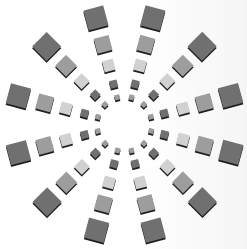

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A Behavioral Physical Activity Intervention to Manage Moderate and Severe Fatigue Among Head and Neck Cancer Patients—Pre-efficacy Study in the National Institutes of Health ORBIT Model

KEY WORDS
Cancer-related fatigue
Exergame
Fitness tests
Head and neck cancer
Physical activity

Background: Cancer-related fatigue (CRF) reduces head and neck cancer (HNC) survival rates and is the most common, severe, and distressing symptom negatively impacting activities of daily living (ADLs) dependence among HNC patients. These patients remain physically inactive after their cancer treatment, although there is consensus that physical activity mitigates CRF in cancer patients. **Objective:** A home-based personalized behavioral **p**hysical **a**ctivity intervention with **fit**ness graded **m**otion **e**xergames (PAfitME) was evaluated for its intervention components, intervention delivery mode, and intervention contact time/duration with initial assessment of the feasibility, acceptability, safety, and outcomes. **Methods:** This study (N=8) was a single-group, pre-post design to evaluate a 6-week PAfitME at

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the end of HNC treatment. Health outcomes were CRF, ADL dependence, and fitness performance. Behavioral outcomes were exergame adherence. **Results:** Positive health and behavioral outcomes support the PAfitME protocol including intervention components, intervention delivery mode, and intervention contact times/duration. The PAfitME intervention is feasible and acceptable with promising adherence rates. No adverse events were reported. There was marked improvement in CRF, ADL dependence, cardiorespiratory fitness, balance, muscle strength, and shoulder forward flexion, with large to moderate effect sizes as a result of the PAfitME intervention. **Conclusion:** The PAfitME protocol is ready for additional testing in a randomized clinical trial. **Implications for Practice:** The PAfitME intervention is a nurse-led nonpharmacological intervention. It can be integrated into home care or telehealth care for HNC patients at the end of their cancer treatment once effectiveness is established.

Head and neck cancers (HNCs) are malignant tumors in the nasal cavity, sinus, lips, mouth, salivary glands, pharynx, or larynx.[1] There were approximately 63 030 estimated patients with newly diagnosed HNC in 2017.[2] Cancer in the oral cavity and pharynx is in the top 10 of the most commonly diagnosed cancers among men in the United States. Compared with lower respiratory tract cancer (ie, lung and bronchus), HNC has a better 5-year survival rate of 60%. Head and neck cancer treatments can include surgery, radiation therapy, chemotherapy, targeted therapy, or a combination of treatments.[1] However, these intensive treatments often lead to debilitating symptoms. One of the key symptoms is cancer-related fatigue (CRF). Patients with HNC in particular report severe CRF after radiation and chemoradiation.[3] In our previous study, CRF was considered the most frequent systematic symptom among HNC patients.[4] Moderate CRF is commonly reported by HNC patients at the end of cancer treatment.[5] But CRF does not improve once HNC treatment is completed. Cancer-related fatigue severity has been reported to significantly worsen by 64% at 6 months when compared with time of diagnosis.[6] Patients with HNC who experience CRF considered this to be one of the most distressing symptoms, surpassing pain or sleep disturbance.[4]

Cancer-related fatigue negatively impacts activities of daily living (ADLs) in HNC patients.[6] The worse the CRF, the greater the ADL dependence. Once again, ADL dependence does not resolve with the end of treatment. When measured, ADL dependence was found to be 4 times greater at 6 months than at time of diagnosis. Activities of daily living dependence was significantly related to lower employment rates among HNC patients.[7] In the same study, employment rates dropped from 76% before diagnosis to 32% at 2 years after HNC treatment.

The American Cancer Society Head and Neck Cancer Survivorship Guideline recommends that HNC patients with CRF engage in physical activity to reduce CRF.[8] However, the decline in physical activity for these patients after their HNC treatment is severe and persistent. Although this decline varies depending on the individual's prediagnosis physical activity status and HNC treatment,[9–11] 80% of HNC patients actually reduce their physical activity or maintain a sedentary lifestyle after cancer treatment.[10] They often have low task self-efficacy related to taking part in physical activity, yet still say that physical activity enjoyment motivates them to engage in such activity.[9,12] They report muscle weakness and deteriorated physical condition as fitness barriers to engaging in physical activity.[9] Given all these factors, there is an important need for a behavioral physical activity program that personalizes the physical activity prescription based on individual fitness levels while maintaining high task self-efficacy and physical activity enjoyment for HNC patients with CRF after cancer treatment.

In exercise science, a physical activity prescription is an individualized physical activity plan based on fitness assessment for the purpose of improving and maintaining physical function.[13] Exergames are video games that use a motion-based interface to allow individuals to engage in physical activity. The benefits of using an exergame to develop a physical activity prescription for HNC patients with CRF are that it can provide (1) dynamic visual feedback on gestures, movement, and center of gravity and (2) feedback on the accuracy and competency during and at the end of an exergame. Exergame technology allows individual independent learning and adjustment to physical activity via biofeedback. The challenge of using exergames to develop personalized physical activity prescriptions lies in the appropriate selection of the exergames to match the fitness level of the patient.[14] In a previous study, we developed the Exergame Grading Scheme.[15] The Exergame Grading Scheme grades energy expenditure and a set of the physical fitness attributes in each exergame. Building on this work, in this article, we describe a 6-week home-based personalized behavioral **p**hysical **a**ctivity intervention with **fit**ness graded **m**otion **e**xergames (PAfitME) that allows HNC patients to self-manage their CRF and reduce their ADL dependence at the end of cancer treatment through enhanced physical activity behavior. The feasibility criteria set up in the following statement were estimated from the results of previous physical activity intervention studies

among HNC patients in the United States or Canada.[16–18] The aims of the study included the following:

Aim 1: To assess the feasibility, acceptability, and safety of the PAfitME intervention in HNC patients after cancer treatment. We expected (1) 50% of HNC patients after cancer treatment to be eligible to participate in the study, (2) 50% of eligible HNC patients invited to participate in the study to actually enroll, (3) 70% of the participants to receive all intervention contacts, (4) 70% of the participants to complete the study, (5) the PAfitME intervention to be acceptable to the participants, and (6) there to be no falling incident or significant body weight reduction after the 6-week intervention.

Aim 2: To describe adherence rates during the 6-week PAfitME intervention in HNC patients after cancer treatment. We expected 70% of the participants to adhere to their personalized physical activity prescriptions during the 6-week intervention.

