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Increasing exercise capacity and quality of life of patients with Heart Failure through Wii gaming: the rationale, design and methodology of the HF-Wii study; a multi-centre randomized controlled trial

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Abstract

Aim: Exercise is known to be beneficial for patients with heart failure (HF) and these patients should therefore routinely be advised to exercise and to be or become physically active.

Despite the beneficial effects of exercise such as improved functional capacity and favorable clinical outcomes, the level of daily physical activity in most patients with HF is low.

Exergaming may be a promising new approach to increase physical activity of patients with HF at home. The aim of this study is to determine the effectiveness of structured introduction and access to a Wii game computer in patients with HF to improve exercise capacity, level of daily physical activity, decrease health care resource use and improve self-care and their health-related quality of life.

Methods and results: A multicentre randomised controlled study with 2 treatment groups will include 600 patients with HF. In each centre, patients will be randomised to either motivational support only (control) or structured access to a Wii game computer (Wii). Patients in the control group will receive advice on physical activity and will be contacted by 4 telephone calls. Patients in the Wii group also will receive advice on physical activity along with a Wii game computer, with instruction and training. The primary endpoint will be exercise capacity at 3 months as measured by the 6 minute walking test. Secondary endpoints include exercise capacity at 6 and 12 months, level of daily physical activity, muscle function, health-related quality of life, hospitalisation or death during the 12 months follow-up.

Conclusion: The HF-Wii study is a randomized study that will evaluate the effect of exergaming in patients with HF. The findings can be useful to health care professionals and improve our understanding of the potential role of exergaming in the treatment and management of patients with HF.
Trial registration: ClinicalTrials.gov Identifier: NCT01785121

Keywords: Exergaming, Heart Failure, serious gaming, exercise capacity, physical activity, self-care
1. Introduction

The number of patients with Heart Failure (HF) is increasing due to the aging of the population and the therapeutic advancements which improve survival of patients with heart disease (1,2). Recent HF guidelines advise regular exercise for patients with HF to improve their functional capacity and decrease their symptoms (1-3). A meta-analysis on exercise training including 801 patients with chronic HF (the ExTraMATCH trial) found that those patients randomized to exercise were less often admitted to the hospital and had a better prognosis than those in the control group (4). The most recent large study on exercise in patients with HF was the HF-ACTION study (Heart Failure: A Controlled Trial Investigating Outcomes of Exercise Training) including 2331 patients with HF. In that study participants who were engaged in a combined hospital and home-based exercise program, had a non-significant reduction in the primary endpoint of all-cause mortality or hospitalization (5) but reported better self-reported health status (6). The two most up to date systematic reviews on the outcomes of exercise in HF are the Cochrane systematic review (7) and a meta-analysis of randomised controlled trials between 1999 and 2013 (8). Although they did not find an effect of cardiac rehabilitation on mortality they did for quality of life and hospitalization.(7,8)

Despite positive outcomes on exercise capacity and quality of life, adherence to exercise in patients with HF is as low as 50% (9), a problem that warrants high priority in health care. Becoming physically active might be the first step to reach the optimal exercise dose to improve health outcomes. Barriers to physical activity are often related to motivation and practical issues, such as time, possibility to travel to a fitness or rehabilitation center or costs (10,11). Another barrier to physical activity could be climate, for example, the cold and rainy weather in countries like Sweden and the Netherlands or the heat and humidity in countries
like Italy and Israel. To increase adherence to exercise, activity at home has been studied in patients with HF showing both feasibility and positive effects on physical capacity in elderly patients with HF (12). But even in home-based physical activity programs adherence might not be optimal due to behavioral and motivational issues (13).

A new approach to increase daily physical activity at home is the use of exergaming. The word ‘exergaming’ is a portmanteau of "exercise" and "gaming", a term for video games that are also a form of exercise. In these kinds of games patients can be encouraged to become active at their own pace, reducing climate impact and social barriers. In a recent scoping review on exergames in older adults, exergaming was described as safe and feasible, resulting in more energy expenditure compared to rest (14). Although the research field of exergaming is small and under development, first results indicate that exergaming might be promising in order to enhance physical activity in patients with HF. In the available studies, the Nintendo Wii exergame platform was the most tested exergame in older adults showing higher energy expenditure and motor function, better balance and cognitive function, decrease in depressive symptoms, a high level of enjoyment and feeling connected with family members (especially grandchildren) without increase in HF symptoms (14). Exergaming seems to have much to offer in the fields of prevention and rehabilitation, however only limited well powered randomized controlled trials are available (14-16). To avoid a new “hype” overestimating the potentials of these games, these new options should be tested in specific groups of patients.

