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² Clinical feasibility of interactive motion-controlled ³ games for stroke rehabilitation

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10 Abstract

Background: Active gaming technologies, including the Nintendo Wii and Xbox Kinect, have become increasingly popular for use in stroke rehabilitation. However, these systems are not specifically designed for this purpose and have limitations. The aim of this study was to investigate the feasibility of using a suite of motion-controlled games in individuals with stroke undergoing rehabilitation.

Methods: Four games, which utilised a depth-sensing camera (PrimeSense), were developed and tested. The 15 games could be played in a seated or standing position. Three games were controlled by movement of the torso 16 and one by upper limb movement. Phase 1 involved consecutive recruitment of 40 individuals with stroke who 17 were able to sit unsupported. Participants were randomly assigned to trial one game during a single session. 18 Sixteen individuals from Phase 1 were recruited to Phase 2. These participants were randomly assigned to an 19 intervention or control group. Intervention participants performed an additional eight sessions over four weeks 20 using all four game activities. Feasibility was assessed by examining recruitment, adherence, acceptability and 21 safety in both phases of the study. 22

Results: Forty individuals (mean age 63 years) completed Phase 1, with an average session time of 34 min. The majority of Phase 1 participants reported the session to be enjoyable (93 %), helpful (80 %) and something they would like to include in their therapy (88 %). Sixteen individuals (mean age 61 years) took part in Phase 2, with an average of seven 26-min sessions over four weeks. Reported acceptability was high for the intervention group and improvements over time were seen in several functional outcome measures. There were no serious adverse safety events reported in either phase of the study; however a number of participants reported minor increases in pain.

Conclusions: A post-stroke intervention using interactive motion-controlled games shows promise as a feasible
 and potentially effective treatment approach. This paper presents important recommendations for future game
 development and research to further explore long-term adherence, acceptability, safety and efficacy.

Q3 32 **Trial registration:** Australian and New Zealand Clinical Trials Registry (ACTRN12613000220763)

33 Background

- Stroke is a leading cause of disability world-wide [1]. 34 Common stroke-related impairments, such as loss of 35 strength, sensation and coordination, lead to difficulties 36 37 in walking [2], balance [3], and upper limb function [4]. This can have a significant impact on an individual's 38 independence, safety and quality of life [5, 6]. Therefore, 39 the implementation of effective interventions to optimise 40 recovery is critical. 41
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Physical therapy has been shown to aid recovery after 42 stroke [7–9]. A recent systematic review and meta- 43 analysis [7] demonstrates strong evidence in favour of 44 physical therapy interventions for gait training, balance, 45 upper limb function, activities of daily living and physical 46 fitness. Although the optimal dosage and type of activity 47 for improving outcomes after stroke remains unclear, 48 research generally favours intensive and repetitive task- 49 specific training [7, 9]. However, barriers such as resource 50 limitations, access to therapy, patient motivation and 51 safety may contribute to the low levels of physical activity 52 observed in hospital settings [10] and reduce long-term 53 adherence to exercise regimes. 54



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Motion-controlled video games, including the Nintendo 55 Wii and Xbox Kinect, have become an increasingly 56 common adjunct to physical therapy and show poten-57 tial as effective and feasible post-stroke treatment options 58 [11, 12]. The engaging nature of a game-based approach 59 may serve to increase motivation and repetitive practice 60 [11, 13, 14]. The variety of activities presented can allow 61 for the practice of a range of physically and cognitively 62 63 challenging tasks [14]. Furthermore, the feedback provided by gaming systems may enhance motor learning 64 and motivation [15], and allow for objective monitoring of 65 performance over time. Although few high-quality studies 66 have been published to date, Nintendo Wii-based training 67 after stroke has demonstrated improvements in upper 68 limb function [11, 16, 17] and balance [18, 19], with 69 high levels of acceptability and minimal safety concerns 70 [11, 16, 17]. The more recently released Xbox Kinect, 71 which uses a three-dimensional (3D) depth-sensing 72 camera, has not been extensively studied. One trial 73 found improvements with additional upper limb train-74 ing after stroke [12], and studies in other neurological 75 populations have demonstrated positive preliminary find-76 ings [20, 21]. 77