Aim 3: To analyze changes in CRF, ADL dependence, and fitness performance at 6 weeks. We expected there to be positive changes in CRF, ADL dependence, and fitness performance at 6 weeks.

■ Methods

Study Design Framework

The National Institutes of Health ORBIT Model for Developing Behavioral Treatments for Chronic Disease was used to conceptualize and design this study.[19] ORBIT includes 4 phases of research progression from the pre-efficacy phase to the effectiveness research phase. Our study was a pre-efficacy phase (IB), single-group design with preintervention and postintervention data collection points. The goal of this phase was to observe whether the intervention components, intervention delivery mode, and intervention contact time/duration were appropriate. In order to move this intervention to the next phase of testing, 3 major milestones needed to be achieved: (1) the feasibility, acceptability, and safety of the intervention must be supported; (2) favorable, clinically significant changes (health outcomes) in the behavior risk factor (behavior outcomes) must be observed as a result of the intervention; and (3) the intervention package, including the defined intervention components, intervention delivery mode, and intervention contact times/duration, must be complete.

Theory-Based Intervention Development Framework

A framework for developing this theory-based behavioral intervention is proposed based on the Intervention Mapping Approach (Figure 1).[20] Health outcomes are CRF, ADL dependence, and fitness performance. The behavior outcome is exergame physical activity. Adherence is used to describe the degree of exergame physical activity completed when compared with the personalized exergame (perExergame) prescription. This includes percentage of adherence and binary adherence ("adherent" or "not adherent"). Antecedents are demographic and clinical factors that may influence the exergame physical activity adherence among HNC patients after cancer treatment.

The PAfitME intervention aims to improve physical activity by integrating a person's individual variations in fitness levels and behavioral perceptions. Task self-efficacy and physical activity enjoyment are 2 behavioral perceptions that have been positively correlated with physical activity behavior in HNC patients.[9,12] These 2 theoretical determinants define the change objectives in this theory-based behavioral intervention: (1) to enhance task self-efficacy and (2) to enhance physical activity enjoyment. We have developed a matrix of methods and applications to achieve these 2 change objectives as behavioral components of the PAfitME intervention (Table 1).

Sample and Setting

The protocol was approved by a university-based institutional review board and the Scientific Review Committee of a National Cancer Institute–designated comprehensive cancer center. Using convenience sampling, our goal was to enroll 10 HNC patients for this pre-efficacy study. To be eligible for the study, HNC

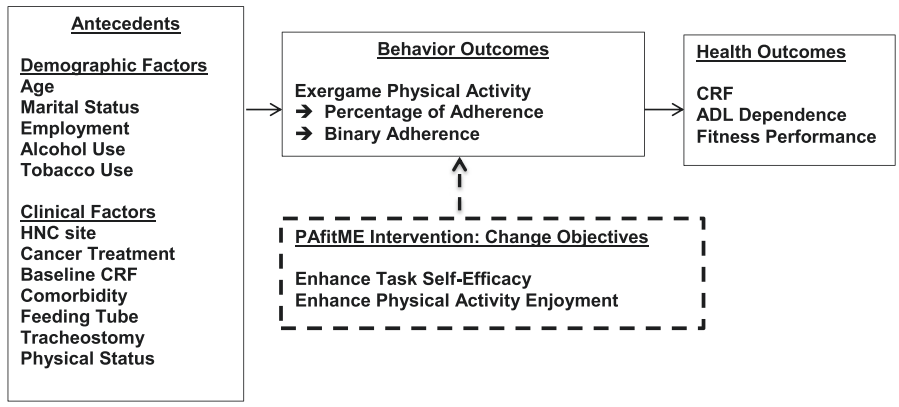

Figure 1 ■ Theory-based intervention framework.

Table 1 • Theory-Based Methods and Practical Applications for Achieving Change Objectives (Enhance Task Self-efficacy and Enhance Physical Activity Enjoyment) in the PAfitME Intervention

Methods	Descriptions	Applications
Enhance Task Self-efficacy: Development of perExergame Prescription		
Activating mastery experience	Provide challenging tasks with feedback to serve as indicators of capability.	Participants perform fitness tests. Their results are categorized into 3 different fitness parameters. The nurse interventionist will use the fitness parameters to select exergames with grading levels from Exergame Grading Scheme that match these parameters. Participants will have a greater likelihood to master the selected exergames because the exergames match their fitness level.
Guided practice	Prompt to rehearse the behavior.	Participants are instructed to perform exergame physical activities by the nurse interventionist and virtual personal trainer in Wii Fit.
Goal setting	Plan what will be done including providing a definition of goal-directed behaviors.	Participants are asked about their confidence level (task self-efficacy) in performing selected exergames without quitting in the next 7 d. The perExergame prescription only includes exergames with at least a 70% confidence level on a 0%–100% scale.
Setting tasks at a gradient of difficulty	Set easy tasks and increase difficulty until the target behavior is performed.	Intensity, duration, and frequency in the perExergame prescription progress until the guideline recommendation (moderate intensity for 30 min/d, and 5 d/wk with strength training twice a week) is achieved.
Enhance Task Self-efficacy: Implementation of PAfitME Intervention		
Guided practice	Prompt to repeat the behavior.	**Wii Fit:** Participants perform exergames with a virtual personal trainer.
Self-monitoring of behavior	Prompt participants to keep a record of specific behaviors.	**Wii Fit:** Wii Fit shows minutes spent after completing an exergame.
Verbal persuasion	Use messages that suggest participants possess certain abilities.	**Wii Fit:** Wii Fit provides accuracy and performance feedback to show competency in the exergame. **Nurse interventionist:** The nurse interventionist reviews the total minutes spent during exergames with the participant to indicate his/her competency weekly.
Planning coping response	Prompt participants to list barriers as well as strategies to overcome these barriers.	**Nurse interventionist:** The nurse interventionist discusses with the participant about his/her barriers to performing the prescribed exergames. The nurse interventionist guides the participant in developing strategies to overcome the barriers.
Enhance Physical Activity Enjoyment: Development of perExergame Prescription		
Goal setting	Plan what will be done to include a definition of goal-directed behaviors.	Participants are asked about their physical activity enjoyment in performing selected exergames without quitting in the next 7 d. The perExergame prescription only includes exergames with at least 70% physical activity enjoyment on a 0%–100% scale.
Enhance Physical Activity Enjoyment: Implementation of PAfitME Intervention		
Promoting instinct motivation	Plan a situation to have the experience of fun doing a specific behavior.	**Wii Fit:** Exergames are designed for the participant to gain experience making in-game choices, becoming good at playing the game, relating to personal values, and having the ability to influence game actions.