Studies of good quality including older chronic patients are scarce, and some evidence shows that older people may have specific playing preferences (e.g. less interest in extreme sports) and particular difficulties handling complex digital games (14). In a pilot study we studied the feasibility in using a game computer in older patients with HF to increase the exercise capacity (17,18). In a non-university hospital setting in Sweden we included 31 patients with a mean age of 63 (±14), 10 women (32%). No injuries occurred in the pilot study and all
patients were able to successfully play the Wii, only one patient needed 2 additional visits of the instructor. The mean time exergaming a day was 28 min (±13). At baseline the mean score on the six minute walk test (6-MWT) was 477 meters compared to 505 meters after 12 weeks access to the Wii. In total 47% of the patients increased their 6-MWT test by more than 30 meters (which is the clinically relevant difference) after 3 months of access to the Wii (18). After this pilot we set out to determine the effects of structured access to a Wii game computer in patients with HF on exercise capacity and their level of physical activity in an randomized controlled trial, the HF-Wii study. We also aim to test the effects on outcomes beyond exercise and physical activity, such as self-care, readmission, mortality and health-related quality of life. Finally we aim to describe the costs and experiences of patients with HF playing exergames.

2. Methods

2.1 Study Design

A multicentre randomized controlled design with a 2 groups (‘HF-Wii study’). Patients will be randomized to motivational support only (control) or structured access to a Wii game computer (Wii) (Figure 1). The study will be conducted according to the principles of the Declaration of Helsinki (version 2008) and in accordance to the Medical Research Involving Human Subjects Act of the country where the intervention takes place. In Sweden the ethical approval was obtained (DNR 2012/247-31) and additional approval is/will be obtained from the local medical ethical committees. The trial is registered in ClinicalTrial.gov, Identifier: NCT01785121.
2.2 Study population

Study population

Patients will be recruited from outpatient HF clinics, cardiology departments, rehabilitation units or primary care in Sweden, Italy, Israel and the Netherlands.

Inclusion criteria

- Diagnosed with HF (NYHA I-IV) by a cardiologist according to ESC guidelines (1)
- (Independent of Ejection Fraction: Both patients with a preserved ejection fraction (HFpEF) or reduced ejection fraction (HFrEF) will be included)
- Older than 18 years, no upper age limit
- Speak/understand the language of the country where the intervention takes place

Exclusion criteria

- Unable to use the Nintendo Wii due to visual impairment (see a TV screen at a distance of 3 m), hearing impairment (the patient is not able to communicate by telephone), cognitive impairment (assessed by a HF nurse or cardiologist) or motor impairment (the patient should be able to swing his arm at least 10 times in a row).
- Unable to fill in data collection material
- Life expectancy shorter than 6 months

2.3 Treatment and control

Motivational support only (Control): Patients will receive regular treatment and information about rehabilitation and daily physical activity. After enrolment in the study, patients will get an exercise advice from the HF team (nurse, cardiologist or physiotherapist). All patients will
be advised to be active for 30 minutes a day. This might not be applicable to all patients, since some patients only may manage to be active for 10 or 20 minutes and others may manage more than 30 minutes. Therefore, the advice is adapted to the capabilities of the individual patient. During the first three months, after 2, 4, 8, 12 weeks from inclusion in the study, patients will be followed up by telephone (in a structured scripted way) to discuss their current activity.

