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UNIVERSITY OF CALIFORNIA, IRVINE

Evaluating the Impact of Exergaming in Patients with Heart Failure

DISSERTATION

submitted in partial satisfaction of the requirements for the degree of

DOCTOR OF PHILOSOPHY

in Nursing Science

by

Marysol Cormanes Cacciata

Dissertation Committee: Professor Lorraine S. Evangelista, Chair Associate Professor Jung-Ah Lee Clinical Professor Dawn Lombardo

 $\label{lem:chapter 2 @ 2019 ELSEVIER}$ All other materials @ 2019 Marysol Cormanes Cacciata

DEDICATION

Tο

My north star, my late mother -- Fanny Villagonzalo Cormanes

In remembrance of her unconditional love, sacrifices, support and guidance. Living out a mother's dream for her daughter. Mamang, this is for you!

To Where You Are

Who can say for certain As my heart holds you
Maybe you're still here Just one beat away
Ifeel you all around me Icherish all you gave me

Yourmemories so clear Everyday

Deep in the stillness 'Cause you are mine

I can hear you speak Forever love

You're still an inspiration Watching me from

Can it be up above

That you are mine And I believe

Forever love That angels breathe and that love will live on and

And you are watching that love will live on and

Over me from up above never leave

Fly me up to where you are

Beyond the distant star

I wish upon tonight to see you smile

If only for a while to know you're there

A breath away's not far to where you are

I know you're there
A breath away's not far

To where you are.

Josh Groban

In his heart a man plans his course but the Lord determine his steps.

~Proverbs 16:9

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Evaluating the Impact of Exergaming in Patients with Heart Failure

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- Rutledge, D. N., Wickman, M. E., **Cacciata, M.**, Winokur, E. J., Loucks, J., & Drake, D. (2013). Hospital staff nurse perceptions of competency to care for patients with psychiatric or behavioral health concerns. *J Nurses Prof Dev*, 29(5), 255-262. doi:10.1097/01.NND.0000433150.18384.1c
- Olivier, R., Gleeson, D., Skinner, C., **Cacciata, M**., & Wickman, M. (2019). Direct-acting oral anticoagulants and warfarin-associated intracerebral hemorrhage protocol reduces timing of door to correction interventions. *J Neurosci Nurs.* doi: 10.1097/JNN.0000000000000430.
- **Cacciata M**, Strömberg A, Lee J-Ah, Sorkin D, Lombardo D, Clancy S, Nyamathi A, Evangelista LS. (2019) Effect of exergaming on health-related quality of life in older adults: A systematic review. *Int J Nurs Stud.* doi: 10.1016/j.ijnurstu.2019.01.0

ABSTRACT OF THE DISSERTATION

Evaluating the Impact of Exergaming in Patients with Heart Failure

By

Marysol Cormanes Cacciata

Doctor of Philosophy in Nursing

University of California, Irvine, 2019

Professor Lorraine S. Evangelista, Chair

Heart failure is a chronic and debilitating condition that affects an estimated 6.5 million adults in the U.S., and the numbers are rising with the aging of the population. Most individuals with heart failure experience deficits in physical functioning, social isolation, decreased quality of life and exhibit psychological challenges, specifically anxiety and depression. Considering the negative consequences of heart failure, it is imperative to explore opportunities to improve the physical and psychological outcomes in this highly vulnerable population. Exercise training is recommended for the management of heart failure. The latest guidelines on the treatment of heart failure recommend regular and structured physical activity. Exercise through video or virtual reality games also known as exergames has grown in popularity among older adults at home or in assisted living facilities to increase physical activity and improve psychological well-being.

This dissertation describes four papers that address the impact of exergaming on psychological well-being and symptom burden in patients with heart failure and examine perceptions related to facilitators and barriers to exergaming. The first paper is a secondary analysis that examined the impact of perceived control on depression in patient with heart failure (Chapter 1). The second paper is a systematic review that analyzed the effect of exergaming on health-related quality of life in older adults (Chapter 2). The third paper is a

qualitative study describing the barriers and facilitators to exergaming using the NintendoTM
Wii Sports platform (Chapter 3). The fourth paper describes a pilot study to evaluate the impact of exergaming in anxiety and depression, health-related quality of life, and symptom burden among patients with heart failure (Chapter 4). These papers contribute to the growing body of research involving patients with heart failure and demonstrate that 1) perceived control is associated with functional status and depression; 2) addressing barriers and facilitators to exergaming may potentially improve acceptance of exergaming in this population; and 3) exergaming has the potential to enhance psychological well-being and reduce symptom burden in patients with heart failure. Additional research is warranted with a larger sample size to explore the true effects of exergaming in improving the psychological well-being and symptom burden in patients with heart failure.

INTRODUCTION

Heart failure is a debilitating chronic illness and a significant health concern associated with high morbidity, mortality, frequent hospitalization, and considerable health care costs.¹ It affects an estimated 6.5 million Americans and the projections show that the prevalence will increase 46% from 2012 to 2030, resulting in >8 million Americans ≥ 18 years of age with heart failure.² Approximately 1 million hospitalizations for heart failure occur annually accounting for over 6.5 million hospital days and costs an estimated \$ 37.2 billion each year in the U.S.³ The aging of the baby boomers and the rise of modern therapeutic innovations have prolonged the lives of cardiac patients resulting in an increasing prevalence of heart failure.⁴,⁵

Individuals who have coronary heart disease, hypertension, diabetes, valvular heart disease and those who smoke or are overweight are at risk for developing heart failure. It causes the heart to ineffectively pump and deliver oxygen-rich blood to body organs. As a result, most patients diagnosed with heart failure often have multiple physiologic system dysfunction and experience limitations in physical functioning and exercise intolerance. Exercise intolerance manifested by symptoms of shortness of breath and muscle fatigue causes progressive functional deterioration. Patients with heart failure also exhibit psychological impairments such as lack of motivation, anxiety and depression. 2,7

Depression is a comorbidity and highly prevalent in patients with heart failure.⁸ Research has shown that at least one in five patients with heart failure had significant clinical depressive symptoms.^{9,10} A recent meta-analyses revealed that patients with heart failure who have depressive symptoms were more than twice as likely to die or experience a cardiac event when compared to heart failure patients without depressive symptoms.^{9,11,12} There appears to be a link between depression and perceived control. Studies have shown that low perceived control was

associated with increased depressive symptoms and reduced health-related quality of life and physical well-being in older patients with cardiovascular disease. ¹³⁻¹⁶ Symptom burden (e.g., shortness of breath, fatigue) also impacts perceived control and depression.

The American Heart Association and the European Society of Cardiology latest guidelines on the treatment of heart failure recommend regular and structured physical activity. ^{1,17} Interventions that support increased physical activity or exercise training can potentially reduce depressive symptoms, symptom burden, healthcare utilization and improve the health-related quality of life. ^{18,19} Research also showed that exercise training reduced depression in patients with coronary heart disease by 50-70% ⁸ and revealed significant improvements in overall survival. ²⁰ However, despite the beneficial effects of exercise, the level of daily physical activity in most patients with heart failure remained low. ²¹ Research has indicated that some of the reasons patients are less likely to engage in physical activity include physical limitations such as shortness of breath, discomfort, fatigue or psychological impairments (e.g., lack of motivation, depression). ^{2,7} Environmental factors such as heat and cold and availability of space and safety also play vital roles in patients' motivation to exercise. ²²

There is a growing acceptance and popularity of exercise-based video games (i.e., exergaming) as a health care intervention among older adults. ^{21,23-25} This type of exercise may be an adjunct to other forms of physical activity rather than a stand-alone intervention. A systematic review showed that exergaming has a potential for reducing depressive symptoms in older adults, ²⁶ and improving their health-related quality of life. ²⁷ Researchers and clinicians expressed that exergaming might overcome the traditional barriers to exercise that include environmental elements, safety, time restriction, service access cost, and boredom. ²²

This dissertation describes four papers. The first paper describes the levels of perceived control and depression in a sample of patients with heart failure (N = 173) who participated in a

larger randomized control trial examining the effects of home-based exercise on several clinical and psychosocial outcomes. Mean perceived control was 10.6 ± 3.1 , range 5 - 20; men reported higher levels of perceived control. Twenty-two percent reported symptoms of depression; there were no gender differences. Data showed that perceived control was associated with gender, functional status, and depression.

The second paper is a systematic review that evaluates the effect of exergaming on improving the health-related quality of life of older adults. Nine randomized controlled studies were included in the analysis and findings showed inconclusive results with a majority of the studies reporting no improvement in health-related quality of life with exergaming. The findings support the need for more research with less heterogeneity and larger sample size to explore the potential benefits of exergaming in older adults.

The third paper explored perceptions of facilitators and barriers to exergaming using the NintendoTM Wii sports platform among patients with heart failure. Four factors emerged as facilitators to exergaming: (1) enjoyment and competition motivated gaming; (2) accessibility at home gave freedom and lowered threshold to exercise; (3) physical benefits when decreasing sedentary lifestyle; and (4) psychosocial benefits on stress, mood and family interactions.

Barriers included: 1) engagement diminished over time due to boredom, and 2) frustration due to lack of mastery and improvement. The fourth paper evaluated the impact of exergaming vs. usual care on psychological well-being (e.g., anxiety, depression, health-related quality of life) and symptom burden (e.g., shortness of breath, fatigue) in patients with heart failure. Thirty patients – mean age 55.6 ± 8.5, 70.0% male; 43% White; 27% Hispanics; 20% Blacks; 10% Asians – were randomized to exergaming (n = 16) or usual care (n = 14) and completed the 12-week study. At 12 weeks, there were no group differences in anxiety and depression (primary outcomes). However, participants in the Wii group showed greater improvements in health-related quality of life in the physical and emotional domains but not overall health. Significant

improvements were also noted in symptom burden (e.g., shortness of breath, fatigue) over time.

All four papers support the benefits of exercise and exergaming on physical function and psychological well-being in a sample of patients with heart failure. Future research that supports the implementation of interventions, promote increased physical activity in community settings, and bring family-centered interventions to scale is needed to achieve more significant public health impact.

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CHAPTER ONE

Low Perceived Control is Associated with Depression in Patients with Heart Failure¹

Abstract

Objectives: We conducted a secondary analysis to 1) describe levels of perceived control and depression in patients with chronic heart failure (HF); 2) examine the relationship between sociodemographic and clinical variables (e.g., age, gender, functional status [max VO₂ & 6 minute walk test]), perceived control and depression in patients with HF; and 3) determine independent predictors of perceived control and depression in this patient population. Methods: Data from 173 patients with HF (average age 54 + 12.7 years, average max VO₂, 13.6 ± 3.3 ml/kg/min, 72% males, 60% whites) who completed the Beck Depression Inventory (BDI) and Control Attitude Scale (CAS) were analyzed. Results: Mean perceived control was 10.6 ± 3.1 , range 5–20 with men reporting higher levels of perceived control. Twenty-two percent reported symptoms of depression (BDI score ≥ 14); there were no gender differences. Univariate data showed that perceived control was associated with gender, functional status and depression. In a multivariate model, 27% of the variance in perceived control was attributed to functional status and depression while 16% of the variance in depression was attributed to perceived control. Conclusion: Strategies to enhance perceived control and functional status may be key to potentially reducing symptoms of depression in patients with heart failure.

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An estimated 5 million people in the U.S. are diagnosed with heart failure (HF) and the numbers are rising with more than 500,000 new cases diagnosed annually. Despite the unprecedented medical advances in the recent years, HF remains a debilitating condition with poor prognosis² and it is associated with increased morbidity and mortality. Depression is a comorbidity and it is highly prevalent in patients with HF. Research has shown that at least one in five patients with HF has significant clinical depressive symptoms. Depression and HF have been extensively explored because of the disease's high prevalence and its propensity to worsen medical prognosis. In addition, depression is a major concern because of its significant effect on health related quality of life and consequently increased mortality and morbidity. A recent meta-analyses revealed that patients with HF who have depressive symptoms were more than twice as likely to die or experience a cardiac event compared to HF patients without depressive symptoms.

Patients with chronic HF are faced with myriad of challenges that make coping with the disease difficult; the unpredictable course of HF is often the source of uncertainty or loss of control in these patients. 13 Perceived control is defined as the person's belief of the resources needed to cope with negative events and the ability to positively influence consequences of those negative events. 14 Lower levels of perceived control have been associated with reduced physical well-being and health-related quality of life and increased depressive symptoms in patients with cardiovascular disease. 15 Likewise, patients with reduced levels of perceived control over symptoms exhibited maladaptive coping behaviors including denial and behavioral disengagement and more severe depressive symptoms. 16 Conversely, perceived control has been found to be crucial in adjusting successfully to stressful occasions and improvement in health-related quality of life in individuals after cardiovascular events. 17

Yet, little is known related to the association between low perceived control over the

heart condition and depression in patients with chronic HF. Filling this gap in knowledge can provide opportunities to explore effective interventions to reduce depression in this highly vulnerable population. Therefore, we conducted a secondary analysis of a dataset involving patients with HF who participated in an exercise trial¹⁸ to: 1) describe levels of perceived control and depression in patients with chronic HF; 2) examine the relationship between sociodemographic and clinical variables (e.g., age, gender, functional status [max VO₂ and 6 minute walk test]), perceived control and depression in patients with HF; and 3) determine independent predictors of perceived control and depression in this patient population.

Methods

Study Design and Sample

A cross sectional descriptive design was used to conduct a secondary analysis of baseline data from patients with HF. A complete description of the study design and methods of the parent study describing the effects of home-based exercise program on clinical outcomes in patients with HF has been published elsewhere.¹¹¹8 In the study, 173 participants -- aged between 18 and 80 years, had a documented medical diagnosis of HF [NYHA class II through IV] and left ventricular systolic dysfunction with a left ventricular ejection fraction ≤40% within the previous 6 months -- were recruited from five HF clinics and cardiology offices in Southern California and randomized to an exercise group and a control group. The study received Institutional Review Board approval and written informed consent was obtained from all participants. Data used for this secondary analysis were de-identified.