Abbreviation: PAfitME, **p**hysical **a**ctivity intervention with **fit**ness graded **m**otion **e**xergames.

patients had to be (1) within a month after cancer treatment (chemotherapy, radiation, or chemoradiation); (2) 18 years or older; (3) able to understand English; (4) with a Karnofsky Performance Status (KPS) score of 60% or greater; (5) cleared by their provider to resume low- to moderate-intensity physical activities; (6) affected by CRF of at least moderate severity; (7) alert and oriented; and (8) living within a 60-mile radius of the cancer center. A KPS score of 60% or greater has been suggested in other exercise trials with this population.[21] Moderate fatigue severity was defined as 3 or higher on a 0- to 10-point intensity scale. Participants were excluded if they (1) were hospitalized, (2) were in hospice, (3) were pregnant, (4) had a cardiac pacemaker, (5) had a history of seizure or loss of consciousness, or (6) had had fibular free flap.

Clinicians at an outpatient HNC clinic referred interested patients to the study recruiter. Patients were then contacted within 1 to 2 treatments of the end of their cancer treatment. The recruiter met with interested patients in a private area, explained the study, and answered questions about study requirements, risks, and compensation. After determining a patient's eligibility, the recruiter obtained written informed consent. A recruitment/enrollment flowchart is presented in Figure 2.

PAfitME Intervention

INTERVENTION COMPONENTS

There were 6 major components delivered during the 6-week PAfitME intervention. These were (1) equipment setup and

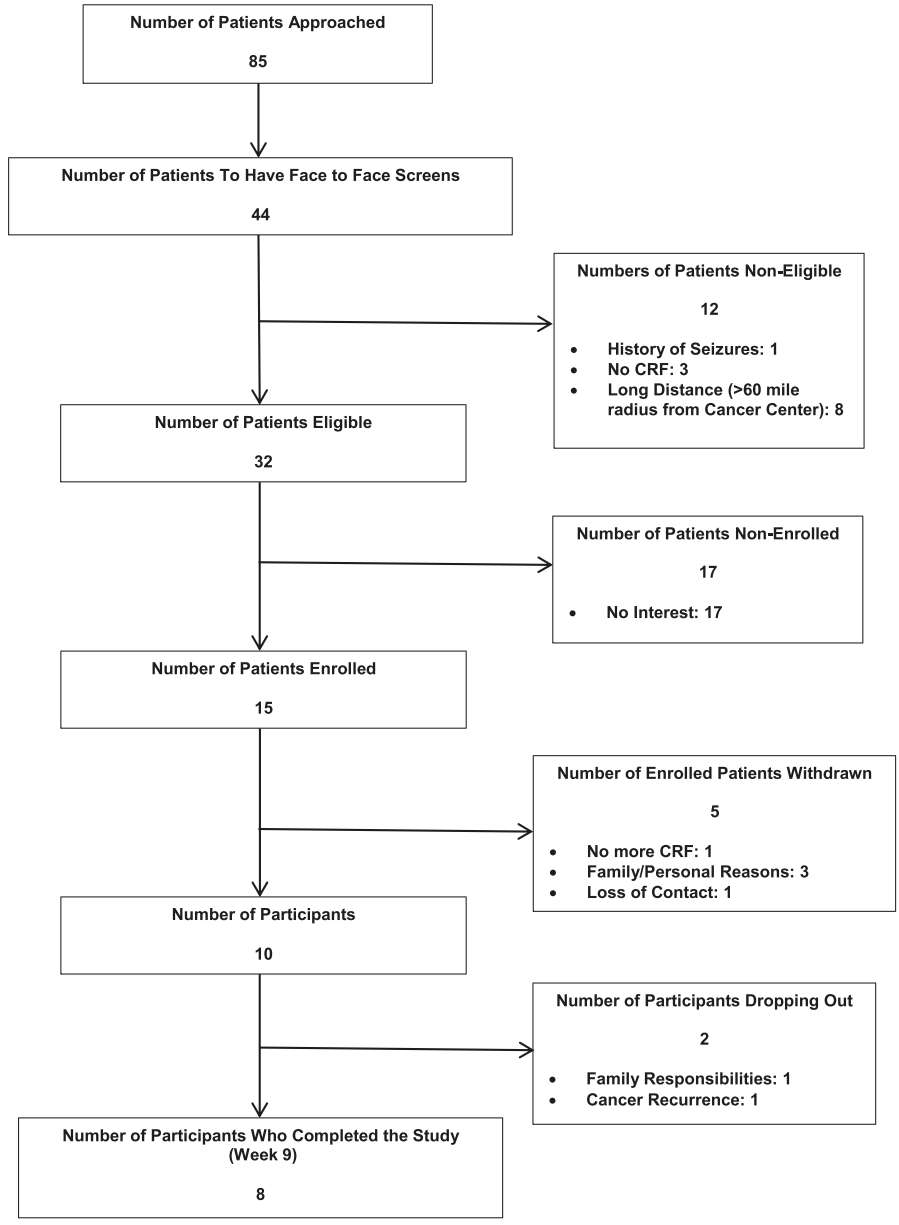

Figure 2 ■ Study flow.

instructions in operation and safety protocol of the exergame platform system, (2) perExergame prescription development/adjustment with fitness tests (Table 1), (3) exergame physical activity coaching, (4) discussion of barriers and strategies to overcome these barriers in order to adhere to the perExergame prescription, (5) review of exergame minutes performed, and (6) question-and-answer session for the perExergame prescription.

The perExergame Prescription

The prescription was built on 3 procedures. First, the Exergame Grading Scheme was used to quantify fitness features for available exergames in the console. The Exergame Grading Scheme contained 14 items that operationalized energy expenditure and a set of the physical fitness attributes (ie, cardiorespiratory fitness, muscular strength, muscular endurance, flexibility, and balance) in each exergame. Its content validity and interrater reliability were supported (Wang et al. "Exergame Grading Scheme: Validity and Reliability Among Cancer Survivors"; 2017, submitted for publication). To determine Exergame Grading Scheme grades for an exergame, a healthy adult acted as the user operating the exergame, while a healthcare provider (ie, nurse) acted as the rater, determining the grading numbers for the items on Exergame Grading Scheme. The rater documented the grading numbers on the Exergame Grading Grid for a list of exergames. During the PAfitME intervention, a nurse interventionist used the standardized fitness tests to determine HNC participants' fitness level for each physical fitness attribute: a 6-minute walk test (6MWT) for cardiorespiratory fitness, hand grip for muscle strength, shoulder range of motion for flexibility, and Berg Balance Scale for balance. The results of the fitness tests were compared with the norm value, and the participant's fitness parameter from 1 (very

