CLINICAL TRIAL REPORT

Non-Immersive Virtual Reality Exercise Can Increase Exercise in Older Adults Living in the Community and in Long-Term Care: A Randomized Controlled Trial

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Purpose: To assess the impact of an 8-week non-immersive virtual reality exercise program for older adults on 1) balance, physical function, community integration and quality of life; 2) falls, emergency room visits, hospital and long-term care admissions; 3) quantity of exercise performed; and 4) acceptance of non-immersive virtual reality.

Patients and Methods: This prospective, assessor-blinded, randomized controlled trial was carried out on two separate samples of older adults: those living in their own homes ("home-based") and those living in long-term care ("facility-based"). Participants were randomized to non-immersive virtual reality or usual activity. Non-immersive virtual reality consisted of 20–30 minutes of customized, gamified exercises for balance, stepping, strengthening, and aerobic conditioning, performed 3–5x/week for 8 weeks. Outcomes were measured before the intervention, immediately after, and 1 month later. Physical testing and questionnaires addressed objective 1). Counts for objectives 2) and 3) were reported by the participants and retrieved from the non-immersive virtual reality platform. Logbooks and a short interview addressed objective 4).

Results: Recruitment was substantially impacted by the COVID-19 pandemic. The facility-based sample had 31 participants; the home-based sample had 16. There were no statistically-significant benefits to non-immersive virtual reality in either sample for objective 1), although the facility-based non-immersive virtual reality group showed a clinically-significant improvement in functional walking. Effect sizes were small (≤ 0.16). No falls occurred during non-immersive virtual reality exercise. The facility-based non-immersive virtual reality group did an average of 14.1 sessions (average 20.1 minutes/session) and the home-based non-immersive virtual reality group did an average of 17.2 sessions (22.6 minutes/session). Participants enjoyed the non-immersive virtual reality, found it challenging and motivating and felt that it improved balance and walking. Most were interested to continue beyond the study. **Conclusion:** Non-immersive virtual reality for home-based and facility-based older adults is safe, enjoyable and feasible and may increase users' weekly levels of physical activity leading to clinical benefits for functional walking in facility-based users. **Trial Registration:** ClinicalTrials.gov (NCT04083885; registered 2019–09-06).

Plain language summary: Regular exercise is so important for older adults. It improves strength, flexibility, endurance and balance, reduces the risk of falls, and increases independence. However, many older adults do not exercise, for a variety of reasons. We tested a fun and safe way for seniors to do a customized exercise program in their own home, using a non-immersive virtual reality platform called Jintronix, which turns exercise into games!

We recruited older adults living in their own homes (home-based sample), and those living in long-term care (facility-based sample) to try the exercise program for 20-30 minutes, 3-5 times a week for 8 weeks. The exercises were customized to each participant by a therapist, who followed up weekly.

A total of 47 participants were recruited. The 16 home-based participants did an average of 17 sessions (23 min/session) over the 8 weeks, and the 31 facility-based participants did an average of 14 sessions (20 min/session). The sessions were safe – no one fell or sustained significant injury while doing non-immersive virtual reality exercise. Participants enjoyed the program and found it

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challenging and motivating, and commented that it improved their balance and walking. Most participants wished to continue once the study was over.

We have confirmed that non-immersive virtual reality exercise can engage older adults to exercise more, with the potential to improve their health and independence. This exercise option is ideal for older adults who find it difficult to leave their home or wish to exercise privately.

Keywords: exergaming, older adults, healthy aging

Introduction

The number of older adults in Canada is growing rapidly. The proportion of Canadians 65 years old and over is expected to increase from 17.5% in 2019 to 22.7% in 2031.¹ Globally, one in six people is expected to be above age 64 by 2050; with Europe and North America having the greatest proportion of older adults currently.² Physical activity is a significant contributor to health outcomes and quality of life for older adults. Notably, numerous studies have shown that exercise reduces risk of falls³ and increases muscle strength,⁴ balance,⁵ gait speed,⁶ and independence in activities of daily living⁷ in older adults.⁸ Multiple outcome measures of frailty, which are directly related to hospitalization and institutionalization, are also improved by exercise.^{9,10} As such, exercise may contribute to the ability of older adults to live in the community for longer or age in place.

Despite the well-known benefits of exercise, the 2018–2019 Canadian Health Measures Survey found that only 33% of Canadians aged 60 to 79 years met the recommended levels of physical activity as defined by the *Canadian 24-Hour Movement Guidelines for Adults aged 18–64 years and for Adults aged 65 years and older: an integration of physical activity, sedentary behaviour, and sleep.*^{11,12} This trend is also seen in Europe; only 17.4% of residents of Spain between 65–69 report engaging in the recommended amount of moderate weekly physical activity (150 minutes/week), as recommended by the World Health Organization.¹³ Research has identified that health problems, a history of inactivity, limited time and space, caring duties, a lack of motivation, misperceptions of physical activity and aging, and a lack of affordable and attractive options are barriers to exercising.^{14,15} Other barriers particularly relevant to Canada include winter weather and difficulties with transportation.¹⁶ It is essential that interventions be put in place to overcome these obstacles.¹⁵ Non-immersive virtual reality (NIVR) exercise, or exergaming, is defined as exercise performed using video games that require physical activity to play. It may provide a more pleasurable and motivating form of exercise compared to traditional forms, and may facilitate higher levels of physical activity in older adults.¹⁷

