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ORIGINAL

Registered exergame and serious game trials with Latin American sites: study design and results reporting

Ensayos registrados de exergames y juegos serios con sedes latinoamericanas: diseño y notificación de resultados

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ABSTRACT

Introduction: Reviews of exergame and serious game trials rarely state where the trials took place or how they were registered. This study described the design, population, conditions and outcome definitions of registered trials with Latin American sites and estimated how often their records show prospective registration and posted results. Methods: Cross-sectional analysis of interventional ClinicalTrials.gov records first submitted between 2011 and 2023 with sites in 24 Latin American and Caribbean countries. Wilson 95% confidence intervals and exploratory Fisher exact tests were used. Results: Of 51 records, 40 were eligible (31 exergame and 9 serious game trials). Brazil hosted 33 trials, 82.5% were randomized, and the median sample size was 48.5. Registration preceded or matched the study start month in 45.0% of trials (95% CI 30.7-60.2), and results were posted for 5.0% (95% CI 1.4-16.5). Serious game trials included children more often than exergame trials (78% versus 23%; Fisher exact p = 0.004). Conclusions: Registered trials with Latin American sites were few, small and concentrated in Brazil, and their records offered little information on results. Prospective registration, results posting and linkage of publications would make these trials easier to find, appraise and combine.

Keywords: video games; serious game; clinical trials as topic; registries; Latin America.

RESUMEN

Introducción: Las revisiones de ensayos de exergames y juegos serios rara vez indican dónde se realizaron o cómo se registraron. Se describieron el diseño, la población, las condiciones y los desenlaces de los ensayos registrados con sedes latinoamericanas, y se estimó la frecuencia de inscripción prospectiva y de resultados publicados. Métodos: Análisis transversal de registros intervencionales de ClinicalTrials.gov enviados entre 2011 y 2023 con sedes en 24 países de América Latina y el Caribe. Se usaron intervalos de Wilson al 95 % y pruebas exactas de Fisher exploratorias. Resultados: De 51 registros, 40 fueron elegibles (31 ensayos de exergames y 9 de juegos serios). Brasil albergó 33 ensayos, 82,5% fueron aleatorizados y la mediana del tamaño muestral fue 48,5. La inscripción fue anterior o coincidió con el mes de inicio en 45,0% de los ensayos (IC 95 %: 30,7-60,2) y se publicaron resultados en 5,0% (IC 95 %: 1,4-16,5). Los ensayos de juegos serios incluyeron niños con más frecuencia que los de exergames (78% frente a 23%; prueba exacta de Fisher, p = 0,004). Conclusiones: Los ensayos registrados con sedes latinoamericanas fueron pocos, pequeños y concentrados en Brasil, con poca información sobre resultados. La inscripción prospectiva, la publicación de resultados y el enlace de las publicaciones facilitarían encontrarlos, valorarlos y combinarlos.

Palabras clave: videojuegos; juegos serios; ensayos clínicos como asunto; sistema de registros; América Latina.

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INTRODUCTION

Calcaterra et al.(1)defined exergames as digital games that require bodily movement to play, so that the game itself works as a form of physical activity. Damaševičius et al.(2)used the term serious game for a game designed for a primary purpose other than entertainment, such as education, training or health promotion. The two terms overlap in clinical research, because a console game that asks a stroke survivor to reach for virtual objects can carry either label. In this study an exergame is a movement-based game used as exercise or rehabilitation, and a serious game is a digital game built for education, cognitive or motor training, assessment, therapy or distraction.

Most of the evidence on exergames comes from syntheses of randomized trials. Ren et al.(3) pooled 23 studies of virtual reality games in older adults with impaired balance, and Lapierre et al.(4) pooled 27 randomized trials with 1415 participants to estimate the effect of exergame-assisted rehabilitation on fall rate and fall risk. For Parkinson disease, Chuang et al.(5) ran a network meta-analysis of 23 trials with 949 participants and found that exergames and virtual technology-assisted rehabilitation were associated with better balance and gait than usual treatment. Wang et al.(6) compared exercise modalities across 60 trials with 3537 participants in a network meta-analysis and reported that exergaming improved Timed Up and Go time (SUCRA 91.5%). Children have received attention too: Tobaiqi et al.(7) reviewed exergaming in cerebral palsy, and Chen et al.(8) analysed 11 experimental studies with 508 children for executive functions.