*Structured access to a Wii game computer (Wii):* Patients will receive regular treatment and information about rehabilitation and daily physical activity. The patients will also receive an activity advice, as described in the control group. In addition, patients in the Wii-group will be introduced to the Nintendo Wii game computer in an introduction lesson of approximately one hour in the participating centre led by a dedicated instructor (knowledgeable of the Wii but no further special training). Thereafter, the Wii will be installed at the patient’s home. The patients will be taught to move the remote control in a similar way as the sport is played in real life; for example, holding and swinging the remote control as a bowling ball or tennis racket. At home, the patients will receive additional instruction on the Wii, if needed, and they will be advised how much they should play on the Wii. In general, the advice will be to play for 30 minutes per day. If needed they are advised to adapt to their capacity, for example to play more often for shorter periods during a day or even play longer if they want. The patients will receive written safety guidelines and information on how to use the Wii computer after the installation. In the first three months after installation, after 2, 4, 8, 12 weeks from inclusion in the study, patients will be followed up by telephone to discuss their experiences with the Wii, to get motivational support or to solve unexpected problems.

Patients will be given the opportunity to call the research staff during the first 3 months of the study in case they experience any technical problems with the Wii game computer.
2.4 Outcomes:

Since we have a rather broad aim to test the concept of exergaming, this study can be defined as a complex intervention study (19). The broad evaluation of outcomes is outlined in figure 2 and the research questions and outcome measures are listed below and in Table 1.

Theme 1: Patient outcomes related to exercise and activity

Primary endpoint: The primary endpoint of the HF-Wii study is improvement in exercise capacity assessed by the 6-MWT between baseline and 3 months. The 6-MWT is a simple, low-cost method for estimating exercise capacity; only a pre-measured level surface and a timing device are needed (20). The mode of exercise is familiar to most patients, although it may represent a maximal test for some. The test has appeared to be useful for the assessment of many interventions such as cardiac resynchronization therapy and has strong predictive power for both mortality and morbidity in patients with HF (20,21).

Secondary outcomes: We will also measure the exercise capacity using the 6-MWT at 6 and 12 months from baseline. Other secondary outcomes include muscle function, exercise motivation, self-efficacy beliefs and perceived physical effort in all patient (see table 1). Muscle function will be assessed with unilateral isotonic heel-lift, bilateral isometric shoulder abduction and unilateral isotonic shoulder flexion using predefined protocols (22). The other outcomes such as exercise motivation, self-efficacy beliefs and perceived physical effort will be assessed by patient self-report with validated questionnaires (see table 1). In a subgroup of 100 patients the level of physical activity will be monitored with an accelerometer (Actigraph). An accelerometer will provide information regarding intensity, frequency and duration of physical activity as well as sedentary time. The ActiGraph GT9X accelerometer (ActiGraph, Pensacola, FL) for hip worn placement will be used for this purpose. The ActiGraph has been found reliable and valid.(23). We will assess the number of times played
on the Nintendo Wii, the mean time of playing and other daily activities by a diary during the first 3 months in the study. We will collect information on attendance to exercise-based rehabilitation

Theme 2: Patient outcomes related to self-care, readmission, survival and quality of life
To measure effects of the intervention on outcomes beyond exercise and physical activity, data will be collected on heart failure symptoms, health related quality of life, global well-being, anxiety and depression, sleep, readmission, mortality and HF self-care. Data will be collected from the medical chart and with validated questionnaires (see table 1).

Theme 3: Costs
In both groups we will calculate the costs of visits to health care professionals. We also will calculate the cost of the intervention.

Theme 4: Patient experiences
Additionally we will collect data on patients’ experiences through open ended questionnaires. In a subgroup of patients qualitative interviews will be conducted, describing the experience of using an exergame from a broader perspective.

2.5 Assessment, randomization and study protocol
Following the confirmation of suitability and informed consent, patients’ baseline characteristics will be assessed from the medical chart and baseline data will be collected from the 6-MWT, muscle function test and questionnaires. After informed consent patients will be randomized (in a 1:1 ratio in each center) into one of these conditions: motivational support only (Control) or structured access to a Wii game computer (Wii). To achieve balance between study arms and to have similar numbers of patients during the introduction lesson the randomization will be made with blocks of 12 including 6 intervention and 6 control conditions. The Linköping the Linköping Academic Research Centre provides a list of
random numbers in blocks of 12 and will generate randomized block allocations for each of
the study sites. Due to the nature of the intervention the study is not blinded, but the
assessment of the primary endpoint is blinded.