Previous studies suggest that exergaming with NIVR platforms may have various benefits, particularly in older adult populations, including improvements in mobility and balance,¹⁸ physical performance,¹⁹ health-related quality of life, and depression.²⁰ Cicek et al (2020) found that nursing home residents (65-85 years of age) who used the Nintendo Wii Fit Plus, an NIVR exergaming platform, experienced statistically significant improvements in the Timed Up and Go (TUG) test for measuring mobility, while participants assigned to treadmill and bicycle ergometer did not, with significant differences between groups.¹⁸ However, as the minimal detectable change for the TUG was not met, results were not clinically significant. Furthermore, Valiani et al (2017) reported statistically significant improvements in the Short Physical Performance Battery (SPPB) of older adults (≥75 years of age) compared to baseline, after an intervention of light-intensity exercise with the Jintronix NIVR platform for 30 minutes, twice a week, for four weeks.¹⁹ Additionally, when reassessed at 3 months after the intervention, participants' Rapid Assessment of Physical Activity questionnaire scores improved significantly compared to baseline, and SPPB scores also remained significantly improved, indicating that participants were more physically active following the intervention. More recently, Lee (2023) studied the effects of home-based exergaming on health-related quality of life in older adults (≥75 years of age) by administering a 36-item short-form health survey (SF-36) to the experimental group before and after completion of an 8-week exercise program which required 50 minutes of exercise, 3 times a week, as well as to a control group which did not exercise.²⁰ The experimental group had statistically significant improvements in physical function, role limitations due to physical health, general health, energy, and fatigue. Furthermore, Lee (2023) found that scores on the geriatric depression scale lowered significantly in the experimental group after the intervention, but not in the control group, resulting in a significant

difference between groups.²⁰ The study also evaluated physical function via the TUG, among other tests, confirming Cicek et al's (2020) results.¹⁸

Of the above three studies, only one is a randomized controlled trial, and it does not include older adults living in long-term care (LTC).²⁰ Therefore, current literature on the use of NIVR for exergaming is limited on older adults living in their home or in LTC. Therefore, the goal of this study was to assess the impact of implementing exercise programs using NIVR to older adults living in their own homes and older adults living in LTC.

The objectives were to assess the impact of eight weeks of home-based or LTC facility-based NIVR on 1) balance, physical function, community integration and quality of life; 2) number of falls, emergency room visits, hospital admissions and LTC admissions; 3) quantity of exercise performed; and 4) acceptance of NIVR for exercise.

Materials and Methods

Study Design

This prospective, assessor-blinded, parallel-group randomized controlled trial was carried out on two separate samples of older adults: those living in their own homes ("home-based") and those living in LTC ("facility-based"). Participants were randomized 1:1 to NIVR or usual activity. The CONSORT checklist is contained in <u>Supplemental Figure 1</u>.²¹ The study complies with the Declaration of Helsinki. Research ethics approval was obtained from the Bruyère Research Institute Research Ethics Board (M16-19-026). The trial was registered at ClinicalTrials.gov (NCT04083885). All participants (or their substitute decision makers) provided informed consent prior to participation, with consent affirmed at each interaction with the research staff. Participants who had substitute decision makers provide consent also provided assent at each interaction.

Participants

Independent older adults (\geq 65 years of age) living in their own homes in the community within 50 km of Fredericton, Canada, were recruited for the home-based sample. Participants were admitted into the program between November 2021 and September 2022. Selection criteria for participants in the home-based sample were: 1) be able to sit or stand without assist (use of a gait aid was acceptable) for 20 minutes (rest breaks were permitted); 2) have sufficient cognitive and visual ability to perform NIVR; 3) have a study partner (family member, friend or volunteer) to assist the participant with the study; 4) speak and understand French or English; 5) have enough space in their home to perform NIVR; and 6) have no health conditions that preclude mild to moderate exercise (ie unstable medical condition, seizures, vertigo, on isolation for infectious disease). There were no exclusion criteria related to possession of necessary equipment. All equipment, including TV and high-speed internet, was provided if required.

Older adults (\geq 65 years of age) living in LTC in central and southern New Brunswick, Canada, were recruited for the facility-based sample between June 2021 and September 2022. Selection criteria for participants in the facility-based sample were the same as for participants in the home-based sample, apart from criterion 5, as they would be performing NIVR at the LTC facility. The "study partner" could be a staff member of the LTC facility, a family member, friend or volunteer.

Sample size calculations estimated that a total of 48 participants would be required for each of the two samples. Sample size estimates were calculated using G*Power 3.1.9.4 software,²² considering a repeated-measures analysis of variance (ANOVA) with within-factor and between-factor interaction ($\alpha = 0.05$; $(1 - \beta) = 0.80$; 2 groups; 3 measurement time-points). For the home-based sample, the effect size used in the calculation was 0.32.²³ For the facility-based sample, the effect size was between 0.32 and 0.42.²⁴ Therefore, each sample required 18 participants per group, with an additional 20% to account for estimated drop-outs, for a total of 48 participants per sample, equally divided into intervention (n=24) and control (n=24) groups.

Participants were randomly assigned to either NIVR or control groups by the Research Therapist with 1:1 allocation and permuted blocks, stratified according to pre-assessed gait speed, using an online randomization platform (Sealed Envelope, London, UK).

The following demographic and health information were collected: age, sex, gender, height, weight, body mass index (BMI, calculated), past medical history, and current medications.

Equipment/Technology

NIVR was provided using a gaming computer (Dell, Round Rock, Texas, US) which ran the Jintronix virtual reality software (Jintronix, Montreal, Québec, Canada). The Jintronix software used a Kinect v2 camera (Microsoft Canada, Mississauga, Ontario, Canada), which integrated infrared and visual cameras to capture the user's movements and allow them to interact with an exercise or game presented on a TV screen (Figure 1). No video was recorded with this camera. Exercises and games addressed range of motion, balance, reaching, stepping, strengthening, coordination, memory/ cognition and aerobic capacity/endurance. Since the software was designed for older adults and those recovering from illness or injury (ie stroke), many parameters (for example, time, number of repetitions, required range of motion, speed, and accuracy) were customizable, allowing the exercises and games to be individualized according to physical abilities, tolerance, fall risk and physical activity goals.

