DMP title

Project Name Development of a clinical screening, diagnostic and evaluation tool for patients with lower limb lymphedema (FWO DMP) - DMP title

Project Identifier s66033

Grant Title 1298022N

Principal Investigator / Researcher Tessa De Vrieze

Description Development of a clinical screening, diagnostic and evaluation set for patients with LLL: -To investigate reliability and clinical feasibility of currently applied (directly edema-related) measurement tools in patients with LLL (AIM 1) (cross-sectional study) - To develop a screening set for patients at risk for developing LLL (AIM 2) (prospective observational study) - To develop a diagnostic set, including a â€˜severity scoreâ€™, for patients with LLL (AIM 3) (cross-sectional study) - To develop an evaluation set for patients with LLL (AIM 4) (prospective observational study)

Institution KU Leuven

1. General Information

Name applicant

Dr. Tessa De Vrieze

FWO Project Number & Title

1298022N

Development of a clinical screening, diagnostic and evaluation tool for patients with lower limb lymphedema

Affiliation

- KU Leuven

2. Data description

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

- Generate new data

Describe in detail the origin, type and format of the data (per dataset) and its (estimated) volume. This may be easiest in a table (see example) or as a data flow and per WP or objective of the project. If you reuse existing data, specify the source of these data. Distinguish data types (the kind of content) from data formats (the technical format).

AIM1:To investigate reliability, concurrent validity and clinical feasibility of currently applied (edema-related) measurement tools in patients with LLL : Cross-sectional study

	Origin/type of data	Storage
Informed consent	paper ICF	study binder
age, body weight, height	interview, clincal assessment	REDCap database (e-CRF) + Formasa or pictures of source docs exported to the patient's medical file of the hospital information system (KWS); the latter only for patients (not for healthy controls), original source docs will be stored in study binder

signs of venous insufficiency	inspection, clinical assessment	REDCap database + Formasa or pictures of source docs exported to the patient's medical file of the hospital information system (KWS); the latter only for patients (not for healthy controls), original source docs will be stored in study binder
co-morbidities : using questionnaire	(online) survey	REDCap database, survey will be stored in study binder
Lymphedema-specific QoL: Lymph-ICL-LL questionnaire	(online) survey	REDCap database, survey will be stored in study binder
Skin integrity: ICC compression questionnaire (ICC-CQ-H) – Part 1, Section « Skin »	(online) survey	REDCap database, survey will be stored in study binder
Palpation (pitting and skinfold thickness leg and genital region)	clinical assessment	REDCap database + Formasa or pictures of source docs exported to the patient's medical file of the hospital information system (KWS); the latter only for patients (not for healthy controls), original source docs will be stored in study binder
Leg volume: Perometry	clinical assessment	REDCap database + Formasa or pictures of source docs exported to the patient's medical file of the hospital information system (KWS); the latter only for patients (not for healthy controls), original source docs will be stored in study binder
Leg and midline volume using circumference measures: Perimetry	clinical assessment	REDCap database + Formasa or pictures of source docs exported to the patient's medical file of the hospital information system (KWS); the latter only for patients (not for healthy controls), original source docs will be stored in study binder
Foot volume: Water displacement	clinical assessment	REDCap database + Formasa or pictures of source docs exported to the patient's medical file of the hospital information system (KWS); the latter only for patients (not for healthy controls), original source docs will be stored in study binder

Foot circumferences	clinical assessment	REDCap database + Formasa or pictures of source docs exported to the patient's medical file of the hospital information system (KWS); the latter only for patients (not for healthy controls), original source docs will be stored in study binder
Extracellular fluid lower limb: bio-impedance analysis (InBody, BodyStat) and bio-impedance spectroscopy (SOZO, L-Dex U400)	clinical assessment	REDCap database + Formasa or pictures of source docs exported to the patient's medical file of the hospital information system (KWS); the latter only for patients (not for healthy controls), original source docs will be stored in study binder
Water content leg and genital region: MoistureMeterD Compact®	clinical assessment	REDCap database + Formasa or pictures of source docs exported to the patient's medical file of the hospital information system (KWS); the latter only for patients (not for healthy controls), original source docs will be stored in study binder
Hardness of the skin leg and genital region: SkinFibroMeter®	clinical assessment	REDCap database + Formasa or pictures of source docs exported to the patient's medical file of the hospital information system (KWS); the latter only for patients (not for healthy controls), original source docs will be stored in study binder

AIM 2: To develop a screening set for patients at risk for developing LLL: Prospective observational study

	Origin/type of data	**Storage**
Informed consent	paper ICF	Study binder

Demographics: age	interview	REDCap database (e-CRF) + Formasa or pictures of source docs exported to the patient's medical file of the hospital information system (KWS); original source docs will be stored in study binder
physical activity level (using a questionnaire)	(online) Survey	REDCap database, survey will be stored in a study binder
signs of venous insufficiency	clinical assessment	REDCap database (e-CRF) + Formasa or pictures of source docs exported to the patient's medical file of the hospital information system (KWS); original source docs will be stored in study binder
co-morbidities using questionnaire)	(online) Survey	REDCap database, survey will be stored in study binder

