PDM - Interaction between muscle mechanics and reflex hyperactivity in CP: from animal experiments to model-based diagnosis of joint hyper-resistance.

A Data Management Plan created using DMPonline.be

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Project abstract:

Joint hyper-resistance to movement is a common and disruptive symptom in neurological disorders caused by a lesion to the brain or spinal cord, such as cerebral palsy (CP), stroke, and spinal cord injury. Both alterations in muscle mechanical properties and in neural control, such as hyperactive reflexes, contribute to joint hyper-resistance. Yet, we lack a mechanistic understanding of how alterations in muscle properties affect spindle firing, driving stretch reflexes, in response to stretch.

This hinders our ability to infer the underlying patient-specific causes of hyper-resistance. Limited specificity in diagnosis may lead to suboptimal treatment selection, explaining why the responses to treatment are highly variable. Here, I will develop a mechanistic model of joint hyper-resistance aimed at identifying neural and muscle contributions to joint hyper-resistance. I will first assess how muscle properties affect spindle firing in response to stretch in a spastic and contracture rat model. Next, I will use the experimental data to develop and validate a computer model of joint hyper-resistance. Finally, I will use this computer model to identify individual-specific neural and muscle deficits underlying joint hyper-resistance, and the effects of treatment on these deficits in children with CP. My project will contribute to improved diagnosis of joint hyper-resistance problems and will consequently lead to improved treatment selection for a variety of neurological disorders.

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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 Other (specify)		Indicate: <1GB <100GB <1TB <5TB >5TB NA	
WP1: Rat data	Muscle-tendon morphological properties of the medial gastrocnemius and soleus and the muscle and spindle response to various stretching protocols in spastic, contracture, and healthy rat models. 1) Whole muscle force exerted at the tendon (force transducer) 2) Muscle fascicle length (sonomicrometry) 3) Tendon length (kinematics) 4) Axon potentials of muscle spindles (intra-axon measurements)	N	D	N	.mat .c3d	< 100 GB	0
WP2: Neuromechanical model	Mechanistic muscle model + Muscle spindle model	E (WP1: rat data)	D	M	.mat	< 100 GB	0
WP3: Identification of neural and non-neural deficits	Identification of model parameters describing muscle-tendon properties, background muscle activity and reflex gains 1) Muscle morphology (3D US) • muscle belly length • muscle volume • muscle fiber length • muscle tendon length 2) Knee and joint angle (goniometer) 3) Instrumented spasticity assessment • muscle activity (EMG) • External force (6D force cell) • Kinematics 4) Computational models from WP 2	E + N	D	N	.mat .c3d	< 1TB	0

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:

WP3 - Identification of neural and non-neural deficits
We will use a combination of existing data sets and data that will be collected in the following year(s).The existing data sets contain data from instrumented spasticity assessments as well as muscle morphology (US) pre- and post treatment with BoNT-A (dataset a, UZ Leuven), casting and stretching (dataset b, UZ Leuven), or selective dorsal rhizotomy (SDR) (dataset c & d, UZ Leuven & KU Leuven) in children with spastic cerebral palsy. Data is available through past and ongoing projects of co-promoter prof. Desloovere, (dataset a-c) as well as our own dataset on pre- and post- SDR measurements (dataset d).

Data is not yet published.

The complete dataset (already collected data and data that will be collected in the near future) will be shared using Belnet.

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)
- Yes, animal data (Provide ECD reference number below)

WP1 - Rat data
Rat data will be collected in prof. Maas' lab (VU Amsterdam). Ethical approval of the CCD (Centrale Commissie Dierproeven) is already obtained (AVD11200202114471). Currently, we are applying for ethical approval at the Central Authority for Scientific Procedures in Animals (VU Amsterdam).

WP3 - Identification of neural and non-neural deficits
Ethical approval was already obtained for the collected data and is not yet closed for the ongoing data collections at the Ethical committee of UZ Leuven (S61641, S59945, S56041). We will apply for ethical approval for retrospective use of these data at the Ethical committee of UZ Leuven when we start with WP2. We will inform all participants that their data will be used for more research purposes.

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)

WP3 - Identification of neural and non-neural deficits
Ethical approval was obtained for processing personal data (S61641, S59945, S56041). We will apply for ethical approval for retrospective use of these data at the Ethical committee of UZ Leuven.

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

N/a

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

N/a

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

N/a

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).

WP1- Rat data
We will provide following information:
1. Table of content (excel and csv) with all project related experiments, including experiment number, date of experiment, researcher performing experiment.
2. Description of the goal of the experiment (word and txt)
3. Detailed protocol, which enables other researchers to repeat the experiment
4. All (raw) data
5. Illustrations and statistical analysis of the data (if appropriate)

WP2 - Neuromechanical models
We will provide following information:
1. Github repository with all code (.mat files)
2. Detailed read-me file (txt) to explain the content of the repository, the the goal of the models, and the explanation on how to use the code.

WP3- Identification of neural and non-neural deficits
We will provide following information:
1. Table of content (excel and csv) with all project related experiments, including experiment number, date of experiment, researcher performing experiment.
2. Description of the goal of the experiment (word and txt)
3. Detailed protocol, which enables other researchers to repeat the experiment
4. All (raw) data
5. Illustrations and statistical analysis of the data (if appropriate)

In the case that documentation is written or available in notebooks or stored on other files, a link will be provided. With the help of this documentation every authorized researcher will be able to look up all necessary information of the performed experiments and repeat the experiments in exactly the same way.