Outcome Measures

To address the impact of NIVR on balance and physical function, all participants were assessed, either in the LTC facility or in the participant's home, with the following outcome measures, by a Research Coordinator who was blinded to group allocation. Assessments occurred at the beginning of the study and after eight weeks of participation. Additionally, there was a follow-up one month later.

- 1. Functional Reach Test (FRT), which evaluates stability by measuring the maximum distance one can reach forward in sitting or standing.^{25,26}
- 2. Berg Balance Scale (BBS), which assesses standing balance and physical function.²⁷
- 3. Timed Up and Go (TUG), which measures the time required to rise from a chair, walk 3 m, return to the chair and sit down. Three versions of TUG were assessed: original, manual dual-task (involves carrying a cup of water) and cognitive dual-task (involves counting backward from 99 in multiples of 7).²⁸
- 4. Five Times Sit to Stand (FTSTS), which measures lower extremity strength.²⁹
- 5. Quick form of the Disabilities of the Arm, Shoulder and Hand questionnaire (QuickDASH), a patient report of disability related to upper extremity pain and impairments.³⁰



Figure I Home-based participant using non-immersive virtual reality in his home. (Written informed consent was provided for the image to be published).

To assess the impact of NIVR on community integration and quality of life, the following assessment was administered, at the beginning of the study, after eight weeks, and one month later for follow-up.

1. Frenchay Activities Index (FAI), which measures the frequency of domestic chores, leisure/work and outdoor activities.^{31,32}

The number of falls, emergency room visits, hospital admissions and LTC admissions (for home-based participants only) were reported by the participants and/or their caregivers at each interaction with the Research Coordinator and Research Therapist. The quantity of exercise (number of days used and number of minutes for each NIVR session) performed by NIVR participants was monitored through the Jintronix online portal. Acceptance and enjoyment of NIVR were assessed by the Research Therapist, who recorded detailed field notes in a logbook, and with a 10-minute semi-structured interview administered to the first 10 NIVR participants and study partners in each study group (facility-based and home-based) (Supplemental Figure 2).

Procedure

After providing informed consent, participants underwent the first series of tests of physical function and quality of life and performed a 10 m or 5 m walk test to assess gait speed. Participants were then randomized, stratified according to gait speed (< 0.5 m/s and \ge 0.5 m/s). Community-dwelling and LTC residents were allocated to separate studies.

For participants randomized to the NIVR groups, the Research Therapist, who was blinded to the results of the outcome measures, consulted with the participant and the LTC staff and/or the participant's caregivers or health care professionals, to create an individualized NIVR program of approximately 20–30 minutes that was safe for the participant and addressed shared goals.

For facility-based NIVR, a Jintronix NIVR platform was kept in a common area within the facility and the study partners were trained by the Research Therapist. For home-based participants, the Research Therapist visited each home to install the platform and train the participant and their study partner on its use. All study partners were required to undergo training to administer the NIVR, assist with the technology, encourage the participant and monitor safety. Training also included how to prevent and, if required, manage falls. They could not change the NIVR program and were directed to refrain from physically assisting the participant with the exercises. For facility-based participants, the study partner was required to stay within a safe range of the participant at all times during the NIVR sessions. For home-based participants, the study partner was required to stay within shouting distance of the participant during the NIVR sessions. A photograph was taken of the home-based NIVR platform installations to document that the location was safe during installation and training.

NIVR group participants were instructed to perform the NIVR session for 20–30 minutes, 3–5 times a week, for 8 weeks, for a total of 480–1200 minutes. The Research Therapist contacted the participant twice in the first week and at least once a week thereafter, and participants were invited to contact the Research Therapist as needed. The Research Therapist monitored the NIVR usage and modified the exercises and games, as required, remotely. Additional home visits could be made if needed, to address technical issues with equipment, answer questions, and aid with proper technique and execution of the exercises. Participants in the control groups did not perform the NIVR intervention and were requested to continue with their usual activities.

After 8 weeks, participants in the NIVR and control groups were reassessed by the blinded Research Coordinator. The NIVR platform was removed from the home-based participants' homes by the Research Therapist, while the NIVR platforms at the LTC facilities remained in place. The first 10 participants and study partners in the NIVR group of each study were asked to provide a 10-minute interview on their experience with NIVR. One month later, all participants underwent a final follow-up assessment with the Research Coordinator.

Analysis

The home-based and facility-based NIVR studies were analyzed separately.

Demographic data were compared between NIVR and control groups using descriptive statistics, *t*-tests and Fisher's exact tests for homogeneity. Data from the physical testing and questionnaires were reported using counts for nominal data, medians for ordinal data (ranges) and means for continuous data (\pm 95% confidence intervals). Continuous data were assessed with mixed-methods ANOVAs [within-subject factor – time (3 levels); between subject factor – group (2 levels)]. ANOVAs remain robust for normality even when sample sizes are small.³³ Bonferroni corrections were made as required to adjust for multiple comparisons. ANOVA analyses were done for intent-to-treat, with no data removed. Observed power and effect sizes (partial Eta Squared) were reported. The analyses were repeated "per protocol", moving NIVR group participants who did fewer than three NIVR sessions to the control group, but leaving in participants who did not perform the second and/or third session(s) of data collection.

Interviews were transcribed and two research staff members coded them, along with logbook data, to identify categories and themes in a manner similar to content analysis.³⁴ Themes were examined to answer the research objective of evaluating the acceptance of NIVR.

