TITLE: EFFICACY AND SAFETY OF A REMOTE CONDITIONING EXERCISE PROGRAM IN PATIENTS WITH LONG-TERM VENTRICULAR ASSIST DEVICES: THE RE-ACTION-VAD TRIAL.

STUDY PROTOCOL and STATISTICAL ANALYSIS PLAN:

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TITLE: EFFICACY AND SAFETY OF A REMOTE CONDITIONING EXERCISE PROGRAM IN PATIENTS WITH LONG-TERM VENTRICULAR ASSIST DEVICES: THE RE-ACTION-VAD TRIAL.

INVESTIGATOR TEAM
Department: Cardiology Service, Advanced Heart Failure and Heart Transplant Unit, Hospital Puerta de Hierro Majadahonda

Collaborating Investigators:
Currently, 10 tertiary centersin Spain have confirmed participation in the project. The collaborating investigators from these centers are listed below:

- Hospital Universitario Puerta de Hierro (Madrid)
- Hospital Universitario Ramón y Cajal (Madrid)
- Hospital Universitario 12 de octubre (Madrid)
- Hospital Universitario Clínico San Carlos (Madrid)
- Hospital Clinic de Barcelona
- Hospital Universitari de Bellvitge (Barcelona)
- Hospital Universitario de Salamanca
- Complexo Hospitalario Universitario de Santiago de Compostela
- Complexo Hospitalario Universitario de A Coruña
- Hospital Universitario Virgen del Rocío (Sevilla)

i. Abstract

The RE-ACTION-VAD TRIAL is the first multicenter randomized clinical trial that will evaluate the efficacy and safety of a remote conditioning exercise program in patients with a recent implant of a long-term left ventricular assist device (LVAD). Seventy-eight patients will be included and randomized 1:1 to:

1. Remote conditioning exercise program group: patients will perform home-based aerobic, strength, and respiratory training for three months, monitored through a mobile application that will also include general recommendations on LVADs, nutrition, and emotional coping strategies; or
2. Standard care group: written general exercise recommendations will be provided. The primary endpoint is to assess whether there is an improvement in the distance covered during the 6-minute walk test at a 6-month follow-up. As secondary endpoints, safety, quality of life, anxiety, depression, as well as the degree of satisfaction and program compliance will be evaluated.

ii. Introduction: the importance of the problem

Despite advances in the treatment of heart failure (HF) (1,2), 10% of patients present an advanced stage. This stage is characterized by signs and symptoms refractory to recommended therapies and presents a morbidity and mortality rate exceeding 50% at one year. Currently, there are three possible treatment pathways in this stage: heart transplantation, long-term left ventricular assist devices (LVADs), and palliative care (3). Although heart transplantation is the option providing the greatest long-term survival and quality of life, only a small proportion of patients end up receiving it; this, along with technological improvements, has made LVADs a prominent option in recent years, either as destination therapy or as a bridge to transplantation. LVAD implants in our country have been growing exponentially in recent years, largely driven by the favorable results regarding increased complication-free survival with the only model currently on the market, the HeartMate 3® (4,5).

However, these devices still have significant limitations that substantially impair patients' functional capacity following implantation (6). Some of these are inherent to the current design of the device itself, which connects to the outside via a driveline exiting the patient's abdomen, accompanied by two 1.2 kg batteries from which the patient cannot be separated. Others are related to the device's functionality, which provides continuous flow at a fixed speed, and any variations in this flow depend on changes in preload and afterload, which are in turn determined by a right ventricle that is not supported by the device. Finally, there are patient-dependent factors, such as physical deconditioning due to advanced HF and the impact of the cardiac surgery required for the implant. The aforementioned reasons explain, at least in part, why they are unable to recover the desirable exercise capacity after implantation.

Therefore, cardiac rehabilitation is proposed as a fundamental element that can help reverse the aforementioned factors. Nevertheless, there is very little existing evidence regarding its usefulness in this patient subgroup. Most studies are single-center, small in size, and non-randomized, employing different LVAD models—some pulsatile and others with continuous axial flow—which might behave differently during exercise compared to the centrifugal-flow HeartMate 3. Despite the limitations, most studies conclude that there is a benefit to cardiac rehabilitation for these patients (7–12). For all these reasons, the guidelines of the International Society for Heart and Lung Transplantation (ISHLT) do recognize the need for a correct assessment of the functional capacity of these patients and the necessity for cardiac rehabilitation programs in LVAD patients (class I recommendation, level of evidence C) (13); the European Society of Cardiology does so similarly in a consensus document (14).

