Plan Overview

A Data Management Plan created using DMPonline.be

Title: Addressing ICU-Acquired Weakness Head-On: An Individualized and Holistic Early Mobilization Approach

Creator: Marine Van Hollebeke

Principal Investigator: n.n.

Data Manager: Marine Van Hollebeke

Affiliation: KU Leuven (KUL)

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Template: KU Leuven BOF-IOF

Principal Investigator: n.n. n.n.

Data Manager: Marine Van Hollebeke

Project abstract:

ICU-acquired weakness (ICU-AW), a syndrome causing rapid-onset limb muscle weakness, persists long after ICU discharge, with detrimental effects on clinical and patient-reported outcomes (PROMs). To counteract this, interventions should ideally begin before ICU-AW develops. While early Mobilization (EM) can mitigate ICU-AW, optimal exercise type, intensity, and motivational support remain unclear. Understanding how EM impacts skeletal muscles (i.e., wasting, structural alterations), is essential for developing effective interventions that improve strength, physical function and PROMs. My aim is to preserve muscle function, reduce ICU-AW incidence and improve short and longer-term outcomes through innovative individualized EM strategies tailored to exercise capacity and cooperation, with virtual reality (VR) as a motivational tool. The novel methods include functional electrostimulation cycling for uncooperative patients, individualized interval cycling for cooperative patients and a VRapp to boost motivation. The novel serial quadriceps assessment pre- and post-EM include microbiopsies for muscle structure (histology) and gene expression, non-volitional strength, muscle activation (electromyography) and muscle metabolism (near-infrared spectroscopy), together with short- and longer-term clinical outcomes and PROMs. This comprehensive approach intends to alleviate the burden of ICU-AW and propel patients forward in their post-ICU rehabilitation.

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Addressing ICU-Acquired Weakness Head-On: An Individualized and Holistic Early Mobilization Approach

Research Data Summary

List and describe all datasets or research materials that you plan to generate/collect or reuse during your research project. For each dataset or data type (observational, experimental etc.), provide a short name & description (sufficient for yourself to know what data it is about), indicate whether the data are newly generated/collected or reused, digital or physical, also indicate the type of the data (the kind of content), its technical format (file extension), and an estimate of the upper limit of the volume of the data.

Dataset name / ID	Description	New or reuse	Digital or Physical data	Data Type	File format	Data volume	Physical volume
		Indicate: ***N****(ew data) or* ***E****(xisting data)*	Indicate: **D**(igital) or **P**(hysical)	Indicate: **A**udiovisual **I**mages **S**ound **N**umerical **T**extual **M**odel **SO**ftware **O**ther (specify)		Indicate: <1GB <100GB <1TB <5TB >5TB NA	
Baseline characteristics	Demographics to charatcerize the included patients	N	D	N	.csv .R	<1GB	
Physiological data	Cycling data and oxygenation and electromyograpy data of quadriceps muscle	N	D	N	.csv .R	<100GB	
Medical data	Central hemodynamic, respiratory parameters, blood gas values	N	P	N	.csv .R	<1GB	paper
Patient-reported outcomes	Symptoms scores	N	P	N	.csv	<1GB	paper

If you reuse existing data, please specify the source, preferably by using a persistent identifier (e.g. DOI, Handle, URL etc.) per dataset or data type:

NA

Are there any ethical issues concerning the creation and/or use of the data (e.g. experiments on humans or animals, dual use)? If so, refer to specific datasets or data types when appropriate and provide the relevant ethical approval number.

- Yes, human subject data (Provide SMEC or EC approval number below)

All datasets are related to experiments on humans.
EC approval: S65934

Will you process personal data? If so, please refer to specific datasets or data types when appropriate and provide the KU Leuven or UZ Leuven privacy register number (G or S number).

- Yes (Provide PRET G-number or EC S-number below)

Baseline characteristics.

EC approval: S65934

Does your work have potential for commercial valorization (e.g. tech transfer, for example spin-offs, commercial exploitation, …)? If so, please comment per dataset or data type where appropriate.

- No

Do existing 3rd party agreements restrict exploitation or dissemination of the data you (re)use (e.g. Material or Data transfer agreements, Research collaboration agreements)? If so, please explain in the comment section to what data they relate and what restrictions are in place.

- No

Are there any other legal issues, such as intellectual property rights and ownership, to be managed related to the data you (re)use? If so, please explain in the comment section to what data they relate and which restrictions will be asserted.