Data on number of falls, emergency room visits, hospital admissions and LTC admissions (for home-based participants only) and NIVR usage were reported using counts for nominal data, medians for ordinal data (ranges), and means for continuous data (\pm 95% confidence intervals). T-tests were used to compare between groups, as appropriate.

Results

Participants

As the recruitment for this study took place during the COVID-19 pandemic in Canada, unforeseen challenges occurred. Strict regulations for LTC facilities postponed data collection for the facility-based sample. Once research staff were permitted to enter LTC facilities, frequent COVID-19 outbreaks and lockdowns created ongoing, intermittent interruptions in recruitment and created difficulties in the ability to perform timely assessments. COVID-19-related staffing shortages and turnover also impacted recruitment and the ability of LTC staff to support the project. COVID-19 exacerbated recruitment challenges in both community settings and LTC facilities, as older adults were unable to gather in social spaces, limiting our ability to reach this demographic. Ongoing incidences of community outbreaks resulted in hesitation for study staff to enter participants' homes, discouraged potential home-based participants from participating in the study, and negatively influenced the ability to find study partners. Therefore, due to limited funding and funder-imposed time limits, recruitment was limited to 31 participants for the facility-based sample and 16 participants for the home-based sample, which fell short of our sample size estimations. See <u>Supplemental Figures 3</u> and <u>4</u> for the CONSORT Diagrams and Table 1 for participant demographics, including timelines and usage data for the NIVR groups.

For both the facility-based and home-based samples, there were no statistically-significant differences between control and NIVR groups for age, gender, or body mass index, although the difference between groups for BMI was close to being statistically significant (p=0.05) for the home-based sample, with the NIVR group having a larger BMI. The number of participants with three or more medical conditions was high, especially in the facility-based sample. There were no statistically-significant differences between control and NIVR groups for most of the timing variables, although the intervention time (number of days over which the intervention was delivered, or equivalent time for the control group) was significantly different between groups for facility-based participants (p<0.01) and almost significantly different between groups were experienced between assessment and beginning of the intervention, between end of the intervention and reassessment, and for the 1-month follow-up, due to scheduling conflicts, difficulty coordinating with LTC facilities, illness/injury/unavailability of participant/staff/study partner, and COVID-19-related facility restrictions. No community-based participants required a second visit by the Research Therapist, ie, to deal with technical issues.

Objective I: Impact on Balance, Physical Function, Community Integration, Quality of Life

There were no statistically-significant differences between groups or over time for either the facility-based or the homebased NIVR samples when analysed on an intent-to-treat basis. See Tables 2 and 3. However, in the facility-based sample, the NIVR group surpassed the minimal clinically important difference (MCID) of the TUG $(-3.6 \text{ s})^{35}$ by several

A) Facility-based Participants				
	Control Group	NIVR Group		
Number of participants	15	16		
Age (years)	82.9	83.3		
	8.6	9.4		
Gender (woman: man)	12:3	9:7		
Body Mass Index (kg/m²)	27.9	24.9		
	6.9	5.3		
Time between Initial Assessment and Start of Intervention (days)	3.9	16.4		
	2.6	5.3		
Number in each Group with Medical Conditions:				
Musculoskeletal/Arthritis	13	14		
Neurological/Stroke	6	6		
Endocrine/Diabetes	7	7		
Cardiovascular/Hypertension	13	14		
Breathing	2	5		
Mental Health Disorders	4	5		
Cognitive Decline	5	П		
Number with 3 or More Medical Conditions	13	14		
Time of Intervention (days) ^a	57.7	65.6		
	1.9	8.8		
Time between End of Intervention and Reassessment (days)	3.8	5.2		
	3.8	6.8		
Time between Reassessment and I-month Reassessment (days)	33.1	33.4		
	3.8	3.2		
B) Home-based Participants				
	Control Group	NIVR Group		
Number of participants	8	8		
Age (years)	75.1	70.9		
	6.0	4.3		
Gender (woman: man)	5:3	6:2		
Body Mass Index (kg/m ²) ^a	27.3	34.3		
	3.8	8.8		

Table I Demographic Data for the Facility-Based (A) and Home-Based (B) Participants

(Continued)

Time between Initial Assessment and Start of Intervention (days)	5.6	13.6	
	2.4	5.6	
Number in each Group with Medical Conditions:			
Musculoskeletal/Arthritis	5	8	
Neurological/Stroke	Ι	2	
Endocrine/Diabetes	2	3	
Cardiovascular/Hypertension	6	6	
Breathing	I	4	
Mental Health Disorders	0	3	
Cognitive Decline	0	0	
Number with 3 or More Medical Conditions	3	6	
Time of Intervention (days) ^a	58.5	66.0	
	2.7	7.5	
Time between End of Intervention and Reassessment (days)	3.7	4.0	
	4.1	2.3	
Time between Reassessment and I-month Reassessment (days)	32.3	31.9	
	1.2	4.6	

Table I (Continued).

Notes: There were no participants who identified with non-binary gender. Results are average + standard deviation unless noted. ^astatistically-significant difference or near difference between groups.

seconds. For the home-based sample, both the control and NIVR groups just met the MCID $(-2.3 \text{ s})^{36}$ for improvement in the FTSTS test and the control group just met the MCID $(+4 \text{ points})^{37}$ for improvement in the BBS. Observed power and effect sizes were small (≤ 0.34 and ≤ 0.16 respectively).