The evidence on serious games covers more varied purposes. Kim et al.(9) analysed 17 studies with 1280 older adults to examine serious games for depression, and Saragih et al.(10) restricted their meta-analysis to 12 randomized trials in people with dementia. Thangavelu et al.(11) synthesised 22 experimental studies of digital serious games for nursing clinical competence, and Tori et al.(12) found that tasks, score and level progression were the game elements most often used in health education games. A Brazilian example is the InsuOnline trial of Diehl et al.,(13) who randomized primary care physicians to an electronic game or to a traditional continuing education session on insulin therapy.

These reviews seldom state where the underlying trials took place, yet trials of both kinds are conducted in Latin America. Saposnik et al.(14) enrolled patients with ischaemic stroke in 14 inpatient units in Canada, Argentina, Peru and Thailand, da Cruz et al.(15) tested virtual reality in maintenance cardiac rehabilitation in Brazil, and Junior et al.(16) recruited stroke survivors at a university hospital in Salvador, Brazil. Furtado et al.(17) identified 94 studies of physical therapy for Brazilian children with cerebral palsy, of which 67% had low levels of evidence and appeared in journals without an impact factor. Their scoping review shows the volume of regional work and the weakness of its evidence, but it does not cover game-based interventions in particular.

How such trials are registered and reported is a separate question. Silva et al.(18) sampled physiotherapy trials published in 2019 and found that 63% were registered, 18% prospectively, and that selective outcome reporting occurred in 73% of those in which it could be assessed. Alayche et al.(19) analysed Canadian trials in ClinicalTrials.gov and reported that 59% were registered prospectively and 39% posted results in the registry. Taylor and Gorman (20) found that 68 of 136 behavioral health trials were prospectively registered. None of these authors examined exergame or serious game trials, and none addressed trials with Latin American sites, so the registry profile of this research field in the region remains undescribed.

The objective of this study was to describe the design, population, condition and outcome definitions of interventional exergame and serious game trials registered in ClinicalTrials.gov between 2011 and 2023 with at least one site in Latin America, and to estimate how often their registry records show prospective registration and posted results, overall and by intervention type.

METHODS

The study was a cross-sectional analysis of trial registry records. It follows the registry-based approach of Alayche et al.,(19)who assessed prospective registration and result reporting in the registry for trials listed in ClinicalTrials.gov, and the unit of analysis is the registered trial. The reporting was guided by the items of the STROBE statement that apply to a study of registry records, and no participants were contacted.

Records were obtained from the ClinicalTrials.gov Data(21)with a single paginated query. The query combined interventional study type, first submission to the registry between 2011 and 2023, and a text search for the terms exergame, exergaming, exer-game, active video game, Nintendo Wii, Wii Fit, Xbox Kinect, Kinect, dance dance revolution, serious game, game-based, gamified,

video game, videogame and virtual reality game. The location filter listed 24 countries and territories: Argentina, Belize, Bolivia, Brazil, Chile, Colombia, Costa Rica, Cuba, the Dominican Republic, Ecuador, El Salvador, French Guiana, Guatemala, Guyana, Haiti, Honduras, Mexico, Nicaragua, Panama, Paraguay, Peru, Suriname, Uruguay and Venezuela. Puerto Rico was left out because it is a territory of the United States. The data correspond to the snapshot available from the public API, which requires no registration or login.

A record was eligible when at least one specified intervention was an exergame or a serious game under the definitions given in the Introduction and when at least one listed site was in the countries above. Records were excluded when the only game element was a gamified application without a game, when the trial treated video game addiction, when the intervention was a sport or physical programme without a digital game, when the trial was surgical or pharmacological and had been retrieved by a keyword, when the intervention was robotic device training, when commercial video games served only as a placebo comparator, or when a video game was one unspecified component of a multicomponent mobilization protocol.