All personal data will be pseudo-anonymized. Each subject will be coded with a number. All data collected from or related to this subject will be stored under the same number. The number attributed to the subject depends on the order they are recruited. A key file will link the subject number to the subject name. The key file will be stored in the office of prof. De Groote (supervisor). Only me and prof. De Groote will have access to this key file.

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

Metadata describing the settings and technical descriptions of the experiments and data processing workflows (i.e., filtering, labeling etc.) will be provided as read-me, word, txt, excel, or csv files.

Data Storage & Back-up during the Research Project

Where will the data be stored?

- OneDrive (KU Leuven)
- Large Volume Storage

All data and documentation will be stored on my KU Leuven managed personal laptop (Jente Willaert) in a folder which is synchronized with

the KU Leuven One Drive. We will back-up the data daily to the L-drive (Large Volume Storage) of our research group.

How will the data be backed up?

- Standard back-up provided by KU Leuven ICTS for my storage solution
- Personal back-ups I make (specify below)

Data will be stored on the KU Leuven One Drive environment (automatic back-up) and we will automatically make a daily back up to the L-Drive (automatic back-ups).

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

Currently available:
- 2 TB on KU Leuven One Drive environment
- 2 TB on my KU Leuven managed personal laptop
- 5 TB on shared L-drive

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

All data will be stored in a protected environment. Research data can only be accessed by a login following KU Leuven's policy and with password.
The key file which links the subject number to the subject name will be stored in the key-locked office, in a key-locked closet of prof. De Groote (supervisor). Only me and prof. De Groote will have access to this key file.

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

The currently available capacity is free (L-drive is payed by the department).

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 25 years according to CTC recommendations for clinical trials with medicinal products for human use and for clinical experiments on humans
- All data will be preserved for 10 years according to KU Leuven RDM policy

Data of WP1 and WP2 will be preserved for 10 years according to KU Leuven RDM policy.
Data of WP3 will be preserved for 25 years according to CTC recommendations for clinical experiments on humans.

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

- Large Volume Storage (longterm for large volumes)

Digital data will be archived on the secured KUL L-drive. Hard copies (e.g., informed consent forms) will be stored in locked cabinets in the office of prof. De Groote (supervisor).

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

For this project, data storage of 2 Tb is anticipated. No costs are expected (L-drive is payed by department). In case of limited space availability, we will 'buy' additional space on the L-drive (€ 522.1/5TB/year). Given the expected size of the project of 2TB, costs for long-term storage are estimated at € 522.1/year. The costs will be carried by prof. De Groote.

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)
- Yes, as open data
- Other (specify below)

WP1 - Rat data
All (raw) data will be available upon reasonable request.
WP2 - Neuromechanical model
New developed models and data used for model development will be available on Github. We will create a DOI through RDR (KU Leuven).
WP3 - Identification of neural and non-neural deficits
Since WP3 consists of personal human data, the ethical committee and participants needs to approve data sharing. However, as this concerns secondary use of data, we will refer to originally published datasets.

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

WP3 - Identification of neural and non-neural deficits

This concerns secondary use of data. The original dataset will be published under restricted access, requiring approval by an ethical committee and permission from participants for data sharing. We will refer to these datasets.

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

WP3 - Identification of neural and non-neural deficits
The ethical committee and participants needs to give permission for data sharing.
If permission is obtained, all data will be shared (pseudonymized)

Where will the data be made available?

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

- KU Leuven RDR (Research Data Repository)
- Other data repository (specify below)
- Other (specify below)

WP1 - Rat data
The main output of the project will be original scientific research papers. These will adhere to the KU Leuven Open Access policy. Original processed dataset will be made available with publication either as supplementary files or using a data-sharing platform.
WP2 - Neuromechanical model
The main output of the project will be original scientific research papers. The models will be available with publication either as supplementary files or on Github. We will create a DOI through RDR (KU Leuven).
WP3 - Identification of neural and non-neural deficits
We will refer to the original publications of the datasets.

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.

- CC-BY 4.0 (data)
- Data Transfer Agreement (restricted data)

WP1 - Rat data
CC-BY 4.0 (data) (if agreement with VU Amsterdam)
WP2 - Neuromechanical model
CC-BY 4.0
WP3 - Identification of neural and non-neural deficits
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 expected. If any costs occur, they will be covered by the requesting party.

Responsibilities

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

Jente Willaert will be responsible for data documentation and metadata during the project, under supervision of prof. Friedl De Groote (supervisor).

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

Jente Willaert will be responsible for data storage and back-up during the project, under supervision of prof. Friedl De Groote (supervisor).

Who will manage data preservation and sharing?

Prof. Friedl De Groote (supervisor) will be responsible for data preservation after the end of the project. Jente Willaert will be responsible for data sharing during the project, under supervision of prof. De Groote. Prof. De Groote will be responsible for data sharing after the end of the project.

Who will update and implement this DMP?

Jente Willaert will update and implement this data management plan througout the project, under supervision of prof. Friedl De Groote (supervisor).