

Feasibility of exergaming to reduce sedentary time in persons with an LVAD: The Heart-eXg LVAD-study

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To determine the feasibility of tailored exergaming for persons with a LVAD (acceptability, the demand, the implementation, practicality, adaption, expansion, and perform limited-efficacy testing).

Ethical review	Approved WMO
Status	Pending
Health condition type	Heart failures
Study type	Interventional research previously applied in human subjects

Summary

ID

NL-OMON57537

Source

Onderzoeksportaal

Brief title

Heart-eXg LVAD study

Condition

- Heart failures

Synonym

Heart Failure, LVAD

Research involving

Human

Sponsors and support

Primary sponsor: University of Linköping

Source(s) of monetary or material Support: Eerste geldstroom (geld van Ministerie van OC&W aan universiteiten)

Intervention

- Life style intervention

Explanation

N.a.

Outcome measures

Primary outcome

We will test acceptability, the demand, the implementation, practicality, adaption, expansion, and limited-efficacy testing.

Secondary outcome

NA

Study description

Background summary

Regular physical activity provides important health benefits for persons with a Left Ventricular Assist Device (LVAD). The use of exergames (games to improve physical activity) is promising to decrease sedentary time and increase physical activity. Such a gaming activity should be attractive, tailored to preferences and to capacity.

Study objective

To determine the feasibility of tailored exergaming for persons with a LVAD (acceptability, the demand, the implementation, practicality, adaption, expansion, and perform limited-efficacy testing).

Study design

A feasibility study.

Intervention

An exergame called Heart Farming. Participants will receive the exergame with feedback on

daily goals and an adapted exergaming advice. Participants will also be able to play with a person in their own network or to play virtually with others.

Study burden and risks

Study participants will be recruited from the UMCUtrecht. For the duration of 3 months, they will have access to an exergame (Heart Farming) and have short contacts with a game coach. At baseline and after 3 months, they will be asked to fill out a questionnaire and perform a 6-minute walk test at home. After 3 months, interviews are performed. In addition, all participants will be asked to wear an activity monitor.

Contacts

Scientific

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Trial sites

Trial sites in the Netherlands

Universitair Medisch Centrum Utrecht
Target size: 59

Listed location countries

Netherlands

Eligibility criteria

Age

Elderly (65 years and older)

Adults (18-64 years)

Inclusion criteria

1. Currently having an LVAD (independent of indication)
2. Older than 18 years
3. Being able to perform a six-minute walk test
4. Wanting to use a smartphone for the study (if participants do not have a smartphone, they can borrow it from the study team for the duration of the study).

Exclusion criteria

1. Unable to use an exergame due to visual, hearing, cognitive impairment assessed by a member of the local study team.
2. Not being able to perform the 6-minute walk test.
3. Not being able or willing to wear an activity monitor.
4. Lack of willingness to play an exergame.
5. Co-morbidity that hinders benefitting for this form of exercise (severe cognitive dysfunction, or a life expectancy shorter than 6 months).

Study design

Design

Study phase:	N/A
Study type:	Interventional research previously applied in human subjects
Intervention model:	Single
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	11-05-2025
Enrollment:	59
Duration:	3 months (per patient)
Type:	Anticipated

Medical products/devices used

Product type:	N.a.
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IPD sharing statement

Plan to share IPD: Yes

Plan description

The data will be available for other researcher upon request.

Ethics review

Approved WMO	
Date:	19-05-2025
Application type:	First submission
Review commission:	METC NedMec

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register

Research portal

ID

NL-009665