Registry variables were read directly from the records. They comprised the year of first submission, the study start date, the listed site countries and number of sites, the lead sponsor class, the enrolment count, allocation, intervention model, masking, phase, overall status, the standard age groups and the conditions. Conditions were grouped into six domains by keyword rules: neurological, cardiometabolic or respiratory, ageing, neurodevelopmental or sensory, musculoskeletal or pain, and perioperative anxiety. The platform was recorded as mentioned when the title, summary or intervention text named a Nintendo Wii or a Microsoft Kinect or Xbox system.

Each trial counted once through its registry identifier, and countries were counted once per record from the listed locations, so a trial with several sites in one country contributed one country. The lead sponsor class is the category assigned by the registry, where the class other covers universities, hospitals and similar organizations and the class individual covers investigator-sponsored records. Enrolment is the number listed in the record, whether estimated or actual, because the enrolment type was not used to exclude records. A trial was said to include children when the child age group was listed in the eligibility module. Masking was treated as present when any level other than none was declared, and the phase was treated as not applicable when the record listed no drug phase.

The distinction between prospective and retrospective registration follows Haslberger et al.,(22)who treated registration after the start of the study as retrospective. A trial was classified as prospectively registered when its first submission fell in the same month as the study start or earlier. For retrospectively registered trials, the lag was the number of months between the start month and the first submission month. Prospective registration was assessed in the 40 eligible trials because every one of them listed a start date.

Outcome definition indicators covered the number of primary outcomes, the presence of a time frame for every primary outcome, the presence of a free-text description for every primary outcome, the number of secondary outcomes, and the domain of the first listed primary outcome. The domain was assigned by keyword rules applied to the outcome title and description. These indicators describe the completeness of the registry entry. They do not test whether the published outcomes differ from the registered ones, which is the comparison made by Holst et al.(23)and Siddiqi et al.(24)and which would require locating each article.

Results reporting was read from the registry flag that marks records with posted results, and linked publications were read from the references section of each record, separating references typed as results from other types. Following Diakonoff et al.,(25)who examined completed, discontinued and unknown-status trials separately, the status of each trial was tabulated, and a second analysis of results posting was restricted to completed or terminated trials whose primary completion year was 2021 or earlier, to allow at least one year between completion and the end of the registration window.

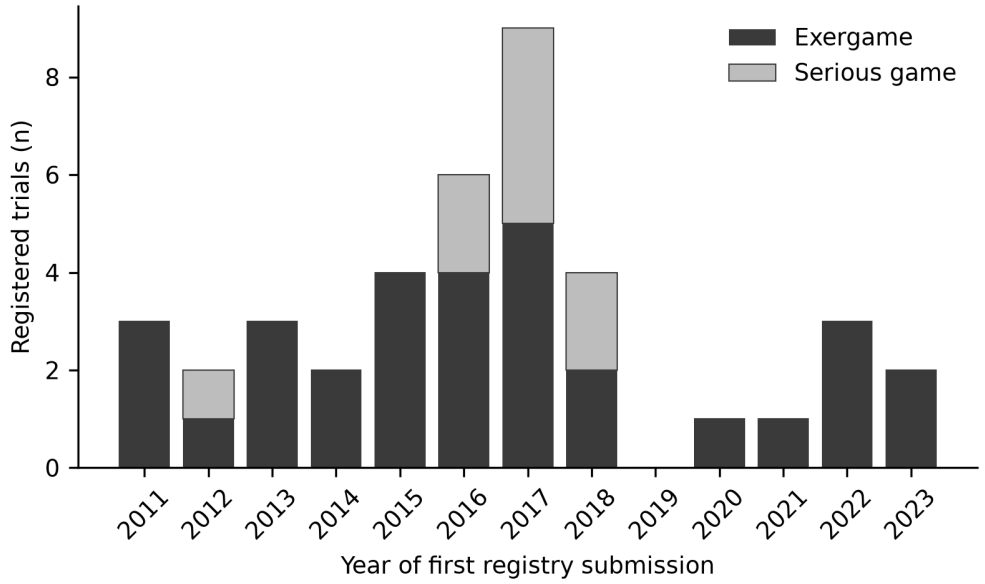
Categorical variables are presented as counts and percentages, and proportions carry Wilson 95% confidence intervals. Continuous variables are presented as medians with interquartile ranges because the sample size distribution was right-skewed. Exergame and serious game trials were compared with the Fisher exact test for randomization, masking, inclusion of children, prospective registration and results posting. These tests are exploratory, no correction for multiplicity was applied, and the significance level was 0.05.