78 Despite the potential utility of consumer video game 79 systems for stroke rehabilitation, a number of limitations have been highlighted. Games designed for the general 80 population can be too challenging or inappropriate for 81 people with physical and cognitive deficits [22-24]. For 82 example, individuals with stroke may struggle with ma-83 nipulating controllers (e.g. Nintendo Wii remote) [24] and 84 responding to activities that are fast and visually complex 85 (e.g. Kinect Sports games) [25]. The difficulty levels and 86 control of the games are often not readily adjustable (e.g. 87 88 calibrating the Wii Balance Board for individuals with asymmetries) and the tasks may lack functional relevance 89 [24]. Furthermore, the feedback and scoring provided can 90 91 be negative and frustrating for the user [24, 25]. Therapists have highlighted desirable features of video games as 92 93 being able to record meaningful data, include a variety of games, provide positive feedback and have the ability to 94 grade the task difficulty [26]. In response to some of these 95 limitations, there has been an emergence of research and 96 development of games specifically designed for rehabilita-97 tion using components of these systems [27-29]. How-98 ever, these approaches have largely not progressed beyond 99 initial development phases with little testing undertaken 100 101 in clinical populations and settings.

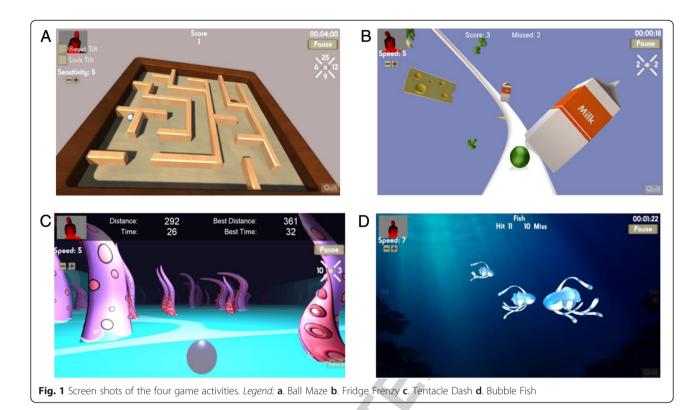
The aims of this study were therefore to: 1) develop a suite of gaming activities using a low-cost depth-sensing camera suitable for use with people affected by stroke undergoing rehabilitation; 2) investigate the usability, acceptability and safety of these activities across a broad range of people with stroke within a clinical rehabilitation setting; and 3) explore changes in clinical outcomes in people exposed to additional game-based exercises 109 compared with standard care. It was hypothesised 110 that: 1) a broad range of people with stroke would be 111 capable of using the developed games; 2) the majority 112 of participants would find the games enjoyable, help-113 ful for their recovery and something they would like 114 to continue using; 3) there would be few safety con-115 cerns. We also aimed to examine changes in functional 116 outcome measures over time to inform future efficacy 117 studies. 118

Methods

Game development

The software for the four games used for testing was de-121 veloped through collaboration between researchers, 122 physiotherapy clinicians and a game development com-123 pany, Current Circus (Melbourne, Australia). Games 124 were selected by the clinicians from a range of proto-125 types already under development and modifications were 126 made prior to implementation in Phase 1 of the study. 127 These games used a PrimeSense 'Carmine' depth camera 128 (PS1080), which was connected via USB to a laptop 129 computer with graphics displayed on a television screen. 130 The camera uses a three-dimensional depth sensor, 131 which is the same technology used in the Microsoft 132 Kinect for Xbox360 and Kinect for Windows V1, enab-133 ling the user to interact with the game environment 134 without the need for controllers or body-worn sensors. 135 The camera is able to detect a range of 0.8 to 3.5 m, 136 with an ideal distance of 2.5 m. The camera's runtime 137 software contains image processing algorithms for the 138 purpose of identifying human shapes. Following an auto-139 calibration process, ideally with the user standing facing 140 the camera, a hierarchy of skeleton joints is constructed. 141 It is able to track multiple users; however, the software 142 was limited to a single user for our purposes. The 143 skeleton data can be tracked while the user is in a seated 144 or standing position. The game activities were designed 145 to minimise inaccuracies with skeleton tracking and to 146 simultaneously trigger the desired movements of the re-147 habilitation exercises. Participants were able to interact 148 with the games whilst having physical assistance from a 149 therapist or using any wheelchair or gait aid if positioned 150 behind or to their side. The software was developed with 151 a Unity3D game engine using runtime libraries 'OpenNI' 152 and 'NITE' developed by PrimeSense. 153

The games were developed to encourage dynamic 154 balance and upper limb activities, and be adaptable to 155 users with different levels of balance, motor control and 156 perceptual problems commonly found after stroke. 157 Three of the games involved weight-shifting movements 158 of the torso and one game encouraged upper limb activ-159 ity. Screen shots of the games can be seen in Fig. 1 and 160 are described below. 161



162 (1) Ball Maze

Motion of the shoulders and hips was tracked. Leaning movements of the torso (forward, backward, left and right) resulted in tilting of the maze board. The aim was to guide the ball around the maze into the hole. The number of movements in each direction was automatically recorded by the program. Points were awarded each the ball

169 time a ball was successfully manoeuvred into the hole.