Stage and type of melanoma/urogenital/gynaecological cancer	medical report hospital	REDCap database (e-CRF) + REDCap database (e-CRF) + Formasa or pictures of source docs exported to the patient's medical file of the hospital information system (KWS); original source docs will be stored in study binder
Melanoma/urogenital/gynaecological cancer treatment characteristics	medical report hospital	REDCap database (e-CRF) + REDCap database (e-CRF) + Formasa or pictures of source docs exported to the patient's medical file of the hospital information system (KWS); original source docs will be stored in study binder
Detection of lymphoedema:Detect-Lymph-OL questionnaire	(online) Survey	REDCap database, survey will be stored in study binder

Skin integrity: ICC compression questionnaire (ICC-CQ-H) – Part 1, Section « Skin »	(online) Survey	REDCap database, survey will be stored in study binder
Disease-specific QoL: Lymph-ICF-LL	(online) Survey	REDCap database, survey will be stored in study binder
Body composition (body weight, height)	interview, clinical assessment	REDCap database (e-CRF) + REDCap database (e-CRF) + Formasa or pictures of source docs exported to the patient's medical file of the hospital information system (KWS); original source docs will be stored in study binder
All the same measurements as reported in Table 1; if in aim 1 they showed sufficient reliability (majority of ICCs ≥ 0.75 and a SEM% <10%) and clinical feasibility (< x% presence of the mentioned limitations; *number x to be discussed with the expert panel after having knowledge about the total number of reported limitations that will result from aim 1*)		

AIM 3: To develop a diagnostic set, including a 'severity score', for patients with clinical signs of LLL : Cross-sectional study

	Origin of data	**Storage**
Informed consent	paper ICF	Study binder

age	interview	REDCap database + Formasa or pictures of source docs exported to the patient's medical file of the hospital information system (KWS); the latter only for patients (not for healthy controls), original source docs will be stored in study binder
signs of venous insufficiency	inspection, clinical assessment	REDCap database + Formasa or pictures of source docs exported to the patient's medical file of the hospital information system (KWS); the latter only for patients (not for healthy controls), original source docs will be stored in study binder
co-morbidities using questionnaire	(online) Survey	REDCap database, survey will be stored in study binder
Disease-specific QoL: Lymph-ICF-LL	(online) Survey	REDCap database, survey will be stored in study binder
Skin integrity: ICC compression questionnaire (ICC-CQ-H) – Part 1, Section « Skin »	(online) Survey	REDCap database, survey will be stored in study binder
Body composition (body weight, height)	interview, clinical assessment	REDCap database + Formasa or pictures of source docs exported to the patient's medical file of the hospital information system (KWS); the latter only for patients (not for healthy controls), original source docs will be stored in study binder

All the same measurements as reported in Table 1; if in aim 1 they showed sufficient reliability (majority of ICCs ≥ 0.75 and a SEM% <10%) and clinical feasibility (< x% presence of the mentioned limitations; *number x to be discussed with the expert panel after having knowledge about the total number of reported limitations that will result from aim 1*)		

AIM 4: To develop an evaluation set for patients with LLL: Prospective observational study

	Origin of data	**Storage**
Informed consent	paper ICF	Study binder
age	interview	REDCap database (e-CRF) + Formasa or pictures of source docs exported to the patient's medical file of the hospital information system (KWS); original source docs will be stored in study binder
signs of venous insufficiency	clinical assessment	REDCap database (e-CRF) + Formasa or pictures of source docs exported to the patient's medical file of the hospital information system (KWS); original source docs will be stored in study binder
co-morbidities using questionnaire	(online) Survey	REDCap database, survey will be stored in study binder
Body composition (body weight, height)	interview, clinical assessment	REDCap database (e-CRF) + Formasa or pictures of source docs exported to the patient's medical file of the hospital information system (KWS); original source docs will be stored in study binder
Disease-specific QoL: Lymph-ICF-LL	(online) Survey	REDCap database, survey will be stored in study binder
Skin integrity: ICC compression questionnaire (ICC-CQ-H) – Part 1, Section « Skin »	(online) Survey	REDCap database, survey will be stored in study binder
GPE Questionnaire	(online) Survey	REDCap database, survey will be stored in study binder
All the same measurements as reported in Table 1; if in aim 1 they showed sufficient reliability (majority of ICCs ≥ 0.75 and a SEM% <10%) and clinical feasibility (< x% presence of the mentioned limitations; *number x to be discussed with the expert panel after having knowledge about the total number of reported limitations that will result from aim 1*)		

3. Legal and ethical issues

Will you use personal data? If so, shortly describe the kind of personal data you will use. Add the reference to your file in KU Leuven's Register of Data Processing for Research and Public Service Purposes (PRET application). Be aware that registering the fact that you process personal data is a legal obligation.

