LymphSens project

A Data Management Plan created using DMPonline.be

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Project abstract:

Breast cancer related lymphedema or BCRL is due to its chronicity and impact an extremely dreaded complication after breast cancer treatment. The prevalence rate of objective arm or trunk/ breast BCRL is declining due to the major shift into the treatment approach of breast cancer. However, prevalence rate of subjective arm or trunk/ breast BCRL is much higher than that of objective BCRL. Subjective BCRL is defined as the diagnosis of BCRL based on the patient’s sensation of a difference in size at the arm and/or trunk without any objectively measurable swelling. At this moment, it is not clear how many breast cancer patients experience subjective arm or trunk/ breast BCRL and what the underlying mechanisms may be.

We hypothesize that four mechanisms might be associated with the presence and the severity of subjective arm or trunk/ breast BCRL, including sensory processing problems (1. nociceptive and/or 2. neuropathic and/or 3. central) and the presence of disturbed lymphatic transport without clinical manifestation (4. subclinical BCRL).

To understand who and why patients after breast cancer treatment report subjective arm or trunk/ breast BCRL, a multi-center longitudinal study will be performed. This will be the first study investigating in 230 breast cancer patients the prevalence rate and underlying mechanisms of subjective arm or trunk/ breast BCRL at different time points (starting pre-surgery up to 12 months post-surgery), using state-of-the art and innovative assessment methods for both different types of BCRL and their underlying mechanisms.

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LymphSens project
FWO DMP (Flemish Standard DMP)

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
LymphSense project	The role of sensory processing and subclinical lymphedema	*Please choose from the following options:* • **Generate new 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, .cvs,.pdf, .txt, .rtf, .dwg, .gml, ... • NA	*Please choose from the following options:* • <100MB • <1GB • <100GB • <1TB • <5TB • <10TB • <50TB • >50TB • 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:

n/a

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

The trial will be conducted in compliance with the principles of the Declaration of Helsinki (current version), the principles of GCP and in accordance with all applicable regulatory requirements.

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

Aan te vullen: Specifieke persoonsgegevens die verzameld worden?
Aan te vullen: Extra gegevens die gevraagd worden bij tekenen van ICF?

Following data is being collected during measurements from participants:

Type of breast cancer-related lymphedema (BCRL)	**Outcome and procedure**	**Evaluation method/ material / reliability**
Self-reported swelling at arm (yes/no) **Duration: 2 min**	**Presence of self-reported BCRL at arm (yes/no);** i.e., if the score on the question about self-reported difference in the sizes of hands, lower arms, and upper arms is “0”, than “no self-reported swelling at arm”; if the score is ≥1, than “yes self-reported swelling at arm”	**Norman questionnaire (difference in size question);** patient-reported outcome measure translated and validated by prof. De Groef et al
Self-reported swelling at trunk/ breast (yes/ no) **Duration: 2 min**	**Presence of self-reported BCRL at trunk/ breast (yes/no);** i.e., if the score on the question about self-reported difference in the sizes of trunk or breast is “0”, than “no self-reported swelling at trunk/ breast”; if the score is ≥1, than “yes self-reported swelling at trunk/ breast”	**Norman questionnaire (difference in size question);** patient-reported outcome measure translated and validated by prof. De Groef et al

