Effects of exergaming to reduce sedentary time in inactive patients with heart failure: An international multi-center, randomized, parallel-group study

Published: 26-07-2023
Last updated: 21-09-2024

To determine the effect of tailored exergaming for inactive patients with HF to reduce their sedentary time, improve their daily physical activity, exercise capacity, decrease frailty and improve health-related quality of life.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Heart failures
Study type	Interventional

Summary

ID

NL-OMON53279

Source
ToetsingOnline

Brief title
Heart-eXg

Condition

- Heart failures

Synonym
cardiac failure, heart failure

Research involving
Human

Sponsors and support

Primary sponsor: Universteit Linkoping

Source(s) of monetary or material Support: Zweedse nationale onderzoeksraad en Zweedse hartstichting

Intervention

Keyword: exergaming, heart failure, randomized controlled study, sedentary time

Outcome measures

Primary outcome

Primary endpoint is sedentary time (actigraphy).

Secondary outcome

Secondary outcomes are daily physical activity, submaximal exercise capacity,

physical frailty, health-related quality of life.

Study description

Background summary

Heart failure (HF) is an increasing global health concern with over 20 million patients worldwide. A decrease in sedentary time can have beneficial effects for a growing group of inactive patients with HF. The use of exergames (games to improve physical activity) is promising for people who are home bound and physically inactive. Such a gaming activity should be attractive, tailored to preferences and to capacity.

Study objective

To determine the effect of tailored exergaming for inactive patients with HF to reduce their sedentary time, improve their daily physical activity, exercise capacity, decrease frailty and improve health-related quality of life.

Study design

A pilot study and a multicentre, open-label 1:1 randomized clinical trial with 6 months follow-up.

Intervention

On a background of standard guideline-directed medical therapy patients will be

randomized to tailored activity advice (control) or the Heart-Exergame (Heart-eXg) intervention for a period of 3 months. Patients randomized to the Heart-eXg group will receive an exergame with feedback and tailoring to adapt the exergaming advice. Patients will also be able to play with a person in their own network or to play virtually with a volunteer.

Study burden and risks

Study participants (patients with HF) will be recruited and treated according to standard clinical practice. They will be randomized for 3 months to a tailored activity advice or the gaming intervention. At baseline, after 3 and 6 months, participants will be asked to fill out questionnaires, perform a 6-minute walk test, a cognition test, and a frailty test. In addition, all patients will be asked to wear an activity monitor for two weeks before baseline randomisation and after 3 and 6 months.
In terms of benefits and risks, physical activity is important for patients with HF. This study will gain insight into the effects of using an exergame that is easily applicable and affordable. Given the vast growing target population of patients with HF worldwide, and the simplicity of the intervention, potentially millions of patients may benefit from the results of this study. Risk is estimated as very low, since activity level and format are adapted to the patient*s capacity.

Contacts

Public
Universteit Linkoping

Linkoping 1
Linkoping 58983
NL
Scientific
Universteit Linkoping

Linkoping 1
Linkoping 58983
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Diagnosed with symptomatic Heart Failure (NYHA II-IV) as diagnosed by cardiologist, (independent of Ejection Fraction)
2. Clinically stable
3. Physically inactive by self-report
4. Older than 18 years, there is no upper age limit,
5. Speak/understand the language of the country where the study is taking place.
6. Wanting to use a smartphone for the study (if patients 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, e.g. cardiologist, physiotherapist, nurse.
2. Not being able to perform the 6-minute walk test.
3. Not being able or willing to wear an activity monitor.
4. Currently included in a rehabilitation program
5. Lack of willingness to play an exergame.
6. Co-morbidity that hinders benefitting for this form of exercise (history of stroke, severe cognitive dysfunction, or a life expectancy shorter than 6 months).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-06-2023
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO Date:	26-07-2023
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	22-12-2023
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	ID
ClinicalTrials.gov	NCT05641662
CCMO	NL84156.042.23