Study Procedure

As part of the parent study, all study participants underwent cardiopulmonary exercise test using a bicycle to determine maximum VO₂ at baseline and a six minute walk test (6MWT); these parameters were used to describe functional status. In addition, participants completed the

4-item Control Attitude Scale (CAS)^{19,20} to measure respondents' degree of control or its opposite (a sense of helplessness) over their cardiovascular illness using a Likert scale from 1 (none) to 5 (very much). The total score ranged from 4 to 20, with higher scores indicating higher (better) perceived control. The instrument had a Cronbach's $\alpha = 0.89$ for the current study reflecting high internal consistency.^{19,20}

The severity of depressive symptoms (i.e. depression) was assessed using the Beck Depression Inventory-II (BDI-II), which consists of 21 items with a 4-point Likert scale from 0 (absence of symptoms) to 3 (severe or persistent presence of the symptom). Total scores ranged from 0 to 63, with higher scores reflecting more severe depressive symptoms. Internal consistency reliability and construct validity have been shown to be acceptable with both psychiatric and non-psychiatric patients. The instrument had a Cronbach's $\alpha = 0.77$ for the current study reflecting high internal consistency.

Data on sociodemographic (e.g., age, gender, race/ethnicity, marital status, education and current employment) were collected through a simple self-administered form. Information on the participant's clinical characteristics, including New York Heart Association (NYHA) functional class and ejection fraction were extracted from medical records.

Statistical Analysis

Data were analyzed using the SPSS for Windows ([SPSS] Version 23.0. Armonk, NY: IBM Corp).²⁵ Descriptive statistics including means ranges and standard deviations were used to describe sociodemographic, clinical characteristics and levels of perceived control and depression.

Comparative analyses of sociodemographic variables, clinical characteristics (e.g., functional status), perceived control and depression were computed using t-tests or chi-square tests, depending on the levels of measurement. We conducted univariate analyses using Pearson's

product moment correlation coefficients to explore relationships between demographic and clinical characteristics (e.g., functional status), perceived control and depression. Variables that achieved univariate significance of p = 0.05 were included in a multivariate analysis. A stepwise linear multiple regression was conducted to identify factors associated with perceived control and depression. Demographic variables (age, gender) were included as covariates and were entered first. Clinical characteristics (NYHA functional class, VO₂ max, 6MWT) were entered in the second step. Next, to depict the impact of depression on perceived control, depression scores were entered last (for the model examining predictors of depression, perceived control was added as a last step). Criteria for entry and removal of variables were based on the likelihood ratio test with enter and remove limits set at $p \le 0.05$ and $p \le 0.10$.

Results

The sociodemographic and clinical characteristics of the sample (N = 173) are illustrated on Table 1. The average age of participants were 54.2 ± 12.7 years (range 21-80). Patients were primarily men (72%), White (60%), and unemployed or retired (70%). Gender differences were noted in race (there were more Black women in the sample), marital status (men were more likely to be married), ejection fraction (women had higher scores then men) and 6MWT (men had higher scores than women) (all Ps < .001).

Mean perceived control was 10.9 ± 3.2 , range 5–20; 23% of the sample reported extremely low perceived control scores (CAS score < 10). Men reported higher levels of perceived control than women (P = .016). The mean depression scores was 10.9 ± 10.7 , range 0-99. Twenty-two percent reported symptoms of depression (BDI score ≥ 14); there were no gender differences in depression scores.

A correlational matrix of the key variables is presented on Table 2. Age was associated with VO₂ max (P < .001) but not 6MWT. Gender was associated with 6MWT and perceived

control with men having higher scores on both. Max VO_2 was associated with 6MWT and perceived control while 6MWT was associated with depression. There was an association between perceived control and depression (P < .001). In a multivariate model, 27% of the variance in perceived control was attributed to functional status and depression (Table 3.A) while 16% of the variance in depression was attributed to perceived control (Table 3.B).

Discussion

The diagnosis of HF is associated with the administration of lifelong pharmacotherapy and frequent hospitalization that affects daily functioning of patients with HF, and worsens their health related quality of life and may also cause symptoms of depression.^{3,8-10} Likewise, as previously stated, patients with chronic HF are faced with myriad of challenges that make coping with the disease difficult and lead to uncertainty or loss of control in these patients.¹³ However, the relationships between perceived control and depression in patients with HF has not been previously reported. Thus, we conducted this secondary analysis to better understand how personal beliefs regarding control over patients' own health are impacted by sociodemographic and clinical variables and in turn how this sense of control affects depression.

Our findings showed that the perceived control of patients with HF in our sample was extremely low. These findings are similar to a cohort of women who had undergone heart transplantation, ¹⁷ but significantly lower compared to a sample of patients undergoing coronary artery bypass surgery ²⁶ and a sample of recipients of implantable cardioverter defibrillator. ²⁷ We speculate that these differences reflect the fact that patients with chronic HF and recipients of heart transplantation share the similar challenge of having to deal with the chronic impact of their disease and less control over one's life. On the other hand, patients who have undergone coronary bypass surgery and those who have received an implantable cardioverter defibrillator are actually faced with renewed hope and possibly greater belief that they can cope with the

negative events associated with their conditions as a result of their surgeries. We did want to acknowledge the fact that number of patients in the current study (23%) with reduced perceived scores (CAS score < 10) was lower than the 41% reported by Dracup and colleagues (2003) in an earlier study of patients with HF.²⁰ This may be a reflection of the efforts that are being made to support engagement and self-care in patients with HF.

We also found that men had higher perceived control than women. This finding confirms previous evidence that women were more likely to have lower perceived control over health than men.^{28,29} Men were also better at interpreting their symptoms as being related to HF and in seeking early treatment than women,³⁰ an initiative that is suggestive of high sense of control. In another study on gender differences and factors related to self-care behaviors, men had better perceived control and HF management knowledge than women.³¹ Researchers postulated that this differences could be attributed to gender identity in men known as "masculinity" which affects how men manage their health or life in general; men's preference for control is perceived through primary responsibility.³⁰ A better understanding of the role of perceived control and differences among men and women could provide insights for gender specific interventions in improving perceived control.

Our findings related to rates of depression in patients with HF confirm earlier work in this area.³² However, our findings revealed that patients with HF who reported lower levels of perceived control also showed depressive symptoms while fairly novel are intuitive. Lower levels of perceived control have also been associated with increased depressive symptoms and reduced physical well-being and health-related quality of life and in older patients with cardiovascular disease.^{15,33-35} Likewise, patients with reduced levels of perceived control over symptoms exhibited maladaptive coping behaviors including denial and behavioral disengagement and more severe depressive symptoms.¹⁶ Clearly, perceptions of control are

critical because they can positively impact depression regardless of clinical factors and socioeconomic status. Goode, et al., reported that cardiac patients with low perceived control had less desire to engage in self-care management (i.e. salt and fluid restriction, diet and exercise, medication management and emergency plans),³⁶ were less likely to seek early assistance and have poorer outcomes than those individuals with normal perceived control.³⁷ Conversely, perceived control has been found to be crucial in adjusting successfully to stressful occasions and improvement in health-related quality of life in individuals after cardiovascular events.¹⁷ Furthermore, having a high sense of control is associated with proactive behavior and positive outlook in life. High perceived control plays an important role in patients' health, positively impacts physical and psychosocial well-being and may buffer negative effects of depression.

We also found an association between perceived control and functional status while age was correlated with VO₂ max but not 6MWT. Although both the VO₂ max and 6MWT are measures of functional status in patients with HF, the specificity and accuracy of the former supports our findings that older patients had lower functional status. High functional status is an important factor of successful aging and may protect against age-related deterioration in central domains of functioning.³⁸ Chronic illness such as HF may impact functional status so implementing strategies that optimize physical functioning, an element of functional status may reduce functional limitations. Liljeroos et al. also found that the relationship between perceived control and physical health status were mediated by depressive symptoms for patients with HF.³³

In summary, a significant proportion of our participants reported extremely low perceived control (23%) which was consistent with other studies of patients with cardiac illness.³⁴ High levels of perceived control mirrors a better adaptation to cardiovascular conditions. Perceived control has been found to be sensitive to psychosocial and educational interventions and is therefore relevant to target in rehabilitation and during follow-up in HF care.³⁵ In our study,

lower levels of perceived control was predicted by lower functional status and higher levels of depression. These findings imply that delivering interventions that encourage improved functional status and increased perceived control over the heart disease in patients with HF may be key to reducing symptoms of depression in this population.

Study Limitations

There are limitations to note. More than 70% of our participants were men; making comparisons of predictors of perceived control and depression based on gender differences difficult. Caution is needed in generalizing the findings of the current study to other races because the majority of the sample was Caucasian. In addition, our sample participants were relatively young and with more severe HF with mean EF<30 and the majority in NYHA III, which limits generalizability of the findings to older age groups and those with less severe HF. Although the parent study was a randomized controlled trial with several data collection points, the current study only reports on baseline data so we were unable to assess any cause and effect relationship between perceived control and depression. Further studies using longitudinal study designs are needed to determine whether improvements in functional status result in improvements in perceived control and whether improvements in perceived control result in reduced depression. Finally, study variables including perceived control and depression were measured using self-reported questionnaires, which may have resulted in bias depending on the emotional status the participants had while completing the questionnaire. However, self-report measures are widely used in research. Despite these limitations, the current study provides important information to researchers and clinicians who are taking care of patients with HF on the relationship between sociodemographic and clinical variables and perceived control and depression and the factors affecting these two important psychological measures in patients with HF.

Conclusion

Findings from this study show that functional status are associated with perceived control and perceived control with depression in patients with HF. Perceived control is a modifiable factor and interventions that may increase perceived control has potential to reduce depressive symptoms. Interventions to support low perceived control need to be explored and warrant additional research.

Implications for practice

- Encourage strategies that will improve functional status including exercise and self-care management to potentially enhance perceived control.
- Acknowledge the association between low perceived control, low physical function and symptoms of depression. All three conditions can be successfully targeted by interventions, but all should preferably be targeted jointly.
- Women who are likely to have lower perceived control scores warrant increased attention

Table 1. Demographic and clinical characteristics of the heart failure patients separated by gender

	Total N= 173	Males N= 124	Females N= 49	P values
Age, (mean±SD)	54.2 ± 12.7	54.2 ± 12.6	54.2 ± 12.8	.992
Ejection fraction,	27.2 ± 6.4	25.4 ± 6.9	29.0 ± 5.9	.001
Race, %				<.001
White	60.1	62.9	53.1	
Black	12.7	4.8	32.7	
Hispanic	12.7	14.5	8.2	
Asians	7.5	10.4	0	
Other	6.9	7.3	6.1	
Education, %				.147
Some high school	6.1	3.8	11.6	
High school graduate	28.6	26.9	32.6	
Vocational School	13.6	15.4	9.3	
Some college	22.4	20.2	27.9	
College graduate	17	18.3	14	
Graduate School	12.2	15.4	4.7	
Employment, %				.179
Employed	30.1	32.7	23.8	
Non-employed/Retired	69.9	67.3	76.2	
Marital Status, %				<.001
Married	63.3	74.0	37.2	
Not married	36.7	26.0	62.8	
VO2 Max L/min	13.6 ± 3.3	14.0 ± 3.7	13.3 ± 2.9	.247

6 minute walk test, feet	1327.4 ± 296.5	1382.9 ± 290.2	1271.9 ± 303.1	.031
Perceived Control	10.6 ± 3.1	11.4 ± 3.0	9.9 ± 3.3	.016
Depression	11.2 ± 9.7	10.6 ± 11.8	11.7 ± 7.6	.598
NYHA Class, %				.504
Class II	43.5	41.9	44.8	
Class III	50.1	52.4	47.0	
Class IV	6.4	5.6	8.2	

Table 2. Correlational matrix of key variables (N=173)

Variables	1	2	3	4	5	6
1 Age	1.00					
2 Gender	001	1.00				
3 VO2 max	246**	093	1.00			
4 6-minute walk test	147	170*	.316**	1.00		
5 Perceived Control	.144	222*	.259**	.162	1.00	
6 Depression	.071	.045	173	182*	368**	1.00

^{*}correlation is significant at .05 level (2-tailed) **correlation is significant at .01 level (2-tailed)

Table 3.A Predictors of Perceived Control

Variable	Adjusted R ²	F	P value	
Step 1: age, gender	.091	4.394	.414	
Step 2: 6MWT, NYHA class, VO ₂ Max	.207	4.442	.001*	
Step 3: Depression	.272	5.222	<.001*	

Table 3.B Predictors of Depression

Variable	Adjusted R ²	F	P value
Step 1: age, gender	.020	.892	.414
Step 2: 6MWT, NYHA class, VO ₂ Max	.091	1.705	.142
Step 3: Perceived Control	.165	2.768	.017*

^{*}correlation is significant at .05 level (2-tailed)

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CHAPTER TWO

Effect of Exergaming on Health-Related Quality of Life in Older Adults: A Systematic Review

Abstract

Introduction: Exercise through video or virtual reality games (i.e. exergames) has grown in popularity among older adults; however, there is limited evidence on efficacy of exergaming on well-being related to health in this population. This systematic review examined the effectiveness of exergaming on health-related quality of life in older adults. **Methods:** PRISMA guidelines for this systematic review. Several databases were searched using keywords to identify peer-reviewed journal articles in English. Randomized control trials that evaluated the effect of exergaming on health-related quality of life in older adults when compared to a control group and published between January 2007 to May 2017 were included. **Results:** Nine articles that in total included 614 older adults with varying levels of disability, mean age 73.6 + 7.9 years old, and 67% female were analyzed. Significant improvements in health-related quality of life of older adults engaged in exergaming were reported in three studies. Sample sizes were small in 7 of the studies (N < 60). The study participants, exergaming platforms, health-related quality of life instruments, study settings and length, duration and frequency of exergaming varied across studies. Conclusion: Exergaming is a new emerging form of exercise that is popular among older adults. However, findings from this analysis were not strong enough to warrant recommendation due to the small sample sizes and heterogeneity in the study participants, exergaming platforms, health-related quality of life instruments, length, duration and frequency of the intervention and study settings. Further research is needed with larger sample sizes and less heterogeneity to adequately explore the true effects of exergaming on health-related quality of life of older adults.

What is already known about the topic?

- Engaging in physical activity is important among older adults since it prevents or slows down functional and psychological deterioration related to aging.
- Exergaming is a new emerging form of exercise that incorporates technology, play and fun with potential to improve physical activity and psychosocial well-being.
- There are currently no systematic reviews evaluating the effect of exergaming in improving the health-related quality of life among older adults.

What this paper adds

- Engaging or adhering to exercise using exergaming among older adults is moderately high and may be related to the enjoyment and convenience of this form of physical activity.
- The heterogeneity in study sample, exergaming devices, study settings, and
 instruments used to measure health-related quality of life is not sufficiently strong
 to determine if exergaming is an effective health care intervention to improve the
 health- related quality of life in older adults.