Presence of objective arm BCRL (yes/no) **Duration: 15 min**	**Relative hand and arm volume difference (%)** an increase of relative hand volume difference between the affected and non-affected hands of ≥5% **OR** an increase of relative arm volume difference between the affected and non-affected arms of ≥5% based on the 3.3% of correction of hand dominance **OR**	**Water displacement method** with volumeter and weighing balance for measuring relative hand volume **Circumference measurements** with a Perimeter for measuring relative arm volume, team of prof. Devoogdt has demonstrated reliability
Local oedema, by circumference measurements at affected and non-affected arm (starting at the ulnar styloid and 10, 20, 30, and 40 cm proximally); 2 standard deviation above the cut-off (normative) values at least one measurement point **OR**	**Circumference measurements with a non-stretch tape,** the high sensitivity (81%) and specificity (96%) for 2 standard deviations of cut-off values are shown	
Extra-cellular water ratio at affected arm >0.3850; in standing position **OR**	**InBody700 device;** reliable and valid bio-impedance analysis device	
Extracellular water ratio affected arm versus unaffected arm (or L-Dex ratio) >10; in standing position	**ImpediMed SOZO**; reliable and valid bio-impedance spectroscopy device	
Presence of Objective Trunk/ Breast BCRL (yes/no) **Duration: 15 min**	**The relative percentage of water content (PWC%) ratio** at affected trunk / breast versus unaffected trunk / breast; mean PWC ratio at the trunk (3 reference points) and at the breast (5 reference points) will be taken. Presence of objective trunk oedema: yes if the mean PWC ratio at the trunk > 1.32 Presence of objective breast oedema: yes if the mean PWC ratio at the breast ≥ 1.40	**MoistureMeter® device;** reliable and valid tissue dielectric measurement device
Skin thickness at the lateral side of the trunk, chest wall, and breast by 2D conventional ultrasonography (with B mode) Definition of objective trunk/ breast oedema: > 2 standard deviations (SD) from the average skin thickness in at least one reference points on the trunk/ chest wall and/or one quadrant of the affected breast	**MACH 30 Ultrasound device (HOLOGIC®, USA) and two different probes;** measuring the trunk and chest wall, a L18-5 transducer will be used. A L10-2 transducer is needed when measuring the quadrants of the breast. Data will be further processed with Matlab®, using the open software ElastoGUI tool.	
Presence and severity of subjective arm BCRL (yes/no – score)	**Presence of subjective arm BCRL:** if self-reported swelling at arm is "yes" and objective arm BCRL is "no" (see above) **Severity of subjective arm BCRL (score 0–21);** for 3 sites, severity of the 'difference in size' is determined by two items: 1) frequency, with range from 0 (not applicable) to 4 (almost always); and 2) severity, with range from 0 (not applicable) to 3 (very noticeable)	**Norman questionnaire (difference in size subscale)**; patient-reported outcome measure translated and validated by prof. De Groef et al.
Presence and severity of subjective trunk/ breast BCRL (yes/no – score)	**Presence of subjective trunk BCRL:** if self-reported swelling at trunk/ breast is "yes" and objective trunk/ breast BCRL is "no" (see above) **Severity of subjective trunk BCRL (score 0–14):** for 2 sites, severity of the 'difference in size' is determined by two items: 1) frequency, with range from 0 (not applicable) to 4 (almost always); and 2) severity, with range from 0 (not applicable) to 3 (very noticeable)	**Norman questionnaire (difference in size subscale);** patient-reported outcome measure translated and validated by prof. De Groef et al.
Contributing variables	**Outcome and procedure**	**Evaluation method/ material / reliability**
Amount of swelling at upper limb or at trunk/ breast	**(1) Arm volume difference (in %) and extracellular water ratio at affected arm (L-dex score) OR** **mean PWC ratio of the trunk (mean PWC ratio at the 3 reference point) or breast (mean PWC ratio at the 5 reference points)**	***See above***
2.1 Subclinical BCRL **Duration: 60 min**	**(2) Severity of dermal rerouting (Dermal rerouting score = 0-33 or 0-6);** Indocyanine green (ICG)/ aqua is injected in the patient's hand; linear (normal) and dermal rerouting patterns are visualised. The body is divided into 13 areas and is score between 0 and 3: 0 (normal pattern), 1 (splash pattern), 2 (stardust pattern), and 3 (diffuse pattern).	**Near-infrared fluorescence imaging device with a Photo Dynamic Eye camera (PDE, Hamamatsu) and Indocyanine Green**; team of prof. Devoogdt has demonstrated interrater reliability
2.2 Alterations in sensory processing **2.2.1 Nociceptive problems** **Duration: 20 min**	**(3) Myofascial adhesions (Score = 0-63):** are assessed at 7 locations (i.e., axillary scar, breast or mastectomy scar, pectoral muscles, frontal and lateral chest wall, axilla, and the inframammary fold). Each location is palpated for adhesions at 3 levels (i.e., skin, superficial, and deep) on a 4-points scale (0- no restriction, 1-limited restriction, 2-hard restriction, and 3-very stiff)	**The Evaluation Tool for Myofascial Adhesions in Patients After Breast Cancer (MAP-BC evaluation tool);** developed by the team of prof. De Groef; reliability and validity has been demonstrated
(4) Myofascial tissue stiffness and elasticity **- Myofascial tissue composition and elasticity by Shear-wave elastography (in m/sec)** at the affected and non-affected sides of the lateral trunk, chest wall, and breast.	**MACH 30 Ultrasound device (HOLOGIC®, USA) and two different probes;** measuring the trunk and chest wall, a L18-5 transducer will be used. A L10-2 transducer is needed when measuring the quadrants of the breast. Data will be further processed with Matlab®, using the open software ElastoGUI tool. This measurement is currently being tested on reliability in breast cancer patients by the team of prof. De Groef.	
- Myofascial tissue tone, stiffness, and elasticity by MyotonPro (in N/m) at the pectoralis major, upper trapezius, infraspinatus, and teres major muscles	**MyotonPRO;** this measurement is currently being tested on reliability in breast cancer patients by the team of prof. De Groef. Reliability and validity have been established in other populations	
(5) Local tenderness (in kg/cm2): pain pressure threshold on affected and non-affected lateral trunk and non-affected tibialis anterior; patient is asked to say 'stop' when the sensation of pressure first changes to pain.	**Digital Wagner FPX™ algometer**, team of prof. De Groef has demonstrated reliability	
(6) Impaired shoulder ROM (°); in sitting position, ROM of arm abduction	**Inclinometer (Dr. Rippstein (Switzerland) Plurimeter-V), ,** team of prof. De Groef has demonstrated reliability	