The study used publicly available registry records and did not involve human participants or the collection of new data, so no ethical review was sought.

RESULTS

The registry query returned 51 interventional records, and 40 met the eligibility rules after 11 exclusions. Gamified applications without a game accounted for 3 exclusions, and the other 8 were mostly surgical, drug or non-game programme trials retrieved by keyword. Exergames accounted for 31 trials (77.5%) and serious games for 9 (22.5%). First submissions ranged from 2011 to 2023, with 29 trials registered in 2011 to 2017 and 11 in 2018 to 2023, and the peak year was 2017 with 9 trials (Figure 1).

Figure 1. Registered exergame and serious game trials with Latin American sites by year of first registry submission.



Note: Bars are stacked by intervention type. Years without bars had no eligible registration.

Sites were located in 7 Latin American countries. Brazil hosted 33 trials, 32 of them with Brazilian sites only, followed by Mexico(3), Chile(2), and one trial each in Argentina, Bolivia, Costa Rica and Peru. Single-site trials numbered 36, 2 trials listed sites in more than one country, and the largest network had 13 sites. The lead sponsor was classed as other, a category that includes universities and hospitals, in 39 trials, and as an individual in one trial. No trial had an industry lead sponsor.

Records named a specific platform or game in 35 trials, and 5 described the intervention only in general terms. The word virtual appeared in the title of 21 trials, and 19 of these described a console system based on Wii, Kinect or Xbox.

Neurological conditions were the largest domain, with 19 trials. Parkinson disease appeared in 7 trials, stroke or cerebrovascular disorders in 6, and cerebral palsy or hemiplegia in 3. The record text named a Nintendo Wii in 12 trials and a Microsoft Kinect or Xbox system in 19. Children were among the eligible participants in 14 trials (35.0%), and the share was higher in serious game trials (7 of 9) than in exergame trials (7 of 31; Fisher exact p = 0.004) (Table 1).

Randomized allocation was recorded for 33 trials (82.5%; 95% CI 68.0-91.3), non-randomized allocation for 4 and no allocation for 3. Parallel-group designs numbered 31, crossover designs 4 and single-group designs 3. Masking of at least one party was declared in 22 trials (55.0%), and the share was lower in serious game trials (22%) than in exergame trials (65%; Fisher exact p = 0.053). The phase was not applicable in 39 trials.

The enrolment listed in the registry had a median of 48.5 participants (IQR 32 to 76), with a range of 13 to 170 and a total of 2,351 participants across the 40 trials. Enrolment was below 50 participants in 21 trials (52.5%) and reached 100 or more in 6. Serious game trials had a larger median enrolment (100; IQR 60 to 120) than exergame trials (40; IQR 27 to 60). Randomization did not differ by intervention type (p = 0.645, Fisher exact test).

Table 1. Characteristics of registered exergame and serious game trials with Latin American sites by intervention type.