When the data were analyzed as treated ("per-protocol"), 3 participants in the facility-based sample were moved from the NIVR group to the control group. There were no statistically significant changes except that the BBS now had a significant interaction between group and time (p=0.02) such that the control group (but not the NIVR group) showed a statistically-significant improvement over the course of the 8 weeks. The BBS score decreased from pre- to post- and increased slightly from post- to 1 month post-; however, this was not clinically significant as the changes were far less than the MCID. All participants completed the intervention in the NIVR group for the home-based study, except for one who withdrew. There were too few participants to add gait speed as a covariate to the analyses.

Objective 2: Number of Falls, Emergency Room Visits, Hospital Admissions and Long-Term Care Admissions

In the facility-based sample, 4 participants experienced falls during their participation in the study, 3 of whom belonged to the NIVR group. That is, 20% of the NIVR group and 8% of the control group had falls during the study. For participants in the NIVR group, falls did not occur while performing the NIVR intervention. In the control group, there was 1 emergency room visit (8% of the control group participants), 2 hospitalizations (16% of control group participants), and 1 death (8% of control group participants). There were no emergency room visits, hospitalizations or deaths in the NIVR group.

In the home-based sample, there were no falls, emergency room visits, hospitalizations or admissions to LTC.

Table 2 Individual Outcome Measures for Facility-Based Participants

	Control			Virtual Reality			Comparison Between Pre and Post [p, (ES)]			Observed Power ^b
	Pre	Post	l-month Post	Pre	Post	l-month Post	Interaction	Main Effect of Group	Main Effect of Time	Between Pre and Post
Functional Reach Test (centimetres), (higher number = improvement)	18.0 (13.8, 22.1) n=15	18.4 (14.1, 22.7) n=13	18.0 (14.2, 21.8) n=13	17.8 (14.0, 21.5) n=16	17.8 (12.2, 23.3) n=14	20.7 (15.2, 26.2) n=14	0.53 (0.03) <i>0.18</i> (0.07)	0.79 (<0.01) 0.745 (0.01)	0.72 (0.01) 0.49 (0.03)	0.06
5 Times Sit To Stand Test (seconds) (lower number = improvement)	17.2 (10.2, 24.2) n=6	16.5 (9.9, 23.1) n=5	I7.2 (7.7, 26.7) n=5	l 6.0 (3.5, 28.4) n=4	17.0 (12.1, 21.8) n=5	14.9 (9.2, 20.7) n=5	0.37 (0.13) <i>0.37</i> (0.13)	0.68 (0.03) <i>0.68</i> (0.03)	0.73 (0.04) 0.73 (0.04)	0.05
Timed Up and Go (seconds) (lower number = improvement)	38.3 (18.9, 57.8) n=10	41.8 (21.0, 62.7) n=9	48.2 (24.2, 72.3) n=9	42.1 (17.2, 67.1) n=13	42.0 (22.5, 61.5) n=12	35.9 (19.2, 52.5) n=11	0.18 (0.10) 0.12 (0.12)	0.78 (<0.01) 0.82 (<0.01)	0.86 (<0.01) 0.93 (<0.01)	0.06
Timed Up and Go (Motor Dual Task) (seconds) (lower number = improvement)	31.3 (-79.2, 141.8) n=2	n=l	n=l	14.6 (-1.7, 31.0) n=3	16.6 (10.8, 22.5) n=3	13.4 (8.5, 18.4) n=3	_	_	-	
Timed Up and Go (Cognitive Dual Task) (seconds) (lower number = improvement)	41.7 (27.6, 55.8) n=9	53.3 (32.0, 74.7) n=8	51.5 (28.2, 74.7) n=8	52.8 (31.6, 74.0) n=13	56.3 (35.8, 77.0) n=12	52.2 (32.2, 72.2) n=11	0.62 (0.03) 0.21 (0.09)	0.73 (0.01) 0.82 (<0.01)	0.25 (0.08) 0.23 (0.08)	0.34
Berg Balance Scale (/56) (higher number = improvement)	22.5 (11.8, 33.6) n=15	21.5 (9.6, 33.5) n=13	21.8 (9.8, 33.7) n=13	27.3 (17.8, 36.9) n=16	26.8 (15.9, 37.7) n=15	27.7 (16.9, 38.6) n=15	0.13 (0.08) 0.02 ^a (0.14)	0.52 (0.02) p>0.05 (<0.10)	0.57 (0.02) 0.03 ^a (control) (0.21) 0.24 (NIVR) (0.12)	0.12
Frenchay Activity Index (/45) (higher number = improvement)	6.5 (4.4, 8.7) n=15	6.5 (4.4, 8.5) n=13	6.2 (4.2, 8.3) n=13	5.9 (2.7, 9.2) n=16	6.7 (3.3, 10.1) n=15	5.9 (2.5, 9.2) n=15	0.67 (0.02) 0.48 (0.03)	0.92 (<0.01) 0.38 (0.03)	0.46 (0.03) 0.38 (0.04)	0.07
Quick Disabilities of the Arm, Shoulder and Hand Questionnaire (/100) (lower number = improvement)	34.4 (25.4, 43.4) n=15	33.0 (21.2, 44.9) n=13	33.2 (21.1, 45.3) n=13	28.8 (19.8, 37.9) n=16	32.3 (21.8, 42.7) n=15	34.8 (22.0, 47.7) n=15	0.26 (0.05) 0.43 (0.03)	0.81 (<0.01) 0.34 (0.04)	0.38 (0.04) <i>0.25</i> (0.05)	0.17

Notes: Data are presented as means and 95% confidence limits for the mean. For intent-to-treat analyses of each outcome measure, with comparisons using participants with both pre-post or pre-I-month post data, there were no significant differences between groups or changes over time (or interactions between group and time). p-values are shown for comparison between pre and post are presented for intent-to-treat analyses (regular font) and as-treated (italics). ^astatistically significant result; ^bobserved power was the same for intent-to-treat analyses.

