DMP title

Project Name My plan (Internal Funds DMP) - DMP title
Project Identifier C2
Grant Title C26M/21/001
Principal Investigator / Researcher Diethard Monbaliu
Project Data Contact Heedfeld Veerle, 016/340602, veerle.heedfeld@kuleuven.be
Institution KU Leuven

1. General Information

Name of the project lead (PI)
Diethard Monbaliu

Internal Funds Project number & title
C26M/21/001

A home-based exercise and physical activity intervention after liver transplantation: impact of exercise intensity – a randomized single blind controlled trial [PHOENIX-liver]

2. Data description

2.1. Will you generate/collect new data and/or make use of existing data?

- Generate new data

2.2. What data will you collect, generate or reuse? Describe the origin, type and format of the data (per dataset) and its (estimated) volume. This may be easiest in a numbered list or table and per objective of the project.

Data(set) name	Origin of data	Type of data	File format
Physical fitness			
Cardiorespiratory fitness	cardiopulmonary exercise test (CPET) on cycle ergometer	numerical	
	The six-minute walking test: observation	observational, numerical	
Musculoskeletal fitness	Jamar Hydraulic Hand Dynamometer	numerical	
	dynamometer (Biodex Medical Systems Inc., 840-000 System 4, New York, USA)	numerical	
Motor fitness	The Short Physical Performance Battery test	observational, numerical	
Body morphology	Medical body weight scale	numerical	
	stretch-resistant measuring tape	numerical	

	DXA scan	numerical	.pdf
Cardiovascular health			
Blood pressure	Omron M6	numerical	
Endothelial function	Flow-mediated dilation (FMD) of the brachial artery using ultrasound (UNEX)		
Arterial stiffness	Carotid–femoral pulse wave velocity (cf-PWV) through SphygmoCor device (AtCor Medical, Australia).		
Blood markers of cardiovascular health	laboratory analysis of venous blood sample	numerical	.pdf
Safety			
Graft health	blood sample		
Adverse events	observation , medical records		
Immunity and infections	diagnosis	observational	
	Wisconsin Upper Respiratory Symptom Survey (WURSS-21) +perceived resilience against infections	paper or electronical survey	
Gut microbiome			
	stool sample		
	Bristol Stool Score chart + data on time of sampling + questionnaire	paper/electronical	
Implementation potential	administrative records	numerical	

	The iMTA Medical consumption questionnaire (iMCQ) and the iMTA productivity cost questionnaire (iPCQ)	paper/electronical	
Other study outcomes			
Quality of life	Surveys : The Short Form Health Survey or SF-36, EQ-5D-5L, FACIT-F +I nterviews	paper/electronical, interview	
Physical activity	Actigraph wGT3X-BT triaxial accelerometer	digital instrument	
	Motivators and Barriers Questionnaire	paper/electronical	
Healthcare use	Questionnaire	paper/electronical	
Frailty	Fried’s Frailty Phenotype (FFP) score		

3. Ethical and legal issues

3.1. Will you use personal data? If so, shortly describe the kind of personal data you will use. Add the reference to the file in KU Leuven's Record of Processing Activities. Be aware that registering the fact that you process personal data is a legal obligation.

Yes,

Short description of the kind of personal data that will be used:
- Identification information (e.g. names, (email) addresses) Personal details (e.g. age, gender)
- Financial data
- Physical traits
- Leisure activities and interests
- Education and training
- Lifestyle and habits
- Family composition
- Occupation and professional activities
- Fysieke kenmerken: lengte, gewicht
- Gezinssamenstelling: aantal kinderen
- Gezinssamenstelling: eigenschappen van kinderen (bv. geslacht, leeftijd)
- Gezinssamenstelling: aantal inwonenden
- Beroep: functie
- Beroep: anciënniteit
- Persoonlijke kenmerken: nationaliteit
- Persoonlijke kenmerken: burgerlijke staat
- Persoonlijke kenmerken: geboortedatum
- Persoonlijke kenmerken:geslacht
- Persoonlijke kenmerken: leeftijd

- Identificatiegegevens: identificatienummers (bv. studentennummer, patiëntennummer)
- Identificatiegegevens: elektronische locatiegegevens (bv. gps, mobiele telefoon)
- Identificatiegegevens: telefoonnummer
- Identificatiegegevens: e-mailadres
- Identificatiegegevens: adressen
- Identificatiegegevens: titels
- Special categories of personal data:
- Data revealing racial or ethnic origin
- Data revealing religious or philosophical beliefs
- Data from or linked to the Electronic Patient Record (EPR)
- Data concerning (physical and/or mental) health
- Health: diagnoses and symptoms
- Health: medication use
- Health: medical history
- Health: medical images and scans (e.g. radiography, EEG, CT, etc.)
- Health: physiological data
- Health: data about mental health such as stress, depression, etc.
- Health: hospitalization data

The registration of the processing of persoal data will be done via the GDPR questionnaire of the CTC of UZLeuven when the clinical trial is registered at CTC.

3.2. 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, add the reference to the formal approval by the relevant ethical review committee(s).

Yes
Approval of EC Research UZ Leuven will be requested

3.3. Does your research possibly result in research data with potential for tech transfer and valorisation? Will IP restrictions be claimed for the data you created? If so, for what data and which restrictions will be asserted?