Characteristic	All trials (n = 40)	Exergame (n = 31)	Serious game (n = 9)
Registered 2011-2017, n (%)	29 (72.5)	22 (71.0)	7 (77.8)
Registered 2018-2023, n (%)	11 (27.5)	9 (29.0)	2 (22.2)
Brazil as the only Latin American country, n (%)	32 (80.0)	25 (80.6)	7 (77.8)
Sample size, median [IQR]	48 [32-76]	40 [27-60]	100 [60-120]
Randomized allocation, n (%)	33 (82.5)	26 (83.9)	7 (77.8)
Any masking, n (%)	22 (55.0)	20 (64.5)	2 (22.2)
Participants include children, n (%)	14 (35.0)	7 (22.6)	7 (77.8)
Condition domain, neurological, n (%)	19 (47.5)	16 (51.6)	3 (33.3)
Condition domain, cardiometabolic or respiratory, n (%)	7 (17.5)	6 (19.4)	1 (11.1)
Condition domain, ageing, n (%)	6 (15.0)	5 (16.1)	1 (11.1)
Condition domain, neurodevelopmental or sensory, n (%)	4 (10.0)	1 (3.2)	3 (33.3)
Condition domain, musculoskeletal or pain, n (%)	3 (7.5)	3 (9.7)	0 (0.0)
Condition domain, perioperative anxiety, n (%)	1 (2.5)	0 (0.0)	1 (11.1)
Status, completed, n (%)	29 (72.5)	23 (74.2)	6 (66.7)
Status, unknown, n (%)	9 (22.5)	7 (22.6)	2 (22.2)
Status, recruiting, n (%)	1 (2.5)	0 (0.0)	1 (11.1)
Status, terminated, n (%)	1 (2.5)	1 (3.2)	0 (0.0)

Note: IQR = interquartile range. Percentages use the number of trials in each column as denominator. Sample size is the enrolment listed in the registry.

Primary outcomes numbered one in 28 trials and more than one in 12, with 7 trials listing three or more and a maximum of 11. Every primary outcome had a stated time frame in all 40 trials, and every primary outcome carried a description beyond its title in 37 trials (92.5%; 95% CI 80.1-97.4). The first listed primary outcome belonged to the motor function domain in 12 trials, to balance, gait or mobility in 11, and to cardiorespiratory function or body composition in 10. Anxiety was the first primary outcome in 2 trials, and 9 trials listed no secondary outcome.

Registration preceded or matched the study start month in 18 of 40 trials (45.0%; 95% CI 30.7-60.2), which leaves 22 retrospectively registered trials. Their registration lag had a median of 10 months (IQR 6 to 18) and exceeded 12 months in 8, with a maximum of 33 months. Prospective registration was found in 10 of 29 trials registered in 2011 to 2017 (34.5%) and in 8 of 11 trials registered in 2018 to 2023 (72.7%). Intervention type made no difference (exergames 14 of 31, serious games 4 of 9; p = 1.000).

Table 2. Registration timing, outcome definition and results reporting indicators.

Indicator	n/N	% (95% CI)
Prospective registration	18/40	45.0 (30.7-60.2)
Single primary outcome	28/40	70.0 (54.6-81.9)
Primary outcome time frame stated	40/40	100.0 (91.2-100.0)
Primary outcome described beyond its title	37/40	92.5 (80.1-97.4)
At least one secondary outcome	31/40	77.5 (62.5-87.7)
Linked publication of any type	23/40	57.5 (42.2-71.5)
Results posted, all trials	2/40	5.0 (1.4-16.5)
Results posted, completed or terminated trials with primary completion by 2021	2/28	7.1 (2.0-22.6)
No posted results and no linked results publication, same subset	23/28	82.1 (64.4-92.1)

Note: CI = Wilson confidence interval. Prospective registration means first submission in the same month as the study start or earlier. The last two rows use completed or terminated trials with primary completion by 2021.

The overall status was completed for 29 trials and unknown for 9. Results were posted in the

registry for 2 trials (5.0%; 95% CI 1.4-16.5), both of them exergame trials, and for none of the serious game trials. Among the 28 completed or terminated trials with primary completion by 2021, 2 had posted results (7.1%; 95% CI 2.0-22.6). A linked publication of any type was listed for 23 trials (57.5%), and a publication typed as results for 5. In the same subset of 28 trials, 23 (82.1%) had neither posted results nor a linked results publication (Table 2).