below the average) to 3 (average) was determined. The fitness parameter was the reference for the nurse interventionist in selecting the exergames from the Exergame Grading Grid. A personalized set of exergames was initially prescribed to HNC patients with moderate or severe CRF for their physical activity routine. Second, a Personalized Exergame Prescription Guideline was used to decide on the types (modes) of exergames, intensity (perceived exertion), frequency (times per week), and duration (numbers of exergames for each time) in the perExergame prescription. This also provided a resource on how to progress in intensity, frequency, and duration. The guideline was adapted from the exercise prescription principles of the American College of Sports Medicine.[13] Third, ratings on behavioral parameters, perceived self-efficacy and perceived physical activity enjoyment, were considered in the perExergame prescription. The final set of exergames in the perExergame prescription was those the participant rated at least 70% in perceived self-efficacy and 70% in perceived physical activity enjoyment in the next 7 days on a 0% to 100% scale.[9]

The Safety Protocol

Participants could stop or rest at any time during the fitness tests, especially when they felt tired. An external monitor was placed on participants to check their heart rate, blood pressure, and oxygen level during the fitness tests. The safety protocol for participants performing exergame physical activities included the following points: (1) potential participants who were at risk of adverse events related to engaging in exergames were excluded from the study, including patients who had seizures or cardiac pacemakers; (2) the nurse interventionist set up the exergame system properly to prevent falls and injuries; (3) the nurse interventionist inspected the exergame system and the battery during the home visit to ensure proper function; (4) Participants were trained by the nurse interventionist in how to properly operate the exergame platform before engaging in the exergame physical activity; (5) participants were instructed in strategies to prevent falling while performing exergame physical activity; and (6) participants were provided phone support for questions and or needs for technical assistance related to the intervention. Participants' body weight was checked routinely to avoid unexpected muscle mass loss. Participants were specifically taught to start with a short period, then progressively increase the activity with the exergame system. More importantly, they were instructed to stop using the exergame system when they felt tired or if symptoms occurred or got worse and to call their physician for medical advice if necessary. A head and neck surgeon served as the medical and safety expert in our study.

INTERVENTION DELIVERY MODE

The PAfitME intervention was delivered by a simple exergame platform that has been tested extensively for its effect on physical activity among adults with chronic disease.[22] This platform technology is safe, low cost, easily transported, and lightweight. Exergames can be categorized into 4 major modes of physical activity as is recommended by the American College of Sports Medicine[23]: aerobics, strength training, flexibility training (eg, yoga), and balance. Each mode contains multiple exergames for personalized selection. These exergames are used to improve the physical fitness attributes listed in the Exergame Grading Scheme, including cardiorespiratory fitness,[24] muscular strength,[25] flexibility,[26] and balance.[27] Wii Fit (Wii Fit U; Nintendo, Redmond, Washington) met all these criteria and so was selected to be the exergame platform to deliver the PAfitME intervention at home.

INTERVENTION CONTACT TIME/DURATION

The 6-week intervention incorporated the Wii Fit exergames with weekly 1-hour home visits from an oncology nurse interventionist. The 1-hour intervention contact was designed to maximize interactions between the participant and the nurse interventionist for the purpose of understanding feasibility and monitoring safety. Table 2 shows various intervention components provided in each visit.

We also designed 10-minute weekly calls for 3 weeks after the 6-week home visit in order to understand the changes in CRF and the adherence during the observation period with minimal intervention contact. During the 10-minute call, the nurse interventionist offered a brief question-and-answer session about the participants' current perExergame prescription.

Table 2 • Intervention Components Designed for Each Intervention Contact

	Home Visits							Calls (Observation)
Intervention Components	Week 0	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Weeks 7–9
Equipment setup and exergame system instruction	X							
perExergame prescription development/adjustment	X			X			X	
Exergame physical activity coaching	X	X	X	X	X	X	X	
Discussion of barriers and strategies		X	X	X	X	X	X	
Review of exergame minutes		X	X	X	X	X	X	
Q&A session for the perExergame prescription		X	X	X	X	X	X	X

Abbreviations: perExergame Prescription, personalized exergame prescription; Q&A, question and answer.

Measures

DEMOGRAPHICS AND CLINICAL FACTORS

A demographic/clinical survey was used for self-reporting by participants. Questions included age, gender, race, marital status, employment status, yearly household income, education background, current tobacco use, current alcohol use, cancer site, cancer stage, cancer treatment, a 13-item comorbidity scale,[28] body weight/height, feeding tube, tracheostomy tube, and continuous positive airway pressure for sleep apnea.[21]

FEASIBILITY, ACCEPTABILITY, AND SAFETY

Feasibility was assessed by calculating the eligibility rate, enrollment rate, completion rate, and attendance rate. The eligibility rate was measured as the percentage of patients approached who were eligible. The enrollment rate was measured as the percentage of eligible patients who enrolled. The attendance rate was determined by the percentage of intervention contacts (home visits) that the participants received. The completion rate was determined by the percentage of participants who stayed in the 9-week study period.

The acceptability of the PAfitME intervention was assessed by participant satisfaction, participant engagement, participant burden, and safety. Participant satisfaction was measured by a 14-item PAfitME Intervention Satisfaction Survey. This survey included 3 items related to how easy it was to operate the exergame system, 3 items related to the enjoyableness of the intervention, 2 items related to the helpfulness of the intervention, 2 items related to the motivation to do more physical activity, 2 items related to convenience and satisfaction, 1 item related to the perception of the personalization, and 1 item related to willingness to recommend the intervention to others. Participant engagement was rated by the nurse interventionist on a 0- to 10-point scale. A higher score indicated more engagement. Participant burden (ie, time commitment) was measured by actual minutes per home visit and per call, respectively. Safety was documented by counting numbers of falling incidents and measuring body weight at each time point. Musculoskeletal events of Common Terminology Criteria for Adverse Events (CTCAE) version 4.0 greater than grade 2 were monitored as well.[29]

BEHAVIOR OUTCOME: ADHERENCE

Adherence was measured by minutes spent on the exergames (exergame minutes) as recorded by the Wii Fit System and operationalized in 2 ways: percentage of adherence to understand individual adherence rates and binary adherence to determine the number of participants achieving the cutoff point in the sample group. The percentage of adherence was calculated as the actual total weekly exergame minutes divided by prescribed total weekly exergame minutes, then multiplied by 100. Binary adherence was defined as whether the exergame minutes met two-thirds of the prescribed total exergame minutes (1 = "adherent," 0 = "nonadherent") in a week. Applying "two-thirds" of the prescribed minutes as the cutoff point for physical activity adherence has been used in the literature.[30]

