**Title Page – Informed Consent:**

# "Eccentric strength training in cardiac rehabilitation: randomized controlled clinical trial aiming to investigate the effectiveness and feasibility in a patient population with heart failure with reduced systolic pump function."

# Participant Information Sheet

**Title of the study:**
“Eccentric strength training in cardiac rehabilitation: randomized controlled clinical trial aiming to investigate the effectiveness and feasibility in a patient population with heart failure with reduced systolic pump function.”

**Sponsor:**
Cardiac Rehabilitation Department UHAntwerp, Drie Eikenstraat 655, 2650 Edegem

**Principal Investigator:**
xxx

**Researchers:**
xxx

**Contact person for information:**
xxx

**Medical Ethics Committee:**
Ethics Committee UZA-UA
UZA, Drie Eikenstraat 655, 2650 Edegem
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Dear participant,

You are invited to voluntarily participate in a study concerning eccentric strength training within cardiac rehabilitation. In this study, two modalities of strength training will be compared: eccentric strength training versus concentric strength training.
Concentric strength training is well-known; in this form of training, the muscle shortens while generating force. Eccentric strength training is training in which the muscle lengthens while generating force. The starting positions for concentric and eccentric strength training are identical. In general, more force can be generated when the muscle is lengthened.
Before you decide whether to participate, it is important that you read this information sheet.

1. **Study-specific information**

This study was approved on 12/12/2022 by the independent Ethics Committee UHAntwerp-UA.

**Purpose and description of the study**
This is a scientific study in which approximately 40 individuals are expected to participate.
The purpose of this clinical study is to investigate the effectiveness and feasibility of eccentric strength training in patients with heart failure and reduced pump function.
The goal of the cardiac rehabilitation program itself remains unchanged.
This is an interventional study. This means that you will participate in a rehabilitation program and undergo testing as foreseen in this program.
If you agree to participate and meet all eligibility criteria, the standard tests of the rehabilitation program (exercise testing, strength testing, anthropometric measurements) will be performed.

In addition to these standard tests, three extra measurements will take place at the start and at the end of rehabilitation.

**a) Additional measurements at the start of rehabilitation:**

- Completing a **questionnaire** (5–10 minutes).
- **6-minute walk test:** a functional test evaluating how many meters you can walk in 6 minutes. This test will take place during the first training week (6 minutes).
- **Timed Up and Go:** a short functional test assessing how quickly you can stand up and begin walking.
- **Biodex measurement:** this muscle strength test will take place at the SPORTS department during the first training week and takes a maximum of 15 minutes (including transport).

**b) At the end of rehabilitation:**

- Completing the same **questionnaire** as at baseline.
- **6-minute walk test** during the final training week.
- **Timed Up and Go** test.
- **Biodex measurement** during the final training week (maximum 15 minutes including transport).

The additional measurements collect data on physical activity level, quality of life, and demographic characteristics.
All data will be processed confidentially and anonymously. You may request access to these data at any time.
Data routinely collected in the context of good clinical care during cardiac rehabilitation will be stored in your medical record (EHR).

**Duration of the rehabilitation trajectory**
This rehabilitation program lasts 13 weeks. You may withdraw at any time.

**Risks and benefits**

- There are few or no health risks associated with the additional measurements.
  *Some individuals may experience muscle soreness or cramps following strength testing. Blood sampling rarely causes complications, though a (painful) bruise may occur.*
- There are few or no health risks associated with strength training. You may experience musculoskeletal discomfort or stiffness due to increased physical activity. Strength training is individualized based on your capacity and prior testing.
  Risk of overload is assessed during screening and the initial exercise test.

## 2. General information regarding participation

**Voluntary participation**
If you agree to participate, you should keep this information sheet. You will be asked to sign the attached consent form.
Your participation is entirely voluntary. You have the right to refuse participation.
You may withdraw your consent at any time, without providing a reason. This will not disadvantage you in any way.
Your decision will not affect your further treatment, nor your relationship with your physician or the hospital.
Your participation may also be terminated at any time by the researchers or the ethics committee without your consent. Possible reasons include:

- You do not follow study instructions
- Continued participation appears harmful
- You are found to no longer meet eligibility criteria

**Costs and compensation**
This study will not entail additional costs for you. All study-related expenses are covered by the sponsor or researchers.
Costs unrelated to the study but related to your standard treatment remain your responsibility or that of your health insurer.

**Protection of your privacy**
Your identity and participation will be treated confidentially. You will not be identified by name in any documents, results, or publications.
To protect your privacy, your data will be **pseudonymized**: your name, first name, date of birth, and address will be replaced by a code. The link between the code and your identity will be retained solely to allow communication of relevant medical findings to you if necessary.

**Protection of your personal data**
By consenting to participate, you agree that your personal data collected for the study may be used.
You may withdraw consent for data collection and processing at any time.
If you withdraw from the study, the data collected up to that point may still be used for scientific purposes.
Only individuals directly involved in the study will have access to your personal data.
Your data will not be shared with third parties.
Researchers will store your study data for **20 years**.
Medical data in your UZA patient record will be stored for **30 years**.
You have the right to request information about your data, to correct or delete data, or to request that your data no longer be used.
All data will be handled in accordance with the **General Data Protection Regulation (GDPR – EU 2016/679)** and applicable Belgian legislation.

The **University Hospital Antwerp (UZA)** is the data controller.
Questions about data protection may be addressed to the study physician, your treating physician, or the Data Protection Officer at: **dpo@uza.be**.
If you believe your rights are not respected, you may contact the Data Protection Officer or file a complaint with the Belgian Data Protection Authority.
More information: https://www.uza.be/privacy.html.

We hope this document has provided sufficient information about the study.
You have the right to ask additional questions at any time about the content, purpose, or procedures of the study, or about the potential risks and benefits.
You may contact the researchers or the designated contact person

Date *(day/month/year)*

**CONSENT FORM**

**"Eccentric strength training in cardiac rehabilitation: randomized controlled clinical trial aiming to investigate the effectiveness and feasibility in a patient population with heart failure with reduced systolic pump function."**

– Eccentric strength training in cardiac rehabilitation –

**Section for the participant**

I, the undersigned …… (full name of participant), hereby confirm that I have been informed about the study and have received a copy of the participant information sheet.

I have read and understood the information. The researcher has provided sufficient explanation regarding the purpose, design, conditions, duration of the study, and its potential known risks or benefits. I was given sufficient time to consider the information and to ask questions, which were answered satisfactorily.

I am aware that I may refuse participation and that I may withdraw my consent for participation and for use of my data at any time, after informing the researcher, without any disadvantage to me. My original consent allows use of my data collected during the period in which I participated.

I am aware of the purpose for which my medical data are collected, processed, and used as part of this study. I understand that my data will be stored for 20 years for scientific research. My medical data will be stored in my medical record for 30 years.

I know that I have the right to access and correct my data. If I have any complaints regarding data management, I may contact the researchers, my physician, or the Data Protection Officer at UZA: dpo@uza.be.

I give my consent to the researcher to collect, process, and use my data as described in the information sheet and in accordance with applicable law. My data will be treated strictly confidentially. When study results are published, my identity will remain anonymous.
I voluntarily agree to participate in this study and to complete all study-related procedures.

Name of participant (block letters) Signature + Date (day/month/year)

**Section for the study team**

I confirm that I have informed ……
(name of participant) and that he/she has given consent to participate in the study.

Name (block letters) Signature + Date (day/month/year)