DISCUSSION

The registry records describe a small set of exergame and serious game trials with Latin American sites. Most were single-site randomized trials of exergames led by academic sponsors, concentrated in Brazil, enrolling around fifty participants and addressing neurological conditions or ageing. Fewer than half were registered by the month the study began, and posted results were present for only a very small share of trials. These features agree with part of the registration literature and diverge from it where authors sampled trials in a different way, as the comparisons below show.

The Brazilian concentration is the clearest pattern. Furtado et al.(17)found 94 studies of physical therapy in Brazilian children with cerebral palsy and reported that two thirds had low levels of evidence, a profile of many small studies that our records resemble. Diakonoff et al.(25)reported that oral health trials conducted in Brazil had higher odds of publication, which suggests that Brazilian investigators use ClinicalTrials.gov enough to make the country visible in it. Brazilian trials may also be entered elsewhere, as Zeigelboim et al.(26)show with a Wii-based protocol that carries a number from the Brazilian clinical trials registry. The Brazilian share seen here is therefore best read as a floor for the country and not as its share of the region. The text search also relied on terms that investigators choose, and a combined search of ClinicalTrials.gov, the WHO International Clinical Trials Registry Platform and the Brazilian registry would raise coverage.

The only multinational network in the records is the one described by Saposnik et al.,(14)who randomized 141 patients in 14 units, among them one in Argentina and one in Peru. Their design contrasts with the usual record in our data, which resembles the trials of Henrique et al.(27)with 31 participants and Gouveia e Silva et al.(28)with 39. Saposnik et al. found that both the Wii group and the recreational activity group shortened their Wolf Motor Function Test time, so a comparison between an exergame and an active comparator has to detect a difference on top of the improvement in each arm. Trials of fifty participants have little precision for such a difference, a limitation that cannot be removed by the registry data alone and that argues for pooled protocols across sites.

For Parkinson disease, the most frequent single condition in our records, the literature does not agree on the position of exergames. Chuang et al.(5)found better balance and gait with exergames and virtual technology-assisted rehabilitation than with usual treatment, and Wang et al.(6) reported improved Timed Up and Go time with exergaming (SUCRA 91.5%) among 60 trials. Rocha et al.(29)reached a more guarded position in an overview of systematic reviews, noting that no consensus exists on whether exergaming beats conventional physical therapy. Marotta et al.(30) added that the evidence for cognitive function remains weak. The disagreement among these authors seems to arise from the outcome chosen and the comparator, and a registry that records an unambiguous primary outcome and a named comparator would let reviewers anticipate it.

In stroke and cerebral palsy, the records fit the interest shown by reviewers and trialists elsewhere. Duta et al.(31)reviewed exergames for cognitive impairment after stroke in older adults, Peláez-Vélez et al.(32)randomized 24 patients to physiotherapy with or without a virtual reality programme, and Junior et al.(16)compared proprioceptive neuromuscular facilitation with Wii games and with their combination in 48 participants in Brazil. Protocols such as the one of Bessa et al.(33) on postural balance and the one of Mazzini et al.(34)on real and virtual environments show that the same question is being posed with planned samples of 36 and 42 participants, close to the median of our records. Tobaiqi et al.(7)named motivation as the reason for choosing exergaming in children with cerebral palsy, an argument that the registry fields cannot test.

Older adults appear in the records through the ageing category and through disease-specific trials. Ren et al.,(3)Leal et al.(35)and Lapierre et al.(4)pooled 23, 20 and 27 studies, respectively, and Chen et al.(36)added a meta-analysis restricted to long-term care facilities. The Brazilian trial of dos Santos et al.(37)with 22 elderly women and a Kinect dance game is typical of what the region contributes, a small community-based study. Because the ageing category in our grouping excluded trials of named diseases such as Parkinson disease or stroke, older participants are present in many more records than the category suggests, and the difference between the review literature and our records may be one of classification. An established condition classification applied by two

coders would remove the dependence of these counts on the order of the keyword rules.