2.2 Alterations in sensory processing **2.2.2 Neuropathic problems** **Duration: 20 min**	**(7) Presence of neuropathic pain (yes/ no);**self-reported questionnaire consists of two parts (interview and examination). The presence of neuropathic pain is “yes” if the total score of DN4 is ≥4 of 10.	**Douleur neuropathique en 4 questions (DN4)**; reliable and valid questionnaire to identify pain of predominantly neuropathic origin
(8) Presence of sensory loss (score between 0.25 – 512 mN): assessed based on Quantitative Sensory Testing (QST). The mechanical detection threshold will be determined at affected and non-affected inner upper arm, lateral trunk, and non-affected tibialis anterior muscle.	**QST with standardized set of 12 nylon monofilaments**(Optihair2-Set, Marstock Nervtest); team of prof. De Groef demonstrated reliability	
(9) Presence of altered thermal function (yes/ no): thermal detection and pain thresholds will be determined at affected and non-affected inner upper arm, lateral trunk, and non-affected tibialis anterior muscle and compared with normative data.	**QST with Thermotest device TSA-2 NeuroSensory Analyser**; team of prof. De Groef demonstrated reliability	
(10) Presence of altered proprioception (in µm); the patient is asked to locate the bump on the plate with the affected and non-affected index finger pad. The BUMPS detection threshold is defined as the lowest bump that successfully detected.	**The BUMPS device,** with five circle shape plates, each plates contains a raised shape cylinder shaped bump; the height of the BUMPS varies between 5-25 µm	
11) Altered sensory acuity (between 0 - 100 mm);assessed as two-point discrimination ability at the affected and non-affected inner side of upper arm and lateral side of the trunk; patient has to indicate when she/ he feels one or two points; test starts with 0 mm and increases until the patient feels two different points.	**Baseline aesthesiometer,** team of prof. De Groef demonstrated reliability	
2.2 Alterations in sensory processing **2.2.3 Central sensory problems** **Duration: 20 min**	**(12) Presence of a dysfunctional inhibitory pain mechanism (yes/ no);**test and conditioning stimulus is applied on the non-affected tibialis anterior muscle and non-affected hand. A test stimulus is used to assess pain sensitivity to a pre- and post-conditioning stimulus. When the second pressure pain threshold (i.e., test stimulus) is similar or lower than the first, dysfunctional inhibitory pain mechanism is “yes”.	**A cold water bath and a digital Wagner FPX™ algometer**; team of prof. Meeus has demonstrated reliability
(13) Presence of enhanced facilitating mechanisms (yes/ no); repetitive 15 stimuli at affected lateral trunk and non-affected tibialis anterior. Perceived intensity of stimulus is measured by Numeric Rating Scale (NRS). If the score on the NRS is increased >2, enhanced facilitating mechanism is “yes”.	**Pinprick stimulator (MRC Systems GmBH, Heidelberg),**team of prof. De Groef demonstrated reliability	
(14) Altered body perception (score 0-36);self-reported questionnaire evaluating neglect-like symptoms, reduced sensory acuity, and perceived limb size and consists of 9 items. Each item is scored on a 5-point Likert scale from 0 (never) to 4 (always).	**Adapted Fremantle Upper Limb Awareness Questionnaire;** reliable and valid questionnaire	