1. Introduction

Individuals age 65 years and older are rapidly growing in numbers, accounting for 15 percent of the total U.S. population in 2016. By 2050, the older adult population (≥ 65 years) is projected to grow to 88 million in the U.S. and 1.6 billion people worldwide. Aging is associated with profound changes in body composition, structure and function that can negatively impact functional status, leading to limited mobility, frailty, isolation and other health problems. Physiological changes (e.g., reduction in muscle mass and strength) impacts mobility, an important aspect in independent living among older adults which plays an important factor in their health- related quality of life.

Health-related quality of life is defined as the way people view and adapt to their symptom burden, functional limitations and prognosis, as well as perceptions of their overall health well-being.⁵ It has been linked to health status and symptoms reflecting the impact of health conditions.⁶ Measuring health-related quality of life is important for understanding the impact of health care interventions on daily life and well-being of older adults.^{7,8} Furthermore, health-related quality of life can be used to determine cost effectiveness of the healthcare intervention(s) when compared to other forms of interventions.⁹

Exercise has shown favorable outcomes among older adults including reduced risk of all- cause mortality, chronic disease, and premature death. Participation in a regular exercise program is strongly recommended because it is an effective intervention in preventing a number of functional declines related to aging and it has been known to improve functional capacity and health-related quality of life. The recommendation for older adults should emphasize moderate- intensity aerobic activity, muscle-strengthening activity, reducing sedentary behavior and risk management to improve cardiovascular health and health-related quality of life. Nowever, older adults are less likely to engage in exercise due to several factors including discomfort, fatigue, access issues (i.e. fitness or rehabilitation center), unable to exercise outdoors due to unfavorable climate conditions, and other motivation and practical issues. Access trategy for improving physical activity among older adults. Exercise through video or virtual reality games (i.e. exergaming) has grown in popularity among older adults to increase physical activity, improve health and physical function including individuals with chronic illnesses.

Exergaming uses technology to monitor body movement and reaction and provides real time feedback on exercise performance, allowing participants to compete individually or with other players²¹ resulting in fun and play. Exergaming has the potential for increasing physical activity among persons 65 years and older due to easy accessibility, fun factor, increase social interaction when playing with peers or family members and may improve health-related quality of life. Systematic reviews have already been published elsewhere assessing the effect of exergaming or virtual reality exercise games in improving physical activity, ²² health status ²³ and depression ²⁴ among older adults. However, evidence to support the benefit of exergaming on health-related quality of life among older adults > 65 years old is limited. Likewise, there is a paucity of systematic reviews assessing the effect of exergaming on health-related quality of life among older adults that use a randomized control trial design. The objective of this systematic review was therefore to evaluate the effectiveness of exergaming on health-related quality of life among older adults in randomized control trials.

2. Methods

2.1 Data Sources and Search Strategies

The PRISMA guidelines²⁵ were adapted to establish the methodology of this review. The methodology included several stages varying from generating consensus on the definition of exergaming to analyzing articles. A systematic search of abstracts, trial data bases and peer reviewed articles published from January 2007 (the year after NintendoTM Wii gaming system was released commercially) through May 2017 in PubMed, CINAHL, Web of Science, PsychInfo and Cochrane were conducted using the following keywords: *exergaming, exercise and game, active video, video games, virtual reality, elderly, geriatric, aged, older adults and health related quality of life.* In addition, hand search and checking reference lists were

conducted to obtain additional articles. Only studies published in English language were included.

2.2 Study Selection

Studies were limited to randomized control trials that included a sample of older adults with a mean age of \geq 65 years old that participated in exergaming or virtual reality exercise games as an intervention. The main intervention was any type of exercise using video games or virtual reality following the criteria established by the American College of Sports Medicine that included: (a) involved technology-driven game playing; and (b) required participants to be sufficiently physically active to exercise or to play the game. For comparison, the control group could be no intervention, conventional treatment (e.g., interventionist tailored exercise, cognitive program, walking, home-based exercise) and other interventions that are non-video or virtual reality based exercise activity. The inclusion criteria were as follows: (1) randomized control trials only; (2) intervention was exergaming that clearly described the exercise program; (3) participants mean age \geq 65 years old; (4) health-related quality of life as primary or secondary outcome, and (5) English language. In addition, due to potential differences in the risk of bias such as selective reporting in abstracts, all identified studies that partially or fully met the inclusion criteria were fully assessed for eligibility.

2.3 Data Extraction and Quality Assessment

Abstracts identified in the initial search were screened by two researchers excluding studies that did not meet the inclusion criteria. A data extraction sheet was developed based on the Cochrane Consumers and Communication Review Group to collect study characteristics and outcomes. With studies reported in more than one publication, the data were extracted from all publication directly into a single data collection form. The study

characteristics extracted from each article included citation, country, design, sample size, participant's mobility, type of intervention, comparison, frequency and duration, adherence and attrition. Studies included in final review were analyzed using the sample composition, interventions/effects of interventions and outcomes descriptions.

The Cochrane risk of bias tool²⁷ was utilized to assess the quality of randomized control trials in this review. The instrument uses specific criteria for scoring as low, unclear or high risk across 7 categories: random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessor, incomplete outcome data, selective outcome reporting and a category of "other bias".

3. Results

3.1 Search Result

A flow diagram (Figure 1) for study selection outlined the steps in choosing the articles. The search generated 213 citations, for which 61 articles were fully assessed for eligibility and 9 studies were selected for the final review and analysis. Because of the heterogeneity of the publications, exergaming devices and instruments used to measure outcomes, a meta-analysis is not feasible.

3.2 Study Characteristics

The studies were conducted worldwide, with three from the U.S., ^{28, 29, 30} two from Australia, ^{31,32} one each from the United Kingdom, ³³ Turkey, ³⁴ Italy, ³⁵ and Denmark. ¹⁶ The 9 studies provided a total of 614 participants, 309 in the intervention group and 305 in the control group. Varying health-status were noted among study participants including healthy and ambulatory, ^{28,30,34} Alzheimer's disease, ²⁹ and with functional impairments, such as stroke, ³³ gait instability, ³¹ vestibular dysfunction, ¹⁶ bone loss condition affecting balance ³⁵ and semi-ambulatory post hospital discharges. ³² Both genders were included, with a higher proportion of

women in the majority of the studies (67%); one study was exclusively female.³⁵ The participants' mean age was 73.6 ± 7.9 years old years old. The comparison or control groups were allocated to no intervention,^{28,31} tailored arm exercise + usual rehabilitation therapy,³³ home-based balance exercise,³⁴ walking,²⁹ conventional therapy,³² standard of care,³⁵ cognitive program³⁰ and printed instructions.¹⁶ All studies included in this review were reviewed and approved by the appropriate Institutional Review Board.

3.3 Quality assessment and bias

Overall, studies varied across bias domain (see Table 1 and Figure 2). All studies were assessed as low risk for random sequence generation bias utilizing computerized random number generator, random permuted blocks and randomization through coin flipping for participant's study selection. Likewise, all but three studies described allocation concealment. Random sequence and allocation concealment prevent foreknowledge of the forthcoming allocation; these are important factors in study reliability and validity. Blinding of participants and personnel was somewhat challenging due to the nature of the intervention, however, outcome assessors were blinded in four studies. 16,31-33

Majority of the studies were assessed as low risk for attrition bias due to participants' dropout rate of less than 20%, ^{16,29,31-34} or a sensitivity analysis was conducted to investigate bias due to missing data for subjects dropped out, ³⁰ and the use of intention to treat analysis. ^{29,30,32} Common reasons for dropouts include illness, losing interest, lack of transportation, lack of time to complete sessions, patient deterioration and death. These reasons were similar across the studies. Furthermore, high risk for detection bias were assessed in four studies for not blinding the outcomes assessors ^{16,28-30} and two studies for use of participant self-reports. ^{31,33} Two studies were assessed for other risk of bias: 1) one study lacked blinding after enrollment ³² that may resulted in prediction of future allocations, hence

threatening patient assignment, and 2) a threat to validity related to a participant's confusion in completing the quality of life survey questionnaire and following the Wii Fit instructions due to language barrier, thus, inaccurate data affected study outcomes.²⁸

All studies lacked adequate information to assess for reporting bias using the criteria established by Higgins et al.²⁷ except for one study that was deemed high risk³⁴ for excluding the attrition rate in the final analysis. Overall, these biases influenced generalizability and publication bias.

3.4 Description of Exergaming

The NintendoTM Wii Fit games comprised soccer heading, ski jumping, ski slalom, tightrope, table tilt, strength training, yoga, table tilt, tilt city, penguin slide, soccer heading, basic run, obstacle course, basic step and balance games. These games required participants to use their arms or body motions to simulate actions performed in real sports. The NintendoTM Wii Balance requires a balance board where participants used certain body parts to simulate actions. The NintendoTM Wii Sports included bowling, tennis, boxing, golf and baseball games.³³ The Microsoft Xbox 360Kinect included Kinect adventures, Kinect sports and Kinect sports season (i.e. football, tennis, table tennis, skiing, golf, volleyball and bowling).³⁴ The non-commercial, video-based devices were the low technology "Kitchen Table Exercise Program," and "Move It to Improve It (Mitti). The "Kitchen Table Exercise Program" involved a video based Digital Video Device and workbook with six types of exercises each with different levels of difficulty that challenged both muscle strength and standing balance.³¹ In the Mitti program, participants watched and followed movements shown in the video. The program included drag-and-drop and follow- the- leader games where the participants manipulated the virtual object on the video screen by grabbing and dragging to different locations or to another virtual object. 16

3.5 Frequency, Duration and Adherence to Exergaming

100 minutes per session. The shortest duration was three weeks and the longest 12 weeks. Data available for participants' adherence to the prescribed exergaming time ranged from 37% to 100%. Exergaming adherence was measured using a diary (self-report), interventionist/clinician log and logs and playtime monitor recorded in the Wii and other exergaming devices. The exergaming sessions were conducted in different venues: three home-based, \$^{16,31,33}\$ two in rehabilitation centers, \$^{32,35}\$ senior housing \$^{28}\$ and assisted living facility, \$^{29}\$ hospital outpatient clinic, \$^{30}\$ and outpatient clinic. \$^{34}\$ Exergaming conducted at the rehabilitation centers, outpatient settings, senior and assisted living facilities and community settings employed physiotherapists, occupational therapists, nurses and research assistants to assist and supervise study participants however, individuals performing exergaming at home were given instructions but no close supervision. It is important to note that adherence to the prescribed exergaming was high in the rehabilitation centers and the outpatient settings and lowest in home-based setting.

The prescribed exergaming regimen ranged from two to seven days a week and for 20 -

3.6 Health-Related Quality of Life Findings

Studies characteristics and findings are shown in Table 2. Quality of life was measured using validated instruments. Four studies examined the impact of the NintendoTM Wii Fit on health- related quality of life, and three studies ^{28,29,32} did not find exergaming to be statistically significant when compared to the control group. However, one study ³⁵ showed NintendoTM Wii Fit significant in improving the Quality of Life –SF 36 physical function scale at 4 weeks, but not significant at the 8-week follow-up; there were no changes in other subscales.³⁰

Conversely, the Wii Balance demonstrated a statistically significant difference in physical function subscale of the Quality of Life SF 36 post intervention at 8 weeks among

older female with balance problems and bone loss condition, but this difference was not sustained at the 3- month follow up. 35 The Wii Sports did not improve health-related quality of life (i.e. Stroke Impact Scale, Euroqol 5D) among stroke patients with arm weakness³³ however, the Microsoft Xbox 360Kinect demonstrated significant improvement among healthy ambulatory older adults in the Quality of Life SF 36 parameters of physical functioning, social role functioning, physical role restrictions, general health perceptions and physical component scores posttest at six weeks after playing the Xbox 360Kinect when compared to the control group using home-based balance exercise regime. ³⁴ Non-commercial video-based device, Kitchen Table Exercise Program was not significant (Eurogol 5D) among older adults with gait instability at 6 months follow up when compared to the control group (i.e. no intervention). 31 Likewise, the Mitti program had no significant impact on the quality of life in older adults with vestibular dysfunction after 12 weeks of intervention versus the control group using printed instructions. 16 Studies that showed statistical significance involved healthy participants with high adherence to exergaming and conducted in a center-based setting. Exergaming was less effective in improving health-related quality of life among participants with disabilities, low adherence and exergaming at home. Five studies reported no intervention related adverse events;²⁹⁻³³ four studies did not report adverse events.^{16,28,34,3}

Discussion

Engaging in physical activity is important among older adults because it prevents or slows down functional and psychological deterioration related to aging and impacts health-related quality of life. However, engaging or adhering to physical activity or exercise among older adults is poor due to different factors that may include lack of enjoyment. Exergaming is a new emerging form of exercise that incorporates technology, play and fun. However, the relationship between exergaming and health-related quality of life among adults 65 years and

older have not been well established in the literature. Establishing this relationship would provide knowledge and value of utilizing a home-based technology as a source of or adjunct modality in improving the physical activity in older adult population.

Exergaming has been used as a healthcare intervention among older adults to increase physical activity in the recent decade. A three-step approach was utilized to determine eligibility for inclusion; the search generated 213 articles and only nine were eligible for analysis. Findings demonstrated that in six out of the nine randomized control trials, exergaming did not show statistically significant results in improving the health-related quality of life in older adults. It is worthwhile to note that the studies used different exergaming devices and technologies to administer the therapies with the interactive games. Likewise, the variation in intervention methods, outcome measures, and control groups made it challenging to translate these preliminary findings into a general recommendation on the effect of exergaming on health-related quality of life. For example, the interventions in two of the nine randomized control trials compared exergaming with conventional therapy or standard of care omitting details making it difficult to conclude whether the beneficial effect or lack thereof was due to exergaming or the comparative therapy. In addition, the study population composed of older adults that were healthy and with disabilities (e.g., stroke, Alzheimer's disease, gait and vestibular problems). Next, the majority of the study participants were female, with one study being inclusive of females only. 35 This may influence gender-based efficacy and efficiency in improving health outcomes. Li et al. reported that gender is a predictor of exergaming motivation and performance; males are more physically active in exergaming and they find it more enjoyable than females.²⁴ This finding may be due to the physicality and competitiveness nature involved in exergaming that is traditionally more favored and enjoyed by the male gender. The differences in the level of enjoyment

between genders may have affected the participants' perceived health-related quality of life.