170 (2) Fridge Frenzy

171 Motion of the shoulders and hips was tracked. Lateral 172 flexion movements of the torso resulted in side-to-side 173 movement of the ball as it progressed along a track, with 174 the aim to hit the milk cartons. The number of left and 175 right movements was recorded by the program. Points 176 were displayed for the number of hits and misses.

177 (3) Tentacle Dash

178 Motion of the shoulders and hips was tracked. Move-179 ment of the torso from the initial midline position, 180 through leaning or side-stepping, resulted in side-to-side 181 movement of the ball as it progressed forwards, with the 182 aim of avoiding hitting the tentacles. If a tentacle was hit 183 the game started again. The distance travelled and time 184 taken was displayed.

185 (4) Bubble Fish

186 Motion of the wrist joint relative to the shoulder was 187 tracked. Movement of the arm resulted in bubbles shooting forwards in different directions, with the aim to hit the188fish. The fish moved in from both the left and right sides189of the screen and at different depths from the user. Points190were displayed for the number of fish hit and missed191and whether these were from the left or right side of192the screen.193

A number of attributes were considered when devel-194 oping the games to allow for maximal participant inclu-195 sion even at very early stages of rehabilitation following 196 stroke. All of the games allowed the user to interact in a 197 seated or standing posture and each had 10 levels of dif- 198 ficulty. With the exception of 'Ball Maze', difficulty levels 199 were based on required response speeds to moving vir-200 tual objects. Difficulty in 'Ball Maze' was adjusted based 201 on the sensitivity of the response of the board tilting to 202 the individual's body movement (i.e. larger movements 203 of the torso at lower levels, versus smaller and more 204 controlled movements at higher levels,). Visual distrac- 205 tions within the games were minimised as this was seen 206 as potentially too challenging, particularly for individuals 207 with cognitive and perceptual post-stroke deficits. How-208 ever, apart from 'Ball Maze' the games inherently became 209 more visually challenging as users were required to re- 210 spond more quickly to visual stimuli. Virtual objects in 211 'Tentacle Dash' and 'Bubble Fish' (i.e. tentacles and fish) 212 were randomly generated at the beginning of each game 213 so that the movement was not predictable. Conversely the 214 'Fridge Frenzy' had a set pattern of objects over a period 215 of time that looped and the 'Ball Maze' had four variations 216

217 based on the orientation of the maze board that were 218 randomly presented.

Features were built into the games to allow for object-219 ive monitoring and feedback on performance. All four 220 games had scoring and time counts as previously de-221 scribed. Additionally, a small depth representation of the 222 user could be seen in the upper left corner (Fig. 1). This 223 224 allowed immediate feedback on movement; however, given the focus on the game activity it was unlikely to be 225 used as a key feedback mechanism. Simple auditory 226 feedback was provided in each game in response to either 227 successful or unsuccessful movements or 'hits'. 228

229 Phase 1: Initial feasibility testing

Forty adults with stroke were consecutively recruited 230 from inpatient and outpatient services at a single re-231 habilitation facility in Melbourne, Australia, from August 232 2012 to April 2013. Eligible participants were adults with 233 haemorrhagic or ischaemic stroke who were able to sit 234 unsupported for greater than 10 s (Motor Assessment 235 Scale - Sitting Balance ≥ 2 [30]). Individuals were exclu-236 ded if they had severe dysphasia, significant cognitive 237 deficits (Mini-Mental State Examination < 20 [31]), other 238 239 medical conditions (e.g. progressive neurological condition, severe arthritis, unstable heart condition) impacting 240 on their ability to participate in the study, or visual 241 problems such that they weren't able to adequately see 242 the games when displayed on the television screen. 243 244 There were no restrictions in regard to the length of time since stroke. All participants were receiving concurrent 245 therapy, at various intensities, either though the inpatient 246 or outpatient rehabilitation services. Ethical approval was 247 obtained from the Melbourne Health Research Ethics 248 Committee (ID: 2011.210) and written informed consent 249 obtained from all participants. 250