HEALTH OUTCOMES: CRF, ADL DEPENDENCE, AND FITNESS PERFORMANCE

Cancer-related fatigue was measured by the Brief Fatigue Inventory (BFI).[31] The BFI includes 3 severity items, which ask for participants' usual and worst level of CRF in the past 7 days and their current level of CRF on a 0-point (no fatigue) to 10-point (fatigue as bad as you can imagine) scale. The mean of the 3 items was determined, with higher scores reflecting more severe CRF. The concurrent validity and discriminant validity of the BFI were satisfactory among a sample of cancer patients, and it had an internal consistency coefficient of 0.96.[31]

Activities of daily living dependence was measured by a self-reporting Lawton Instrumental Activities of Daily Living Scale (IADL).[32] The 8-item IADL measures dependence/independence of telephone use, shopping, food preparation, housekeeping, laundry, mode of transportation, responsibility for own medications, and ability to handle finances. Participants responded concerning their highest level of independence on that activity. Our study used the sum of the polytomous scores (1–3, 1–4, or 1–5) to yield 8- to 31-point total scores.[32] The lower the score, the more dependent the ADLs. Its concurrent validity has been evaluated in older adults.[33] Test-retest reliability was 0.99 in patients with dementia.[34] The IADL has been applied in HNC patients.[6]

Fitness performance included 4 tests:

1. *Cardiorespiratory fitness*. The 6MWT was a submaximal measure of aerobic capacity. The procedure for testing was based on guidelines given by the American Thoracic Society statement.[35] The participant was asked to walk back and forth on a 30-m walking course for 6 minutes. The distance of 6MWT in meters was used to indicate cardiorespiratory fitness.
2. *Balance*. The Berg Balance Scale includes 14 simple balance-related tasks, ranging from standing up from a sitting position to standing on 1 foot. Each task was determined by a 0- to 4-point scale. The higher the score, the better the static and dynamic balance.[36]
3. *Muscle strength*. Hand grip was determined by combined grip sum. The participant was instructed to squeeze a dynamometer 3 times with each hand. Combined grip sum, considered to indicate muscle strength, was the result of the sum of maximum left hand strength and maximum right hand strength divided by body weight.[37]
4. *Flexibility*. Shoulder range of motion was determined by shoulder abduction and shoulder forward flexion. The range of motion was measured by a goniometer and used to show flexibility.[38]

Data Collection Procedure

Data were collected by a research assistant and entered into Qualtrics (© 2016 Qualtrics LLC, Provo, Utah) at baseline, 6 weeks after completion of the intervention, and 9 weeks after the 3-week observation period. Participants were given $10 after each survey was completed. To evaluate participant burden before this study,

the longest (baseline) survey was pilot tested with 1 HNC survivor and found to last 20 minutes, which the participant expressed was acceptable.

Data Analyses

Analyses were performed with IBM SPSS Statistics (IBM Corporation, Armonk, New York). Descriptive statistics were performed to obtain the means, SDs, frequencies, and percentages of demographics, clinical factors, intervention data, and adherence outcomes. Because of the small sample size (not normal distributions), Wilcoxon signed rank tests were conducted to compare outcome and fitness performance data between preintervention (baseline) and postintervention (week 6). $P \leq .05$ was used to determine statistical significance. Cohen *d* value was used to estimate effect sizes.

■ Results

Characteristics of Participants

Participants (N = 8) were on average 57.6 (±13.3) years of age, ranging from 27 to 73 years old (Table 3). The majority were male, white, married/living with a partner, and retired. Approximately 50% of the participants had a yearly household income of more than $30 000, and 87% had at least a high school diploma. Few participants still used tobacco (13%) or alcohol (13%). In clinical factors, 38% participants had oral cancer, and 62% had laryngeal cancer. Half of them had stage II cancer, and the other half had either stage III or stage IV. They all had had cancer surgery, and 75% had had chemotherapy, and 87% had radiation. There was an average of 3.8 chronic diseases (range, 2–7 chronic diseases) among the participants. Most chronic diseases seen in this group included high blood pressure (63%) and back pain (50%). The mean of their body mass index at baseline was 25.2 kg/m^2 (range, 20.7–30.4 kg/m^2). Some participants had a feeding tube (38%), tracheostomy (25%), or continuous positive airway pressure for sleep apnea (13%).

In order to understand the disease and treatment burden, we further classified the characteristics of the oral and laryngeal cancer groups, respectively. Three participants with oral cancer had stage II cancer. One had surgery, chemotherapy, and radiation. The other 2 participants had surgery only or surgery with chemotherapy. Among the 5 participants with laryngeal cancer, 3 had stage III cancer, 1 had stage IV cancer, and 1 had stage I cancer. All 5 participants had surgery, chemotherapy, and radiation.

Feasibility of the PAfitME Intervention

Figure 2 shows 85 patients who were referred by the HNC clinic; 73% of these patients were eligible for the study. The noneligible reasons included history of seizures, no CRF, or living outside a 60-mile radius from the cancer center. The enrollment rate was 47%. A total of 10 participants started the intervention. Two participants dropped out of the study because of family responsibilities (n = 1) or cancer recurrence (n = 1). There were 6 intervention contacts (home visits) for each participant and 48 intervention contacts for the 8 participants

Table 3 • Demographics and Clinical Factors

	Mean (SD)	n (%)
Demographics		
Age, y	57.6 (13.3)	
Gender		
Male		7 (87)
Female		1 (13)
Race		
White		7 (87)
Black/African American		1 (13)
Marital status		
Married/living with a partner		5 (62)
Single/divorced/widowed		3 (38)
Employment status		
Full time		1 (13)
Retired		5 (62)
On disability		2 (25)
Yearly household income		
<$30 000		3 (37)
$30 000–$49 999		1 (13)
≥$50 000		3 (37)
Preferred not to answer		1 (13)
Education background		
Less than high school		1 (13)
High school graduate/GED		3 (37)
College/graduate/professional degree		4 (50)
Current use of tobacco		
Yes		1 (13)
No		7 (87)
Current use of alcohol		
Yes		1 (13)
No		7 (87)
Clinical Factors		
Cancer site		
Oral cancer		3 (38)
Laryngeal cancer		5 (62)
Cancer stage		
II		4 (50)
III		3 (37)
IV		1 (13)
Cancer surgery		
Yes		8(100)
No		0 (0)
Chemotherapy		
Yes		6 (75)
No		2 (25)
Radiation		
Yes		7 (87)
No		1 (13)
Comorbidity (no. of chronic diseases)	3.8 (1.6)	
BMI at baseline	25.2 (3.1)	
Current feeding tube		
Yes		3 (38)
No		5 (62)
Current tracheostomy		
Yes		2 (25)
No		6 (75)

(continues)

Table 3 • Demographics and Clinical Factors, Continued

	Mean (SD)	n (%)
Current CPAP for sleep apnea		
Yes		1 (13)
No		7 (87)

Abbreviations: BMI, body mass index; CPAP, continuous positive airway pressure; GED, General Equivalency Diploma.

who completed the study. Only 1 participant missed a home visit because of severity of symptoms, resulting in an attendance rate of 98% for the whole group. This article reports data from the 8 participants who completed the study.