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).

Self-reported data (survey): collected through REDCap. A readme.txt file in every folder explaining the structure and content of the data. Structure will be logged in REDCap.
Lymphofluoroscopic data: data will be entered in RedCap
Clinical assessment data: data will be entered in RedCap

Quantitative Sensory Testing: data will be entered in RedCap.

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.

- Yes

Metadata standards imbedded in REDCap will be used.
REDCap has the ability to export an entire REDCap project (its metadata of forms and events, as well as its data) as an XML file in CDISC ODM format. New projects can also be created in REDCap using an ODM metadata file that has originated from REDCap itself or from any other ODM-compatible system

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

Where will the data be stored?

All data and document will be stored and organized with the electronic application REDCap (Research Electronic Data Capture). It is a web-based software and tool set that allows researchers to create secure online forms for data capture, management and analysis. It is already widely used in many academic medical centers. Data will be stored for at least 25 years.

How will the data be backed up?

Data will be stored and automatically backed up in REDCap and the server of KU Leuven. The REDcap server is hosted and managed by the KU Leuven ICT department. The data is backed up on a daily basis in addition to daily snapshots of the server. The backups and snapshots are retained for a period of 14 days.

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

Yes, the KU Leuven provides hosting for the REDcap application and will provide sufficient storage

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

Authentication is based on a personal username and password, using the KU Leuven's Active directory server for authentication. Authorisation in REDcap is granted on a project basis through REDcap's internal authorisation mechanism.

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

Data are stored in REDcap. The costs for the hosting and licence for REDcap are covered by the university. A yearly fee per project is paid with project funding.

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 data will be stored for a period of 25 years in REDcap. If the application will be taken out of commission before this period and without a datamigration to a new platform, data will be exported to ODM XML, an XML format for exchanging and archiving clinical data, associated metadata and audit information.

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

The data will be stored in REDcap, which is hosted in the datacenter of the KU Leuven. Should the application be taken out of commission, the data will be exported to ODM XML and stored in a secure archive or file server.

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

The cost of storing the data in REDcap will be covered by the KU Leuven. A yearly fee per project (€80) is paid with project funding.

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 data will be made available after the project upon request by mail.

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

Data will be made available after the project upon request by mail.

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.

- No

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

Upon request by mail

When will the data be made available?

Upon publication of the research results

Which data usage licenses are you going to provide? If none, please explain why.

Data can only be used after approval by the PI and after setting up a data transfer agreement between KU Leuven and the other party

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.

- No

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

No costs are expected

6. Responsibilities

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

An De Groef, Nele Devoogdt, Ceren Gursen

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

An De Groef, Nele Devoogdt, Ceren Gursen

Who will manage data preservation and sharing?

An De Groef, Nele Devoogdt, Ceren Gursen

Who will update and implement this DMP?

The PI bears the overall responsibility for updating & implementing this DMP.