3. Statistical Issues

Analysis
The primary analysis will consist of comparing the results of the change in 6-MWT from
baseline to 3 months between the group of patients in the Wii group compared to the control
group. The statistical analysis will be performed using a two-sample t-test, and two-sided
95% confidence intervals will be constructed to describe the treatment differences. An
analysis of covariance will be used to test for the treatment effect controlling for different
baseline characteristics. The results will be analysed using an intention-to-treat analysis
including the full set of all randomised patients (primary efficacy population). In addition, a
‘per protocol’ analysis will be performed, including only patients who actually played the Wii
(as assessed by the diary and questionnaire) during the study period. Qualitative data will be
analysed with content analysis. A multivariate analysis will be performed with stratification
on research center and NYHA classification.

Power calculation: To achieve a 30 meter difference between the control group and the Wii
group (which is described to be a clinical significant difference in heart failure patients based
on 80% power, 5% significance), 250 patients in the intervention group and 250 patients in
the control group are needed. To ensure appropriate patient number at the end of the study, 2x
300 patients will be included.

4. Organization and progress
In order to recruit the 600 patients, international HF clinics, cardiology departments and primary care centres have agreed to participate in this research. So far four hospitals in Sweden participate, two hospitals in Italy, a hospital in Israel and a hospital in the Netherlands. The first patient was included in September 2013 and in February 2015 28% of the required sample was included, mainly from the 3 Swedish centres that started first. Recruitment is expected to be completed by December 2016 and the study should close at the beginning of 2018.

To guide this investigator initiated and driven study, a scientific advisory board was established with the main goal to advice the HF-Wii study team with regard to issues on data collection, sub studies, analysis, future implementation and publications. Members included in the scientific advisory board are the principle investigators for each Wii-site and additional experts from primary care, cardiology, physiotherapy and nursing (M. Bäck RPT PhD, T Ben Gal MD, J Boyne RN PhD, Prof. K. Dickstein MD PhD, Prof. B Fridlund RN, PhD, Prof. A.W. Hoes MD PhD, Prof J Mårtensson RN PhD, Prof. M.F. Piepoli MD PhD, E Vellone RN, PhD).

5. Discussion

There is a need for evidence on the long term effects of affordable and available interventions that are both ‘patient friendly’ and easy to implement. The proposed study will allow insight on the effects of access and structured introduction of an easy applicable and available virtual reality application. If using a commercially affordable and available game-computer is effective in increasing exercise capacity in patients with HF, this might be a recommendation that should be given to patients, in addition to other current recommendations.
Heart failure is a common, costly and disabling disease with a lot of suffering in patients and their families (32). Improving patients’ exercise capacity and increasing their ability to perform more daily physical activity is expected to improve their quality of life. Currently there is no universal agreement on exercise prescription for patients with HF and thus guidelines recommend an individualized approach with careful clinical evaluation, including behavioral characteristics, personal goals, and preferences (2). The rationale behind the HF-Wii study is that by introducing an innovative and user-centered way of physical activity we can motivate people to be more physically active in their daily life and feel more confident with exercise. In this way patients will improve exercise capacity, which in its turn can increase physical activity and participation in everyday life. Increased functional capacity is known to improve relevant outcome measures such as symptoms and quality of life (7,8).
Funding

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References


status in patients with chronic heart failure: HF-ACTION randomized controlled trial.


Figure 1. Design of the HF-Wii study

- Baseline assessment
  - Structured access to a Wii game computer (Wii)
  - Motivational support only (Control)

  R

  3 month follow-up
  6 month follow-up
  12 month follow-up
Figure 2. Outcomes in the HF-Wii study

Randomized controlled Trial (HF-Wii)

Theme 1
Patient outcomes related to exercise and activity

Theme 2
Patient outcomes related to self-care, readmission, survival and quality of life

Theme 3
Costs

Theme 4
Patient experiences

Case study and pilot study
Table 1. Variables and instruments in the HF-Wii study

<table>
<thead>
<tr>
<th>Variable</th>
<th>Instrument</th>
<th>baseline</th>
<th>3 mo</th>
<th>6 mo</th>
<th>12 mo</th>
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<td>HF symptoms</td>
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</table>

HF, Heart Failure; MLwHFQ, Minnesota Living with Heart Failure Questionnaire; HADS, Hospital Anxiety and Depression Scale; MISS, The Minimal Insomnia Symptom Scale; EHFScBS, European Heart Failure Self-care Behavioural Scale