Recently, a group from Berlin published a randomized study comparing a 12-week supervised cardiac rehabilitation program against standard clinical care (15). Fifty-four patients with a HeartMate 3 were included, with no significant differences observed in the increase of peak oxygen consumption between groups. However, a greater positive effect was observed in the group of patients undergoing cardiac rehabilitation regarding submaximal exercise capacity and the 6-minute walk test, as well as in quality of life measured by the Kansas City questionnaire. It is important to highlight that overall adherence was high and there were no differences in adverse events between both groups. Despite international recommendations, the reality is that very few centers worldwide are offering cardiac rehabilitation to these patients. In many cases, patients receive written general exercise recommendations, which, in other cardiology scenarios, correlates with a higher rate of all-cause hospitalizations and poorer quality of life according to the most current meta-analyses (16).

Our group (Dr. Rivas Lasarte, Dr. Garrido González), thanks to the collaboration between Hospital Puerta de Hierro and Hospital Ramón y Cajal in Madrid (Dr. Carmen de Pablo), conducted a pilot study between 2023 and March 2025 on the safety and efficacy of a 12-week supervised cardiac rehabilitation program, followed by monitoring via a mobile application for 6 months (REHAB ASSIST Study). The preliminary results of this study were presented at the national congress of the Spanish Society of Cardiology (SEC) in 2024 and 2025 (17), and at the annual meeting of the International Society for Heart and Lung Transplantation (ISHLT) in Boston in 2025. 15 patients have been included, and, analogous to our German colleagues, we observed an improvement in the 6-minute walk test and the Kansas City quality of life

questionnaire, as well as in submaximal cardiopulmonary exercise testing parameters. Furthermore, the program was safe, with no events attributable to the supervised rehabilitation sessions or those the patients performed at home.

One of the limitations of our pilot study was that approximately 50% of the patients offered the opportunity to participate in the rehabilitation program declined the offer, mostly due to the distance to the rehabilitation center. Hence the need arises to offer an alternative to these patients, who receive no intervention regarding exercise beyond general recommendations.

The COVID-19 pandemic has taught us the importance of telemedicine and moving patient care outside of hospitals. This has several objectives: to be more efficient in optimizing resources; to reach a larger number of patients; and to advance the personalization of medicine. In this regard, cardiac rehabilitation has made efforts to adapt by establishing hybrid systems that combine supervised sessions with home-based ones. However, for patients with LVADs, there are no published experiences in this regard to date.

For all the aforementioned reasons, we consider it a priority, both for patients and for the public health system, to generate evidence regarding the efficacy (improvement in functional capacity and quality of life) and safety of a remote conditioning exercise program via a mobile application following LVAD implantation, compared to standard practice in patients unable to attend a supervised rehabilitation program. A program requiring few supervised visits, which is customizable and can be performed remotely with the aim of improving patients' exercise capacity and quality of life. In addition, this program is designed to support the patient and their caregivers in the immediate post-implantation stage, as this is the period of greatest vulnerability when the patient faces the fears of going home with a new life-dependent device. If this study succeeds in demonstrating the efficacy and safety of this program, it could be exported to all patients implanted with an LVAD regardless of their place of residence and the implanting center, thus maximizing the outcomes of this costly therapy.

iii. Methods

- **Hypothesis:** A remote conditioning exercise program monitored via a mobile application in patients following LVAD implantation will be efficacious and safe compared to standard care (general exercise recommendations).
- **Study Design:** Multicenter and randomized clinical trial. Participation will be proposed to all patients with a recent LVAD implant (< 6 months) who are unable to carry out a supervised rehabilitation program (patients undergoing supervised rehabilitation will be included in the previously mentioned REHAB ASSIST prospective registry). Included patients will be randomized 1:1 (via the REDCap application, stratified by the participating center's region) to:
    1. Remote conditioning exercise program monitored via a mobile application, or
    2. Standard exercise recommendations and conventional follow-up according to each center's protocol.

- **Primary Endpoint:** To evaluate the efficacy of a remote conditioning exercise program monitored via a mobile application in patients following LVAD implantation regarding the distance walked in the 6-minute walk test compared to standard practice (general exercise recommendations).
- **Secondary Endpoints:** To evaluate the efficacy of a remote conditioning exercise program monitored via a mobile application in patients following LVAD implantation compared to standard practice regarding:
    1. To evaluate the program's safety: device alarms, symptomatic hypotension, driveline infections, device-related thromboembolic or hemorrhagic complications, cardiovascular events, ventricular arrhythmias, and heart failure decompensations.
    2. Oxygen consumption and other submaximal cardiopulmonary exercise testing parameters.