Demographic information and stroke details were 251 collected at baseline, in addition to the Functional 252 Independence Measure (transfers, walking and stairs) 253 [32], Motor Assessment Scale [30] and the Functional 254 Reach [33]. Feasibility outcomes addressed: 1) recruitment 255 rate and willingness to participate; 2) adherence, through 256 documentation of session attendance and length; 3) ac-257 ceptability, using 5-point Likert scales [34] to rate enjoy-258 259 ment (from 1: "really didn't enjoy" to 5: "really enjoyed" in response to "I enjoyed my treatment session") and per-260 ceived helpfulness (from 1: "really not helpful" to 5: "really 261 262 helpful" in response to "I thought my session today was helpful for my recovery"), and 'yes/no' response for con-263 tinued use of the game; and 4) safety, through documenta-264 tion of any adverse events, including pre- and post-session 265 ratings of pain and fatigue using an 11-point vertical visual 266 267 analogue scale (VAS) [35, 36] and a post-session rating of perceived exertion using the Borg scale (rated 6-20) [37]. 268 269 Serious adverse events were classified as falls or any safety events requiring medical attention. Furthermore, any sub-
jective reports of other symptoms were recorded. Finally,
participants were asked to give feedback during each ses-
sion to provide further information in regard to accept-
ability and suggestions for improvements and this was
recorded by the treating therapist.270

Stratified block randomisation was used to allocate 276 each participant to one of the four gaming activities. 277 Each participant completed one gaming activity during a 278 single session, under the supervision of a physiotherapist. The protocol involved participants completing all 10 280 levels of the game, first in sitting, then in standing as 281 able, with each level lasting approximately one minute. 282

Phase 2: Pilot randomised controlled trial

Of the 40 participants in Phase 1, 16 were consecutively re-284 cruited to participate in Phase 2 of the study. Recruitment 285 for Phase 2 commenced after 15 participants had com-286 pleted Phase 1 of the study, with all participants from this 287 time point onwards invited to take part. Eligibility criteria 288 were identical to the Phase 1 participants. Participants in 289 Phase 2 were randomly assigned to an intervention or con-290 trol group. The intervention group (n = 8) completed eight 291 40 min sessions over four weeks, in addition to their stand-292 ard inpatient or outpatient therapy. During the first two 293 sessions participants used all four gaming activities. In the 294 subsequent sessions they were able to choose which activ-295 ities they wished to undertake. Participants in the control 296 group (n = 8) continued with standard care only, consist-297 ing of inpatient or outpatient therapy. 298

Feasibility data collected in Phase 2 were identical to 299 Phase 1; however, in addition to the documentation of 300 informal feedback during the sessions, participants in 301 the intervention group were specifically asked 'What 302 three things did you like the most?' and 'What things 303 would you change?' at the completion of their study par-304 ticipation. Furthermore, the following functional out-305 comes were assessed at baseline and four weeks for 306 Phase 2 participants: Functional Independence Measure 307 (transfers, walking and stairs) [32], Motor Assessment 308 Scale [30], Functional Reach [33], Step Test [38], and 309 6-min walk test [39]. An assessor, blinded to group 310 allocation, collected the post-intervention outcome 311 data. Both the intervention and control groups continued 312 their usual therapy sessions during their study participa-313 tion. This typically consisted of one to three hours of 314 physiotherapy and occupational therapy five days per 315 week for inpatients, and one to two therapy sessions per 316 week for outpatients. Participant opinions and feedback 317 regarding their usual care were not sought. 318

Statistical analysis

Participant characteristics and functional outcome mea- 320 sures at baseline for both Phase 1 and Phase 2 participants 321

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were summarised using descriptive statistics. The normal-322 ity of data distribution was evaluated using Shapiro-Wilk 323 tests. One-way analysis of variance (ANOVA) or Kruskall-324 Wallis tests were used to assess baseline differences 325 between the four groups in Phase 1. Independent t-tests, 326 Mann-Whitney U tests or Chi square tests were used to 327 assess differences in baseline characteristics between 328 the two Phase 2 groups, and between the Phase 1 and 329 Phase 2 groups. 330

Descriptive statistics were used to summarise ses-331 sion times, times spent in each game activity, stand-332 ing versus sitting times, and difficulty levels reached. 333 Likert ratings of enjoyment and perceived helpfulness 334 were reported descriptively for participants in both 335 phases. Kruskall-Wallis tests were used to assess dif-336 ferences in acceptability ratings between the four Phase 1 337 groups. Participant feedback was compiled by a member 338 of the research team and key themes and comments 339 340 described.

