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Effects of Different Exercise Doses Through an Augmented Reality Exergame in Older Adults: A Pilot Randomized Controlled Trial

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Abstract: (1) Background: Growth in the use of video games has spurred innovations in the health sector, especially through exergames, which promote physical activity using interactive technologies like augmented reality. Exergames are shown to enhance exercise motivation and engagement, yet enjoyment remains inconsistent across studies. This pilot study aims to provide evidence on how different exergaming doses affect exercise heart rate, perceived exertion, adverse effects, and enjoyment in older adults. (2) Methods: A pilot randomized controlled trial was conducted to compare different doses of exercise through video games (13 vs. 28 min) in older adults living in a nursing home. A single bout of exergaming was provided to assess the outcomes: heart rate, rate of perceived exertion, physical activity enjoyment scale score, and adverse effects. (3) Results: Thirty-two older adults were recruited. This study revealed no significant differences in heart rate between groups ($p = 0.1$). There is a weak correlation between the rate of perceived exertion and the level of enjoyment ($r_s = -0.193$) and between the total time of the intervention and the incidence of adverse effects ($r_s = 0.295$). (4) Conclusions: The use of a higher dose of exergaming is effective in achieving moderate physical intensity. Also, the results suggest the intervention was generally well tolerated and enjoyed by older adults, with no serious adverse effects reported.

Keywords: exergaming; video games; older adults; perceived exertion; heart rate; adverse effects

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1. Introduction

In recent years, the rapid global growth in the use of video games has opened up new avenues in the health sector through the development of exergames, or active video games. These exergames encourage physical activity by utilizing screens or virtual environments, leveraging advanced technologies such as motion capture systems, sensors, controllers, platforms, and various methods for providing real-time feedback [1,2]. Research indicates that these types of video games can effectively improve functional status across different age groups while enhancing exercise experience in terms of engagement and motivation [3–5]. As highlighted in the previous systematic reviews, the primary method for delivering this interactive content is through augmented reality (AR), a technology that overlays virtual elements onto the real world [6]. This technology creates an interactive experience by blending digital elements with the real world, which requires a digital device, such as a smartphone or tablet, to view and interact with the augmented environment.

Physical activity is defined as any bodily movement produced by skeletal muscles that results in energy expenditure [7]. Exercise, on the other hand, is a subset of physical activity that is planned, structured, and repetitive and is aimed primarily at improving physical fitness [7]. Following the recommendations of the American College of Sports Medicine (ACSM), exercise prescriptions should adhere to the FITT principles: frequency, intensity, type, and time [8]. However, adding a fifth 'F' representing fun has been suggested because of its importance in exercise adherence [9].

Exercise intensity refers to the rate of energy demand during physical activity [10]. To measure the desired intensity, several tools provided objective data, such as heart rate (HR), and subjective data, such as the Borg Rating of Perceived Exertion (RPE) [10]. Numerous studies have reported a strong correlation between HR and the RPE, validating both measures as indicators of exercise intensity [11]. Nevertheless, this relationship may be altered in the context of exergames, as the introduction of visual and auditory stimuli could lead to a decrease in perceived RPE [12,13].

The primary goal of engaging in physical activity or exercise is to achieve the optimal stimulus without compromising the safety of the individual or inducing adverse side effects. Engaging in physical activity is associated with a 19% increase in the risk of non-serious adverse effects, with pain and fatigue being the most common complaints [14]. Understanding how exercise exposure, in terms of intensity and duration, is related to the occurrence of these adverse effects is essential for observing the dose–response relationship and for improving safe and effective exercise recommendations.

Exercise provides numerous health benefits because of its various modalities [15,16]. However, the enjoyment and satisfaction derived from the type of exercise used are often overlooked. The literature presents inconsistencies regarding the enjoyment associated with exergames. Some studies suggest that not all individuals find these video games enjoyable, with preferences leaning toward other forms of physical activity [17,18]. Conversely, other research indicates that exergames can elicit a high level of enjoyment, particularly when played in pairs [17,18]. These discrepancies may stem from factors such as patient preferences, self-efficacy, or social influences [17]. This aspect is crucial as enjoyment could be a key factor in adherence to treatment, as previously described in older adults, potentially encouraging individuals to exercise more regularly and at higher intensities [18–21].

