Beneficial effects of cannabidiol on muscle recovery, sleep and exercise performance in athletes; beyond the hype.

A Data Management Plan created using DMPonline.be

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Project abstract:

Cannabidiol (CBD) is a non-intoxicating constituent of the cannabis plant that recently gained popularity amongst athletes because of its potential to reduce pain perception and improve muscle recovery and sleep quality. More specifically, CBD is believed to alleviate symptoms of exercise induced muscle damage via its anti-inflammatory and analgesic effects. However, compelling evidence from human intervention studies is lacking and the underlying mechanisms through which CBD exerts these actions remain poorly understood. Additionally, interventional trials concerning the effects of CBD supplementation on sleep quality in athletes are non-existent. The increasing popularity of CBD amongst athletes, in combination with the lack of scientific knowledge about CBD supplementation is alarming. Therefore, the current project aims to study the ergogenic potential of CBD. A first important step in this project is to determine an optimal dose to be used in subsequent work packages. Next, the effect of CBD on muscle recovery after a single bout of resistance training is evaluated as well as the effect of CBD on sleep quality following a late evening exercise training. Lastly, the long-term effects of CBD on muscle recovery, sleep and exercise performance are evaluated during a period of overload training. As such, this project will be amongst the first to critically evaluate the ergogenic potential of CBD creating a scientific background that can be used to properly advise athletes.

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Application DMP

Questionnaire

Describe the datatypes (surveys, sequences, manuscripts, objects …) the research will collect and/or generate and /or (re)use. (use up to 700 characters)

In this project primary, quantitative, experimental data is collected.

Biological samples include human blood samples, urine samples and muscle tissue.

Other personal information includes: name, address, phone number, e-mail, length, weight, medical history (based on medical questionnaire), information on sleep parameters via questionnaires and via polysomnography, dietary information (via food diaries), performance outcomes (muscle strength, jump height and performance during a time trial and isokinetic sprint), subjective muscle soreness (via VAS) muscle and blood analyses, adverse events and overall well-being via questionnaires.

Metadata are generated using metadata standards for microscopy images (OME-XML standard), statistical analyses (metadata of database in SPSS and GraphPad Prism).

Specify in which way the following provisions are in place in order to preserve the data during and at least 5 years after the end of the research? Motivate your answer. (use up to 700 characters)

1. Designation of responsible person (If already designated, please fill in his/her name.)
2. Storage capacity/repository
    - during the research
    - after the research

Professor Katrien Koppo is designated as responsible person (support via our departmental data manager Evelien Nackaerts).

All participant data is collected on a paper CRF (hard copy) and transferred into the eCRF (RedCap). For the purpose of statistical analyses, data from REDCap will be exported to SPSS and .xls format. Once the intervention is finished and all analyses have been performed, all trial data will be exported from REDCap (as .csv files) to a password-protected KU Leuven drive (j-drive), which can only be accessed by registered researchers. Only the PI can request access to the network drive for study personnel.

Any source data documents and hard copy files remain stored in a lock-secured closet at the office of Prof. K. Koppo.

Biological material (-80 or -20°C) will be registered and stored within the regulations of Biobank at UZ/KU Leuven.

What's the reason why you wish to deviate from the principle of preservation of data and of the minimum preservation term of 5 years? (max. 700 characters)

We will not deviate from the principle of preservation of data and of the minimum preservation term of 5 years.

Are there issues concerning research data indicated in the ethics questionnaire of this application form? Which specific security measures do those data require? (use up to 700 characters)

Personal data will be acquired and registered in the KU Leuven's PRET platform. All study data will be pseudonymized and the coding (the link between a subject and his/her data) will be stored for 15 years by the supervisor. Therefore, the supervisor is the only person who can relate the data to a specific person. None of the acquired data will contain elements that may result in identifying a particular subject.

Which other issues related to the data management are relevant to mention? (use up to 700 characters)

There are no further issues to address.

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FWO DMP (Flemish Standard DMP)

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1. 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.

				Only for digital data	Only for digital data	Only for digital data	Only for physical data
Dataset Name	Description	New or reused	Digital or Physical	Digital Data Type	Digital Data format	Digital data volume (MB/GB/TB)	Physical volume
		Please choose from the following options: • Generate new data • Reuse existing data	*Please choose from the following options:* • Digital • Physical	*Please choose from the following options:* • Observational • Experimental • Compiled/aggregated data • Simulation data • Software • Other • NA	*Please choose from the following options:* • .por, .xml, .tab, .csv,.pdf, .txt, .rtf, .dwg, .gml, … • NA	*Please choose from the following options:* • <100MB • <1GB • <100GB • <1TB • <5TB • <10TB • <50TB • >50TB • NA	
Human blood, urine and muscle samples	Human blood samples collected during the study intervention	Generate new data	Physical	Experimental	NA	NA	WP1 360 blood samples WP2 196 blood samples and 56 muscle biopsies WP3a 48 blood samples WP3b 128 blood samples 64 muscle biopsies

Spreadsheet with numeric data from all functional parameters (i.e. jump height, muscle strength etc), biochemical analyses and personal data	Spreadsheet with all numeric data that is collected during the studies	Generate new data	Digital	Experimental	.csv	<100GB	NA
Western Blot images	Digital images of western blot analyses that will be performed on the collected muscle samples	Generate new data	Digital	Experimental	.tiff	<1GB	NA
Microscope images	Digital images of immunohistochemical analyses that will be performed on the collected muscle sampels	Generate new data	Digital	Experimental	.tiff	<100GB	NA

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:

We will not use existing data.