Changes in pain and fatigue were reported descrip-341 tively for participants in both phases. One-way ANOVA 342 were used to examine differences in changes in pain and 343 fatigue within and between the four Phase 1 groups. 344 345 Borg ratings of perceived exertion were compared between Phase 1 groups using a Kruskal-Wallis test, and 346 between Phase 1 and Phase 2 groups using a Mann-347 Whitney U test. 348

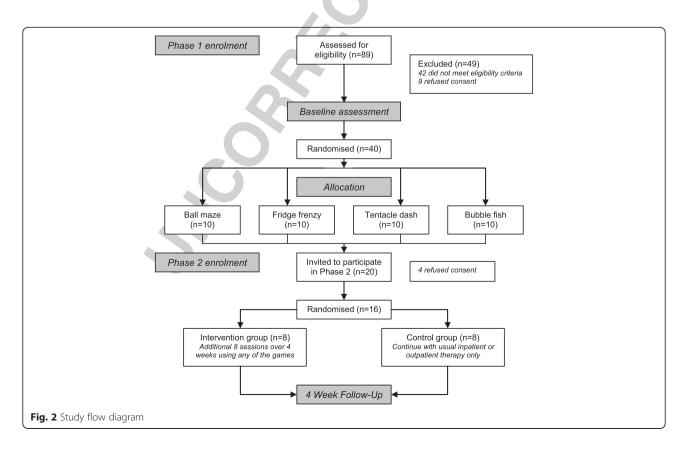
The number of usual therapy sessions received by the 349 intervention and control group in Phase 2 was compared 350 using independent t-tests. Phase 2 functional outcomes 351 were presented descriptively, including within-group 352 change scores (mean (SD)) and between-group differences 353 (mean 95 % CI). Within-group changes were evaluated 354 using Wilcoxon signed-rank tests and between-group differences at Week 4 were assessed using Mann–Whitney 356 U tests." 357

Results

Recruitment and participant details

Phase 1: Forty of 89 individuals screened agreed to take 360 part in Phase 1 of the study; 42 were ineligible and seven 361 declined consent (Fig. 2). As people with stroke from 362 F2 slow-stream rehabilitation wards were also screened, the 363 primary reasons for exclusion were due to significant 364 cognitive or physical deficits (i.e. unable to sit unsup- 365 ported or adequately follow instructions). Phase 1 partic-366 ipants were a mean age of 63.1 years, with a median 367 time since stroke of 5.5 weeks (Table 1). Mini-Mental 368 T1 State Examination scores ranged from 20 to 30 and 369 Motor Assessment Scale scores ranged from 9 to 48. No 370 significant differences between the four groups within 371 Phase 1 were observed. 372

Phase 2: Twenty participants included in Phase 1 were 373 consecutively invited to participate in Phase 2 and 16 374



t1.2	Demographics, stroke details and functional	Phase 1	Phase 2		
ŧ1: 3	status	(<i>n</i> = 40)	Intervention $(n = 8)$	Control $(n = 8)$	
t1.5	Age, mean (SD), years	63.1 (15.4)	60.8 (16.1)	60.9 (14.0)	
t1.6	Male : Female	27:13	5:3	6:2	
t1.7	Inpatient : Outpatient	29:11	5:3	4:4	
t1.8	Time since stroke, median (IQR), weeks	5.5 (2.5-23.4)	12.8 (3.9-137.8)	24.7 (5.8-51.1)	
t1.9	Infarct : Haemorrhage	31:9	4:4	6:2	
t1.10	Left : Right side of lesion	16:24	3:5	3:5	
t1.11	Mini-Mental State Examination, mean (SD), /30	26.3 (3.2)	26.6 (3.2)	24.0 (3.1)	
t1.12	Functional Independence Measure, mean (SD), /7				
t1.13	Transfers	6 (4–6)	6 (4–6)	5.5 (4.3-6)	
t1.14	Walking	5 (2-6)	5.5 (2.5-6)	5 (2–6)	
t1.15	Stairs	5 (1-6)	5.5 (1.8-6)	5 (1–6)	
t1.16	Motor Assessment Scale, median (IQR), /48	36.0 (27.0-43.5)	29 (24–36)	35.5 (24.8-39)	
t1.17	Functional Reach, mean (SD), cm	26.1 (9.0)	24 (8)	25.4 (8.9)	

Q41.1 Table 1 Participant baseline characteristics

accepted. Four Phase 1 participants declined to partici-375 pate due to lack of interest, time commitments or dis-376 377 charge date from the inpatient ward occurring within the next four weeks. Phase 2 participants were a mean 378 age of 60.8 years, with a median time since stroke of 379 18.5 weeks (Table 1). Mini-Mental State Examination 380 scores ranged from 20 to 30 and Motor Assessment 381 Scale scores ranged from 11 to 44. With the exception 382 of time post-stroke (P = 0.04), Phase 2 participants were 383 not significantly different to Phase 1 participants at 384 baseline. 385

