organization Nagoya Medical Center	Mika Ono, Ns, MS Keisuke Mizutani, PT Takumi Iwasaki, ST
Showa University School of Medicine	Toru Kotani, MD Yumi Igarashi, MD

	Fumihito Kasai, MD, PhD Naonori Tashiro, PT, PhD
Yokohama City University Hospital	Takuya Saeki, PT, MS Mei Yamamura, PT Hideyuki Oritsu, PT, MS
Akita University Graduate School of Medicine	Kazuki Okura, PT, PhD
Hitachi General Hospital	Takahiro Fujita, PT Naho Watanabe, PT
National Hospital Organization Beppu Medical Center	Akinobu Takeshita, PT Hayato Sato, PT Kenichi Maeda, PT Takuro Toyoda, PT
National Hospital Organization Hokkaido Medical Center	Daigo Kato, PT Wataru Yamamoto, PT Hiroaki Yasue, PT Ryota Ogata, PT Taichi Takeuchi, PT Yuki Omata, PT

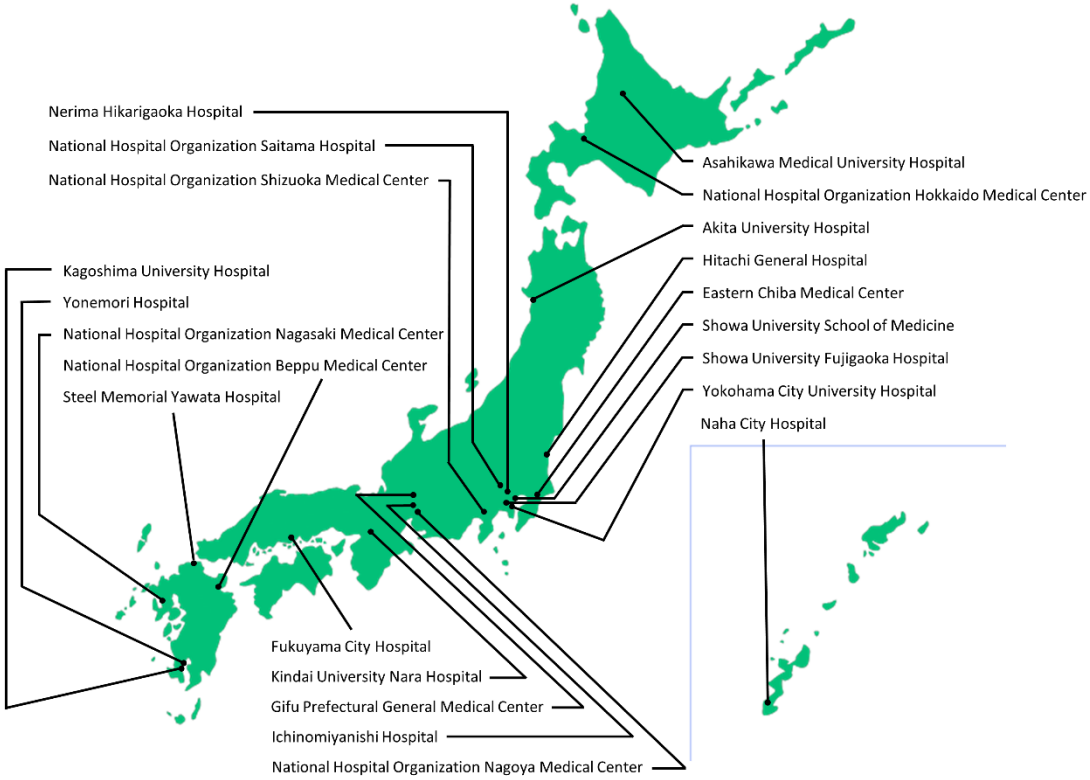
National Hospital Organization Shizuoka Medical Center	Yuji Mori, PT Naoki Takeshita, PT Fumiaki Senzaki, PT Kazuya Kito, PT Kazuki Ogawa, PT
National Hospital Organization Saitama Hospital	Ichiro Hirayama, MD
National Hospital Organization Nagasaki Medical Center	Ryuji Yoshinaga, PT
Fukuyama City Hospital	Masaru Takenoue, Ns Norimasa Inohara, Ns Kazuki Fujii, PT
Yonemori Hospital	Naoki Sugiyasu, PT Takuya Higashiseto, PT
Steel Memorial Yawata Hospital	Kota Yamauchi, PT Kei Goto, PT Shota Tanaka, PT
Kindai university Nara Hospital	Tomoya Nanba, PT Shiroyama Jun, PT

Nerima Hikarigaoka Hospital	Shigeru Koba, MD
Showa University Fujigaoka Hospital	Kazuki Komaba, OT
Kagoshima University Hospital	Tsubasa Yoshinaga, PT Takeshi Nojima, PT Tomohiro Uema, PT Hiroshi Michiyama, PT
Naha City Hospital	Daisetsu Yasumura, PT, MHA Yuuichi Miyagi, PT Takuya Tonaki, PT Shinya Kawabata, PT Hiroyuki Touyama, PT Taisuke Kamiya, PT Mituru Kume, PT
Ichinomiyanishi Hospital	Shohei Kawabata, PT Kenji Tsujimoto, PT
Division of Rehabilitation Medicine, Eastern Chiba Medical Center	Yusuke Maetani, PT, MS
Japanese Society for Early Mobilization	Hajime Katsukawa, PT, PhD Tomoya Kuroda, PT

Department of Scientific Research	

Additional file 10. List of Collaborators

11. Map of participating facilities



Additional file 11. Map of participating facilities

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