Thus, for these reasons, this study aims to provide evidence on how different exergame doses may influence exercise intensity, perceived exertion, and enjoyment in older adults. Additionally, the study will examine the occurrence of adverse effects, with the goal of optimizing exercise strategies in clinical practice.

2. Materials and Methods

2.1. Study Design

A double-blind (assessor and participants) randomized controlled pilot study was conducted with 2 arms. This study has the approval of the Toledo Health Area Drug Research Ethics Committee (No. 1186 19 June 2024) and was registered at clinicaltrials.gov (NCT06526975). The study was conducted following CONSORT guidelines [22].

2.2. Participants

Participants aged 65 years and older were recruited from the Nueva Esperanza Nursing Home in Fuensalida, Toledo, Spain, between July and September 2024. Inclusion criteria required participants to be at least 65 years old, score 20 or higher on the Mini-Mental State Examination (MMSE) to confirm no significant cognitive impairment, demonstrate the ability to stand upright independently or with the assistance of a walking aid, and be willing to participate in the intervention. Exclusion criteria included severe visual impairment that could hinder participation, any medical contraindications for physical activity as determined by a healthcare professional, and the presence of physical or mental health issues that could compromise safety or the effectiveness of the intervention. These criteria were designed to ensure a homogeneous sample capable of safely engaging in the exergame intervention while maximizing the validity of the study outcomes.

Most participants regularly took one or more of the following medications: antihypertensives, analgesics, and cholesterol-lowering drugs. Additionally, some participants were on blood thinners, type II diabetes medications, or dietary supplements.

2.3. Intervention

The intervention was identical for both groups, differing only in the duration of application. Group I (n = 16) participated in the intervention for approximately 13 min, while Group II (n = 16) engaged for 28 min. This study consisted of a single intervention session for each participant.

Both groups completed various exercises using the Party Fowl application (Nex Inc., San Jose, CA, USA), which features multiple games requiring the movement of different body parts, performed in pairs. The sequence of games included was "Helicopter Hips", "Free Range Frenzy", "Don't Forget to Wipe", "Ice Breaker", "Shake It Off", "Red Light Rat Race", "Peek 'n' Pop", and "Bottle Waddle". The intervention was facilitated through this software, projected onto a large screen, with a mobile device equipped with a camera to capture movement during the exercises.

A total of eight games were used, each lasting between 30 to 45 s, with a loading time of 10 to 12 s between games. Group I played the video games twice, resulting in a total duration of approximately 13 min, whereas Group II played the games four times, with a 2-min rest midway through the session, for a total time of approximately 28 min.

2.4. Outcomes

Demographic data (age, sex, height, weight and BMI) were collected before the start of the study. A total of 4 outcomes were measured, all related to exercise. The first two were physical outcomes, being heart rate and perceived exertion index, and the other two were related to enjoyment, monitoring, and other possible side effects caused by the intervention.

Heart rate: Heart rate (HR) was measured using a Polar H10 sensor (Polar Electro Oy, Kempele, Finland), a device shown to be highly valid for HR measurement in comparison to the gold-standard electrocardiogram, with a correlation coefficient of (r = 0.997) [23]. The Polar Flow app was used to save participants data, recording the minimum, mean, and maximum HR throughout the intervention for subsequent analysis.

Rate of perceived exertion: Before the start of the session, participants were instructed on how to rate their exertion using the Borg scale (6–20) [24]. RPE has been shown in prior studies to correlate strongly with HR, the primary outcome for measuring exercise intensity (r = 0.57–0.88) in different exercise activities [11,25,26]. Scores were recorded at the middle and end of the training session; if participants were unable to continue the session, the maximum score was recorded.