Adherence

Phase 1: All 40 participants completed a single session 387 using one of the four games. Mean (SD) session time 388 was 33.6 (7.9) minutes. The full 10-level sitting and 389 standing protocol was completed by 58 % (n = 23) of 390 participants. Five participants in Phase 1 were unable to 391 complete any game levels in standing. The mean (SD) 392 percentage time spent in standing across all participants 393 was 43 (16) %. Those who were unable to complete the 394 full protocol tended to have a lower level of functional 395 ability or became fatigued during the session. The mean 396

Q32.1 Table 2 Phase 2 functional outcomes

t2.2	Outcome measures ^a	Week 0		Week 4		Within-group difference (Week 4 – Week 0)ª		Between-group difference (Mean 95 % Cl)	
t2.3		Intervention	Control	Intervention	Control	Intervention	Control	Intervention - Control	
t2.4	FIM transfers, /7	6.0 (4.0-6.0)	5.5 (4.3-6.0)	6.5 (6.0-7.0)	6.0 (5.0-7.0)	1.0 (1.1)*	0.6 (1.1)	0.4 (-0.8 to 1.6)	
t2.5	FIM mobility, /7	5.5 (2.5-6.0)	5.0 (2.0-6.0)	6.5 (6.0-7.0)	6.0 (2.8-7.0)	1.8 (1.7)*	1.0 (1.7)	0.8 (-1.0 to 2.6)	
t2.6	FIM stairs, /7	5.5 (1.8-6.0)	5.0 (1.0-6.0)	6.0 (4.3-6.0)	5.0 (2.0-6.0)	0.6 (1.4)	0.5 (1.9)	0.1 (-1.7 to 1.9)	
t2.7	Motor Assessment Scale, /48	29.0 (24.0-36.0)	35.5 (24.8-39.0)	33.5 (26.3-39.8)	35.5 (23.5-44.8)	2.4 (4.7)	2.4 (5.6)	0 (–5.5 to 5.5)	
t2.8 t2.9	Functional Reach, cm <i>Unable to do, N (%)^b</i>	24.0 (8.0) 1 (12.5 %)	25.4 (8.9) 1 (12.5 %)	26.3 (8.3) 1 <i>(12.5 %)</i>	28.3 (14.0) 1 <i>(12.5 %)</i>	2.3 (8.4)	3.8 (9.1)	-1.5 (-10.9 to 7.8)	
t2.10 t2.11 t2.12	Step Test (affected), number of steps in 15 s <i>Unable to do, N (%)^b</i>	0 (0–9.8) 5 <i>(62.5 %)</i>	8.0 (0–11.0) 3 <i>(37.5 %)</i>	2.5 (0–13.0) <i>4 (50 %)</i>	1.0 (0–8.3) 4 (50 %)	1.6 (5.0)	-2.4 (5.3)	4.0 (-1.5 to 9.5)	
t2.13 t2.14 t2.15	Step Test (unaffected), number of steps in 15 s <i>Unable to do, N (%)^b</i>	2.0 (0–10.3) <i>4 (50 %)</i>	6.0 (0–7.0) 3 <i>(37.5 %)</i>	6.0 (0–11.5) 3 <i>(37.5 %)</i>	2.5 (0–10.3) <i>4 (50 %)</i>	2.0 (4.0)	0 (5.8)	2.0 (-3.3 to 7.3)	
t2.16 t2.17	6 min Walk Test, m <i>Unable to do, N (%)^b</i>	82 (0–248) <i>3 (37.5 %)</i>	95 (0–288) <i>3 (37.5 %)</i>	160 (110–276) <i>0</i>	274 (45–306) 1 <i>(12.5 %)</i>	64.3 (69.4)*	75.1 (151.9)	-10.8 (-137.4 to 115.8)	

t2.18 Abbreviations: FIM, Functional Independence Measure; affected, affected leg in stance; unaffected, unaffected leg in stance during test

t2.19 ^aPresented as mean (SD) or median (IQR); ^bIf unable to do, the score was recorded as zero

t2.20 *Significant within-group difference P < 0.05 (Wilcoxon signed-rank test)

(SD) time spent actively using the games within each 397 session and the number of movement counts (where 398 applicable) were as follows: 'Ball Maze' 22.2 (7.2) mi-399 nutes and 466 (209) leaning movements of the torso 400 in all four directions; 'Fridge Frenzy' 19.1 (4.0) minutes 401 and 218 (85) leaning movements to the left and right; 402 'Tentacle Dash' 21.3 (10.6) minutes; and 'Bubble Fish' 18.9 403 404 (3.7) minutes.