The majority of the randomized control trials were pilot or feasibility studies.

Therefore, generalizability was compromised and at least in one study, it was not a priori powered to address all outcomes. Another factor that may have contributed to inconsistent findings in health-related quality of life outcome was the variability in the length, frequency and duration of the interventions. The shortest intervention was three weeks and the longest was 12 weeks. The prescribed frequency ranged from two to seven days a week and for 20 - 100 minutes per session. The Global Recommendations directive on Physical Activity for Health frecommended that older adults engage in moderate aerobics physical activity for at least 150 minutes or at least 75 minutes of vigorous aerobic exercise over a course of a week. However, with exergaming or video based interactive exercise games, there have been no established guidelines with intervention times needed for functional or physical improvement. Increased functional and physical capacities have been associated with improved health-related quality of life in older adults.

Most importantly, findings from the studies demonstrated varying degrees of adherence to exergaming in the interventions group. The variability in adherence may result in inconsistent or non-significant findings. Adherence to exergaming is important as it affects study outcomes. The three studies that showed statistical significance in health-related quality of life reported high to 100 % adherence rate even though the dose and frequency of exergaming differed. However, exergaming sessions were conducted at rehabilitation centers and outpatient clinic. Indeed, study settings or exercise venues may be an important factor in determining exercise adherence. In this review, exergaming sessions were held in different settings: rehabilitation centers, outpatient clinics, senior housing and assisted living facilities, and at participants home. Findings from these studies demonstrated that adherence to the

prescribed time, length and duration of exergaming were high in the rehabilitation centers and the outpatient clinic and lowest in home-based setting.

One can ascertain that the high adherence rate in the rehabilitation centers and clinics can be attributed to the interventionist or clinicians on site where assistance and support were readily available. These findings also suggest that exergaming is more efficient in group activities such as those occurring at rehabilitation centers where individuals exercise with other people. This may result in social interaction and connectedness, a motivating factor to engage in exercise. ¹⁴ In contrast, home-based exercise had the lowest adherence rate. This may be due to participants' lack of motivation to engage in exercise regimen or lack of support from family members. Exergaming provide opportunities for social interactions and connectedness with family members and peers, ³⁸ however, for those individuals with no family members, social support, or lacking motivation, adherence to home-based exergaming program may not be attainable.

All studies used validated instruments to assess health-related quality of life, but the instruments vary. These variations may pose a challenge to compare studies and draw relevant conclusions. Also, health-related quality of life is a complex concept that involves several distinctions between measures and different dimensions. As mentioned earlier, health-related quality of life was measured using both generic and disease specific instruments. One can argue that it is justified to include studies with different assessment procedure for health-related quality of life, however, it should be noted that the heterogeneity may restrict the degree to which studies can be compared. In addition, multiple distinctions between instruments and the evaluation of different health dimensions to produce a single expression of health status makes health-related quality of life difficult to measure because different health problems are not of equal concern for different people.

The three studies that showed statistical significance in health-related quality of life reported high to 100% adherence rate with interventions conducted at rehabilitation clinics and outpatient clinics. 30,34,35 These findings suggest that adherence is an important factor in improving exercise regimen and may result in increased physical function and health-related quality of life. Notably, study settings may have influence on exercise adherence. Settings such as rehabilitation centers and outpatient clinics have clinicians and other staff available to provide support and guidance. Also, exercising with other individuals provide social support, interaction and connectedness, ³⁸ that may result in an increased motivation to exercise, thus improving adherence. Therefore, these findings call for the question of why other forms of exercise have positive impact on older adults health-related quality of life but not exergaming? A systematic review that reported on other types of exercise with positive impact on health-related quality of life included strength training, tai chi, combined exercise (strength, aerobic, balance and flexibility) but in individuals with depression. ²⁶ Likewise, a systematic review on aerobic exercise and resistance training with varying intensities in patients with heart failure also showed positive effect on health- related quality of life.³⁷ Another study that reported a positive effect of exercise on health-related quality of life among patients with heart failure involved exercise intensity; greater improvement in exercise capacity and intensity is strongly associated with increased health-related quality of life.³⁹ Both systematic reviews and the study conducted by Evangelista and colleagues³⁹ reported that moderate to high intensity exercise is associated with improved health-related quality of life in older adults. In this systematic review, exergaming intensity was not evaluated suggesting the need to explore and evaluate exergaming intensity in order to determine the impact of this intervention on health-related quality of life.

4.1 Strength and Limitations

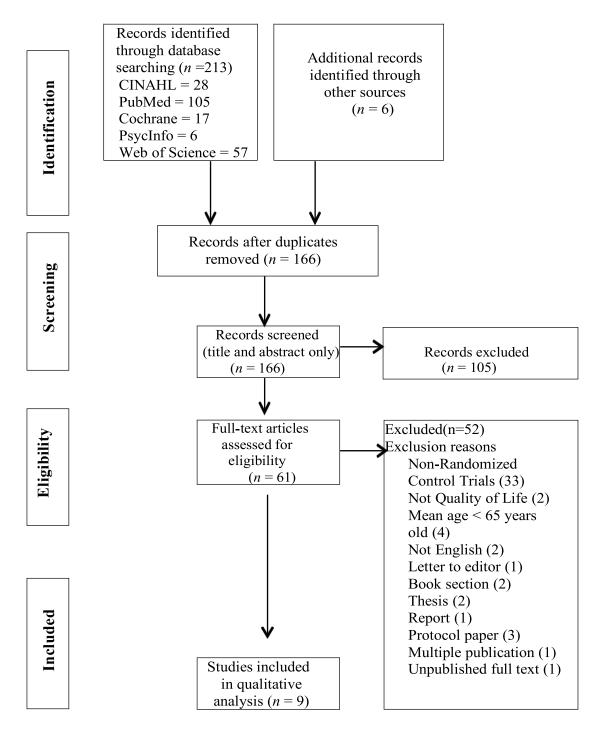
The major strength of this systematic review is the use of PRISMA guidelines (i.e., comprehensive search strategy including hand searching and checking reference lists, duplicate and independent screening, methodological data extraction and quality assessment). Next, only randomized control trials were included in the analysis using validated instruments to measure outcomes. Although this review chose only randomized control trials, the studies included in the analysis presented methodological limitations; these limitations pose biases in generating evidence regarding the efficacy of intervention with exergaming. One of the limitations is the relatively small sample size in most studies. Most studies were pilot or feasibilities studies that tested the efficacy of the interventions. Studies with a small sample size are at risk of being underpowered resulting in less reliable findings. Since health-related quality of life was the secondary outcomes, if a sample size calculation was performed prior to the study it was for the primary end-point. Finding statistically significant differences using a generic health-related quality of life instrument often required larger sample sizes than most studies provided in this review. Also, health-related quality of life was measured using different instruments and the heterogeneity in measurement tools would make it challenging to do a meta-analysis. Due to the nature of the healthcare intervention, blinding participants and interventionist were not feasible leading to performance bias. However, blinding of assessors was used in six studies. Most significantly, the clinical heterogeneity of the studies included in this analysis revealed diversity in study population, exergaming devices, outcomes measure, outcomes instruments, study settings, and dose, frequency and duration of the interventions. Such limitations pose challenges in drawing relevant conclusion for exergaming as an effective intervention to improve health-related quality of life in older adult. Finally, the review was limited to studies in the past 10 years. A search was conducted prior to 2007 for randomized control trial studies on exergaming and health-related quality of life among older

adults but unable to find articles that met criteria for this systematic review. Studies not referenced in PubMed, CINAHL, Web of Science, PsychInfo or Cochrane and unpublished studies were not identified; thus, this study is subject to publication bias.

4. Conclusions

This systematic review appraised randomized control trials that evaluate the effect of exergaming on health-related quality of life in older adults. Of the 219 articles retrieved, 9 articles were reviewed in the final analysis after meeting the inclusion criteria. At present, participants with high adherence to exergaming and those in a center-based setting appear to have the most promising effect. Overall, the evidence was not sufficiently strong to determine if exergaming is an effective health care intervention to improve health-related quality of life in older adults. Furthermore, interventions were conducted in heterogeneous patient population, exergaming devices, frequency, duration and length of the intervention, and study settings. Such factors do not allow for definitive conclusions to be made on the use of exergaming for improving health-related quality of life in this patient population. Further research is needed with larger sample size and less heterogeneity in design and measurements to explore the true effects of exergaming on the health- related quality of life in this patient population.

Figure 1. Flow diagram for study selection



Study selection according to PRISMA.²⁵

Figure 2. Risk of bias summary

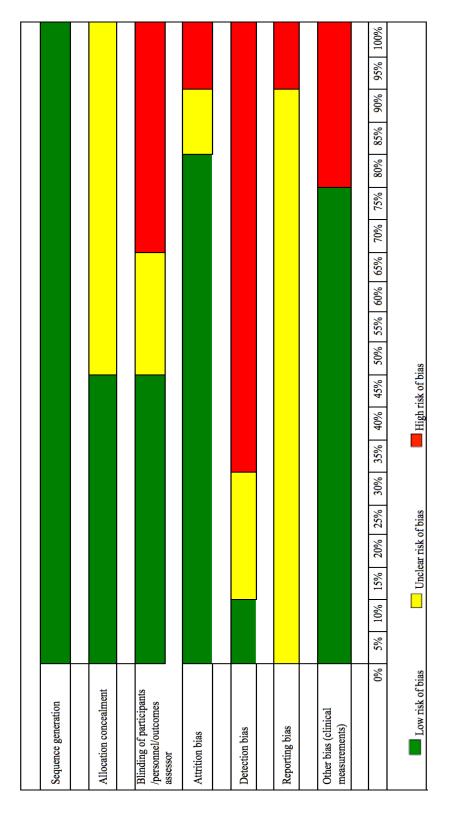


Table 1. Bias Risk Assessment within Studies following the Cochrane Handbook methodology.

Citation	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants, personnel and outcomes assessor (performance bias)	Incomplete Outcome Data (attrition bias)	Blinding of participant, personnel and outcome assessors (detection bias)	Selective Reporting (reporting bias)	Other potential threats to validity
:	-(,	,	,	,		,
Adie et al., 2017^{33}	0	0	0	0	0	<i>د</i> .	0
Franco et al., 2012^{28}	Ó	¿	-i-	:-	-;	¿	*-
Haines et al., 2008^{31}	Ó	Ó	Ó	Ó	Q	¢.	Ó
Karahan et al., 2015^{34}	Ó	÷	ن	Ó	;	⊹	Ó
Laver et al., 2012^{32}	Ó	Ó	Q	Ó	Q	<i>ċ</i>	*-
Morone et al., 2016^{35}	Q	Q	٠	3	٠	¿	Ó
Padala et al., 2012^{29}	,O	٠.	-	Q	-	?	Ó
Padala et al., 2017^{30}	Q	?	-}- -	Ó	-	÷	Q
Smaerup et al., 2016 ¹⁶	Ō	ċ.	Q	Q	÷-	3	Q

† = high risk of bias; $\dot{O} = low risk of bias; ? = unclear risk of bias$

Table 2. Characteristics of Studies and Result

Findings	No significant improvement in I group when compared to C group at 6 weeks and 6 months follow up	No significant improvement in I groups when compared to C group post intervention	No significant improvement in I group when compared to C group post intervention and at 6 months follow up
Quality of Life Measures	SIS, EQ-5D 3L	SF 36	ЕQ-5D
Dropouts	I = 6 (5%) C = 9 (7%) Lost to follow up = 6 (3%)	$I_1 = 3 (27\%)$ $I_2 = 2 (18\%)$ $C = 0$	I = 0 C = 3 (8%) at 6 months follow up
Adherence	Exercise adherence I = 82% C = 71%	Exercise adherence I1 = 87% I2 & C = data not clear	Adherence unclear Participants weekly participation declined starting at 3 week until week until
Frequency and Duration	Every day for 45 minutes 6 weeks 6 months follow up post intervention	2 days/week 10-15 min/session 3 weeks No follow up post intervention	100 minutes duration of video frequency not specified 6 months follow up post intervention
Comparative	Tailored arm exercise	No intervention	No intervention
Type of Intervention and Format	Arm exercise Wii Sports Games: bowling, tennis, golf, baseball, Sitting position	Balance exercise I ₁ = Wii fit Games: soccer heading, ski jumping, ski slalom, Wii tightrope, table tilt, balance bubble I ₂ = Matter of Balance	Lower limb strength and balance exercise Video based = "Kitchen Table Exercise Program"
Participants Physical Mobility	Stroke patients with arm weakness	Senior housing residents; healthy, ambulatory	Older adults with gait instability
Sample size; % Female; age (years) (SD)	N = 235 I = 177; C = 118 Female I = 51%; C = 53% Mean age I = 66.8 (± 14.6) C = 68 (± 11.9)	$N = 32$ $I_1 = 11; I_2 = 11$ $C = 10$ Female $I_1 = 82\%; I_2 = 73\%$ $C = 80\%$ Mean Age $I_1 = 79.8 (\pm 4.7)$ $I_2 = 77.9 (\pm 6.9)$ $C = 76.9 (\pm 6.3)$	$N = 53$ $I = 19$; $C = 34$ Female $I = 74\%$; $C = 63\%$ $I = 80.9 (\pm 8.9)$ $C = 80.5 (\pm 6.5)$
Design/Setting	Randomized Control Trial Multicenter Two groups Home- based	Randomized Control Trial Three groups Community	Randomized Control Trial Pilot Two groups Home-based
Citation, Country	Adie et al. 2017 ³³ United Kingdom	Franco et al. 2012 ²⁸ United States	Haines et al. 2008 ³¹ Australia