Wellness questionnaire: Muscle pain, stress, fatigue, and sleep were monitored 24 and 48 h after the intervention using the Hooper and Mackinnon questionnaire [27]. Additionally, an open-ended question was included to capture any other potential side effects experienced by participants. All reported adverse effects were considered, with a focus on fatigue and delayed onset muscle soreness (DOMS), the primary adverse effects observed in this trial.

Satisfaction with the intervention: The Spanish version of the Physical Activity Enjoyment Scale (PACES) was used to measure this outcome, with higher scores indicating greater enjoyment [28]. In this study, PACES scores were divided into positive and negative components, with the positive items having a maximum score of 45 and the negative items a maximum score of 35. PACES has demonstrated good to excellent test-retest reliability (ICC = 0.6–0.93) in healthy adults [29]. This scale was administered on the same day as the intervention to assess participants' immediate satisfaction and enjoyment of the exergaming activities.

2.5. Procedure

Before the study commenced, participants received both oral and written information about the study, and they signed an informed consent form prior to the start of data collection. Once they agreed to participate, they underwent a trial session to test the video games that would be utilized in the study.

During the trial, participants entered an empty room in pairs, accompanied by the physiotherapist overseeing the intervention. A tablet was placed on a table, and the content of the video game was projected onto a large screen measuring 329 × 235 cm, as depicted in Figure 1. The equipment used for this session included a Lenovo tablet (Lenovo Tab M10 3rd Gen) for playing the game, a Google TV Chromecast for casting the tablet's content to the projector, and a Panasonic PT-VMZ40 projector.