Children were more often included in serious game trials than in exergame trials, and this difference was the only one among our comparisons that reached the conventional level. Vacca et al.(38) reviewed serious games in neurodevelopmental disorders, and Simon-Martinez et al.(39) designed a crossover trial of stereoptic serious games for residual amblyopia, so the link between games and paediatric visual or developmental conditions is established outside the region. In exergame research Cavalcante Neto et al.(40) randomized 32 children with developmental coordination disorder, Lee and Jin (41) 23 children with developmental disabilities, and Suarez-Villadat et al.(42) 49 adolescents with Down syndrome. Those samples are of the same order as our median. The test was one of five and carries no correction, so the result should be read as a pointer for confirmation.

Larger samples in serious game trials fit the nature of the interventions. Diehl et al.(13)recruited primary care physicians by telephone and email in southern Brazil and allocated them to a game or a traditional session, a recruitment route that does not depend on a flow of patients. Al Kahf et al.(43)and Aster et al.(44)likewise randomized medical students, and Chagas et al.(45) randomized schools in the Federal District of Brazil in a cluster trial of 319 adolescents. Rehabilitation exergame trials draw on patients attending a service, which limits enrolment. The reading is a hypothesis, because the serious game category is heterogeneous and contains only nine trials, including motor-task games for people with neuromuscular disease and a tablet game used to distract children before anaesthesia. With so few trials the confidence intervals are wide and the comparisons cannot rule out differences of moderate size, so pooling records from other registries is the way to test them.

Labels deserve attention in their own right. The word virtual appeared in the title of about half of our trials, and most of these described commercial console systems. Peláez-Vélez et al.(32) present virtual reality and videogames as one treatment in stroke, and Radwan et al.(46)compared transcranial direct current stimulation with virtual reality training for gait in 40 children with bilateral spastic cerebral palsy. A reviewer who searches a registry for exergames will miss trials labelled virtual reality, and one who searches for virtual reality will retrieve immersive headset trials such as the MOVE protocol of Fraga et al.(47)in acute decompensated heart failure, set in Brazil. Naming the platform and the game, as most of our records did, is the practice that allows these trials to be classified. Our own classification of the trials was made by an AI language model that applied written rules, so borderline records may be misplaced, and an audit by two human coders with agreement statistics should precede any reuse of the categories.

The conditions addressed by registered serious game trials differ from those that dominate the review literature. Kim et al.(9)and Saragih et al.(10)focused on depression and dementia, and Vacca et al.(38)on neurodevelopmental disorders, whereas none of the nine serious game trials listed depression or dementia as a condition. Thangavelu et al.(11)and Tori et al.(12)covered the education of health professionals, which our records represent with the InsuOnline trial. Diehl et al.(48)published the design of that trial before the results article,(13)an example of traceability from protocol to report that registry indicators alone do not capture.

Pilot and confirmatory work share the same registry fields. The Costa Rican record names the game Bootle Blast for home rehabilitation of children with hemiplegic cerebral palsy and lists 15 participants. Chan-Víquez et al.(49)studied the same game in four children over 12 weeks at home in a mixed methods case series, and Shih et al.(50)describe a later stage in which a Kinect-based constraint-induced program was compared with therapist-based therapy in children with unilateral cerebral palsy. A reader of the registry cannot tell a feasibility study from a definitive trial unless the record says so, which weakens any count of trials by size.

Combination designs add another difficulty. Vojciechowski et al.(51) combined Wii Fit Plus training with protein supplementation in five groups, Kunitake et al.(52) added transcranial direct current stimulation to video game balance training, and Bezerra et al.(53) paired pelvic floor training with game therapy in 32 women. In such trials the game is one component, and a keyword search retrieves the record only if the registrant mentions it. The records we excluded because a game was one unspecified component of a protocol belong to the same family of designs.

Games also act as an exposure in the region, and this affects how trials are justified. Custódio et al.(54)surveyed 495 adolescents in Curitiba and reported that one in five used exergames while 55.5% did not reach recommended levels of physical activity. Chagas Brandão et al.(55)found that 85.85% of 3939 Brazilian eighth-grade students had played video games in the past year and 28.17% met their criteria for problematic use. Calcaterra et al.(1)described exergames as a possible strategy against weight gain in children with obesity, a purpose present in our records of overweight children. These surveys do not show that trials of game-based interventions are justified, but they show that the population exposed to games is large.