LymphSens project
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)

Type of breast cancer-related lymphedema (BCRL)	**Outcome and procedure**	**Evaluation method/ material / reliability**
Self-reported swelling at arm (yes/no) **Duration: 2 min**	**Presence of self-reported BCRL (yes/no);** i.e., if the score on the question about self-reported difference in the sizes of hands, lower arms, and upper arms is "0", than "no self-reported swelling at arm"; if the score is ≥1, than "yes self-reported swelling at arm"	**Norman questionnaire (difference in size question)**; patient-reported outcome measure translated and validated by prof. De Groef et al
Self-reported swelling at trunk/ breast (yes/ no) **Duration: 2 min**	**Presence of self-reported BCRL at trunk/ breast (yes/no);**i.e., if the score on the question about self-reported difference in the sizes of trunk or breast is "0", than "no self-reported swelling at trunk/ breast"; if the score is ≥1, than "yes self-reported swelling at trunk/ breast"	**Norman questionnaire (difference in size question);** patient-reported outcome measure translated and validated by prof. De Groef et al.
Presence of Objective Arm BCRL (yes/no) **Duration: 15 min**	**Relative hand and arm volume difference (%)** an increase of relative hand volume difference between the affected and non-affected hands of ≥5% **OR** an increase of relative arm volume difference between the affected and non-affected arms of ≥5% based on the 3.3% of correction of hand dominance **OR**	**Water displacement method** with volumeter and weighing balance for measuring relative hand volume **Circumference measurements** with a Perimeter for measuring relative arm volume, team of prof. Devoogdt has demonstrated reliability
Local oedema, by circumference measurements at affected and non-affected arm (starting at the ulnar styloid and 10, 20, 30, and 40 cm proximally); 2 standard deviation above the cut-off (normative) values at least one measurement point **OR**	**Circumference measurements with a non-stretch tape,** the high sensitivity (81%) and specificity (96%) for 2 standard deviations of cut-off values are shown	
Extra-cellular water ratio at affected arm of >0.3850; in standing position **OR**	**InBody700 device;** reliable and valid bio-impedance analysis device	
Extracellular water ratio affected arm versus unaffected arm (or L-Dex ratio) >10.0; in standing position	**ImpediMed SOZO**; reliable and valid bio-impedance spectroscopy device	
Presence of Objective Trunk/ Breast BCRL (yes/no) **Duration: 15 min**	**The relative percentage of water content (PWC%) ratio**at affected trunk / breast versus unaffected trunk / breast; mean PWC ratio at the trunk (3 reference points) and at the breast (5 reference points) will be taken. Presence of objective trunk oedema: yes if the mean PWC ratio at the trunk > 1.32 Presence of objective breast oedema: yes if the mean PWC ratio at the breast ≥ 1.40	**MoistureMeter® device;** reliable and valid tissue dielectric measurement device
Presence of Objective Trunk/ Breast BCRL (yes/no)	**Skin thickness at the lateral side of the trunk, chest wall, and breast** by 2D conventional ultrasonography (with B mode) Definition of objective trunk/ breast oedema: > 2 standard deviations (SD) from the average skin thickness in at least one reference points on the trunk/ chest wall and/or one quadrant of the affected breast	**MACH 30 Ultrasound device (HOLOGIC®, USA) and two different probes;** measuring the trunk and chest wall, a L18-5 transducer will be used. A L10-2 transducer is needed when measuring the quadrants of the breast. Data will be further processed with Matlab®, using the open software ElastoGUI tool
Presence and severity of subjective arm BCRL (yes/no and score) **Duration: 2 min**	**Presence of subjective arm BCRL:** if self-reported swelling at arm is "yes" and objective arm BCRL is "no" (see above) **Severity of subjective arm BCRL (score 0–21);**for 3 sites, severity of the 'difference in size' is determined by two items: 1) frequency, with range from 0 (not applicable) to 4 (almost always); and 2) severity, with range from 0 (not applicable) to 3 (very noticeable)	**Norman questionnaire (difference in size subscale)**; patient-reported outcome measure translated and validated by prof. De Groef et al.
Presence and severity of subjective trunk/ breast BCRL (yes/no – score) **Duration: 2 min**	**Presence of subjective trunk BCRL:** if self-reported swelling at trunk/ breast is "yes" and objective trunk/ breast BCRL is "no" (see above) **Severity of subjective trunk BCRL (score 0–14):**for 2 sites, severity of the 'difference in size' is determined by two items: 1) frequency, with range from 0 (not applicable) to 4 (almost always); and 2) severity, with range from 0 (not applicable) to 3 (very noticeable)	**Norman questionnaire (difference in size subscale);** patient-reported outcome measure translated and validated by prof. De Groef et al.
Contributing variables	**Outcome and procedure**	**Evaluation method/ material / reliability**
Amount of swelling at upper limb or at trunk/ breast	**(1) Arm volume difference (in %) and extracellular water ratio at affected arm (L-dex score) OR** **mean PWC ratio of the trunk (mean PWC ratio at the 3 reference point) or breast (mean PWC ratio at the 5 reference points)**	***See above***