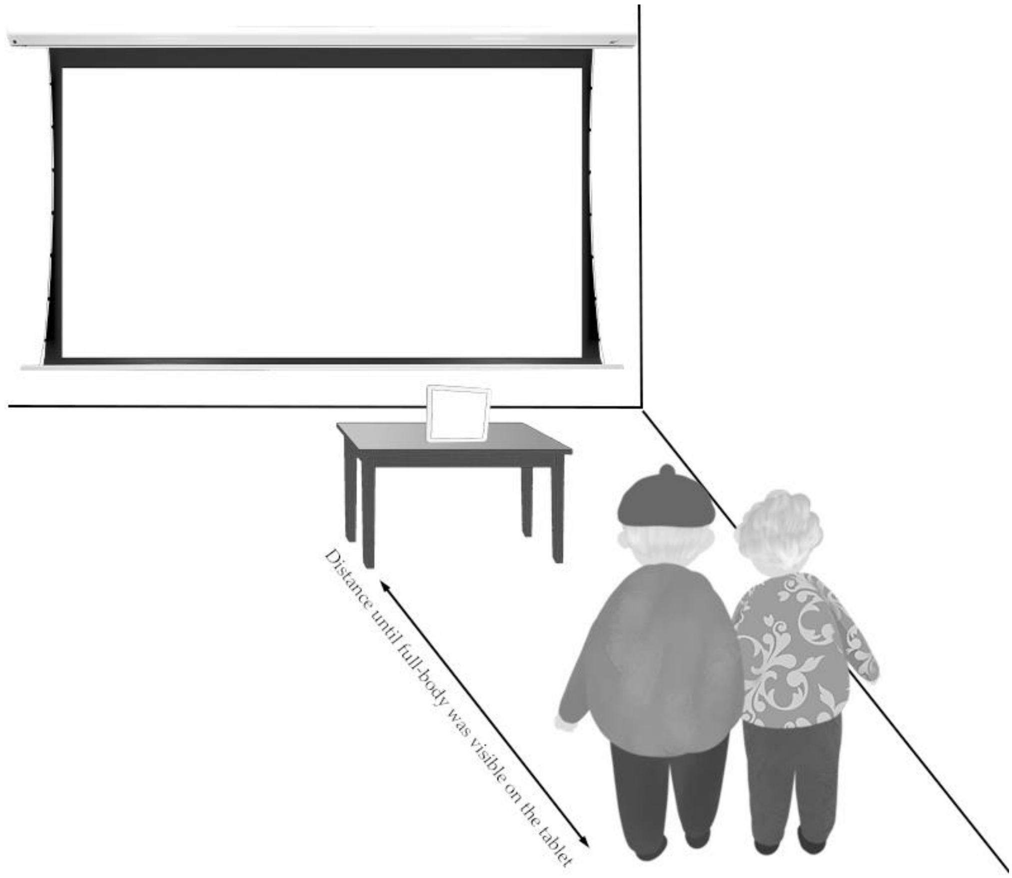

Figure 1. Visuospatial representation of the intervention.

Initially, participants were seated in chairs while wearing Polar H10 monitors, and the rate of perceived exertion (RPE) scale was explained to them. RPE was assessed at half-time (approximately 7 min for Group I and 13 min for Group II) and again at the end of the intervention. After all participants had completed the session for the day, they filled out the PACES scale to evaluate their enjoyment.

In the 48 h following the intervention, participants were monitored by the nursing home staff, including nurses, physiotherapists, or psychologists, using a wellness questionnaire to assess their overall well-being.

2.6. Sample Size

The aim of this study was to conduct a randomized pilot study designed to explore the tolerability of various doses of video game exercise among participants. The sample size was predetermined based on prior pilot studies in this field, which typically ranged from 20 to 40 participants. This pilot study serves as an initial investigation to gather preliminary data that can inform the design of a larger, more definitive study. By assessing participants' responses to different exercise doses, the research aims to identify the most effective and acceptable levels of video game exercise for future trials, ultimately enhancing the understanding of its impact on physical activity engagement.

2.7. Randomization and Blinding

The participants were randomly assigned to one of two groups at a 1:1 ratio via an electronic randomization tool (GraphPad) by the study coordinator. Once participants consented to join the study, electronic masking was performed as the physiotherapist responsible for administering the interventions received the randomization assignments. The physiotherapist was also responsible for scheduling the sessions for each group. The assessor and the participants were blinded to the group assignments, whereas only the physiotherapist conducting the interventions was unblinded.

2.8. Data Analysis

The Statistical Package for the Social Sciences (SPSS) version 28 (SPSS Inc., Chicago, IL, USA) was used for statistical analysis. Descriptive statistics were employed to summarize the data, including means and standard deviations for continuous variables and absolute values and percentages for categorical variables [*n* (%)]. A *p* value of <0.05 was considered to indicate statistical significance for all analyses.

For categorical variables, the chi-square test was used. The normal distribution of continuous variables was assessed via the Shapiro–Wilk test. Differences between groups were compared via the *t* test for normally distributed data (parametric) and the Mann–Whitney U test for non-normally distributed data (non-parametric).

Finally, correlations between the study variables were analyzed for each group via Spearman's Rho test as parametric and non-parametric data were used. The correlation results were interpreted as follows: 0.01 to 0.19 indicates a very low correlation, 0.2 to 0.39 a low correlation, 0.4 to 0.69 a moderate correlation, 0.7 to 0.89 a high correlation, 0.9 to 0.99 a very high correlation, and 1 a perfect correlation [30].

3. Results

3.1. Participant Characteristics

A total of 32 participants were randomly assigned to either Group I (*n* = 16) or Group II (*n* = 16), with both groups engaging in exercise through video games. One participant ultimately withdrew from the study due to a decision to discontinue participation. A flow chart detailing participant allocation and withdrawal is provided in Figure 2.

The overall sample comprised 16 females and 16 males, with a mean age of 87.44 years (SD: 6.1), a mean height of 1.62 m (SD: 0.1), a mean weight of 72.39 kg (SD: 14.28), and a mean body mass index (BMI) of 27.19 kg/m² (SD: 4.14). Demographic and physical data, categorized by group allocation, are summarized in Table 1.