Registration timing is the point on which the literature differs most from our result. Silva et al.(18)reported that 18% of physiotherapy trials published in 2019 were prospectively registered, while Alayche et al.(19)found 59% among Canadian trials registered in ClinicalTrials.gov. Our estimate of 45% sits between them. The two authors sampled differently, since Silva et al. started from published articles and searched for registrations, which favours trials that were registered at all, and Alayche et al. started from registry records, as we did. Haslberger et al.(22)found that 53.7% of German trials with a results publication were registered retrospectively, a share close to the retrospective share in our records, even though they limited their sample to trials with a publication.

The improvement over time deserves comment. Silva et al.(18)reported that prospective registration in physiotherapy trials rose from 6% in 2009 to 18% in 2019, and our records point in the same direction, since the proportion rose between the 2011-2017 and 2018-2023 registration periods. Imam et al.(56)and Taylor and Gorman(20)describe low prospective registration in shoulder arthroplasty and behavioral health trials, so the problem is not unique to game-based research. The time trend in our data comes from small groups of trials, and a registry cannot tell whether the change reflects journal policies, funder requirements or the composition of the groups.

Outcome definitions were complete on the fields the registry form demands. All records stated a time frame, and most described each primary outcome beyond its title. Mello et al.(57) reached a more critical conclusion for nutrition trials, 69% of which were registered but often lacked a sufficient specification of outcomes and intended treatment effects. The discrepancy comes from the standard applied: Mello et al. required elements such as the metric and the method of aggregation, whereas we counted the presence of a time frame and a description. Our indicator therefore overstates completeness relative to their standard, and a reanalysis with their elements would be a direct way to compare the fields.

Selective reporting is the next step that registry records alone cannot settle. Siddiqi et al.(24) found inconsistencies in 13% of heart failure trials published in high-impact journals, Syed et al.(58) found a low risk of outcome reporting bias in stroke trials that had a registry record or protocol but could locate a record in only one fifth of their sample, and Liu et al.(59)compared registrations and publications in nursing journals. Holst et al.(23)added that the history of registry entries reveals changes that the last version hides. We examined the current entry only, and our trials with a linked publication are the natural sample for a comparison with the published outcomes.

Posting of results was the weakest indicator. Alayche et al.(19)found that 39% of Canadian trials reported results in the registry, and our figure is far lower. Part of the gap is regulatory, because Zarin et al.(60)described a rule that makes results submission mandatory for a defined class of trials regulated in the United States, a class that academic trials with Latin American sites only are unlikely to belong to. Part of it may be a matter of habit, since Diakonoff et al.(25)found that more than half of the oral health trials in their sample were unpublished. Salholz-Hillel et al.(61)showed for COVID-19 trials that results travel through registries, preprints and journal articles, which is why we also counted linked publications. Even so, most completed trials in our subset had neither route documented. The results flag reflects the registry as it stood when the data were drawn and cannot capture later postings, which repeated extractions at fixed intervals would reveal.

For practice, the findings support three actions by trialists in the region: registering before the first participant is enrolled, naming a single primary outcome with its measurement method and time point, and posting results or linking the results article to the record. Journals and funders can ask for the registration date to be stated in the article, as Haslberger et al.(22)found that retrospective registration is seldom disclosed or explained. Reviewers of exergame and serious game trials can use the registry to find studies that have not been published, following the nonpublication problem that Diakonoff et al.(25)documented in another field.

CONCLUSIONS

The registered exergame and serious game trials with Latin American sites were few, mostly single-site randomized trials of exergames in neurological and ageing conditions, concentrated in Brazil and small in sample size, with serious game trials larger and more often including children. Their registry entries defined primary outcomes with a time frame and, in most cases, a description, but fewer than half were registered by the month the study began. Posted results were rare in both intervention types, and linking publications to the records, registering before enrolment and posting results would make this research easier to find and to combine.

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