- No

Documentation and Metadata

Clearly describe what approach will be followed to capture the accompanying information necessary to keep data understandable and usable, for yourself and others, now and in the future (e.g. in terms of documentation levels and types required, procedures used, Electronic Lab Notebooks, README.txt files, codebook.tsv etc. where this information is recorded).

Documentation on the physiological data that will be collected for this study will be stored with clear indication of the content of the .csv file (studyID_data type_condition_date). Raw files will be saved in a separate file then the processed files and files will be clearly indicated raw or proc for raw data and processed data, respectively. Data will be processed with Rstudio.
The other datasets will be collected in .csv file and notes will be added to this file.
All data will be merged into one dataset in R and analysed with Rstudio.
The Rscript and data needed used for the results reported in the manuscript will be available with publication of the manuscript and only upon request. Data will be fully anonymized. A general Lab notebook will be kept.

Will a metadata standard be used to make it easier to find and reuse the data?
If so, please specify which metadata standard will be used.

If not, please specify which metadata will be created to make the data easier to find and reuse.

- No

FAIRsharing is not applicable for the domain of rehabilitation sciences.

Data Storage & Back-up during the Research Project

Where will the data be stored?

- Large Volume Storage
- OneDrive (KU Leuven)

How will the data be backed up?

- Standard back-up provided by KU Leuven ICTS for my storage solution
- Other (specify below)

Data will be backed-up on the OneDrive of the KU Leuven

Is there currently sufficient storage & backup capacity during the project?

If no or insufficient storage or backup capacities are available, explain how this will be taken care of.

- Yes

How will you ensure that the data are securely stored and not accessed or modified by unauthorized persons?

All datasets will be password protected.
Passwords will only be shared with a strictly needed personnel.
Including researchers responsible for data collection and data analyses.

What are the expected costs for data storage and backup during the research project? How will these costs be covered?

Data will be stored on the L-drive and backed-up on the OneDrive, for which the costs are financed through the department of rehabilitation. No additional costs are therefore foreseen for this specific project.

Data Preservation after the end of the Research Project

Which data will be retained for 10 years (or longer, in agreement with other retention policies that are applicable) after the end of the project?

In case some data cannot be preserved, clearly state the reasons for this (e.g. legal or contractual restrictions, storage/budget issues, institutional policies...).

- All data will be preserved for 10 years according to KU Leuven RDM policy

Where will these data be archived (stored and curated for the long-term)?

- Other (specify below)

Data will be stored on the archive K-drive of the KULeuven

What are the expected costs for data preservation during the expected retention period? How will these costs be covered?

Data will be archived on the K-drive, for which the costs are financed through the department of rehabilitation. No additional costs are therefore foreseen for this specific project.

Data Sharing and Reuse

Will the data (or part of the data) be made available for reuse after/during the project?
Please explain per dataset or data type which data will be made available.

- Yes, as restricted data (upon approval, or institutional access only)

Only data related to the published study results will be made available, making sure all data is fully anonymized.

If access is restricted, please specify who will be able to access the data and under what conditions.

Data will be made available upon request and only with a methodological sound justification.

Are there any factors that restrict or prevent the sharing of (some of) the data (e.g. as defined in an agreement with a 3rd party, legal restrictions)?

Please explain per dataset or data type where appropriate.

- Yes, privacy aspects
- Yes, ethical aspects

Personal data related to the human subjects included in the study may not be shared for GDPR regulation and ethical reasons. Therefore, data access will be restricted to strictly anonymized data.

Where will the data be made available?

If already known, please provide a repository per dataset or data type.

- Other (specify below)

Not yet known.

When will the data be made available?

- Upon publication of research results

Which data usage licenses are you going to provide?

If none, please explain why.

- Data Transfer Agreement (restricted data)

Do you intend to add a persistent identifier (PID) to your dataset(s), e.g. a DOI or accession number? If already available, please provide it here.

- Yes, a PID will be added upon deposit in a data repository

What are the expected costs for data sharing? How will these costs be covered?

No costs are foreseen for data sharing.

Responsibilities

Who will manage data documentation and metadata during the research project?

Dr. Marine Van Hollebeke, postdoctoral researcher on the project.

Who will manage data storage and backup during the research project?

Dr. Marine Van Hollebeke, postdoctoral researcher on the project.

Who will manage data preservation and sharing?

prof. Dr. Daniel Langer, principal investigator of the project

Who will update and implement this DMP?

Dr. Marine Van Hollebeke, postdoctoral researcher on the project.