Table 1. Demographic and physical characteristics of the participants and normality test results.

	Group 1 (*n* = 16)	Group 2 (*n* = 16)	*p* Value
Age (yr), mean (SD)	90.06 (4.81)	84.81 (6.25)	*p* = 0.06 *
Gender	M: 9 (56.25%)	M: 7 (43.75%)	*p* = 0.48 **
Height (m), mean (SD)	1.61 (0.11)	1.64 (0.1)	*p*= 0.181 *
Weight (kg), mean (SD)	72.52 (12.69)	72.16 (16.13)	*p* = 0.48 *
BMI (kg/m^2), mean (SD)	27.85 (4.18)	26.54 (4.12)	*p* = 0.158 *

* *t* test was used, ** chi-squared test was used. SD: Standard Deviation, M: Male.

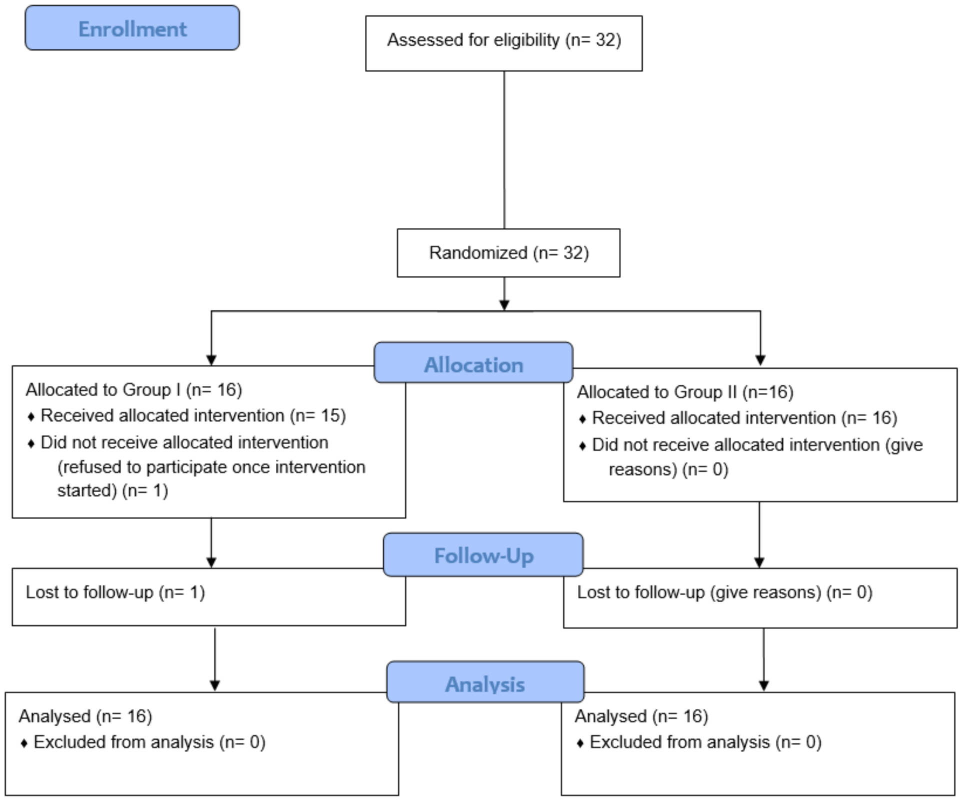

Figure 2. Flow diagram.

3.2. Main Results

No significant differences were found in the main outcomes between groups, with the only notable difference being the total duration of activity ($p < 0.01$). These findings are summarized in Table 2.

Table 2. Comparison between groups.