Findings	Significant (p = < 005) improvement in the parameters of physical functioning, social role functioning, physical role restrictions, general health perceptions and physical component scores post-test in the I group when compared to the C group	No significant improvement in I groups when compared to C group post intervention	Significant (p = 031) difference for physical activity score post intervention No significant difference at 3 month follow up
Quality of Life Measures	SF - 36	EQ-5D 3L	SF - 36
Dropouts	Lost to follow up I = 6 (11%) C = 4 (8%)	I = 2(9%) C = 0	Not discussed
Adherence	adherence	90% adherence with mean length of stay 12.3 (+5.6)	100% adherence
Frequency and Duration	30 min, 5 days/week 6 weeks No follow up post intervention	25 min/day; 5 days/wk. duration of stay on the unit No follow up post intervention	1 hour training; 2 days/wk. 8 weeks Follow up at 3 months
Comparative	Home based balance exercises	Conventional	Standard of care No description
Type of Intervention and Format	Balance exercise Xbox 360 Kinect Games: Kinect adventures, sports, (football, tennis, skiing, golf, volleyball, bowling)	Balance exercise Nintendo TM Wii Fit Games: Balance board	Balance exercise Wii balance
Participants Physical Mobility	Older adults attending physical and rehabilitation medicine outpatient clinic; ambulate independently	Older patients from a geriatric rehabilitation unit in the hospital Able to preform sit to stand transfers without physical assistance	Older females with bone loss condition with balance problems
Sample size; % Female; age (years) (SD)	N = 100 I = 54; C = 46 Female I = 44%; C = 43% Mean Age I = 71.3 (± 6.1) C = 71.5 (± 4.7)	N = 44 I = 22; C = 22 Female I = 86%; C = 74% Mean Age I = 85.2 (± 4.5) C = 84.6 (± 4.4)	$N = 38$ $I = 19$; $C = 19$ Female 100% Mean Age $I = 67.8 (\pm 2.9)$ $C = 70.05 (\pm 4.9)$
Design/Setting	Randomized Control Trial Two groups Outpatient clinic	Randomized Control Trial Pilot Two groups Hospital Geriatric rehabilitation	Randomized Control Trial Two groups Rehabilitation Center
Citation, Country	Karahan et al. 2015 ³⁴ Turkey	Laver et al. 2012 ³² Australia	Morone et al. 2016 ³⁵ Italy

Citation, Country	Design/Setting	Sample Size; % Female; age (years) (SD)	Participants Physical Mobility	Type of Intervention and Format	Comparative	Frequency and Duration	Adherence	Dropouts	Quality of Life Measures	Findings
Padala et al. 2012 ²⁹ United States	Randomized Control Trial Pilot Two groups Assisted living facility	N = 22 I = 11; C = 11 Female I = 73%, C = 73% Mean Age I = 79.3 (± 9.8) C = 81.6 (± 5.2)	Older adults with mild Alzheimer Uses cane or walkers for ambulation	Balance and gait exercise Wii Fit Games: strength training, yoga and balance games	Walking	30 min/day, 5 days/week 8 weeks No follow up post intervention	Exercise time 11.5 (+3.5) hours -37%	I = 1 (9%) C = 1 (9%)	QOL-AD	No significant difference in the I group but significant difference in the C group (p = .03)
Padala et al. 2017 ³⁰ United States	Randomized Control Trial Two groups Community	N = 30 I = 15; C = 15 Female I = 13%; C = 1 13% Mean Age I = 67.5 (± 8.1) C = 69 (± 3.8)	Healthy older veterans Ambulate independently with mild to moderate balance problems	Balance Exercise Wii Fit and Training Plus	Computer based cognitive program (Brain Fitness) games: memory, language, attention, executive function, visual and spatial domain	45 min/ 3 days week for both groups 8 weeks No follow up post intervention	High adherence to the program	C = 0 $C = 0$	SF-36	Significant within group improvement in physical function scale at 4 weeks in I group (p = .03) but not at 8 weeks in all scales
Smaerup et al. 2016 ¹⁶ Denmark	Randomized Control Trial Two groups Home-based	N = 60 I = 30; C = 30 Female I = 57%; C = 63% Mean Age I = 76.4 (± 7.6) C = 78.9 (± 6.6)	Older adults with vestibular dysfunction	Exercise to reduce dizziness and improve physical function Computer program "Move It To Improve It" (Mitti)	Home exercise using printed instructions	20 to 30 min daily for 12 weeks (84 recommended sessions) No follow up post intervention	39% adherence	I = 2 (7%) C = 1 (3%)	SF-12	No significant difference between two groups post intervention

QL=Quality of Life; RTC = Random Control Trial; I = Intervention; C = Control (PPT); SIS = Stroke Impact Scale; EQ5D = EuroQol 5 Dimensions; SF = Short Form

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CHAPTER THREE

Facilitators and Barriers to Exergaming: Perspectives of Patients with Heart Failure Abstract

Background: Exergaming has gained popularity among generally healthy older adults and older adults with chronic illness. While most studies focused on improving physical activity and psychosocial well-being, few have explored barriers and facilitators of exergaming among patients with heart failure which are essential to exercise adherence. Aims: This qualitative study was done to explore facilitators and barriers to using an exergame platform at home utilizing the Nintendo^{TMTM} Wii Sports in patients with heart failure. **Methods**: Semi-structured face-to-face interviews were conducted in 13 participants diagnosed with heart failure (5 women, age range 34-69 years old) who participated in a pilot study on exergaming. Participants were asked about their experience with exergaming. Transcribed interviews were analyzed with conventional content analysis. Results: The following four facilitators were identified: (1) enjoyment and competition motivated gaming; (2) accessibility at home gave freedom and lowered threshold to exercise; (3) physical benefits when decreasing the sedentary lifestyle; and (4) psychosocial benefits on stress, mood and family interactions. Barriers included: 1) engagement diminished overtime due to boredom; and 2) frustrations due to lack of mastery and improvement. Conclusion: Patients described how exergaming gave enjoyment alone or with family, motivation to be physically active, as well as relieving stress and distress. However, patients claimed that their engagement diminished over time due to exergaming getting monotonous and boring and if they did not improve their gaming as anticipated it led to frustration. Additional strategies to sustain interest in exergaming are warranted to potentially achieve the intended aim of improving physical activity and ultimately improving the overall well-being and health care delivery in this patient population.

Exercise training has been associated with reduced risks of cardiovascular disease. The American Heart Association (AHA) has recommended physical activity in adults to improve cardiovascular health, and health-related quality of life. Exercise has also been promoted as an important modality in the treatment of chronic heart failure to improve functional status and quality of life and reduce clinical events and health care utilization. Older adults with heart failure and preserved ejection fraction who engaged in short term exercise training reported significant improvements in functional capacity. Moreover, exercise training was associated with favorable improvements in cardiac, vascular and skeletal muscle function that resulted in increased oxygen transport, improved leg blood flow and attenuated left ventricular remodeling. However, despite the beneficial effects of exercise, the level of daily physical activity in most patients with heart failure was low. Research has shown that some of the reasons patients are less likely to engage in physical activity include physical limitations such as difficulty breathing, shortness of breath, discomfort, fatigue or psychological impairments (e.g., lack of motivation, depression). Play vital roles in patients' motivation to exercise.

The use of technology as a strategy for encouraging exercise and other forms of physical activity among older adults is on the rise. 7,10-13 The growing acceptance of exercise-based video games (i.e., exergaming) as a health care intervention among older adults has been well documented in the literature. 7,11,12,14 This form of exercise may be an adjunct to other forms of physical activity rather than a stand-alone intervention. Researchers and clinicians felt that exergaming might overcome the traditional barriers to exercise that include environmental elements, safety, time restriction, service access cost, and boredom. 10 It is surmised that exergaming can deter boredom because of the fun factor and competitive nature of video games and can promote socialization through group play. 10,14,15

There is an increasing body of work addressing the effect of exergaming on the physical and psychosocial well-being in older adults such as improving physical capacity, ^{10,16} balance, ¹⁷⁻²² muscle strength, ^{23,24} mobility, ¹⁸ cognitive function, ^{25,26} reducing depressive symptoms ^{27,28} and improving health-related quality of life. ^{29,30} However, few have explored older adults' experiences and perspectives related to facilitators and barrier to exergaming, important factors that may determine adherence to this form of exercise program. Research has shown that older adults with impaired balance experienced enjoyment and high motivation with exergaming, especially when playing with grandchildren. ²² Similarly, older women living in the community expressed an improved sense of physical, social and psychological well-being after six weeks of exergaming. ³¹

While the positive benefits of exergaming have been described, most studies in various groups of older adults reflected on both the positive and negative effects of exergaming occurring concurrently. One study looked at exergaming experiences in patients with multiple sclerosis. They reported that exergaming helped participants engage in exercise, build confidence in their abilities, removed barriers associated with going to the gym and helped achieve goals related to engagement in leisure activities.³² Conversely, the same study reported that exergaming also brought about initial reactions of intimidation related to the games' negative feedback reminding participants of their impairment and worries about falling.³² Research exploring the experiences of exergaming among older adults with depression reported that at the beginning of the study, participants were nervous about their game performance and understanding of the technical aspects of the game. However, towards the end of the study, participants expressed game satisfaction, enjoyment and fun.²⁷ Residents in an assisted living facility cited health and mobility, increased alertness, social interactions and program structure as facilitators to exergaming while age or health-related impairments and unpleasant experiences to

exercise were identified as barriers.³³ In a similar study population, older adults in residential care centers experienced feelings of empowerment and achievement after initial reluctance and anxiousness. They also reported that the games were fun and offered an avenue for more socialization.³⁴ While exergaming promoted active aging, older adults encountered challenges with physical and media literacies.³⁵

While these studies provided an understanding on motivators, barriers, attitudes, abilities, and preferences to exergaming in older adults that are healthy or with varying chronic conditions and disabilities, to our knowledge few studies have been conducted on perceived facilitators and barriers of exergaming in patients with heart failure. Klompstra and colleagues reported that patients with heart failure experienced exergaming as enjoyable, easy to use, convenient and improved physical fitness but was less appealing over time. However, this study was conducted in a cohort of participants who participated in an exergaming intervention conducted outside the U.S. Therefore, the purpose of this study was to explore facilitators and barriers to exergaming in in a cohort of patients with heart failure.

Methods

This study was part of a randomized pilot study that examined the effect of exergaming using the Nintendo™ Wii Sports in improving the physical and psychosocial well-being in patients with heart failure in the U.S. Participants were recruited from a university-based heart failure program in Southern California. Eligibility criteria for the study included individuals ≥18 years of age, diagnosed with heart failure [New York Heart Association class I–III] by a cardiologist, in stable condition, able to speak, read and understand the English language, absence of mobility or balance problems, communication deficits (vision, speech or hearing), and severe cognitive impairments or psychiatric illness. Although the feasibility study randomized patients to either exergaming or usual care over a period of 12 weeks, only

participants randomized to the exergaming arm were included in this study.

The University Institutional Review Board approved the study and informed consent was obtained from all study participants. Semi-structured face-to-face interviews were conducted by the principal investigator (MC) at the end of the 12-week study duration. All interviews were audio recorded and field notes and impressions of the interview were written to capture non-verbal data. The interviews were conducted during the 12-week follow-up visit, which was completed at the heart failure clinic. Participants were asked: "Can you describe your experience with the NintendoTM Wii Sports games?" Participants were asked to elaborate on their responses to better understand their perspectives. Finally, participants were asked to share their ideas of what they would recommend improving the exergaming experience.

Data Analysis

Upon completion of the interviews, the audio files were transcribed verbatim and transcriptions checked against the audio recordings by the research team. Transcribed interviews were analyzed through conventional content analysis using inductive code generation.³⁷ Each transcript was independently coded by three coders (MC, LE, AS) to ensure that the identified themes reflected the actual participants' statements; coding disagreements were resolved through discussion. This comparative analysis was used to validate the data ensuring credibility and dependability. Codes were condensed into higher-level themes structured around two related topics: facilitators and barriers to exergaming.

Results

Interviews were taken from 13 participants (mean age 57.3 ± 10.1 range, 34-69 years, 62% males); 31% were White, 23% were Blacks, Hispanics, and Asians, respectively. Less than half (46%) were married with children and/or grandchildren, and 54% were employed.

Four factors emerged as facilitators to exergaming: (1) enjoyment and competition

motivated gaming; (2) accessibility at home gave freedom and lowered threshold to exercise; (3) physical benefits when decreasing the sedentary lifestyle; and (4) psychosocial benefits on stress, mood and family interactions. Barriers included: 1) engagement diminished overtime due to boredom; and 2) frustrations due to lack of mastery and improvement. Table 1 presents some examples of quotes provided by participants in each category.

Facilitators to Exergaming

Enjoyment and competition motivated exergaming

All participants stated that the exergaming device was overall user-friendly after the initial familiarization with the technology. They stated that the games were initially fun and kept their interest and they felt enjoyment with playing different games. They enjoyed competing against themselves or the computer and that motivated them to play more. They wanted to get better scores or beat their best game every time they played. Others expressed that as the level of difficulty in gameplay increased, the games became more engaging because of the new challenges especially when game goals were attained. The novelty and game challenges were cited reasons for continued play.

Accessibility at home gave freedom and lowered threshold to exercise

The accessibility of Nintendo™ Wii device at home emerged as a motivating factor to engage in physical activity. Participants claimed that being able to play at times that were convenient to them provided a sense of control. Others felt that the convenience of a home-based exercise such as exergaming provided a good alternative when unable to go to the gym or exercise outdoors.

Physical benefits when decreasing the sedentary lifestyle

Participants described a surge of energy when they played, and this energy is what kept them moving. They reported that the platform provided an outlet to be active and fit as opposed to being sedentary and physically exhausted. One participant stated that exergaming helped improved his stamina while another said that it kept his blood pumping. The participant reported spending a lot of time watching television before they had the NintendoTM Wii, but exergaming allowed them to utilize arm movements even while sitting down and helped boost their confidence in being active for their own benefits.

Psychosocial benefits on stress, mood and family interactions

Participants in our study reported that exergaming made them feel more active and that being more active made them feel good. Some described that exergaming helped with relieving stress most notably when playing boxing. Other participants claimed that exergaming helped with reducing their feelings of depression by filling a void. Spending family time with exergaming was another perceived benefit that participants reported.

Barriers to Exergaming

Engagement diminished over time due to boredom

Engagement declined over time due to boredom. Initial impressions of exergaming were mostly positive at the beginning of the study. However, over time, participants reported getting bored playing with the platform. They cited that the repetitiveness and predictable nature of the games made them lose interest in exergaming. Also, achieving mastery of the games or "beat the games" did not provide further motivation to keep exergaming. Others felt that playing in the room in front of a TV screen was not appealing and they would rather be outdoors especially when the weather was nice. Many suggested that adding a variety of games would be beneficial and would enhance their desire to play more.