2.1 Subclinical BCRL **Duration: 60 min**	**(2) Severity of dermal rerouting (Dermal rerouting score = 0-33 or 0-6);** Indocyanine green (ICG)/ aqua is injected in the patient's hand; linear (normal) and dermal rerouting patterns are visualised. The body is divided into 13 areas and is score between 0 and 3: 0 (normal pattern), 1 (splash pattern), 2 (stardust pattern), and 3 (diffuse pattern).	**Near-infrared fluorescence imaging device with a Photo Dynamic Eye camera (PDE, Hamamatsu) and Indocyanine Green**; team of prof. Devoogdt has demonstrated interrater reliability
2.2 Alterations in sensory processing **2.2.1 Nociceptive problems** **Duration: 20 min**	**(3) Myofascial adhesions (Score = 0-63):**are assessed at 7 locations (i.e., axillary scar, breast or mastectomy scar, pectoral muscles, frontal and lateral chest wall, axilla, and the inframammary fold). Each location is palpated for adhesions at 3 levels (i.e., skin, superficial, and deep) on a 4-points scale (0- no restriction, 1-limited restriction, 2-hard restriction, and 3-very stiff)	**The Evaluation Tool for Myofascial Adhesions in Patients After Breast Cancer (MAP-BC evaluation tool);** developed by the team of prof. De Groef; reliability and validity has been demonstrated
(4) Myofascial tissue stiffness and elasticity **- Myofascial tissue composition and elasticity by Shear-wave elastography (in m/sec)** at the affected and non-affected sides of the lateral trunk, chest wall, and breast.	**MACH 30 Ultrasound device (HOLOGIC®, USA) and two different probes;** measuring the trunk and chest wall, a L18-5 transducer will be used. A L10-2 transducer is needed when measuring the quadrants of the breast. Data will be further processed with Matlab®, using the open software ElastoGUI tool	
- Myofascial tissue tone, stiffness, and elasticity by MyotonPro (in N/m) at the pectoralis major, upper trapezius, infraspinatus, and teres major muscles. The higher value shows the stiffer muscle.	**MyotonPRO;** this measurement is currently being tested on reliability in breast cancer patients by the team of prof. De Groef. Reliability and validity have been established in other populations	
(5)Local tenderness (in kg/cm2):pain pressure threshold on affected and non-affected lateral trunk and non-affected tibialis anterior; patient is asked to say 'stop' when the sensation of pressure first changes to pain.	**Digital Wagner FPX™ algometer**, team of prof. De Groef has demonstrated reliability	
(6) Impaired shoulder ROM (°);in sitting position, ROM of arm abduction	**Inclinometer (Dr. Rippstein (Switzerland) Plurimeter-V),** team of prof. De Groef has demonstrated reliability	
2.2 Alterations in sensory processing **2.2.2 Neuropathic problems** **Duration: 20 min**	**(7) Presence of neuropathic pain (yes/ no);**self-reported questionnaire consists of two parts (interview and examination). The presence of neuropathic pain is "yes" if the total score of DN4 is ≥4 of 10.	**Douleur neuropathique en 4 questions (DN4)** ; reliable and valid questionnaire to identify pain of predominantly neuropathic origin
(8) Presence of sensory loss (score between 0.25 – 512 mN): assessed based on Quantitative Sensory Testing (QST). The mechanical detection threshold will be determined at affected and non-affected inner upper arm, lateral trunk, and non-affected tibialis anterior muscle.	**QST with standardized set of 12 nylon monofilaments** (Optihair2-Set, Marstock Nervtest); team of prof. De Groef demonstrated reliability	
(10) Presence of altered thermal function (yes/ no): thermal detection and pain thresholds will be determined at affected and non-affected inner upper arm, lateral trunk, and non-affected tibialis anterior muscle and compared with normative data.	**QST with Thermotest device TSA-2 NeuroSensory Analyser**, team of prof. De Groef demonstrated reliability	
(10) Presence of altered proprioception (in µm); the patient is asked to locate the bump on the plate with the affected and non-affected index finger pad. The BUMPS detection threshold is defined as the lowest bump that successfully detected.	**The BUMPS device**, with five circle shape plates, each plates contains a raised shape cylinder shaped bump; the height of the BUMPS varies between 5-25 µm	
(11) Altered sensory acuity (between 0 - 100 mm); assessed as two-point discrimination ability at the affected and non-affected inner side of upper arm and lateral side of the trunk; patient has to indicate when she/ he feels one or two points; test starts with 0 mm and increases until the patient feels two different points.	**Baseline aesthesiometer,** team of prof. De Groef demonstrated reliability	
2.2 Alterations in sensory processing **2.2.3 Central sensory problems** **Duration: 20 min**	**(12) Presence of a dysfunctional inhibitory pain mechanism (yes/ no);**test and conditioning stimulus is applied on the non-affected tibialis anterior muscle and non-affected hand. A test stimulus is used to assess pain sensitivity to a pre- and post-conditioning stimulus. When the second pressure pain threshold (i.e., test stimulus) is similar or lower than the first, dysfunctional inhibitory pain mechanism is "yes".	**A cold water bath and a digital Wagner FPX™ algometer**; team of prof. Meeus has demonstrated reliability
(13) Presence of enhanced facilitating mechanisms (yes/ no); repetitive 15 stimuli at affected lateral trunk and non-affected tibialis anterior. Perceived intensity of stimulus is measured by Numeric Rating Scale (NRS). If the score on the NRS is increased >2, enhanced facilitating mechanism is "yes".	**Pinprick stimulator (MRC Systems GmBH, Heidelberg),**team of prof. De Groef demonstrated reliability	
(14) Altered body perception (score 0-36);self-reported questionnaire evaluating neglect-like symptoms, reduced sensory acuity, and perceived limb size and consists of 9 items. Each item is scored on a 5-point Likert scale from 0 (never) to 4 (always).	**Adapted Fremantle Upper Limb Awareness Questionnaire;** reliable and valid questionnaire	