No

3.4. Do existing 3rd party agreements restrict dissemination or exploitation of the data you (re)use? If so, to what data do they relate and what restrictions regarding reuse and sharing are in place?

No

4. Documentation and metadata

4.1. What documentation will be provided to enable understanding and reuse of the data collected/generated in this project?

- Data will be stored on RedCap . Using RedCap, a Data Dictionary Codebook will be generated containing variable-level information for all captured information: Variable / Field name, Field Label (including question text) and Field Attributes (including Field Type, Validation, Choices, Calculations etc.)
- Survey data: Metadata (e.g. timestamp, electronic instructions) are automatically captured during survey completion in RedCap
- Research methods and practices will be fully documented. Details on the setting of the data collection, the selection of participants and the instructions given to researchers will be documented.
- For the interviews, details on the setting of the interviews, the informed consent process, the subjects discussed and the instructions given to interviewers will be documented in a Word document. Also steps taken to remove direct identifiers in the data will be described.
- Experimental protocols: description how the data are collected and generated (software, materials, set-up, settings (.docx) and how data are processed (software, protocol, guidelines, ...) (.docx)
- Measurement forms: notes during data collection (voice-recording & printed paper)

- Raw experimental data: storage of original physical data and folders with original digital data in software specific files
- Patient identifier record: name of included subject, and subject study code (.xls) This patient record file is the only document that provide the link between the study code of the patient and patient's identity
- The progress of data collection, and final report, will be provided to the leading ethical committee (UZ Leuven).

4.2. Will a metadata standard be used? If so, describe in detail which standard will be used. If not, state in detail which metadata will be created to make the data easy/easier to find and reuse.

No

5. Data storage and backup during the project

5.1. Where will the data be stored?

- The paper (source) documents will be stored in the office of the primary researcher, in an locked drawer or cupboard that can only be accessed by the researcher.
- The digital data will be stored on the University's central servers with automatic daily backup procedures: Secured networkdrive KU Leuven (J-schijf)
- OneDrive linked to a KU Leuven-account
- REDCap: REDCap is hosted on dedicated KU Leuven data servers at Campus Heverlee

5.2. How will the data be backed up?

The data will be stored on the University's central servers and UZ leuven IT services with automatic daily back-up procedures.
REDCap: data is backed up as follows:

- The web server backup regime is specified below:
- An hourly backup, the last 6 versions of which are saved
- A daily backup, the last 7 versions of which are saved
- A weekly backup, the last 6 versions of which are saved
- The database backup regime is specified below: -A nightly cold backup of all databases- One month's storage of the nightly cold backups

5.3. 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
The university and department infrastructure is able to provide sufficient capacity
RedCap allows data storage of 2-4 MB

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

The expected total volume of data will not require a budget for data storage or preservation. The university and department infrastructure is able to provide sufficient capacity.

5.5. Data security: how will you ensure that the data are securely stored and not accessed or modified by unauthorized persons?

The data will be stored at the university's secure enviroment for private data.
Data on the UZ Leuven networks is only accessible for researchers with personalized UZ Leuven login and password, and thus secured by a strickt acces right management controlled by the PI. Patient record files will be stored with password security only accessable for researchers involved in the projects and controlled by the PI . Patient data can only be accessed by clinicans who are both involved in this project and who are taking care of these patients

6. Data preservation after the end of the project

6.1. Which data will be retained for the expected 10 year period after the end of the project? If only a selection of the data can/will be preserved, clearly state why this is the case (legal or contractual restrictions, physical preservation issues, ...).

The (personal) data will be preserved for 25 years (guideline EC Research UZ/KU Leuven). Samples will be kept for 50 years in the Biobank UZ Leuven, for later research related to this research.

6.2. Where will these data be archived (= stored for the long term)?

The digital data will be stored on the university's central servers (with automatic back-up procedures) for 25 years.
Hard copies (eg. the Informed Consent forms, measurement forms and paper lab notebooks) are kept in locked cabinets in the offices of the PIs concerned.
Samples will be kept for 50 years in the Biobank UZ Leuven.

6.3. What are the expected costs for data preservation during these 10 years? How will the costs be covered?

No additional costs are expected.

7. Data sharing and re-use

7.1. Are there any factors restricting or preventing the sharing of (some of) the data (e.g. as defined in an agreement with a 3rd party, legal restrictions or because of IP potential)?

No

7.2. Which data will be made available after the end of the project?

Data are only accessible on specific requests and after signing a formal agreement.

7.3. Where/how will the data be made available for reuse?

- Upon request by mail

7.4. When will the data be made available?

- Upon publication of the research results

7.5. Who will be able to access the data and under what conditions?

Everybody with a specific request, and after formal approval of all research university/hospital.

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

no costs

8. Responsibilities

8.1. Who will be responsible for the data documentation & metadata?

Principal investigator

8.2. Who will be responsible for data storage & back up during the project?

Principal investigator

8.3. Who will be responsible for ensuring data preservation and sharing?

Principal investigator

8.4. Who bears the end responsibility for updating & implementing this DMP?

The end responsibility for updating and implementing the DMP is with the supervisor (promotor).