	Group 1 Mean (SD) (95% CI)	**Group 2 Mean (SD) (95% CI)**	***p* Value**
Min HR (bpm)	72.13 (13.4)	67.94 (9.45)	$p = 0.158$ *
Mean HR (bpm)	85.83 (15.9)	86.75 (11.59)	$p = 0.391$ *
Max HR (bpm)	98.13 (17.67)	105.75 (15.2)	$p = 0.1$ *
Half-time RPE (6–20)	9.53 (2.12)	9.31 (2.182)	$p = 0.626$ **
End-time RPE (6–20)	11.2 (2.65)	11.5 (2.83)	$p = 0.74$ **
Total time mean (SD)	0:13:08 (0:00:48)	0:27:55 (0:00:57)	$p < 0.01$ **
Enjoyment PACES	35.13 (5.24)	36.94 (4.39)	$p = 0.287$ **
Non-enjoyment PACES	11.62 (4.91)	10.31 (3.03)	$p = 0.616$ **
Adverse effects	1.44 (0.96)	1.81 (0.83)	$p = 0.287$ **
Fatigue 24 h mean	1.69 (1.45)	1.31 (0.87)	$p = 0.564$ **
Fatigue 48 h mean	1.31 (0.873)	1.19 (0.54)	$p = 0.956$ **
DOMS 24 h mean (SD)	1.69 (1.01)	1.94 (1.12)	$p = 0.539$ **
DOMS 48 h mean (SD)	1.25 (0.58)	1.19 (0.4)	$p = 0.956$ **

* *t*-test was used, ** Mann–Whitney U test was used. CI: Confidence Interval, Bpm: beats per minute.

Heart rate was presented as the minimum, mean, and maximum throughout the exercise time. No significant differences in minimum HR ($p = 0.158$), mean HR ($p = 0.391$) or maximum HR ($p = 0.1$) were observed.

RPE was measured at mid-session and the end of the session, and no significant differences were found at half-time ($p = 0.626$) or at the end of the exercise time ($p = 0.74$).

The Spanish PACES scale was divided into two parts, enjoyment and non-enjoyment items, and no differences were found in enjoyment ($p = 0.287$) or non-enjoyment ($p = 0.616$).

There were no differences between groups in terms of total adverse effects ($p = 0.287$), nor in fatigue at 24 h ($p = 0.564$) and 48 h ($p = 0.956$) post-exercise, or DOMS during the same period (24 h ($p = 0.539$) and 48 h ($p = 0.956$)).

3.3. Correlations

The relationships between rate of perceived exertion (RPE) and enjoyment items from the PACES scale were generally low in both groups at the end of the intervention, with a correlation coefficient of ($r_s = -0.193$). Specifically, in Group I, the correlation was slightly stronger at ($r_s = -0.256$) while Group II showed a similar low correlation of ($r_s = -0.194$). However, a significant difference was noted for half-time RPE, which had a moderate correlation of ($r_s = -0.359$) ($p = 0.047$). This relationship suggests that as participants perceived higher levels of exertion, their enjoyment during the activity decreased.

In Group I, there appeared to be no meaningful correlation between RPE and non-enjoyment items from the PACES scale, indicated by a coefficient near zero ($r_s = -0.063$). Conversely, Group II displayed a moderate correlation of ($r_s = 0.401$) for the same items, as shown in Table 3. Nonetheless, none of these correlations reached statistical significance.

Table 3. Spearman's Rho correlations between BORG and PACES.

		Enjoyment PACES	**Non-Enjoyment PACES**
Groups 1 and 2	Half-time RPE	$r_s = -0.359$ *	$r_s = -0.249$
	End-time RPE	$r_s = -0.193$	$r_s = -0.181$
Group 1	Half-time RPE	$r_s = -0.281$	$r_s = -0.01$
	End-time RPE	$r_s = -0.256$	$r_s = -0.063$
Group 2	Half-time RPE	$r_s = -0.434$	$r_s = 0.471$
	End-time RPE	$r_s = -0.194$	$r_s = 0.401$

* Significant correlation $p < 0.05$.

The correlation between total exercise time and adverse effects was weak in both groups ($r_s = 0.295$), with low to very low correlations observed for adverse effects measured 24 h and 48 h after exercise. A notable exception was the moderate statistically significant correlation between total time and adverse effects in the subsequent days, which was higher ($r_s = 0.598$) ($p = 0.015$).

