Enhancing exercise capacity and daily activity of patients with heart failure through Wii gaming
A randomized controlled trial

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

Summary

ID

NL-OMON44600

Source
ToetsingOnline

Brief title
Wii study

Condition

- Heart failures

Synonym
exercise capacity, heartfailure

Research involving
Human

Sponsors and support

Primary sponsor: Linkoping University Sweden

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: excercise capacity, heartfailure, wii gaming

Outcome measures

Primary outcome

Exercise capacity measured by 6 minute walking test

Secondary outcome

Daily physical activity, muscle function, exercise motivation, self-efficacy

beliefs, perceived physical effort, heart failure symptoms, health related

quality of life mortality, global well-being, number of readmissions,

mortality, costs and patient experiences.

Study description

Background summary

Heart failure (HF) is highly prevalent, the estimate total prevalence of heart failure worldwide is 1-2 % The number of HF patients is increasing, due to the aging of the population and the therapeutic advantages which improve survival in patients An increasing number of HF patients is living longer in the community. As part of the treatment in HF, patients are advised to be or become more physically active, because exercise in HF is related to improved outcomes such as decreased symptoms, improved survival and better quality of life . A meta-analysis including 801 patients who had been randomized in trials of exercise training found that patients randomized to training were less often admitted to hospital and had a better prognosis . The most recent study on training in HF patients was the HF-ACTION (Heart Failure: A Controlled Trial Investigating Outcomes of Exercise Training) In this study HF patients who trained in a hospital and home based program improved exercise capacity and had a significant benefit in all-cause mortality.
However, despite positive outcomes of the effects of exercise, adherence to exercise in HF patients is low (around 50%) and non-adherence to recommendations has a negative effect on clinical outcome such as HF readmission and mortality . Also, the main limitation in the HF-ACTION was the

poor adherence to the prescribed training regimen (only 30% after 3 years) and in the COACH study, only 39% of patients reported to be adherent with exercise recommendations, despite the fact that 80% of them recognized its importance . Barriers to being and staying active are often related to motivation and practical issues, such as time, possibility to travel to an exercise or rehabilitation center or costs.
Activity in the home is increasingly studied, by for example introducing walking programs or exercise programs in primary care. Becoming physically active is a first step to get to an excise level to improve outcomes. However, it is not easy to stay motivated and in addition, climates (e.g. cold weather in countries like Sweden or heat in countries like Italy, Australia and Israel) can make it difficult for patients to leave their homes to engage in exercise activities.
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A new approach to increase physical activity at home is the use of *serious virtual reality games*. The use of so-called *serious gaming* are recognized to have much to offer to the fields of prevention and rehabilitation . On the other hand, to avoid a new *hype* overestimating the potentials of these games, these new options should be tested in specific groups of patients.
In a pilot study a promising potential of increasing exercise capacity was seen by introducing a selected group of HF patients to the Wii game computer. However, to test the effectiveness of this intervention a larger randomized study is needed.

Study objective

The overall purpose of the study is to determine the effectiveness of structured introduction and access to a Wii game computer in patients with heart failure (HF) to improve their exercise capacity, their daily physical activity, decrease health care use and improve quality of life.

Study design

A multicentre randomised controlled design with 2 treatment groups/conditions. In each centre, patients will be randomised into one of these conditions: motivational support only (CONTROL) or structured access to a Wii game computer (Wii).

Intervention

Two types of interventions will be tested. All patients receive usual treatment and care. Patients in the Control group will receive an advice on activity and 4 telephone calls. Patients in the Wii group will receive an advice on activity, 4 telephone calls and a Wii game computer.

Study burden and risks

No extra risk associated with participation.Burden to patient due to questionnaires.
Following daily advice regarding physical activity is not an extra burden, but is similar to usual physical activity advice

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

heart failure (Nyha I-V)
> 18 jears
Speaking and understanding Dutch language

Exclusion criteria

patient is unable to use the Nintendo WII due to visual, cognitive or motor impairment
life expectancy shorter than 6 months
The patient is already playing a WII at home

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-09-2015
Enrollment:	81
Type:	Actual

Ethics review

Approved WMO Date:	06-05-2015
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	26-10-2016
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit

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
CCMO	NL48647.068.14

Study results

Date completed: 12-03-2018

Actual enrolment: 84

Summary results
Trial is onging in other countries