

# Impact of cardiovascular rehabilitation and in TAVI (transcatheter aortic valve implantation) patients. Comparison with the impact of telerehabilitation as an alternative method in TAVI in Covid-19 era

<b>Submission date</b> 11/01/2023	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 10/02/2023	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 02/02/2023	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Transcatheter aortic valve implantation (TAVI) is a surgery that is done to treat a narrowed heart valve. After the surgery, patients can do a program to help improve their heart health, called cardiovascular rehabilitation. Another way to do this program is through a computer or phone, called telerehabilitation. Some studies have shown that these programs can help patients feel better and live longer. This study wants to find out more about how these programs help patients by looking at how well their hearts work, and by measuring certain chemicals in their blood and doing pictures of their hearts.

### Who can participate?

Elderly men and women, 60 to 85 years old, who will have undergone TAVI within a period of time 6 months before the start of the cardiovascular rehabilitation program, with a functional class of heart failure I to III, according to the functional classification of the New York Heart Association (NYHA). Patients should be under medication, have an ejection fraction (EF)  $\geq 40\%$ , and be able to perform mild-intensity exercise.

### What does the study involve?

Participants will be randomly allocated to three groups. Group A (intervention group) will follow a combined exercise protocol (a 12-week combined program of aerobic exercise with strengthening). Group B (intervention group) will follow the same protocol but it will be home-based (telerehabilitation). Group C (control group) will follow a "usual treatment" protocol. The progress of the three groups will be monitored and recorded. Then the results of the three groups will be recorded and correlated.

What are the possible benefits and risks of participating?

There are no risks of participating in the study. The benefits of participating in the study are the improvement of symptoms and quality of life.

Where is the study run from?

University of West Attica (Greece)

When is the study starting and how long is it expected to run for?

January 2021 to December 2024

Who is funding the study?

Investigator initiated and funded

Who is the main contact?

Maria Petridou, mpetridou@uniwa.gr

## Contact information

### Type(s)

Public

### Contact name

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### ClinicalTrials.gov (NCT)

Nil known

### Protocol serial number

Nil known

## Study information

### Scientific Title

Comparative evaluation of cardiovascular rehabilitation programs in patients after transcatheter aortic valve replacement; with evaluation of ergospirometric, functional, imaging and biochemical data and markers

## **Acronym**

CERIVA

## **Study objectives**

The main hypothesis of the study is that the implementation of cardiovascular rehabilitation programs after transcatheter aortic valve replacement (TAVI) improves parameters of ergospirometry, biochemical function, functional capacity and quality of life. In particular, results will be assessed in important indicators of functional capacity, such as peak oxygen uptake ( $VO_{2peak}$ ), slope of respiratory equivalent for carbon dioxide ( $VE/VCO_2$ ), in ultrasound (ejection fraction) and biochemical indices (BNP), in indices of cardiac function, such as heart rate recovery (HRR), while the results will also be investigated in patients' quality of life.

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Approval pending, University of West Attica, Research Ethics Committee (28 Ag. Spyridonos Street, 12243 Egaleo, Greece; +30 (0)21053872948; ethics@uniwa.gr)

## **Study design**

Single-centre randomized single-blind controlled parallel study

## **Primary study design**

Interventional

## **Study type(s)**

Treatment

## **Health condition(s) or problem(s) studied**

Cardiovascular rehabilitation in patients after TAVI

## **Interventions**

Initially, the intervention will include a thorough medical examination, all relevant laboratory and diagnostic tests will be recorded, as well as pathological psychosocial factors and disorders. The first intervention group (group A) will follow a combined exercise protocol (a 12-week combined program of aerobic exercise with strengthening) and the second group (group B) the same protocol as A but taking place in the home of each patient under supervision (with modern means of communication - telerehabilitation). The control group (group C) will receive the usual treatment after TAVI (optimal medication, increased physical activity, correct healthy dietary habits). After the completion of the therapeutic interventions, a final re-evaluation will follow with measurement and recording of all parameters and variables (outcomes) under study, data will be collected and possible differences between the two groups will be investigated. Simple randomisation is used to assign participants to groups.

## **Intervention Type**

Mixed

### **Primary outcome(s)**

Measured at the initial visit and at the end of the study protocol:

1. Functional capacity will be measured using ergospirometric indicators as peak oxygen uptake ( $VO_2$ peak), respiratory equivalent slope for carbon dioxide ( $VE/VCO_2$ )
2. Survival rate will be assessed with the heart rate recovery index (HRR)
3. The effects of cardiac symptoms will be assessed with the SF-36 quality of life scale

### **Key secondary outcome(s)**

There are no secondary outcome measures

### **Completion date**

30/12/2024

## **Eligibility**

### **Key inclusion criteria**

1. Men and women aged 60-85 years
2. Will have undergone TAVI within a period of time 6 months before starting the cardiovascular rehabilitation program
3. Functional class of heart failure I to III, according to the functional classification of the New York Heart Association (NYHA)
4. Patients will be under medication and should have an ejection fraction (EF)  $\geq 40\%$
5. Willing to be assigned to the study

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

60 years

### **Upper age limit**

85 years

### **Sex**

All

### **Key exclusion criteria**

1. Patients with severe-grade coronary artery disease
2. Genetic and non-genetic diseases that cause systolic or diastolic dysfunction
3. History of thromboembolic and vascular events diseases
4. Patients with an individual history of syncope fainting episodes and dangerous arrhythmias
5. Autoimmune patients or endocrinological diseases
6. Respiratory ailments

7. Neoplastic, hepatic, nephrological and infectious disease
8. Patients with disorders affecting the ability to exercise

**Date of first enrolment**

01/02/2023

**Date of final enrolment**

01/06/2024

## Locations

**Countries of recruitment**

Greece

**Study participating centre****University of West Attica**

Laboratory of Neuromuscular and Cardiovascular Study of Motion (LANECASM)

Physiotherapy Department

School of Health and Caring Sciences

28 Ag. Spyridonos Street

Egaleo – Attica

Greece

12243

## Sponsor information

**Organisation**

University of West Attica

**ROR**

<https://ror.org/00r2r5k05>

## Funder(s)

**Funder type**

Other

**Funder Name**

Investigator initiated and funded

# Results and Publications

## Individual participant data (IPD) sharing plan

Individual participant data collected during the trial will be available after de-identification (text, tables, figures, and appendices), beginning 9 months and ending 36 months following article publication. Access will be granted to researchers who provide a methodologically sound proposal, in order for them to achieve the aims in the approved proposal. Proposals should be directed to Ms Maria Petridou (mpetridou@uniwa.gr). To gain access, data requestors will need to sign a data access agreement. After 36 months the data will not be applicable. During recruitment, patients are informed of the purposes of this study. Upon acceptance, and prior to baseline measurements, participants give their written informed consent (document in Greek).

## IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol file</a>	in Greek		16/01/2023	No	No