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Abbreviations: n, sample size. NIVR, non-immersive virtual reality. ES, effect size as measured with Partial Eta Squared.

Table 3 Individual Outcome Measures for Home-Based Participants

	Control			Virtual Reality			Comparison Between Pre and Post [p, (ES)]			Observed Power
	Pre	Post	l-month Post	Pre	Post	l-month Post	Interaction	Main Effect of Group	Main Effect of Time	Between Pre and Post
Functional Reach Test (centimetres) (higher number = improvement)	19.8 (15.1, 24.5) n=8	20.7 (13.5, 27.9) n=6	23.6 (18.7, 28.6) n=6	23.7 (18.2, 29.1) n=8	22.4 (15.1, 29.6) n=7	21.6 (18.2, 25.1) n=7	0.48 (0.07)	0.84 (<0.00)	0.75 (0.03)	0.05
5 Times Sit To Stand Test (seconds) (lower number = improvement)	12.7 (8.9, 16.5) n=7	l 2.4 (4.3, 20.4) n=6	10.2 (7.8, 12.6) n=6	.3 (7.6, 5.) n=8	9.3 (7.7, 10.8) n=6	8.9 (8.2, 9.6) n=6	0.60 (0.05)	0.24 (0.03)	0.17 (0.16)	0.09
Timed Up and Go (seconds) (lower number = improvement)	12.2 (4.5, 19.9) n=8	9.9 (3.6, 16.2) n=6	9.4 (3.8, 15.0) n=6	8.9 (5.9, 11.8) n=8	8.4 (5.5, 11.2) n=7	8.6 (5.5, 11.7) n=7	0.51 (0.04)	0.62 (0.02)	0.26 (0.12)	0.21
Timed Up and Go (Motor Dual Task) (seconds) (lower number = improvement)	14.3 (3.4, 25.1) n=7	3.5 (5.7, 21.4) n=6	4. (4.3, 22.8) n=6	10.7 (7.8, 13.6) n=8	9.9 (8.3, 11.6) n=7	10.1 (7.6, 12.7) n=7	0.76 (0.01)	0.32 (0.09)	0.49 (0.05)	0.12
Timed Up and Go (Cognitive Dual Task) (seconds) (lower number = improvement)	17.6 (3.9, 31.2) n=8	14.0 (1.1, 26.9) n=6	I4.2 (−I.2, 29.7) n=6	10.9 (7.3, 14.5) n=8	8.9 (6.9, 10.9) n=7	9.2 (6.3, 12.1) n=7	0.72 (0.02)	0.37 (0.08)	0.20 (0.14)	0.24
Berg Balance Scale (/56) (higher number = improvement)	48.6 (37.4, 59.9) n=8	52.7 (46.1, 59.2) n=6	53.2 (47.4, 58.9) n=6	53.6 (50.5, 56.8) n=8	53.0 (49.0, 57.0) n=7	53.4 (50.1, 56.7) n=7	0.82 (0.02)	0.88 (<0.01)	0.26 (0.12)	0.14
Frenchay Activity Index (/45) (higher number = improvement)	31.4 (22.3, 40.4) n=8	33.8 (24.0, 43.7) n=6	34.8 (24.5, 44.2) n=6	32.8 (26.2, 39.3) n=8	33.6 (26.5, 40.6) n=7	34.0 (26.2, 41.8) n=7	0.93 (0.01)	0.89 (<0.01)	0.41 (0.08)	0.22
Quick Disabilities of the Arm, Shoulder and Hand Questionnaire (/100) (lower number = improvement)	I2.8 (I.9, 23.6) n=8	14.0 (-12.0, 40.1) n=6	12.5 (-10.4, 35.4) n=6	I 3.1 (0.85, 25.3) n=8	16.2 (3.3, 29.2) n=7	21.8 (-4.5, 48.0) n=7	0.63 (0.04)	0.67 (0.02)	0.78 (0.02)	0.06

Notes: Data are presented as means and 95% confidence limits for the mean. For intent-to-treat analyses of each outcome measure, with comparisons using participants with both pre-post or pre-I-month post data, there were no significant differences between groups or changes over time (or interactions between group and time). Abbreviations: n, sample size; ES, effect size as measured with Partial Eta Squared.

Objective 3: Quantity of Exercise Performed

The 16 facility-based NIVR group participants did an average of 14.1 sessions (ranging from 0-24 sessions) of NIVR exercise over 8 weeks, with an average total of 20.1 minutes of exercise per session (ranging from 0-28.6 minutes/ session). If the 3 participants who did not perform any NIVR were removed from the dataset, the average number of sessions was 17.2 (ranging from 5–24 sessions), with an average of 22.6 minutes per session (ranging from 17.2–28.6 minutes/session).

The 7 home-based NIVR group participants did an average of 20.3 sessions (ranging from 16–25 sessions) with an average of 27.11 minutes/session (ranging from 19-32.0 minutes/session). There were no participants in this sample who were allocated to the NIVR group but who did not perform NIVR.

Objective 4: Acceptance of Non-Invasive Virtual Reality Exercise

Themes created from data collected through the logbooks and interviews included "Challenge", "Motivation", "Improvement", and "Game Feedback".

Regarding "Challenge", 8/16 of the facility-based participants initially found the NIVR games difficult. To address this, the Research Therapist adjusted the parameters of the NIVR program to better suit the needs and abilities of participants. Home-based participants enjoyed the level of challenge and some participants appreciated how the NIVR program challenged them to improve each day.

"Motivation" emphasized that most participants enjoyed doing NIVR and described the experience as positive, engaging and a good use of time. Six out of seven home-based participants found the variety of games and exercises very motivating, enjoying it more than regular exercise. They were also motivated to "get out more". Some facility-based participants, though, found that the repetition was irritating and led to boredom.