Acceptability and Safety of the PAfitME Intervention

The data of acceptability and safety are presented in Table 4. A mean score of 3.2 (1- to 4–point scale) on the PAfitME Satisfaction Survey was reported. Participants agreed that the intervention equipment was easy to operate and that the intervention was enjoyable, helpful, motivational, convenient, personalized, and satisfying. They were willing to recommend the intervention to other HNC patients. The nurse interventionist also rated the level of participant engagement with a mean of 9.1 (0- to 10–point scale). The participant burden included a mean of 43.0 minutes (range, 37–47 minutes) for a home visit. Concerning safety, body weight did not significantly decrease from baseline at weeks 3, 6, and 9 ($P > .05$). No falls related to the intervention occurred during the 9-week study period. No musculoskeletal events of CTCAE version 4.0 greater than grade 2 occurred either.

Behavior Outcome: Adherence

The adherence outcomes are presented in Table 5. Participants engaged in exergames 3 to 5 days a week. In the first 3 weeks, approximately 36 minutes per week were prescribed. Participants were adherent a mean of 78.9% of their prescribed exergame minutes. Six of 8 participants (75%) were fully adherent to their perExergame prescription, whereas 2 participants even exceeded their perExergame prescription. In the second 3 weeks, the mean perExergame prescription was 40.1 min/wk (range, 23–80 min/wk) of exergame physical activity. All the participants (100%) adhered to their perExergame prescription, whereas the exergame performance of 5 participants exceeded their prescription. In the last 3 weeks with minimal intervention contacts for the observation (calls), 4 participants (50%) adhered to their perExergame prescription. Among the 8 participants, there was a mean adherence rate of 77.0% (±55.7%) of the prescribed exergame minutes.

Health Outcomes: CRF, ADL Dependence, and Fitness Performance

The health outcome variables were analyzed by comparing the data at baseline with those at week 6 after the maximal intervention contact duration (Table 6). Statistical improvements were found in the BFI (mean $\Delta = -2.0$, $d = 1.3$) and Berg Balance Scale (mean $\Delta = 1.8$, $d = 1.2$). Cancer-related fatigue was significantly reduced and balance significantly improved after the 6-week intervention. Participants experienced reduced ADL dependence and improved cardiorespiratory fitness after the PAfitME intervention. Positive changes in IADL (mean $\Delta = 1.8$, $d = 1.0$) and the 6 MWT (mean $\Delta = 51.3$, $d = 1.0$) were in the right direction, suggesting a large effect size. Participants' muscle strength and left shoulder forward flexion became better at the end of the 6-week intervention. Two fitness variables also showed improvement, with a moderate effect size: combined grip sum (mean $\Delta = 0.1$, $d = 0.7$) and left shoulder forward flexion (mean $\Delta = 9.1$, $d = 0.6$). More importantly, a dose-dependent effect was observed at week 9 after 3 weeks of minimal intervention contact: as the percentage of adherence dropped, CRF increased (Figure 3).

Intervention Fidelity

Fidelity was maintained and evaluated through standardized manuals and audio recordings. Home visit/call sessions were evaluated for compliance to the protocol using checklists. Intervention fidelity ratings across a randomly selected 10% of sessions for each participant were greater than 90%.

■ Discussion

Milestone 1: Feasibility, Acceptability, and Safety

The PAfitME intervention has a great potential to be successfully translated into clinical practice. Compared with similar exercise/physical activity intervention studies conducted among HNC patients in the United States and Canada,[16–18] our study showed better eligibility (73%), attendance (99%), and completion (80%) rates. Rogers and colleagues[16] developed a 12-week resistance exercise training during radiation for HNC patients. A supervised training at the radiation clinical site was provided

Table 4 • Intervention Acceptability and Safety

	Mean (SD)	n (%)
PAfitME Satisfaction Survey (1- to 4-point scale)	3.2 (0.5)	
Participant engagement (1- to 10-point scale)	9.1 (0.9)	
Participant burden		
Minutes per home visit	43.0 (3.7)	
Minutes per call	8.2 (5.4)	
Body weight		
Baseline	168.9 (26.4)	
Week 3	168.6 (26.7)	
Week 6	169.0 (24.9)	
No. of falls		0 (0)

Abbreviation: PAfitME, **p**hysical **a**ctivity intervention with **fit**ness graded **m**otion **e**xergames.

Table 5 • Adherence Outcomes

	First 3-wk Period			Second 3-wk Period		
	Range	Mean (SD)	n (%)	Range	Mean (SD)	n (%)
Prescribed exergame physical activity, min/wk	22–80	35.9 (19.6)		23–80	40.1 (20.4)	
Minutes of exergame activity, min/wk	9–98	31.5 (29.4)		20–85	44.2 (25.5)	
Mean adherence rate of prescribed exergame physical activity (performed exergame minutes ÷ prescribed minutes × 100%)	35–140	78.9 (35.9)		68–149	111.9 (34.1)	
No. of participants achieving adherence			6 (75)			8(100)

during the first 6 weeks, and phone counseling for the home-based training was provided during the second 6 weeks. Their eligibility rate was 24%. The attendance rate was 83% for the supervised sessions and 62% for the phone counseling. The completion rate for the 12-week intervention was 71%. In addition, Capozzi and colleagues[18] developed a 12-week progressive strength-training (ENHANCE) program for HNC patients who were undergoing or had completed radiation/chemoradiation. Weekly group exercise sessions were provided at a wellness center. The attendance rate of the weekly group sessions was 66%, and the completion rate was 57%. Later, Capozzi and colleagues[17] developed a 12-week ENHANCE plus lifestyle education intervention. Participants met twice weekly for the group exercise session along with lifestyle education. The eligibility rate was 24%. The study compared outcomes between HNC patients who had the ENHANCE plus lifestyle education intervention during radiation and those who had the intervention after radiation. The completion rate was 52% during radiation and 69% after radiation. The attendance rate was 45% during radiation and 62% after radiation. In our study, the enrollment rate (47%) was close to the expected 50%. This result might be a function of our decision to limit the study to those living within a 60-mile radius of the cancer center. This is easily addressed in future studies by increasing the radius.