Additionally, an outcome that could be correlated with adverse effects is the RPE; RPE showed a moderate correlation with adverse effects in both groups ($r_s = 0.627$) ($p < 0.001$), with Group I exhibiting a strong correlation ($r_s = 0.762$) ($p < 0.001$). Moderate correlations were also noted for all adverse effects at 24 h and 48 h post-exercise, with statistical significance for both groups, except for DOMS at 48 h, which was significant only in Group II. Detailed data for these findings are available in Table 4.

Table 4. Spearman's Rho correlations between total time and adverse effects.

		Adverse Effects	**Fatigue 24 h**	**Fatigue 48 h**	**DOMS 24 h**	**DOMS 48 h**
Groups 1 and 2	Total time	$r_s = 0.295$	$r_s = -0.156$	$r_s = -0.08$	$r_s = 0.176$	$r_s = 0.05$
	End-time RPE	$r_s = 0.627$ **	$r_s = 0.424$ *	$r_s = 0.445$ *	$r_s = 0.422$ *	$r_s = 0.301$
Group 1	Total time	$r_s = 0.598$ *	$r_s = 0.129$	$r_s = -0.095$	$r_s = 0.328$	$r_s = -0.039$
	End-time RPE	$r_s = 0.762$ **	$r_s = 0.739$ **	$r_s = 0.499$	$r_s = 0.419$	$r_s = 0.093$
Group 2	Total time	$r_s = -0.178$	$r_s = -0.253$	$r_s = -0.177$	$r_s = -0.02$	$r_s = 0.313$
	End-time RPE	$r_s = 0.484$	$r_s = 0.09$	$r_s = 0.397$	$r_s = 0.408$	$r_s = 0.542$ *

* Significant correlation $p < 0.05$, ** Significant correlation $p < 0.01$.

4. Discussion

This trial suggests that extended exergaming sessions (28 min) are similarly well-tolerated compared to shorter sessions (13 min) for older adults in a nursing home setting. Both session lengths appeared capable of reaching moderate intensity levels and were generally well received by participants. The study also found a moderate relationship between perceived exertion and enjoyment, indicating that participants' exertion levels might influence their enjoyment of the activity. No significant differences were observed in heart rate, perceived exertion, enjoyment scores, or adverse effects between the two exercise durations.

This study aimed to observe the response of the outcomes HR and RPE while the participants were performing physical activity through video games. Both outcomes progressively increased as the training session advanced, allowing for an observation of the participants' training intensity. The average workout of both groups was moderate in intensity, taking into account the RPE of the participants which exceeded the 10.8 points established for moderate intensity [11,31]. Exercising at this range of intensities has been shown to have positive effects on different functional and physical outcomes in adults, especially those who are less active [32,33].

Studies have shown that video games can foster enjoyment and satisfaction among older adult participants [4,34]. However, the connection between this enjoyment and the perceived exertion during exercise (RPE) is less clear. McAuliffe's research findings align with ours in showing that as the intensity of physical activity increases, older adults tend to report lower positive affective responses meaning they feel less enjoyment or satisfaction as they exert more [35]. Contrarily, studies by Glen and Röglin found that higher-intensity levels achieved through video games led to greater enjoyment and satisfaction, but these studies focused on younger participants and did not examine the link between intensity and perceived exertion in detail [36,37].

To explain these varied findings, theories like Ekkekakis' dual-mode model and attentional models, such as Tenenbaum's social-cognitive model of attention and Leventhal and Everhart's parallel processing model, offer valuable insights. While these theories differ, they all suggest that as exercise intensity rises and disrupts physiological homeostasis, the body's physical response can overpower one's cognitive or attentional focus. In other words, when intensity reaches a threshold that the body perceives as strenuous, it becomes harder to concentrate on positive distractions, resulting in less enjoyment. If the intensity remains below this threshold however, individuals are able to maintain a positive outlook and avoid focusing on the sensation of exertion, which leads to an increased sense of enjoyment [38–40].