Are there any ethical issues concerning the creation and/or use of the data (e.g. experiments on humans or animals, dual use)? Describe these issues in the comment section. Please refer to specific datasets or data types when appropriate.

- Yes, human subject data

Human subject data will be collected. Ethical guidelines will be followed, all personal data will be pseudonomyzed and all studies will be registered using the PRET tool of the KU Leuven.

Will you process personal data? If so, briefly describe the kind of personal data you will use in the comment section. Please refer to specific datasets or data types when appropriate.

- Yes

Personal data of competent, healthy adult volunteers.
Categories of data:
- Ordinary personal data: name, age, gender, weight, height, telephone number and email address
- Special personal data: performance parameters (muscle strength, jump height and cycling performance); biomarkers and hormones in the blood, urine and muscle samples; information on sleep pattern (via questionnaires and polysomnography); parameters of overall well-being (via questionnaires); dietary habits (via food diaries)

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/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

2. 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).

README.txt files will be included within the folder construction on the protected KU Leuven drive (J-Drive) to make sure that me and others (with access), now and in the future know where to find all recorded information.

Will a metadata standard be used to make it easier to find and reuse the data? If so, please specify (where appropriate per dataset or data type) which metadata standard will be used. If not, please specify (where appropriate per dataset or data type) which metadata will be created to make the data easier to find and reuse.

- No

3. Data storage & back-up during the research project

Where will the data be stored?

During the project data will be collected via RedCap. For the purpose of statistical analyses, data from RedCap will be exported to SPSS and .xls format. Once the intervention is finished and all analyses have been performed, all trial data will be exported from RedCap (as .csv files) to a password-protected KU Leuven drive (j-drive), which can only be accessed by registered researchers. Only the PI can request access to the network drive for study personnel.

How will the data be backed up?

During data collection all data will be backed up via the RedCap system. Once all the data has been exported from RedCap it will be saved on the KU leuven drive (j-drive) of which a backup is created by the departmental ICT manager on a daily basis.

Is there currently sufficient storage & backup capacity during the project? If yes, specify concisely.
If no or insufficient storage or backup capacities are available, then explain how this will be taken care of.

- Yes

Currently 1.82 PB is available on the secured KU Leuven network drive and there are spare freezers available for the biological samples.

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

The KU leuven drive (J-drive) is secured and is only accessible for authorized study personel and acces can only be granted via permission of the supervisor Katrien Koppo and the datamanager.

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

There are no expected costs for data storage foreseen.

4. Data preservation after the end of the research project

Which data will be retained for at least five 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 collected data within this research project will be stored for 15 years. Biological samples are stored for at least 5 years.

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

All data will be saved on the KU Leuven drive (J-drive) that can only be accessed by authorized study personel.
Biological materials will be stored at appropriate temperature (blood at -20°C; muscle at -80°C; spare freezers available).

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

there are no expected costs for data preservation foreseen

5. Data sharing and reuse

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

- Yes, in a restricted access repository (after approval, institutional access only, …)

All digital data will be made available in a restricted acces repository.

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

Scientific researchers will have to motivate why they want access to the data:
What topic are you studying?
How is the data linked to your research domain?
Why do you think you need this data?
Which question/problem will the data help with?
What do you expect the data to provide you?

Do you have approval from an ethical committee to reuse these data?
We will always ask to give credit to the original data creators when the data is being used by other researchers.

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 in the comment section per dataset or data type where appropriate.

- Yes, Privacy aspects

We work with confidential data (e.g., name, sex, age, several subjective perceptions,…)

Where will the data be made available? If already known, please provide a repository per dataset or data type.

Via RDR, the KU Leuven institutional repository.

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 from the project that can be shared will be made available under a creative commons attribution license (cc-by 4.0), so that users have to give credit to the original data creators.

Do you intend to add a PID/DOI/accession number to your dataset(s)? If already available, you have the option to provide it in the comment section.

- Yes

A DOI will be available through RDR, but is not yet available.

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

RDR is free for KU Leuven personnel, hence, no costs are expected for data sharing.

6. Responsibilities

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

The PhD researcher (Moniek Schouten) will be responsible for data documentation & metadata, under supervision of the PI (Katrien Koppo).

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

Data management, storage and back up will be performed by the PhD researcher (Moniek Schouten), under supervision of the PI (Katrien Koppo).

Who will manage data preservation and sharing?

The PI (Katrien Koppo) will be responsible for ensuring data preservation and sharing.

Who will update and implement this DMP?

The PhD researcher (Moniek Schouten) will be responsible for updating this DMP. The PI (Katrien Koppo) bears the end responsibility for updating and implementing this DMP.