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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

Submission date 11/01/2023	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 10/02/2023	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 02/02/2023	**Condition category** Circulatory System	[_] Individual participant data [_] 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) ≥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

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Study information

Scientific Title
Comparative evaluation of cardiovascular rehabilitation programs in patients after transcutaneous 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 transcutaneous 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)

Primary study design
Interventional

Study design
Single-centre randomized single-blind controlled parallel study

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_2peak), 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) ≥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
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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?
Protocol file	in Greek		16/01/2023	No	No