Previous research has indicated that enjoyment levels—whether low or high—can significantly impact a person's willingness to adhere to an exercise routine. Low enjoyment acts as a barrier, discouraging consistent participation, while high enjoyment serves as a facilitator, encouraging regular engagement. Thus, implementing interventions that successfully promote enjoyment, such as those involving video games could play a critical role in supporting adherence to healthier lifestyle habits over the long term [20,21].

The total training time showed a weak to moderate correlation with the occurrence of adverse effects. While training duration serves as one measure of the external training load, a stronger correlation appears when assessing the internal training load through perceived exertion (RPE). Since training times varied between groups, the primary factor influencing overreaching symptoms was not the duration alone but rather the intensity of exercise performed within that duration. These findings align with research on football players, where training load was closely associated with indicators of fatigue and delayed-onset muscle soreness (DOMS) reported in the wellness questionnaire [41]. Another study involving football players reported a similar relationship between training dose and delayed-onset muscle soreness (DOMS). This study also examined other metrics to assess when adverse effects like DOMS, appeared. One such metric was the amount of time players spent exercising at an intensity above 80% of their maximum heart rate (HR max), which provided additional insight into how training intensity contributes to muscle soreness and fatigue [42].

4.1. Implications for Practice and Future Research

Monitoring both external and internal exercise doses can support optimized exercise prescription, especially for patients who commonly have comorbidities limiting their physical and functional capacities. Overreaching in these cases could temporarily worsen functional issues due to acute effects like strength loss or changes in other wellness indicators [43].

This study indicates that higher-intensity exercise through video games results in lower enjoyment. As such, video games might be better suited for lower-intensity activities such as warm-ups. However it remains uncertain whether traditional exercise or video game-based exercise offers greater satisfaction when matched for intensity.

Future research could investigate what contributes more to enjoyment or satisfaction in adults—conventional exercise or video game-based exercise. Additionally, studies might examine the effects of these different interventions on physical and functional outcomes in older adults, using the 28-min session length from this study, which has proven to be as well tolerated as shorter sessions.

4.2. Study Limitations

A primary limitation of this study is its small sample size of 32 participants, which may affect the robustness of the findings and the effectiveness of the intervention. The participants formed a highly heterogeneous group with varying physical and functional issues, and age differences between groups approached statistical significance ($p = 0.06$), potentially impacting results—particularly in Group I, where perceived exertion (RPE) could tended to be higher.

Furthermore, the study included only a single training session and a brief testing period for the video games, leaving it unclear how enjoyment and satisfaction might evolve over a longer intervention period. Previous research has indicated that individuals with no prior experience in video games tend to experience greater enjoyment than those with experience; this is a limitation [44]. Although this is a limitation, this is the first study to compare different exercise doses through an augmented reality exergame.

Additionally, although participants tolerated the interventions well and no serious adverse effects were observed, further and longer research is needed to better assess potential adverse effects in exergaming interventions.

Another study limitation is the approach to exercise prescription, which ideally should be tailored to each participant to control intensity. In this case, participants self-selected their exercise intensity, potentially introducing variability in the prescribed intensity across individuals.

5. Conclusions

This study found no significant differences in heart rate between the two intervention durations (13 min vs. 28 min) in an augmented reality exergame. Additionally, a weak correlation was observed between perceived exertion and enjoyment, and there was no correlation between total time and adverse effects. These findings cautiously suggest that a longer exergaming session (28 min) may help achieve moderate physical intensity in older patients, potentially allowing them to tolerate it and with some level of enjoyment.

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Informed Consent Statement: Informed consent was obtained from all the subjects involved in the study.

Data Availability Statement: The data presented in this study are available at the request of the corresponding author for privacy and ethical reasons.

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Conflicts of Interest: The authors declare that they have no conflicts of interest.

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