3. Global score on the Kansas City Cardiomyopathy Questionnaire (KCCQ) and the Minnesota Living with Heart Failure Questionnaire (MLHFQ).
4. Psychological questionnaires: Beck Depression Inventory (BDI-II), Hospital Anxiety and Depression Scale (HADS).
5. Frailty measured by the Fried scale.
6. To assess satisfaction with the program (questionnaires and adherence).

- **Exploratory Analyses:**
  1. Endpoints will be evaluated by sex and by LVAD intention (bridge to transplantation or destination therapy).
  2. The results of the remote conditioning exercise program will be compared with those of the supervised rehabilitation cohort (REHAB-ASSIST).

Study Subjects, Inclusion/Exclusion Criteria

Inclusion criteria (must meet all):

- Adult patients with a recent LVAD implant (<6 months).
- Inability to perform a supervised rehabilitation program due to a lack of availability in their region or an inability to attend sessions due to distance from their home.
- Clinical stability defined as meeting all of the following: having been discharged from the implant hospitalization, absence of inotropic medication, hemoglobin >9 g/dL, and absence of active infection.

Exclusion criteria (any):

- Functional inability to perform cardiopulmonary exercise testing.
- Patients who have followed a supervised rehabilitation program after implantation.

Summary of the Intervention

For all patients:

Baseline, 12-week, and 6-month visits will be conducted and will include:

- Clinical evaluation of the patient and the device.
- Comprehensive laboratory tests including cardiac biomarkers (NT-proBNP, CA125).
- 6-minute walk test.
- Cardiopulmonary exercise testing.
- Quality of life and psychological questionnaires: Kansas City Cardiomyopathy Questionnaire, Minnesota Living with Heart Failure Questionnaire (MLHFQ), Beck Depression Inventory (BDI-II), Hospital Anxiety and Depression Scale (HADS), frailty by the Fried scale, Caregiver burden by the Zarit scale.
- Habits questionnaire: daily steps and nutrition.
- Measurement of respiratory muscle strength (MIP device: RP Check Sibelmed Diagnostics LTD).
- Tinetti balance test. If impaired, it will be repeated at the end of the program.

Remote conditioning exercise program group:

- Supervised educational period during the first week of the program (Monday, Wednesday, and Friday) during which warm-up exercises, treadmill walking, strength exercises, and incentive spirometry will be performed.
- Subsequently, the exercise will be continued at home with remote monitoring for 12 weeks.
- The exercise prescription will be individualized, recommending:
  - Specified warm-up routines (supported by educational videos).
  - Respiratory training using incentive spirometers (PowerBreathe Medic device) 5 days a week.
  - Walking, either on a treadmill or cycling, at an intensity close to the first ventilatory threshold or its equivalent using a Borg scale of 12-14, in a 30-minute session in the morning and 30 minutes in the afternoon, at least 3 days a week (ideally 5).

    - Strength training: physiotherapy routine with weighted dumbbells (1-2 kg) for lower and upper limbs 3 days a week.
- Each session will last at least 10 minutes, with a progressive increase in duration up to a maximum of 20 minutes depending on the patient's tolerance.
- The patient's activity will be monitored using an activity tracker bracelet and questionnaires through the mobile application. Motivational messages will be sent periodically to encourage compliance. Weekly video calls will be held to resolve questions and conduct follow-up. The application will also contain educational videos on the general care and management of LVADs, healthy lifestyle habits, nutrition, psychology, and relaxation and exercise techniques.

Control Group:
These patients will be provided with general exercise recommendations (written material).

Statistical Analysis
All statistical analyses will be performed according to the intention-to-treat principle. Continuous variables will be expressed as mean and standard deviation or median and 25th and 75th percentiles. Categorical variables will be compared using the Chi-square test or Fisher's exact test. The analysis of the primary endpoint and other continuous variables will be performed using the Student's t-test or the nonparametric alternative with the Mann-Whitney U test. P-values less than 0.05 will be considered statistically significant.

Sample Size Calculation
According to our pilot study, the supervised rehabilitation program resulted in an improvement in the distance covered in the 6-minute walk test of 58 meters. In the aforementioned German study (15), the difference between both groups was 43 meters. Considering that 1) training via remote conditioning may not be as effective in improving functional capacity, as demonstrated by previous experiences in patients with ischemic heart disease, and 2) there is a consensus that a difference of + 30 meters in this test in HF patients is clinically relevant, the following sample size calculation was performed: To achieve 80% power to detect differences in the testing of the null hypothesis $H_0:\mu_1=\mu_2$ using a two-sided Student's t-test for two independent samples, considering a significance level of 5%, and assuming a difference between both groups of 35m and a standard deviation in both groups of 50m, it will be necessary to include 33 patients in each group, totaling 66 patients in the study. Taking into account that the expected dropout rate is 15%, it would be necessary to recruit 39 patients in each group, totaling 78 patients in the study.