Frustrations due to lack of mastery and improvement

Feelings of frustration were noted to influence participants' behavior when playing some of the Wii game components that were fast paced and required visual acuity (e.g., tennis,

baseball). Reports of inability to hit the ball, difficulty with hand and eye coordination and their inability to advance to the next game level resulted in annoyances and defeat. Some participants reported that they avoided playing some of the games due to the level of difficulty and feelings of disdain toward the game and self-failure. These feelings of frustrations led to a decreased engagement in exergaming and sporadic play in some participants while others stopped playing the games altogether.

Discussion

This study explored the barriers and facilitators to exergame among patients with heart failure. It appeared that all participants initially engaged in exergaming with the hope that this novel form of exercise would be beneficial for their health and improve physical activity. Our findings were consistent with earlier research that showed the NintendoTM Wii platform was highly usable in terms of fun, enjoyment, and satisfaction. ^{31,32,34,36} Fun and engagement appeared to play critical roles in motivating patient with heart failure to participate in exergaming. Our study suggests that fun and engagement was strongly associated with the competitiveness the games foster, similar findings to that reported by Millington (2015) on exergaming among older residents in retirement facilities.³⁵ Also, participants' game preference was evident depending on past and present experiences, skills required for the game and game mastery. Providing the participants with a choice of games was essential to generate and sustain interest in exergaming.³¹ The majority of our participants preferred bowling which they found easy to learn and play. Games such as bowling that is slow paced and did not require visual acuity was a favorite whereas baseball and tennis that involved small, fast-moving features and hand-eye coordination and required skill and visual acuity were less desired. These findings are consistent with prior work in this area.^{31,35} Given the multitude of exergaming platforms in the market, it is important to note the choices that are available, as well as the game skill requirements that can

result in personalized games explicitly tailored to preferences and capacities of end-users.

Findings also showed that fun and enjoyment was associated with a sense of accomplishment. A study by Diaz-Orueta, et al. demonstrated that learning a new technology such as playing video games and achieving newfound mastery in novel tasks are vital factors for older adults playing digital games.³⁸ The sense of accomplishment and pride that the patients with heart failure in our study experienced as their game mastery increased may have also been key to exergaming becoming fun rather than an activity that reminded them of their physical limitations or disabilities.³² Many older adults do not adhere to exercise regimens due to a lack of enjoyment. Finding fun, sustainable physical activities that motivate patients to exercise consistently and frequently is essential and makes these technological tools a promising opportunity to promote physical activity in patients with heart failure.

Accessibility was also identified as a facilitator to exergaming that is supported by in previous research that described NintendoTM Wii games as convenient because they could be played at home.³² This console-based platform is portable and can be set up in any settings. The accessibility of the NintendoTM Wii games also meant that participants were able to overcome time and resource related barriers, such as transportation to rehabilitation centers or gym membership and allowed them to exercise at times that were convenient for them. This accessibility is a potential benefit to individuals with physical limitations or who are unable to leave their home (e.g., immunocompromised). Allowing participants to decide when and how much to exercise provided motivation for continued play. However, NintendoTM Wii games may pose challenges such as patient safety,³⁹ home distractions (i.e., competing desire to complete household chores), television accessibility (i.e., only one TV in the home) and lack of accountability and social support (no family members).³² Thus, it is important for clinicians to consider the physical and social environment that allows for engagement in such programs while

improving physical function.

Physical benefits emerged as another facilitator to exergaming among our study participants which is consistent with findings in recent research involving older women living in the community³¹ who claimed that playing the NintendoTM Wii games kept them active regardless of age or health condition. Our findings showed that exergaming could provide an outlet to be active regardless of mobility factors as patients in the study were able to play the games in a sitting position or standing up. Furthermore, participants in our study cited exergaming as a stress reliever, made them feel good, helped with managing depression and increased interactions with family members. These perceived psychosocial benefits were similar to findings reported among older adults where exergaming led to reduced depression^{27,28} and stress, 40 essential motivating factors to engage in exergaming and promote adherence to activity. Using a novel technology that was initially marketed to younger generations for entertainment value allowed older persons to be more connected to their family members, especially grandchildren. ^{22,33} ³⁶ These intergenerational connections and shared experiences with younger family members promoted social support and may lead to improved psychosocial well-being among patients with heart failure. Indeed, the playful qualities generated through exergaming make them suitable for use with people in stressful situations, 41 including patients with chronic diseases such as heart failure and older adults living in long-term care facilities.

Although the NintendoTM Wii Sports helped the participants engage in exercise, there were also barriers to exercising. One notable barrier to exergaming was boredom. Participants reported feelings of boredom after a few weeks of playing and reduced exergaming overtime. This finding is supported by a similar study among heart failure patients that was conducted in Sweden³⁶ and among older adults with multiple sclerosis.³² Furthermore, findings from a systematic review showed that exergaming declined over time, with the highest use occurring

upon receiving the exergaming consoles and games. ⁴² Interestingly, in exergaming that involved group play such as those conducted at assisted living facilities, ^{33,34} community health service centers, ³¹ and retirement centers, ³⁵ participants did not report boredom. These findings suggest that exergaming maybe be more beneficial when integrated into group activities such as those occurring at rehabilitation centers where individuals exercise with other people over solitary play at home. Also, one can argue that boredom was perhaps not due to exergaming itself, but rather due to lack or absence of interaction between the participants and other players. Group play involves social interaction and connectedness, a motivating factor to engage in exercise. ^{10,35} Likewise, support from friends and family and playing with others may facilitate long-term exergame play. ⁴²

Boredom in our study was also strongly associated with a lack of game variety. This finding is similar to a study conducted among obese adolescents on the motivating effects of cooperative exergaming, where participants reported boredom after playing repetitive games which led to them dropping out of the study.⁴³ It is evident that "one size does not fit all," thus, the game variety must be taken into consideration when starting a home-based exergaming program to ensure that games are tailored to the individuals' interests and capacities. Providing participants with a variety of exergames is important to generate and sustain interest at home.

Another barrier to exergaming was game disdain and self-frustration. Specific aspects of exergaming were particularly frustrating for some participants in prior research, especially games that required a precision of movement. For instance, the tennis game needed players to align their arm at a certain angle and use precise timing to hit a virtual ball at a target or small rapidly moving features such as baseball that required both skill and visual acuity.³¹ This study corroborated our findings that participants failure to coordinate their movements appropriately while exergaming led to self-frustration. The failure to properly execute movements could itself

become a barrier to exergaming. Such challenges seemed to reduce enjoyment, mainly because participants had to complete a certain number of successful hits to progress to the next game.⁴³

Participants' frustrations with playing the NintendoTM Wii games appeared to be compounded by having doubts about their ability to interact with this new technology, especially playing the more difficult games. It is highly suggestive that proper instructions, training, support, and encouragement are needed to help participants overcome their lack of confidence in technology and gameplay. Developing an understanding of the participants' perceived barriers to exergaming and how these can be mitigated is vital for ensuring adherence and persistence with exergaming. This is particularly important in home-based interventions where family or clinician support may be lacking, and participants may feel less motivated to participate in exergaming. Additional training and encouragement may potentially reduce or avert feelings of frustration related to exergaming in our sample.

Limitations

There was diversity among participants with variations in ethnicity and socio-economic status. Diversity in the cultural context might garner different perspectives of exergaming due to one's beliefs and norms. Also, findings from this study are unique to this patient population and influenced by the researchers' beliefs and perceptions about exergaming. Future research is warranted to explore perspectives of other individuals with chronic disease, especially older adults who are not keen on using technology for exercise purposes. This would provide insight for their lack of interest in integrating technology and other barriers as well as facilitators for engaging with devices like the NintendoTM Wii to improve physical activity.

Conclusion

This research was conducted to examine facilitators and barriers to exergaming among

patients with heart failure. As interactive technologies are introduced and used as health interventions to promote physical activity such as the NintendoTM Wii games, clinicians must take into consideration facilitators and barriers and include them in a framework for improving knowledge about establishing exergaming programs at home. Our findings support the idea that the NintendoTM Wii exergame play, much like the real sports, can promote fun, social interaction and competition while increasing physical activity. However, participants' past experiences, preferences, capacities, game variety, and social support must be taken into consideration especially when a solitary play is expected to avoid boredom and frustrations.

Table 1 Themes with representative quotations

Theme

Quotations

Facilitators to exergaming

Enjoyment and competition motivated gaming

Accessibility at home gave freedom and lowered threshold to exercise

Physical benefits when decreasing the sedentary lifestyle

Psychosocial benefits on stress, mood and family interactions

Barriers to Exergaming

Engagement diminished over time due to boredom

Frustrations due to lack of mastery and improvement

- It's easy that anyone can just practice and you can get better because I've gotten better since I started playing it
- I love it, it's fun, it's competitive...it's always fun to have games and that is engaging
- Fun! Soaks up a lot of time... Enjoyable as the games can get competitive, even if it's against the computer...enjoyable especially when I get to the next level
- I can play the game whenever I want to ... I feel in total control
- The nice thing about the Wii was when I wasn't working in the gym or didn't feel like going out then I can turn on the Wii and exercise
- You can do it anytime you want...like 2:30 in the morning I'm up bowling...
- I feel that it keeps me moving so I felt like I'm doing something... It got me to stand during the time where I would normally be sitting
- It helped me with stamina, I can say that it motivated me to get up and do more things, 'cuz I was a lazy.... Depending on the game it gets my blood pumping
- ...doing something in front of the TV... It helps create an environment where you are more active even if I'm just using my arms
- It got me motivated a bit. It's a good stress reliever ...if I get stressed I would come home and box a couple rounds
- It helped the bored time because you have too much time on your hands, become bored and it can lead to depression... With the Wii you just turn it on, play something and all of a sudden next thing you know half an hour's gone... time goes by and stuff it takes care of depression.
- It was a good way for the family for us to get together
- Wii was good but it gets boring after a while ...it's the same game I play over and over again... you kind of anticipate the moves... I already beat the game
- ...to keep my interest I would play different games (other than the Wii Sports) like the dance and do different things ...add a Wii Zumba something that keeps you excited so you don't get bored I love to dance I love to move around... I think it just needs variety
- It's (the Wii games) cool, but it gets old playing after a while. ... I am kind of getting tired of playing the same five games ... I don't feel like playing the game when it's nice and warm outside
- ...I couldn't figure out really the swing and the bat to really connect at the right place consistently (when playing baseball)... I lost interest ... not playing the game as expected
- Not being able to do it. Not being able to play the game. Not being able to return a serve. It's so frustrating!
- ... tennis because I can't return a serve to save my life. Baseball is another one. I either swing too soon or too late. That was the other one that I get upset with. I stopped playing...when I better the score I had that's how I feel success otherwise I feel mediocre. I feel like a failure.

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CHAPTER FOUR

Impact of Exergaming on Psychological Well-Being and Symptom Burden in Patients with Heart Failure: A Pilot Study

Abstract

Background: Little is known regarding the impact of exergaming on the psychological wellbeing and symptom burden in patients with heart failure. Purpose: To obtain pilot data on recruitment, retention and adherence to exergaming vs. standard of care (SC) and assess the impact of exergaming on psychological well-being and symptom burden in patients with heart failure. **Methods**: Patients were recruited and randomized to SC -- motivational support where they received exercise advice from the heart failure team -- vs. SC plus structured access to exergame (e.g., NintendoTM Wii Sports). Participants in the Wii group were advised to exergame 30 minutes per day for 12 weeks. Data were obtained at baseline and 12 weeks. Results: Thirty patients – mean age 55.6 ± 8.5 , 70.0% male; 43% White; 27% Hispanics; 20% Blacks; 10% Asians – participated in the study. At 12 weeks, participants in the Wii group showed greater improvements in physical and emotional quality of life and greater reductions in symptom burden (e.g., shortness of breath, fatigue) compared to the SC group. There were no significant group differences in other outcomes. Conclusions: A 12-week home-based exergaming program was feasible and showed potential for improving the psychological well-being and reducing symptom burden in patients with heart failure. However, these preliminary findings need to be confirmed with larger sample size and long-term follow-up.

Introduction

Heart failure is a debilitating chronic illness that afflicts about 6.5 million people in the United States and costs the nation an estimated \$32 billion each year related to health care services cost, medication, treatment and loss of productivity care. It is a chronic condition that is often associated with poor prognosis. With the advancement in technology and evidence-based care, survival among patients with chronic heart failure has improved. However, these therapies are seldom curative and may expose patients with chronic heart failure to psychological impairments such as anxiety, depression, and overall decreased quality of life. Patients also suffer greater symptom burden over time; classic symptoms include dyspnea and fatigue. Symptoms can be the hallmark of worsening heart failure and when left untreated can lead to increased clinical events including emergency department visits, hospitalizations and mortality. Considering the negative consequences of heart failure on patients and its burden on the healthcare system, it is important to explore opportunities to improve psychological well-being and symptom burden in this highly vulnerable population.

The American Heart Association and the European Society of Cardiology latest guidelines on the treatment of heart failure recommend regular and structured physical activity.^{1,7} Physical activity reduces the prevalence of anxiety and depression in patients with coronary heart disease by 50-70% and led to significant improvements in overall survival when depressive symptoms were successfully reduced.⁹ Also, physical activity in patients with heart failure is known to have positive outcomes such as improved symptom management and quality of life and reduced healthcare utilization.^{3,10,11} However, despite the beneficial effects of exercise, the level of daily physical activity in most patients with heart failure remained low.¹² Some of the reasons patients were less likely to engage in physical activity include physical limitations such as difficulty breathing, shortness of breath, discomfort, fatigue or psychological impairments

(e.g., lack of motivation, depression).^{5,13} Environmental factors such as temperature, availability of space, access and safety also played vital roles in patients' motivation to exercise.¹⁴

There is a growing acceptance and popularity of exercise-based video games (i.e., exergaming) as a healthcare intervention among older adults. 12,15-18 This interactive form of exercise may be an adjunct to other methods of physical activity rather than a stand-alone intervention. Researchers and clinicians expressed that exergaming might overcome the traditional barriers to exercise that include environmental elements, safety, time restriction, service access cost and boredom. 14 Recent studies have shown that the NintendoTM Wii is the most frequently used platform for exergaming; 19-22 it is safe and feasible in promoting increased energy expenditure among older adults. 16,22 A systematic review showed that in older adults exergaming has potential for reducing depressive symptoms, ²³ and improving the health-related quality of life. 15 Also, exergaming might be a better alternative for heart failure patients to engage in physical activity at home. 14,24 However, there is a paucity of research that describes the impact of exergaming on the psychological well-being and symptom burden in patients with heart failure. This pilot study was based on achieving two key aims: 1) obtaining pilot data on recruitment, retention and adherence to exergaming using the NintendoTM Wii Sports and standard of care (SC) (motivational support where patients received exercise advice from the heart failure team), and 2) estimating the potential impact of exergaming vs. SC on improving psychological well-being (e.g., anxiety, depression, health-related quality of life) and reducing symptom burden (e.g., shortness of breath and fatigue) in patients with heart failure.