In relation to "Improvement", both home- and facility-based participants perceived that they improved at their NIVR program over time and found that it led to physical improvements in balance, walking and other components of physical fitness and activities of daily living.

"Game Feedback" demonstrated that some participants were frustrated due to the camera not always adequately tracking their movements, and some of the commands and feedback within the program were unclear or repetitive. Overall, most facility- and home-based participants reported that they were interested to continue using the NIVR beyond the study. Reported barriers to using NIVR beyond the study included space in the home and potential cost.

De-identified quantitative data are available from the Corresponding Author upon reasonable request, until August 22, 2033. There are no other related, unreported data available.

Discussion

Eight weeks of home-based or facility-based NIVR was safe, enjoyable and increased the amount of exercise performed by older adults by an average of 35 minutes (facility-based sample) or 69 minutes (home-based sample) per week. While the repeated outcome measures did not show a statistically significant impact on balance, physical function, community integration or quality of life, these results may be impacted by a lack of power due to lower-than-expected recruitment. The observed power (≤ 0.34) was smaller than the target power ($1 - \beta$) of 0.80. suggesting that the small sample sizes affected the ability to determine statistically significant differences. The use of outcome measures with poor responsiveness or sensitivity to change could have contributed to the lack of statistically significant outcomes; however, most of the outcome measures have reported moderate to excellent sensitivity to change and/or responsiveness.^{36,38–41} Responsiveness for the TUG with cognitive dual-task, which had the best observed power, has not been reported, A clinically-significant benefit was found for functional walking in facility-based participants in the NIVR group.

The only outcome measure addressing balance and physical function that produced clinically-significant improvements in an NIVR group exclusively was the TUG for the facility-based NIVR group. The improvement (reduction in time) was 6.1s, 2.5s beyond the MCID of 3.6 s, suggesting an important impact from the NIVR intervention. Clinicallysignificant improvements were seen in the FTST for the home-based sample in both the NIVR and control groups, which indicates that the intervention may not have been responsible for improvements in lower extremity strength. The control group also experienced a clinically-significant improvement in balance as measured by the BBS, while the NIVR group did not. There were no improvements in stability (FRT), disability related to upper extremity pain and impairments (QuickDASH), or quality of life (FAI) indicated by this study.

Beyond a small sample size, there are other reasons why participants in the two samples may not have benefited significantly on outcomes of balance, physical function, community integration and quality of life from the exercise programs. The participants were older adults, but were not recovering from a specific illness or injury and were not in particular need of rehabilitation. Therefore, observation of rapid improvement was not expected. It is possible that more than eight weeks would be needed to see a change in physical abilities in these samples, particularly at the intensity delivered. Indeed, even 10 weeks may not be enough to show changes.⁴² The Canadian 24-Hour Movement Guidelines for Adults aged 65 years or older suggest that older adults perform at least 150 minutes of moderate- to vigorous-intensity physical activity a week on an ongoing basis, plus additional strengthening and balance exercises.¹² Participants in our samples did only a fraction of that, although this was beyond their usual activities which could have included other forms of exercise such as gardening and walking.

Regarding facility-based exercise, a recent scoping review confirmed that older adults living in LTC are highly sedentary and do not meet physical activity recommendations.⁴³ Systematic reviews and meta-analyses showed that older adults living in LTC do benefit from exercise programs, including NIVR.^{44,45} Participation in a minimum of 35 minutes of physical activity at least three times a week is recommended.⁴⁶ For community-based older adults, 150 minutes of moderate-intensity aerobic exercise combined with two sessions of strengthening exercise is suggested by the World Health Organization; a target that most do not reach.^{11–13,47} A recent meta-analysis of facility- and community-based NIVR exercise programs found that 20-45 minutes of exercise, 3 times a week for 5 to 8 weeks can also provide significant benefit⁴⁸ while another meta-analysis found moderate improvements in balance, upper and lower body strength and endurance, and small benefits for gait and overall physical function.^{3,49} Specifically, programs providing more than three sessions of exercise a week showed greater improvement in BBS scores for LTC residents than programs with less than three sessions a week.⁴⁸ Our program was unable to meet those dosages, partly due to a lack of consistent study partners to supervise. This may explain our lack of significant results somewhat. However, regarding home-based exercise for older adults, Gschwind et al (2015) showed a benefit with only 44 minutes of at-home technology-based exercise per week for 16 weeks.⁵⁰ Therefore, extending our program from 8 to 16 weeks might have garnered more significant outcomes. Other authors have found that the use of technology (including NIVR) to provide exercise for older adults is associated with improvements in physical function, balance and falls prevention, at least 80% of the time, with even greater improvements compared with conventional exercise.^{48,51} Future studies performed outside of a pandemic environment may show more positive effects.

Twenty to thirty percent of all older adults in Canada fall each year, on average, with six percent reporting injury.^{52,53} This increases to over 50% for residents living in LTC.⁵⁴ The rate of fall-related hospitalizations is approximately 1.5% per year. For TUG, the cut-off score that indicates a risk of falls is 13.5 s for community-dwelling adults and 32.6 s for frail elderly.^{55,56} The home-based sample was, on average, well below this threshold for community-dwelling adults, indicating a low risk of falls, while the facility-based sample scored well above the threshold for frail elderly, indicating a heightened risk of falls. Indeed, the facility-based sample experienced more falls during the study than the home-based sample but overall, our data showed fewer falls than expected, and in particular, no falls or other adverse events occurred during NIVR sessions. Therefore, it is concluded that NIVR is safe for older adults who meet the study's eligibility criteria. Careful attention to safety procedures and training about what to do in the event of a fall remain important features of all exercise programs for older adults. One barrier to participation in the study was the necessity of a study partner to be present during each NIVR session. Other studies have shown that similar NIVR and game-based exercise programs for community-dwelling older adults are safe even when performed alone,^{50,57} which would remove a barrier to participation for the many older adults who live alone.