The PAfitME intervention was found to be acceptable. Participants in our study were satisfied with the PAfitME intervention, including both the intervention delivery mode (stating that it was easy to operate) and the intervention components (saying that they were enjoyable, helpful, motivational, convenient, personalized, and satisfying). Most importantly, participants were willing to recommend this intervention to other HNC patients. From the nurse interventionist's perspective, participants were highly engaged while she implemented the intervention components. This high level of engagement suggests that the PAfitME intervention is acceptable to HNC patients. The participant burden of a home visit in our intervention was approximately 43 minutes per visit. A typical group session was scheduled for an hour with additional time spent on transportation.[16] A study conducted by the US General Accountability Office found that a home care visit for a patient's assessment/treatment took an average of 40 minutes.[39] Therefore, the participant burden of the PAfitME intervention was quite reasonable when compared with the national data.

The PAfitME intervention was relatively safe. Participants did not experience significant weight loss. No falls occurred while participants were engaging in exergames. No musculoskeletal events of CTCAE version 4.0 greater than grade 2 occurred during the 9-week period. These findings were similar to those of other physical activity studies that have been implemented in HNC patients[16–18,40] or that used exergames as an intervention delivery mode among populations with cancer diagnosis, such as lung cancer,[24] prostate cancer,[41] and hematologic cancer.[42] We suggest that HNC patients are capable of engaging in physical activity at the end of their cancer treatment and that the exergame platform (ie, Wii Fit) is a safe intervention delivery mode for this population.

Table 6 • Health Outcomes: Wilcoxon Signed Rank Test Results

	Baseline	Week 6			
	Mean (SD)	Mean (SD)	*Z*	*P*	Cohen *d*
Outcome variables					
Brief Fatigue Inventory (severity items)	5.7 (1.9)	3.7 (3.5)	−2.2	.03	1.3
Lawton Instrumental Activities of Daily Living	27.0 (4.4)	28.8 (3.2)	−1.8	.06	1.0
Fitness performance					
6-Minute walk test	357.2 (114.8)	408.5 (64.7)	−1.8	.07	1.0
Berg Balance Scale	52.6 (3.9)	54.0 (2.6)	−2.1	.04	1.2
Combined grip sum	0.8 (0.2)	0.8 (0.3)	−1.3	.18	0.7
Shoulder abduction (left)	131.6 (35.7)	130.0 (45.2)	−0.7	.50	0.3
Shoulder abduction (right)	148.6 (31.0)	148.9 (34.7)	0	1	0
Shoulder forward flexion (left)	140 (37.0)	149.1 (25.9)	−1.1	.26	0.6
Shoulder forward flexion (right)	143.1 (44.1)	145.1 (29.9)	−0.3	.78	0.1

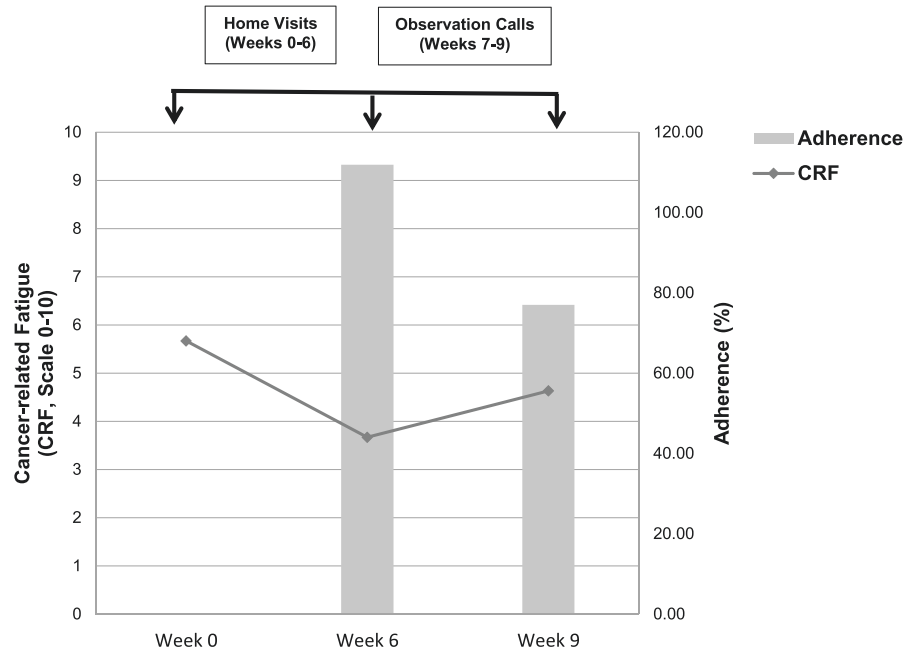

Figure 3 ■ Dose-dependent effect between cancer-related fatigue and adherent rate.

Milestone 2: Clinically Significant Changes in the Behavior Risk Factor

Our results showed large to moderate effect sizes in the positive direction in CRF, ADL dependence, cardiorespiratory fitness (6MWT), balance (Berg Balance Scale), muscle strength (combined grip sum), and left shoulder forward flexion. It is necessary to discuss minimal clinically important difference (MCID) within subject because of the nature of the pre-efficacy study. Minimal clinically important difference is defined as the change in a clinical intervention that is meaningful for the patient.[43] In our study, CRF significantly decreased with the greatest effect size after the 6–week intervention. While the PAfitME intervention focused on mitigating "moderate to severe CRF," we found that the mean change from 5.7 to 3.7 in CRF exceeded the MICD (↓ 1.1 on a 0- to 10-point scale) for fatigue.[44] For fitness performance, improvements in both 6MWT and the Berg Balance Scale exhibited large effect sizes. In particular, the change from 357.2 m to 408.5 m exceeded the MCID (↑ 40 m) for 6WMT, while the participant's cardiorespiratory fitness was relatively weak at baseline (norm, 535 m).[45] These findings indicate that the PAfitME intervention improved both subjective CRF perception and objective cardiorespiratory fitness.