405 Phase 2: Participants attended a mean (SD) of 7.3 (1.4) or 91 % of planned sessions with an average session time 406 of 26.3 (9.3) minutes. One participant ceased participa-407 tion after four sessions secondary to fatigue and neck 408 pain. Phase 2 participants spent an average of 75 % of 409 the time in standing, with two participants performing 410 all activities in a standing position. Participants were 411 allowed the freedom to choose which games they used 412 in sessions 3 to 8. This percentage of utilisation was: 413 'Ball Maze' 29 %, 'Fridge Frenzy' 28 %, 'Tentacle Dash' 414 30 % and 'Bubble Fish' 13 % of total time. The median 415 (range) maximal level of difficulty (out of 10) reached 416 for each game was: 'Ball Maze' 7.5 (1-10), 'Fridge Frenzy' 417 8 (1-10), 'Tentacle Dash' 6 (1-10), and 'Bubble Fish' 3 418 (3-10), with N=4, 3, 2 and 2 participants able to 419 420 reach the maximal difficulty level for the four games respectively. 421

422 Acceptability

Phase 1: The majority of participants reported the ses-423 sions to be enjoyable (92.5 % rated "enjoyed" or "really 424 enjoyed" on the 5-point Likert scale) and felt the session 425 was helpful for their recovery (80 % rated "helpful" or 426 "really helpful"). One participant did not find the game-427 based session to be enjoyable or helpful, whereas others 428 429 were neutral in their response. When asked whether they would like to continue the game intervention as 430 part of their ongoing therapy, 87.5 % responded 'Yes'. 431 There were no significant differences in acceptability 432 ratings of enjoyment (P = 0.74) or perceived helpfulness 433 434 (P = 0.29) between the four games in Phase 1.

Phase 2: Six of the eight Phase 2 participants reported
enjoying the game sessions and five felt the activities
were helpful for their stroke recovery.

438 Participant feedback

Feedback from participants was mainly related to enjoyment, perception of benefit, ease-of-use and suggestions
for improvement.

Participants' felt the games were a fun and novel way
of performing exercise and appreciated the competitive
element. *"It's a bit of fun and something different"*(Tentacle Dash P36). *"I like the variety. It's good to test your skills with something new"* (Phase 2 P16). *"I want to know if I'm the winner. That's what happens - you become competitive"* (Tentacle Dash). However, others

felt the games were quite monotonous and lacked 449 interest. *"It's a bit repetitive if you just keep doing this* 450 *game"* (Fridge Frenzy P28). *"I never really liked games* - 451 *it's not for me"* (Ball Maze P39). 452

Comments were made in regard to perceived helpful-453 ness of the games on both physical and cognitive abil-454 ities. "It helped me move my arm, which I haven't done 455 in a long time. I've been scared to move it" (Bubble Fish 456 P35). "This game is good for my memory - I have to think 457 ahead where to move the ball" (Phase 2 P12). Others did 458 not feel the game activities were of benefit. "I don't 459 understand how it would help. It would probably help 460 for a younger person but not for me. I'm over 80. It's hard 461 to understand for elderly people" (Tentacle Dash P8). 462

Participants' commented on issues related to usability. 463 Some found the games either too easy or too difficult. 464 "It's pretty easy for me. I felt like I would perform the 465 same whether I had a stroke or not" (Ball Maze P30). 466 "It's hard to get the coordination and speed of movement 467 right" (Fridge Frenzy P31). Others expressed frustration 468 with the movement controls. "See you hit them and 469 nothing happens!" (Bubble Fish P11). "Sometimes it 470 doesn't move when you're leaning" (Tentacle Dash P26). 471 Participants' also commented on their improvements 472 over time. "I've started to plan ahead better and look 473 what's coming" (Phase 2 P8). 474

Finally, several suggestions were made for improvements to the games. Participants' commented that more 476 variety and challenge would be desirable. "*Make the* 477 games go faster - to level 15 or so - (as) I got used to it" 478 (Phase 2 P2). "You could make it more colourful with 479 more interesting things" (Fridge Frenzy P37). It was also suggested that better feedback on scores would be helpful. "I want the scoreboard to come up on the screen" 482 (Phase 2 P8). 483