Study variables
Data collection will be performed using a secure and validated electronic data capture system provided by a Contract Research Organization (CRO). Access will be restricted to the study investigators, ensuring the confidentiality, integrity, and traceability of information. All data will be stored on secure servers in compliance with current ethical and legal regulations for the protection of personal and sensitive data in biomedical research.

The study variables will include the following:
- Patient-related variables: anthropometric data, demographics, comorbidities, and characteristics of heart failure.
- Cardiopulmonary exercise testing (CPET) before and after the program: peak VO_2, VE/VCO_2 slope, oxygen uptake efficiency slope (OUES), aerobic and anaerobic thresholds, $PETO_2$ and $PETCO_2$, ventilatory class.
- 6-minute walk test before and after the program.
- Safety events: device alarms, symptomatic hypotension, driveline infections, device-related thromboembolic or hemorrhagic complications, cardiovascular events, ventricular arrhythmias, and heart failure decompensations.
- Laboratory analyses: basic biochemical profile including NT-proBNP and CA125, before and after the program.
- Quality of life and psychological questionnaires: Kansas City Cardiomyopathy Questionnaire (KCCQ), Minnesota Living with Heart Failure Questionnaire (MLHFQ), Beck Depression Inventory

(BDI-II), Hospital Anxiety and Depression Scale (HADS), frailty by Fried scale, caregiver burden via Zarit scale.
- Weekly step count: measured with a smart watch at baseline, at the end of the program, and at 3 months.
- Muscle strength before and after the program: Daniels scale, calculation of 1RM for each muscle group, and body composition (via bioimpedance).
- Lifestyle questionnaire: daily steps and nutrition.
- Respiratory strength measurement: using PIM device (RP Check, Sibelmed Diagnostics LTD).
- Balance assessment: Tinetti test; if impaired, it will be repeated at the end of the program.

iv. Doctoral program and scientific research

Since the initiation of the REHAB-ASSIST pilot study and continuing into this study, Dr. Ramón Garrido González has launched a line of research for his doctoral thesis, supervised by Dr. Mercedes Rivas Lasarte and Dr. Javier Segovia Cubero.

Preliminary results from the REHAB-ASSIST pilot study have been presented at major national and international conferences and are currently being prepared for publication in an international peer-reviewed journal. Likewise, results from the upcoming RE-ACTION-VAD TRIAL are expected to be published in scientific journals and disseminated through general media.

v. Study development phases and estimated timeline

Phase 1: Preparatory Stage (M0–M6)
- June 2025: Ethics committee approval at Hospital Universitario Puerta de Hierro Majadahonda; initiation of procedures at other participating centers.
- January–June 2026: Development of the mobile application (including patient sessions to validate content) and recording of program materials.
- January–June 2026: On-site rotation at Hospital Universitario Ramón y Cajal for all centers to harmonize the exercise protocol.

Phase 2: Patient Enrollment in the Clinical Trial (M6–M33)
- June 2026: Start of patient recruitment.
- March 2028: End of recruitment.
- September 2028: Completion of the program for the last enrolled patients.

Phase 3: Data Analysis and Dissemination (M33–M36)
- September–October 2028: Data analysis.
- November 2028: Writing of the main manuscript.
- December 2028: Publication of study results.

vi. Study limitations, risks, and contingency plan

Although the use of long-term ventricular assist devices (VADs) has grown exponentially in recent years, implantation rates in our country remain limited. To achieve a sample size sufficient to detect differences between groups, we have contacted the Advanced Heart Failure Units with the highest LVAD volumes in Spain, as well as leading national cardiac rehabilitation units, to facilitate recruitment and standardize patient follow-up.

To minimize variability in the intervention, the following measures are planned:
1. Pre-study meetings to standardize the protocol.
2. On-site rotations of all participating centers through the Rehabilitation Unit at Hospital Universitario Ramón y Cajal.
3. Monthly supervision meetings to monitor adherence.
4. Availability of urgent contact (within 24–48 hours) with the coordinating center to resolve any questions.

If patient enrollment is abnormally low during the first year, two contingency strategies are planned:
1. Include patients up to 1 year post-implant.
2. Expand recruitment to additional centers.

vii. Ethical considerations and data confidentiality

Published evidence to date indicates that cardiac rehabilitation in patients with long-term ventricular assist devices (VADs) is both effective and safe. Although the available evidence remains limited, scientific societies recommend participation in structured rehabilitation programs for this population. Therefore, participation in this study does not entail harm to the patient.