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: Nele Devoogdt (PI) and An De Groef
2. Storage capacity/repository during and after the research:
   All data and document will be stored and organized with the electronic application REDCap (Research Electronic Data Capture). It is a web-based software and tool set that allows researchers to create secure online forms for data capture, management and analysis. It is already widely used in many academic medical centers. Data will be stored for at least 25 years.
   Data will be stored and automatically backed up in REDCap and the server of KU Leuven. The REDcap server is hosted and managed by the UKU Leuven ICT department. The data is backed up on a daily basis in addition to daily snapshots of the server. The backups and snapshots are retained for a period of 14 days.
   Authentication is based on a personal username and password, using the KU Leuven's Active directory server for authentication. Authorisation in redcap is granted on a project basis through REDcap's internal authorisation mechanism.
   All data will be stored for a period of 20/25 years in REDcap. If the application will be taken out of commission before this period and without a datamigration to a new platform, data will be exported to ODM XML, an XML format for exchanging and archiving clinical data, associated metadata and audit information.

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)

n/a

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 from human participants will be collected and stored on a secured and private server. In exception of the identification log; all data will be pseudonymized (using a personal study number per participant)

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

n/a

LymphSens project
DPIA

DPIA

Have you performed a DPIA for the personal data processing activities for this project?

- Not applicable

LymphSens project
GDPR

GDPR

Have you registered personal data processing activities for this project?

- Not applicable