Data collected by the Jintronix NIVR software showed that home-based participants spent, on average, more time exercising with the NIVR platform than facility-based participants. The exercise program prescribed in this study was a total of 480–1220 minutes of exercise over 8 weeks (20–30 minutes of exercise, 3–5 times a week). Adherence to the prescribed exercise program for participants enrolled in the program was moderate, at an average of 283 total minutes for facility-based participants (59% of the lower suggestion) and 550 total minutes for home-based participants (46% of the higher suggestion). Previous research is quite variable. For home-based NIVR, Gschwind et al (2015) found 26%

adherence (out of a request of 180 minutes/week for 16 weeks) in terms of minutes spent exercising,⁵⁰ but in a study from Sheehy et al (2021), home-based participants living with mild cognitive impairment performed 99% of the requested exercise minutes (30 minutes, 5 times a week for 6 weeks).⁵⁸ For facility-based NIVR programs, Padala et al (2012) found that LTC residents with mild dementia perform 56% of their requested Wii-Fit program (30 minutes, 5/ week for 8 weeks).⁵⁹ Our results were likely influenced by the COVID-19 pandemic and its impact on the availability of study partners to be present.

With support, older adults readily accept the use of technology to increase exercise. Enjoyment and motivation were high in both study groups, and participants noted benefits in fitness and physical function. General interest in continuing the NIVR program after the study shows promise for the acceptance of NIVR for exergaming among older adults living in the community and in LTC. However, some barriers were identified, such as issues with the NIVR hardware, annoyance with the commands, and boredom over time. These have been identified in the past and should be addressed to enhance the user experience.⁵¹ Comments regarding details of the NIVR intervention itself show that ongoing enhancements to specific NIVR programs may maximize their impact on motivation.

Limitations

Not all outcome measures were appropriate for all participants. For example, some facility-based participants could not walk or stand. For home-based participants, the BBS showed a ceiling effect. Pardasaney et al (2011) found a similar effect, with a low standardized response mean (0.20) for individuals with a baseline BBS score of \geq 50/56, compared with those with a baseline score of <50/56 (0.85).⁴⁰ A better test for this cohort might have been the Community Balance and Mobility Scale,⁶⁰ which includes more difficult and functional items.

We did not describe "usual activities" of the participants in the study. It is possible that home-based participants, in particular, might have substituted NIVR for other physical activities, which may partly explain the lack of significant improvements in physical outcomes. Future studies should at least track formal exercise and rehabilitation programs performed by the participants, to describe the sample and note changes over the length of the study. Also, participants could not be blinded with respect to the intervention; this is an unavoidable feature of most exercise-based randomized controlled trials.

We did not assess psychosocial factors such as mental health, isolation, or fear of falling, nor did we specifically assess cognition. These factors, as well as the many comorbidities listed in Table 1 may have had an influence on the outcome of the study. Future work should clarify the influence of these conditions on the impact of NIVR on balance, mobility, community integration and quality of life.

Poor timeliness of some assessments and beginning the intervention after the initial assessment were another limitation of this study. The time between initial assessment and start of intervention was much longer with the NIVR groups than the control groups (who in effect "began" the control intervention immediately), but this should not impact the outcomes as long as the participants were stable in their mobility. Ideally there would only be one or two days between the end of the intervention and the reassessment, however the reassessment was frequently delayed. Since the delays between the end of the intervention and the reassessment were similar between intervention and control groups, it is unlikely that this would cause a difference between groups. There is a concern that the effect of the NIVR may diminish before the reassessment, since any exercise program needs to be perpetuated to maintain the benefit.

Several inequities were present in this study. All participants needed a study partner, and this proved to be challenging, particularly during the COVID-19 pandemic. Potential participants who lived alone or at LTC facilities that did not have enough staffing or volunteers to support the use of NIVR frequently were not able to participate. The Jintronix platforms were provided, which avoided a potential barrier to participation due to lack of equipment. However, for the home-based sample, the use of technology to support exercise is likely to be desirable and accessible only to those who are already comfortable with technology.⁵¹ These individuals are also more likely to have a higher level of education and a higher standard of living.

Conclusion

In conclusion, NIVR for home-based and facility-based older adults is safe and feasible, and increases users' weekly levels of physical activity. Further research with larger sample sizes to allow sufficient power should be performed to confirm a beneficial impact on physical function and quality of life.

Acknowledgments

We would like to thank all our participants and their study partners, the staff at the LTC facilities, and Emma Gal-Dev, for her work on the manuscript. We would also like to acknowledge Jintronix, Inc., for providing equipment at a discount.

Since data collection, some authors have moved to different institutions. Lalita Bharadwaj is now at Horizon Health Network, Fredericton, NB, Canada; Kelsey Annie Nissen is now at the New Brunswick Chiropractors Association, Fredericton, NB, Canada; Justine L. Estey is now at the Office of the New Brunswick Advocate, Fredericton, NB, Canada.

Funding

This project was supported by a grant from the Healthy Seniors Pilot Project fund #C0020 (Government of New Brunswick and the Public Health Agency of Canada) and sponsored with a financial contribution from Jintronix Inc.

Disclosure

Jintronix Inc. sponsored the project to help pay Lisa Sheehy's salary. Jintronix Inc. does not have the right to bar dissemination of the research results.

The other authors report no conflicts of interest in this work.

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