Patients who decline participation in this study had declined a supervised cardiac rehabilitation program outside the study (provided no contraindications are present), as it is considered beneficial and clinically indicated.

The data used for the development of this project will be processed as follows:

1. In accordance with Regulation (EU) 2016/679 (General Data Protection Regulation, GDPR) and Ley Orgánica Española 3/2018 on Personal Data Protection;
2. In accordance with the Privacy and Information Security Policy of the Instituto de Investigación Puerta de Hierro–Segovia de Arana (IDIPHISA);
3. In compliance with ethical principles governing biomedical research.

The Principal Investigator (PI) will be responsible at all times for data custody and for ensuring that data processing during the study period and for 10 years thereafter complies with the aforementioned ethical and legal standards.

Data will be recorded and stored in a secure, validated electronic data capture system managed by a Contract Research Organization (CRO). The system supports longitudinal follow-up and collaborative research workflows. Authorized investigators will be provided with individualized login credentials to enter anonymized and coded data. Patient identities will be stored separately in an offline, password-protected file accessible only to authorized personnel.

The platform will maintain audit trails to monitor data handling and user activity and will incorporate role-based access controls. It will comply with applicable national and international regulatory requirements, including GDPR (EU) 2016/679. Data exports for analysis will be restricted to the Principal Investigator.

The PI will ensure that all analyses remain consistent with the terms of the informed consent and that any data transfers are performed using appropriate anonymization procedures.

Upon completion of the project and publication of the primary analysis, appropriately anonymized datasets will be deposited in the Zenodo repository. The uploaded dataset will be accompanied by metadata describing:

1. Data provenance;
2. Patient population characteristics;
3. Variable definitions.

Access to internally stored data for other legitimate researchers will require approval from the corresponding Ethics Committee. This approach ensures compliance with open-access requirements applicable to publicly funded projects while maintaining a restricted environment appropriate for personal data protection.

Data may be collected directly from participants who consent to participate in the study or through medical and/or laboratory testing. In certain cases, pre-existing data from medical records may also be accessed by authorized clinical research personnel, with the participant's consent. For the purposes of this project, personal data will be categorized as: identifying data, demographic data, personal characteristics, and health-related data (including questionnaires, physical examination findings, laboratory tests, imaging studies, and other clinical assessments).

All details will be further specified in a Data Management Plan to be developed prior to data collection, ensuring that the data are Findable, Accessible, Interoperable, and Reusable (FAIR principles).

The mobile application used for the intervention is being developed. Similar versions of this application have previously been used in other cardiac telerehabilitation projects at our center. The application complies with all applicable regulatory requirements for medical software, including medical device regulations and data protection standards:

- Manufacturing license for medical devices (AEMPS, Spanish Ministry of Health)

- Registration in EUDAMED (EU) as a medical device manufacturer
- Registration as a medical device distributor (Generalitat de Catalunya)
- CE marking – Class I (MDR)
- GDPR and HIPAA compliance
- EU trademarks and copyrights
- ISO 27001
- ISO 14971:2019
- ISO 62304:2006
- ISO 13485
- IEC 62366-1:2015 / COR1:2016

The platform will not be integrated into the hospital's internal system. Healthcare professionals will access it via a secure web portal.

The results of the project will be disseminated in high-impact, peer-reviewed scientific journals, with preference given to open-access publication. A specific budget allocation has been planned to support this objective.

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Supplementary material. Central figure:

EFICACIA Y SEGURIDAD DEL REACONDICIONAMIENTO FÍSICO REMOTO EN PACIENTES CON ASISTENCIA VENTRICULAR DE LARGA DURACIÓN

THE RE-ACTION-VAD-TRIAL

Ensayo clínico multicéntrico

Hospitales Puerta de Hierro, Ramón y Cajal, 12 Octubre, Clínico San Carlos, CHUAC, CHUS, Clínic, Bellvitge, Salamanca, Virgen del Rocío

Población de estudio

Pacientes> 18 años
Implante asistencia ventricular< 6 meses
Incapaces de hacer rehabilitación presencial

Intervención

Aleatorización 1:1
Grupo re acondicionamiento remoto: programa supervisado online entrenamiento aeróbico, fuerza y respiratorio
Grupo control: recomendaciones generales de ejercicio

Enpoints (6 meses)

Eficacia: distancia recorrida en TM6M, ergoespirometría, calidad de vida
Seguridad: alarmas del dispositivo, infecciones de *driveline,* arritmias ventriculares, sangrados digestivos.