- Yes

Privacy Registry Reference: Toetsing Pivacy en Ethiek G-2021-4346

Short description of the kind of personal data that will be used:

After signing the Informed Consent Form, following demographics and prognostic variables are collected: age (through interview), body height (stadiometer), physical activity level (through IPAQ) (only for aim 2), signs of chronic venous insufficiency (through inspection), co-morbidities (through self-developed co-morbidity questionnaire, based onIDEWE questionnaire).Only for aim 2: Demographics that are additionally collected: physical activity level (through IPAQ). At 6 weeks, information regarding the stage of the urogenital/gynaecological/ skincancer is collected. At 6 weeks, 6 months and 12 months cancer treatment characteristics are collected (i.e. type of surgery,number and region of lymph nodes removed, number of positive lymph nodes, adjuvant therapies; by exploring the patient’s medical file).

Also, in the ICF is asked for permission to use following data:

Familienaam Ja / Nee Voornaam Ja / Nee

Adres Ja / Nee

Telefoonnummer: ..... (gelieve in te vullen) Ja / Nee

E-mailadres: ..... (gelieve in te vullen) Ja / Nee

Geboortedatum Ja / Nee

EAD-nummer (Eenmalig Administratief Dossier nummer UZ Leuven) Ja / Nee

VOOR DEELNEMERS MET OEDEEM

Datum ontstaan oedeem Ja / Nee

Type oedeem: primair lymfoedeem/ kanker-gerelateerd secundair lymfoedeem/ niet-kanker gerelateerd secundairlymfoedeem/ lipoedeem Ja / Nee

Locatie oedeem: bovenste lidmaat en/of romp – onderste lidmaat en/of romp - beide Ja / Nee

Ernst lymfoedeem: stadium 1- 2- 3 Ja / Nee

Naam van mijn behandelende oncoloog Ja / Nee (Aim 2)

Datum van de diagnose van kanker Ja / NeeType kanker, diagnose van de kanker Ja / Nee (Aim 2)

Ziekte-ernst (TNM-stadium) Ja / Nee (Aim 2)

Gekregen/ geplande behandeling (operatie, chemotherapie, radiotherapie, hormoontherapie, immuuntherapie) Ja / Nee (Aim 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/KU Leuven was granted on 11/01/2022.

Does your work 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

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 are in place?

- No

4. Documentation and metadata

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

Data will be stored on RedCap and in the patient's medical file of the hospital information system (KWS) . These data can be requested by official bodies/organisations. The progress of data collection, and final report, will be provided to the FWO and the ethics committee (UZ/KU Leuven).

Survey data: Metadata (e.g. timestamp, electronic instructions) are automatically captured during survey completion in 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.)

Will a metadata standard be used? If so, describe in detail which standard will be used. If no, state in detail which metadata will be created to make the data easy/easier to find and reuse.

- No

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.)

5. Data storage and backup during the FWO project

Where will the data be stored?

- The paper (source) documents will be stored in the office of the PI, in an closet/drawer only accessible for the PI.
- The data will be stored on the University's central servers with automatic daily back-up procedures: Secured networkdrive KU Leuven (for example. I- / J-schijf)
- OneDrive linked to a KU Leuven-account

- REDCap: REDCap is hosted on dedicated KU Leuven data servers at Campus Heverlee
- Formasa form in the medical file of the patient in the hospital information system (KWS) or by taking pictures of the original source documents and upload them in the patient's medical file in KWS.

How is backup of the data provided?

The data will be stored on the University's central servers 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

Formasa form (or pictures of the source documents uploaded) in the medical file of the patient (hospital information system KWS)

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.

What are the expected costs for data storage and back up 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.

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.

6. Data preservation after the FWO project
Which data will be retained for the expected 5 year period after the end of the project? In case only a selection of the data can/will be preserved, clearly state the reasons for this (legal or contractual restrictions, physical preservation issues, ...).
Pseudonomyzed data will be stored on the university's central servers (with automatic back-up procedures) for 25 years, conform the policy of EC Research UZ Leuven/KULeuven .

Where will the data be archived (= stored for the longer term)?
The data will be stored on the university's central servers (with automatic back-up procedures)

What are the expected costs for data preservation during the retention period of 5 years? How will the costs be covered?
no additional costs

7. Data sharing and reuse
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)?

- No

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.

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

- In an Open Access repository
- In a restricted access repository
- Upon request by mail

Publications will be uploaded in a restricted Open Access repository after publication (Lirias). After 12 months, Lirias automatically will change in an Oped Access repository for these publications.

When will the data be made available?

- Upon publication of the research results

Upon request by mail.

Who will be able to access the data and under what conditions?
Everybody with a specific request, and after formal approval of the researcher.

What are the expected costs for data sharing? How will the costs be covered?
none

8. Responsibilities
Who will be responsible for data documentation & metadata?
Tessa De Vrieze (PI)

Who will be responsible for data storage & back up during the project?
The Principal Investigator

Who will be responsible for ensuring data preservation and reuse ?

The Principal Investigator

Who bears the end responsibility for updating & implementing this DMP?
The PI bears the end responsibility of updating & implementing this DMP.