In contrast, the significant improvement in Berg Balance Scale scores (P=0.04) did not clear the bar for clinically meaningful change. The mean score of the Berg Balance Scale at baseline in our participants was a relatively high 52.6 (maximum score, 56).[46] This could be a function of one of our inclusion criteria, which was that participants had to have a KPS score of 60% or greater (ie, ambulatory and capable of self-care with minimal assistance). A score of 42 or higher from the Berg Balance Scale is considered as functionally "independent" with very low risk of falling. This lack of variability led to a restriction in range, resulting in a small increase in score of 1.4, which did not exceed the MCID (a score of 3) for the Berg Balance Scale.[47]

We had a robust finding on grip strength. We used combined grip sum to operationalize muscle strength because this leveled out the dominant hand effect (by using the sum of left hand and right hand strength) and represented the ratio of hand muscle strength and body weight. The improvement in grip strength of either the right hand (↑ 3.3 kg) or the left hand (↑ 2.8 kg) in our study was approximately half of its MCID (5.0-6.2 kg).[48] Compared with the norm (1.1), the baseline combined grip sum among our participants (mean, 0.8) was relatively low. After the 6-week intervention, the grip strength increased, whereas no change in body weight was found. The strength training exergames in the PAfitME intervention (ie, in Wii Fit) were designed for muscle conditioning but not for traditional resistance training. For those HNC patients whose muscle strength is very weak, muscle conditioning exercises might be more appropriate to improve muscle strength without losing body weight during the early posttreatment period. Continuing improvements in muscle strength might have occurred if the participants had continued to perform their perExergame prescription after 6 weeks before they started resistance training.

Finally, although left shoulder forward flexion improved 9.1 degrees with a moderate effect size, this change might not have influenced shoulder-related daily functioning because there were no significant changes for other simultaneous shoulder range-of-motion measures. However, the large effect size of improvement in ADL dependence in our study showed that our intervention has the potential to enhance overall daily functioning among HNC patients.

The adherence rate to prescribed exergame physical activity in our study (78.9% for the first 3 weeks, 111.9% for the second 3 weeks) was superior to the adherence rates reported in previous

physical activity intervention in HNC patients.[16–18] This may be a function of intervention location or intervention components. The interventions in these previous studies were institution based and focused on resistance training. In contrast, the PAfitME intervention was home based and personalized based on both individual fitness attributes and behavioral perception. The calls designed for the last 3 weeks (weeks 7–9) in our study contained minimal intervention components for observational purposes. During this period (Figure 3), the results showed a dose-dependent effect between adherence rate (↓) and CRF (↑). In our study, 5 of 8 participants exceeded their prescribed exergame minutes during the second 3 weeks (weeks 4–6). This suggests that our perExergame prescription can be increased more aggressively in frequency/duration if tolerated.

Milestone 3: Completed Intervention Package

The results of our study support the current PAfitME protocol including intervention components, intervention delivery mode, and intervention contact times/duration. In this pre-efficacy study, the PAfitME intervention had strong eligibility, attendance, and completion rates. Participants' satisfaction with the intervention mode and intervention components was positive. They were highly engaged during the home visit. The participant burden of the home visit was similar to the burden in the national data. No adverse event was related to the intervention protocol. During the 6-week intervention, all of the 6 intervention components were delivered. The results showed improvements in CRF, ADL dependence, cardiorespiratory fitness, balance, muscle strength, and left shoulder forward flexion, with large to moderate effect sizes. Clinically significant changes were supported by positive changes in CRF and 6MWT exceeding MCID. The improved grip strength (muscle strength) approached its MCID with no change of body weight. Most importantly, participants' exergame physical activity adhered to or exceeded the prescribed behavior with potential opportunities to intensify the duration/frequency of the perExergame prescription.

Capozzi and colleagues[17] compared the effects of the physical activity intervention provided during the radiation period with the postradiation period among HNC patients. They found no differences in 6 MWT and grip strength between these 2 groups. However, the self-reported physical activity minutes decreased after the radiation when HNC patients obtained the physical activity training only during the radiation period. Our intervention package was offered at the end of cancer treatment (chemotherapy, radiation, or chemoradiation). Both 6MWT and grip strength improved, with moderate to large effect sizes in our study. This means that a behavioral physical activity intervention offered at the end of cancer treatment may be the most efficient from the healthcare service perspective.

Future Research

The findings of our study indicate that all 3 milestones in the pre-efficacy phase were accomplished and that the PAfitME intervention was ready for the next phase testing. The major limitation of this study is its sample size, which was limited to 8 participants. Because of the nature of pre-efficacy design, this sample size was considered adequate to confirm a complete intervention protocol for future testing.[19] The goal of the next phase testing is to replicate clinically significant changes in the intervention group when compared with an adequate control group in a randomized clinical trial with an adequate sample size. There are many types of control conditions, ranging from a less rigorous usual care to a more rigorous attention control. The choice of the control group should be based on the research question of interest. For the PAfitME intervention, the next phase testing may focus on the intervention effect and determine whether this is better than the control. "At the end of cancer treatment" is a critical time point for CRF improvement among HNC patients. Therefore, at a minimum, a usual care group is suggested for controlling passage of posttreatment time to determine whether the CRF improves more and earlier in the intervention group than in the usual care group without the PAfitME intervention. A medical record review may be necessary to examine, if any, the treatments/services participants receive during the study period that may affect their CRF.

Clinical Implications

While the PAfitME intervention still needs to be tested for efficacy and effectiveness, nurses and healthcare providers may gain insights from our study related to facilitating physical activity behavior among HNC patients. First, the statistical improvement in balance found in our study might be a result of the increasing muscle strength in the lower extremities. The 30-second chair stand test has been frequently applied in HNC studies and is suggested for clinical assessment.[16–18] Our intervention is one way to improve this metric. Second, the PAfitME intervention can be part of the transitional care of HNC survivors as they go back to their normal lives and their outdoor activities when they have just completed cancer treatment. Rogers and colleagues[49] reported that the preferred location of physical activity among HNC patients was outdoors. However, for those who have just completed HNC cancer treatment, an outdoor physical activity intervention may not be the best option. Based on our study, both cardiorespiratory fitness and muscle strength at baseline were relatively low in comparison to the norm; therefore, safety would be a major issue for activities performed outdoors. The home-based and personalized PAfitME may be a better option for HNC patients. Third, there is a possibility of integrating the PAfitME intervention into the telehealth care delivery model. Real-time video conferencing has been found to make no difference in chronic illness outcomes when compared with face-to-face delivery.[50] The PAfitME intervention components delivered during the home visit (face-to-face delivery) can be offered through real-time video conferencing that may save time and cost of traveling to patient's location.[51]

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