Methods

Design

Randomized controlled pilot study

This is a randomized parallel controlled pilot study design where 30 adults (age range 35-85 years) diagnosed with heart failure (NYHA I-III) were randomly assigned with a 1:1

distribution using computer-generated blocking. Participants were randomized to either the SC -motivational support where patients get exercise advice from the heart failure team -- vs. SC plus
structured access to NintendoTM Wii video game for 12 weeks. A complete description of the
study design and methods of the parent study describing the effects of exergaming on the
physical and psychological well-being in patients with HF has been published elsewhere. The
sample size was chosen based on feasibility (i.e., number feasible to recruit within timeframe)
and recommendations for an optimal number of participants for use in pilot studies.

Setting and Participants

Participants were recruited at a heart failure clinic in an academic institution in Southern California. Individuals with heart failure diagnosis were recruited using provider, staff referral and face-to-face contact. Members of the research team contacted all potentially eligible patients to determine their interest, availability and eligibility for participation. Eligibility included age between 35-85 years old, diagnosed with heart failure (NYHA I-III) independent of ejection fraction. Patients were excluded if they were unable to use the NintendoTM Wii due to visual impairment (must see a TV screen at a distance of 10 feet), hearing impairment (must be able to communicate by telephone), cognitive impairment that precludes an individual from understanding the consent process or completing surveys (clinically documented by the heart failure nurse or cardiologist), motor impairment (should be able to swing arms at least 10 times in a row), has restrictions that would prevent them from completing the study protocol and has a life expectancy shorter than 6 months. Only English-speaking patients were deemed eligible to participate in the study because safety instructions for NintendoTM Wii and other pertinent study materials (i.e., questionnaires) were only available in English.

Procedures

All participants were given informed consent in English. Recruitment materials, study protocol, and consent documents were approved by the appropriate university Institutional Review Board prior to conducting the study. Eligible participants were informed of the study risks and benefits and a member of the research staff obtained signed, informed consent and the Health Insurance Portability and Accountability Act (HIPPA) of 1996 (P.L.104-191) [HIPPA] research authorization. Study participants underwent cognitive function screening using the Montreal Cognitive Assessment (MoCA). Results from the MoCA assessment helped the research team determine if participants were able to fill out the questionnaires and follow simple instructions.

Baseline testing included completion of questionnaires (e.g., anxiety, depression, health-related quality of life, symptom burden) using a paper and pencil approach. Next, patients were randomized using computerized random number generator (in a 1:1 ratio) to SC or SC plus structured access to a NintendoTM Wii Sports game (both are described in greater depth in the subsequent section). To achieve a balance between study arms and to have similar numbers of patients during the introductory lesson, the randomization was made with blocks of 4 comprising two interventions and two control conditions. Participants were not allowed to change groups to avoid random sequence generation bias. Compensation of \$25 was given at baseline test and \$25 at 12-week follow-up visit to each participants. Participants in the Wii group kept the Wii console and game at the conclusion of the study.

Standard of Care

All participants in SC group received regular treatment and exercise advice from the heart team (e.g., nurse, cardiologist, nurse practitioner). All participants were advised to be active for 30 minutes a day. This might not apply to all patients since some patients may only manage to be active for 10 or 20 minutes and others may manage exercising for more than 30

minutes. Therefore, the advice was adapted to the capabilities of the individual patient. During the study duration, at 2, 4, 8 and 12 weeks after inclusion in the study, participants were followed up using a structured telephone script to discuss their current activity and given motivational support. This ensured that both groups received equal attention from the research team.

NintendoTM Wii Sports Game

Participants assigned in SC + Wii group received activity advice, as described for the control group. In addition, the principal investigator (MC) trained the participants on the use of the Nintendo™ Wii sports in their homes. Participants were taught to move the remote control in a similar way the sports were played in real life; for example, holding and swinging the remote control as a bowling ball, tennis racket, baseball, golf and boxing. They were also advised to play for 30 minutes per day. If needed, they were advised to adapt to their capacity, for example, to play more often for shorter periods during the day or even play for longer if they wanted to.

Participants received written safety guidelines and information on how to use the Nintendo™
Wii after installation. The principal investigator (M. C.) also assessed participants' home surroundings for safety issues. During the study duration, at 2, 4, 8 and 12 weeks, participants were contacted using a structured telephone script to discuss their experiences with the Nintendo™ Wii games, given motivational support and if needed, provided with assistance to resolve unexpected problems. Technical assistance was provided during the intervention period.

Adherence to exercise was measured using a self-reported diary and a logbook. Questions about exercise frequency were asked in a scripted follow-up phone call at 2, 4, 8 and 12 weeks.

Adherence to exergaming was also asked during a face-to-face interview for the Wii group.

Measures

Anxiety and Depression

Anxiety and depression were assessed with the Hospital Anxiety and Depression Scale

(HADS), 26,27 a 14-item self- assessment scale that asks the individual to reflect on their mood in the past week. The HADS measures symptom severity and presence of anxiety disorders and depression in somatic, psychiatric and primary care patients and in the general population (Cronbach's $\alpha = .83$).²⁷ The HADS has two subscales, the HADS-A (anxiety subscale, seven items) and the HADS-D (depression subscale, seven items). Each item was rated on a 4-point scale (ranging from 0 = no not at all, to 3 = yes definitely), for a total score ranging from 0-21 for each subscale; higher scores indicate higher distress. A score between 8-10 was suggestive of the presence of the state, and a score of ≥ 11 indicate the probable presence ('caseness') of a mood disorder.²⁶ The Cronbach's α of the HADS for this study was 0.93.

Health-Related Quality of Life

The Minnesota Living with Heart Failure Questionnaire (MLHFQ)²⁸ is a 21-item questionnaire used to assess how heart failure has affected the life of the respondent during the last month. The MLHFQ has a scoring range between 0-5, with lower scores indicating better quality of life. The questions cover symptoms and signs relevant to heart failure, physical activity, social interaction, sexual activity, work and emotions. Three scores can be determined: an overall score (21 items, 0-105 possible score), the physical domain (8 items, 0-40 possible score) and the emotional domain (5 items, 0-25 possible score). The current study Cronbach's α for MLWHFQ was 0.83.

Symptom Burden

The Edmonton Symptom Assessment Scale (ESAS) is a patient-rated nine-item visual analog scale developed for use in assessing the symptoms of patients receiving palliative care (Cronbach's $\alpha = 0.79$).³⁰ For this study, participants were only queried regarding two individual symptoms: dyspnea and fatigue). The ESAS has been used to assess burden symptom among community-dwelling older persons with advanced chronic disease including heart failure.³¹ It is

rated from 0-10 with higher scores reflecting greater severity of symptoms. The Cronbach's α for the ESAS for the current study was 0.97.

Demographic Questions

Demographic information including age, gender, ethnicity/race, marital status, highest educational degree obtained, ejection fraction, New York Heart Association (NYHA) classification, etiology, co-morbidities, and medications were abstracted from the electronic medical record.

Statistical Analyses

All statistical data were analyzed using the Statistical Package for the Social Sciences ([SPSS] Version 23.0. Armonk, NY: IBM Corp). 32 Descriptive statistics (mean \pm SD) and Chisquare were used to describe the sociodemographic and clinical characteristics of study participants. The general method entails an initial analysis that employs the t-test (or Wilcoxon rank sum test if non-normality is observed) to compare the outcomes between the two groups. Psychological status (e.g., anxiety, depression, health-related quality of life) and symptom burden were compared between participants in the exergaming and control groups using the analysis of covariance statistic. First, we determined whether there were significant group differences in mean scores between baseline and 12 weeks. Then, to account for the possibility that similar group means might be found only because outcomes improved over time for one group while worsening for the other, we conducted analyses of group × time interactions. To control for the baseline group differences, we controlled for baseline values by entering them as covariates in the analysis of covariance equation. The adjusted means presented herein account for the influence of baseline values. The level of significance is set at $\alpha = .05$.

Results

Study Participants

Sociodemographic and clinical characteristics are shown in Table 1. Thirty patients – mean age 55.6 ± 8.5 , 70.0% male; 43% White; 27% Hispanics; 20% Blacks; 10% Asians – participated in the study.

Recruitment, retention and adherence

A total of 90 subjects were screened for the study, but only 30 (33%) provided informed consent and completed the baseline visit; 35 (39%) did not meet the inclusion criteria, 15 (17%) declined to participate and 10 (11%) met eligibility and initially agreed to participate but did not attend baseline testing. Reasons for declining to participate in the study included a lack of interest in playing video games or lack of time (see Figure 1). Two participants in both groups were lost to follow-up.

In the Wii group, adherence to exergaming was initially high with participants reporting exergaming 5-7 days a week for 20-45 minutes at the third and fourth week then to 1-3 times a week for 15-20 minutes at 8 weeks and 0-2 times per week at 12 weeks. Common reasons for not exergaming included illness, lack of time, motivation and boredom with exercise games. In the control group, most of the participants lacked structured exercise training, but rather they reported that most of their physical activity came from doing household chores, walking in the grocery store, running errands, work-related activities and occasional walking around the block in their area of residence. Non-completion of the diary or activity log among participants in the SC group was prevalent and posed a challenge in quantifying exercise adherence.

There were no technical issues reported with exergaming except for one participant whose power cord needed replacement. The attrition rate for the exergaming group was 2 (12%) and 2 (14%) for the control group. There were no adverse events related to the study.

Psychological well-being and symptom burden

At 12 weeks, patients in the Wii group did not show significant improvements in anxiety

and depression scores (anxiety p=.186; depression p=.109) (see Table 2.). Data also show that five participants were taking anti-depressants (Wii group n = 3; SC group n = 2). Group differences in the physical and emotional domains of health-related quality of life were noted over time in favor of the exergaming group (p=.035 and p=.001, respectively). There were no significant differences in overall health-related quality of life (p=.236). Data showed group differences over time in both shortness of breath (p=.009) and fatigue (p=.042) with the exergaming group reporting greater reductions in symptom burden compared to the SC group.

Discussion

This pilot study was based on achieving two key aims. The first aim was to obtain data on recruitment, retention and adherence to both interventions in a cohort of patients with heart failure. Findings showed that the study protocol for recruitment and retention and for carrying out both interventions was feasible. Adherence to exercise among the exergaming group was initially high but declined over time. These findings are similar to a study Klompstra and colleagues (2014) where patients with heart failure reported decreased exergaming overtime. Also, findings from a systematic review revealed that exergaming declined over time, with the highest use occurring upon receiving the consoles and games. As anticipated, adherence to exercise or physical activity among participants in the SC group was lower than the exergaming group.

The second aim of the pilot study was to estimate the potential impact of exergaming vs. SC on improving psychological well-being and reducing symptom burden. Our findings that there were no group differences over time in anxiety and depression is likely due to the small sample size and lack of power to detect differences. However, despite the small sample size, our data showed that there were changes in the emotional and physical domains of health-related quality of life in the exergaming group compared to the SC group over time. Our finding is

similar to findings from other studies in a systematic review conducted by Cacciata, et al. (2019) where exergaming improved the health-related quality of life of older adults with other chronic health conditions. Health-related quality of life is highly associated with increased physical activity, therefore, using an innovative and user-centered way of performing physical activity such as exergaming may motivate individuals to be more physically active in their daily life and feel more confident to exercise. 15

The current study also demonstrated significant reductions in self-reported symptom burden (i.e., dyspnea and fatigue) in the Wii group after exergaming for 12 weeks. These findings are supported by a study on patients with chronic kidney disease who experienced a high symptom burden. Researchers in this study reported favorable effects on fatigue after patients underwent 12 weeks of aerobic and resistant training. Symptoms are the patient's subjective perception of disease manifestations. Symptom burden is known to affect the quality of life in older persons. Specifically, patients with chronic heart failure are known to struggle with high-level symptoms and symptom burden (e.g., edema, pain, depression, gastrointestinal distress, difficulty sleeping) with dyspnea and fatigue as the most prevalent symptoms. And the identification and alleviation of symptoms are essential aspects of chronic disease management such as heart failure. Clinicians continue to seek strategies to alleviate symptom burden and interventions such as exergaming may reduce severity, distress and overall symptom burden in this vulnerable patient population.

The possibility of using a home-based exergaming platform using the Wii Sports to improve the psychological well-being and symptom burden in patients with heart failure is appealing for several reasons. First, it is a low cost, commercially available device when compared to a gym membership or rehabilitation fees. It is accessible at all times, which is an advantage when time constraints or transportation issues become barriers to exercise. It may

alleviate barriers to a traditional form of exercise that includes environmental factors such as hot or cold, safety, and service access cost.³⁸ Most of all, the interactive nature, competition and entertainment value incorporated into exergaming allow for increase mental stimulation and gameplay engagement, thus, making exercise fun. Exergaming with peers, friends or family allows for social interconnectedness,^{33,39} an essential component for exercise adherence.

However, exergaming at home may not be sustained due to boredom especially when game variety is limited or solitary play.³³ Therefore, when designing a home-based exercise program such as exergaming, clinicians need to be cognizant of the participants' ability, capacity, resources and support systems to become successful and achieve desired outcomes.

Limitations

There are several limitations to this study. First, the sample size is small; although results are promising in favor of exergaming; further research is needed with a larger sample size before results can be generalized. The lack of significant changes in anxiety, depression and the overall health-related quality of life may be due to an insufficient number of participants needed to detect a change. Second, our study examined results at the conclusion of 12 weeks. This timeline may not be long enough to detect improvements in outcomes of interest. Third, the study cohort was selective and not representative of the general heart failure population. Also, the participants in this study were younger than the average cohort of patients with chronic heart failure. Fourth, participants' activities outside the study were not strictly controlled. Instructions were given to continue with their daily normal routine and not required to stop any activity, which may have affected our results. Finally, as depicted on table 1, the exergaming group appeared to have obtained higher education and received better treatment when compared to the control group, essential variables that could influence outcomes.

Conclusion

Exergaming using the NintendoTM Wii sports games in this pilot study showed significant improvements in the physical and emotional domains of health-related quality of life and reductions in symptom burden in patients with heart failure. Further research is warranted with a larger sample size and a longer study duration at 6 to 12 months to determine the true effect of this innovative form of exercise as a healthcare intervention to improve health and well-being in patients with heart failure.

Table 1. Baseline Sociodemographic and Clinical Characteristics (N = 30)

	All (N=30)	Exergaming Group (n = 16)	Control Group (n = 14)	Sig.
Age, years (Mean ± SD)	55.6 ± 8.5	55.5 ± 9.8	55.7 ± 7.1	.945
Male, N (%)	21 (70.0%)	11 (36.7%)	10 (33.3%)	.596
Race, N (%)				.112
White	13 (43.3%)	4 (13.3%)	9 (30.0%)	
Hispanic	8 (26.7%)	5 (16.7%)	3 (10.0%)	
African American	6 (20.0%)	4 (13.3%)	2 (6.7%)	
Asian	3 (10.0%)	3 (10.0%)	0 (0.0%)	
Married, N (%)	15 (50.0%)	8 (26.7%)	7 (23.3%)	.642
Education, N (%)				.035
< high school	1 (3.3%)	1 (3.3%)	0 (0.0%)	
High school	11 (36.7%)	3 (10.0%)	8 (26.7%)	
College	18 (60.0%)	13 (43.3%)	5 (16.7%)	
Ejection fraction,	35.01 ± 15.8	32.2 ± 13.9	38.2 ± 17.8	.311
(Mean ± SD)				
NYHA class, N (%)				.762
Class 1	6 (20.0%)	3 (10.0%)	3 (10.0%)	
Class 2	19 (63.3%)	11 (36.7%)	8 (26.6%)	
Class 3	5 (16.7%)	2 (6.7%)	3 (10.0%)	
Etiology, N (%)				.116
Ischemic	6 (20.0%)	5 (16.7%)	1 (3.3%)	
Non-ischemic	24 (80.0%)	11 (36.7%)	13 (43.3%)	

	All (N=30)	Exergaming Group (n = 16)	Control Group (n = 14)	Sig.
Co-morbidities				
Hypertension N (%)	20 (66.7%)	11 (36.7%)	9 (30.0%)	.550
Diabetes N (%)	11 (36.7%)	8 (26.7%)	3 (10.0%)	.142
Depression N (%)	5 (16.7%)	3 (18.7%)	2 (14.2%)	.724
Medications use, N (%)				
ACE Inhibitors	16 (53.3%)	8 (26.7%)	8 (26.7%)	.491
Angiotensin Receptor Blockers	7 (23.3%)	6 (20.0%)	1 (3.3%)	.061
Beta-Blockers	24 (80.0%)	14 (46.7%)	10 (33.3%)	.261
Diuretics	22 (73.3%)	14 (46.7%)	8 (26.7%)	.071
Aldosterone	18 (60.0%)	12 (40.0%)	6 (20.0%)	.078
Digoxin	2 (6.7%)	0 (0.0%)	2 (6.7%)	.209
Anticoagulants	7 (23.3%)	4 (13.3%)	3 (10.0%)	.581
Anti-depressants	5 (16.7%)	3 (18.7%)	2 (14.2%)	.567

Table 2. Baseline and 12-week outcomes (N = 30)

	Exergaming Group	ng Group	Control Group	Group		
	(n=16)	16)	(n = 14)	[4]		
Variable	Baseline (mean ± SD)	12Week (mean ± SD)	Baseline (mean ± SD)	12-Week (mean ± SD)	P (time)	P (T x G)
Psychological Well-being						
Anxiety	18.4 ± 3.2	18.2 ± 2.8	17.6 ± 2.2	18.7 ± 1.8	.378	.186
Depression	14.4±1.9	14.5 ± 1.3	15.9 ± 1.3	17.4±2.1	.065	.109
Health-Related Quality of Life						
Overall	45.4 ± 23.7	38.1 ± 22.6	44.2 ± 24.6	47.3 ± 19.8	.628	.236
Physical	16.4 ± 10.7	13.7 ± 7.9	18.2 ± 11.5	22.9 ± 10.1	.560	.035
Emotional	13.6 ± 6.3	9.9 ± 7.7	11.5 ± 7.5	19.3 ± 10.7	.207	.001
Symptoms						
Shortness of breath	3.3 ± 1.5	2.1 ± 1.2	2.8 ± 2.2	4.4 ± 2.5	.572	600.
Fatigue	4.1 ± 2.0	2.6 ± 1.2	3.6 ± 2.3	4.0 ± 2.1	.198	.042

CONSORT Flow Diagram

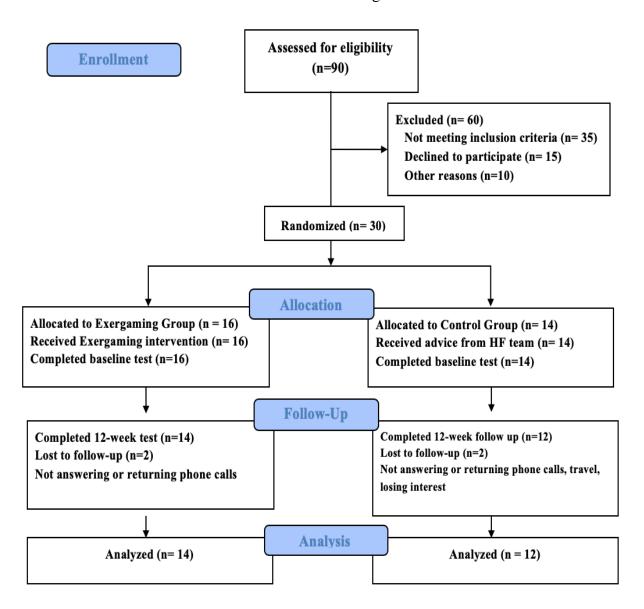


Figure 1. CONSORT diagram to show enrollment and retention of participants through the study.

Abbreviation: CONSORT, Consolidated Standards Reporting of Trials.

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APPENDIX A Search Strategies

PubMed Clinical Queries

"exercise game" OR "exercise games" OR "exercise gaming"

(exergam* OR (exercise AND (game* OR gaming)) OR (digital exercis*) OR ("virtual reality" AN (game* OR gaming)) OR Kinect OR Wii OR (activevideo AND (game* OR gaming)) OR ("active v AND (game* OR gaming)) OR (interactive AND (game* OR gaming)) OR ("Video Games"[mesh] "Exercise Therapy"[mesh]))

AND

"Quality of Life" [Mesh] OR "quality of life" OR "Health-related Quality of Life" AND (aged OR elderly OR elder OR geriatric)

WEB of Science

(exergam* OR (exercise NEAR/3 gam*) OR (digital NEAR/3 exercis*) OR ("virtual reality" NEAR gam*) OR Kinect OR Wii OR (activevideo NEAR/3 gam*) OR ("active video" NEAR/3 gam*) OR (interactive NEAR/2 gam*)) AND (exercise* OR physical activity* OR physical function*) AND (q of life) OR health-related quality of life)

exergam* OR (exercise AND (game* OR gaming)) OR (digital exercis*) OR ("virtual reality" AND (game* OR gaming)) OR Kinect OR Wii OR (activevideo AND (game* OR gaming)) OR ("active v AND (game* OR gaming)) OR (interactive AND (game* OR gaming))

AND

(quality of life) OR health-related quality of life)

AND

(aged OR elderly OR elder OR geriatric)

CINAHL

((MH "Exergames") OR exergame* OR (exercise N3 gam*) OR (digital N3 exercis*) OR ("virtual N3 gam*) OR Kinect OR Wii OR (activevideo N3 gam*) OR ("active video" N3 gam*) OR (interac NEAR/2 gam*))

AND

(MH "Quality of Life") OR (MH "Comfort") AND (aged OR elderly OR elder OR geriatric)

PsycInfo

(exercise NEAR/3 (game* OR gaming)) OR (digital NEAR/3 exercis*) OR ("virtual reality" NEAR/3 (game* gaming)) OR Kinect OR Wii OR (activevideo NEAR/3 (game* OR gaming)) OR ("active video" NEAR/3 (ga gaming)) OR (interactive NEAR/2 (game* OR gaming)) AND

SU.EXACT("Lifestyle") OR SU.EXACT("Life Satisfaction") OR SU.EXACT("Lifestyle Changes") OR SU.EXACT("Life Changes") OR SU.EXACT("Well Being") AND

elderly OR geriatric

APPENDIX B INSTITUTIONAL REVIEW BOARD DOCUMENTS

OFFICE OF RESEARCH
INSTITUTIONAL REVIEW BOARD
PAGE 1 OF 2

July 24, 2018

MARYSOL CORMANES
CACCIATA NURSING SCIENCE

RE: UCI IRB HS# 2016-2955 Exergaming to Improve the Physiological and Psychosocial Well Being in Patients with Heart Failure

The above-referenced human-subjects research project has been approved by the University of California, Irvine Institutional Review Board (UCI IRB). This approval is limited to the activities described in the approved Protocol Narrative, and extends to the performance of these activities at each respective site identified in the Application for IRB Review. In accordance with this approval, the specific conditions for the conduct of this research are listed below, and informed consent from subjects must be obtained unless otherwise indicated below. Additional conditions for the general conduct of human-subjects research are detailed on the attached sheet.

NOTE: Approval by the Institutional Review Board does not, in and of itself, constitute approval for the implementation of this research. Other institutional clearances and approvals may be required (e.g., EH&S, Radiation Safety, School Dean, other institutional IRBs). Research undertaken in conjunction with outside entities, such as drug or device companies, are typically contractual in nature and require an agreement between the University and the entity. Such agreements must be executed by an institutional official in Sponsored Projects, a division in the UCI Office of Research. The University is not obligated to legally defend or indemnify an employee who individually enters into these agreements and investigators are personally liable for contracts they sign. Accordingly, the project should not begin until all required approvals have been obtained.

Questions concerning the approval of this research project may be directed to the Office of Research, 141 Innovation Drive, Suite 250, Irvine, CA 92697-7600; 949-824-6068, 949-824-2125, or 949-824-0665 (biomedical committee) or 949-824-6662 (social-behavioral committee).

Expedited Review: Categories 4,5,7

IRB Determinations as Conditions of Approval:

Informed Consent Determinations:

Signed Informed Consent Required

•Signed UC HIPAA Research Authorization Required

Valerie M. Sanchez, MA, CCRP Alternate Member, Institutional Review Board

Approval Issued: 7/18/2018

Expiration

Date: 7/17/2019 UCI (FWA) 00004071, Approved: January 31, 2003

UNIVERSITY OF CALIFORNIA

UC IRVINE: OFFICE OF RESEARCH INSTITUTIONAL REVIEW BOARD (IRB) PAGE 2 OF 2

APPROVAL CONDITIONS FOR ALL UCI HUMAN RESEARCH PROTOCOLS

UCI RESEARCH POLICIES:

All individuals engaged in human-subjects research are responsible for compliance with all applicable UCI Research
Policies. The Lead Researcher (and Faculty Sponsor, if applicable) of the study is ultimately responsible for assuring all study team members adhere to applicable policies for the conduct of human-subjects research.

LEAD RESEARCHER RECORDKEEPING RESPONSIBILITIES:

Lead Researchers are responsible for the retention of protocol–related records. The following web pages should be reviewed for more information about the Lead Researcher's recordkeeping responsibilities for the preparation and maintenance of research files: Lead Researcher Recordkeeping Responsibilities and Preparation and Maintenance of a Research Audit File.

PROTOCOL EXPIRATION:

The UCI IRB approval letter references the protocol expiration date under the IRB Chair's signature authorization. A courtesy email will be sent approximately 60 to 90 days prior to expiration reminding the Lead Researcher to apply for continuing review. For studies granted Extended IRB Approval, a courtesy e-mail will be sent annually to verify eligibility for the continuation of extended approval. It is the Lead Researcher's responsibility to apply for continuing review to ensure continuing approval throughout the conduct of the study. Lapses in approval must be avoided to protect the safety and welfare of enrolled subjects.

MODIFICATIONS & AMENDMENTS:

Per federal regulations, once a human research study has received IRB approval, any subsequent changes to the study must be reviewed and approved by the IRB prior to implementation <u>except when necessary to avoid an immediate, apparent hazard to a subject.</u> Accordingly, no changes are permissible (unless to avoid an immediate, apparent hazard to a subject) to the approved protocol or the approved, stamped consent form without the prior review and approval of the UCI IRB. All changes (e.g., a change in procedure, number of subjects, personnel, study locations, new recruitment materials, study instruments, etc.) must be prospectively reviewed and approved by the IRB before they are implemented.

APPROVED VERSIONS OF CONSENT DOCUMENTS, INCLUDING STUDY INFORMATION SHEETS:

Unless a waiver of informed consent is granted by the IRB, the consent documents (consent form; study information sheet) with the UCI IRB approval stamp must be used for consenting all human subjects enrolled in this study. Only the current approved version of the consent documents may be used to consent subjects. **Approved consent documents are not to be used beyond the expiration date provided on the IRB approval letter.** Current consent documents are available on the IRB Document Depot.

UNANTICIPATED PROBLEMS REPORTING:

In accordance with Federal regulations and HRP policies, only internal (where UCI serves as the IRB of record), Unanticipated Problems must be reported to the UCI IRB. Unanticipated Problems should also be reported to the UCI IRB when UCI is relying on an external IRB, and the incident occurred at UCI or the incident occurred at an offsite location on a study conducted by a UCI LR. Unanticipated Problems must be submitted to the IRB via the Unanticipated Problems (UP) Report within 5 business days upon the Lead Researcher's (LR) knowledge of the event. For additional information visit the updated HPR webpage on <u>Unanticipated Problems</u>.

CHANGES IN FINANCIAL INTEREST:

Any changes in the financial relationship between the study sponsor and any of the investigators on the study and/or any new potential conflicts of interest must be reported immediately to the UCI Conflict of Interest Oversight Committee (COIOC). If these changes affect the conduct of the study or result in a change in the text of the currently-approved informed consent document, these changes must also be reported to the UCI IRB via a modification request. Research subject to COIOC oversight is not eligible for Extended IRB Approval.

CLOSING REPORT:

A closing report should be filed with the UCI IRB when the research concludes. Visit the HRP webpage <u>Closing a Protocol</u> for complete details.