Safety

There were no falls or serious adverse events requiring medical attention during any of the Phase 1 486 or Phase 2 sessions. However, pain, which is common 487 after stroke, was present prior to commencing the 488 game-based session in 25 % of Phase 1 and 20.7 % of 489 Phase 2 sessions. 490

Phase 1: At the end of Phase 1 there was no significant 491 overall change in pain rating (mean (SD) of 0.4 (2.2), 492 P = 0.27) compared with the pre-session score. How-493 ever, changes in pain were reported in 42.5 % (n = 17) 494 of participants. Pain increased in 12 participants (ranging 495 from 1 to 8 points), while five participants reported im-496 provements in pain (ranging from 1 to 5 points) following 497 the game-based session. The rate of pain occurrence was, 498 in general, evenly spread between the four game activities, 499 with no significant difference between change in pain 500 scores (P = 0.87). 501

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Phase 2: Six of eight Phase 2 participants reported an 502 increase in pain (ranging from 1 to 8 points) in 13 of 58 503 total sessions. Pain reductions were seen in 10 sessions 504 (ranging from 1 to 2 points). The highest rating of 505 increased pain was reported in the participant who 506 discontinued the study after four sessions due to neck 507 discomfort. Although these symptoms were likely exac-508 509 erbated by study participation, they were also reported during their usual physiotherapy sessions. Furthermore, 510 one participant in Phase 2 complained of dizziness, 511 which increased by 2 to 3 points (on an 11-point scale) 512 during each session and limited their study session dur-513 ation. This dizziness was also reported during their usual 514 physiotherapy sessions and was related to their type 515 of stroke. 516

517 Overall pre to post-session fatigue in Phase 1 participants increased by a mean (SD) of 1.6 (2.4) on an 518 11-point VAS (P < 0.001). Fatigue increase (ranging from 519 1 to 8 points) occurred in 22 of 40 Phase 1 participants. 520 Three participants reported a decrease in fatigue, ranging 521 from 1 to 2 points. There was no significant difference 522 between change in fatigue scores between the four game 523 groups in Phase 1 (P = 0.41). Similarly, Phase 2 partici-524 525 pants were found to have fatigue increases in 25 of the 58 total sessions (ranging from 1 to 5 points and re-526 ported by all eight participants), and decreases in 527 three sessions (ranging from 1 to 3 points and reported by 528 three individual participants). The post-session Borg 529 rating of perceived exertion was a median (IQR) of 530 11.0 (9.5-13) in Phase 1, with no significant differ-531 ences between the four groups (P = 0.45). Phase 2 532 participants reported a median (IQR) of11.9 (8.9-13.1), 533 which was not significantly different than Phase 1 ratings 534 (P = 0.97).535

536 Phase 2 functional outcomes

Outcome data for Phase 2 are presented in Table 3. Q6 537 There were no significant between-group differences at 538 539 baseline or at 4 weeks on any outcome measure. The intervention group improved significantly over time on 540 several outcomes including FIM transfers (P = 0.04), FIM 541 mobility (P = 0.03), and the 6-min walk test (P = 0.01). 542 There were no significant within-group changes in the 543 544 control group in any of the outcomes measures. A large number of participants were unable to perform the Step 545 Test at either baseline or after 4 weeks (50 %; n = 8); and 546 547 the 6-min walk test at baseline (37.5 %; n = 6). The number of usual therapy sessions (including physio-548 549 therapy, allied health assistant and exercise group sessions) received during the period of study participation 550 did not significantly differ between the two Phase 2 551 groups (mean (SD) session number 15.5 (10.4) and 12.3 552 (10.5) in the intervention and control group, respectively; 553 554 P = 0.54).

Discussion

This study found that a treatment approach utilising 3D 556 motion-tracking games was a feasible option for use in 557 people with stroke, with high levels of acceptability. 558 However, concerns in regard to safety and applicability 559 across different functional levels require further explor- 560 ation. Participant acceptability, in terms of enjoyment, 561 perceived benefit for their stroke recovery, and desire for 562 continued use, was relatively high. Participants were able 563 to engage in repetitive physical activity without major 564 safety concerns. However, there were a relatively large 565 number of participants reporting minor increases in pain 566 before and after the game-based sessions. More research 567 is needed to explore the efficacy and longer-term feasi- 568 bility of this approach. 569

This study aimed to develop games suitable for a 570 broad range of people with stroke and sought to recruit 571 participants who reflected this diversity. Although the 572 heterogeneity of the study population may strengthen 573 the generalisability of the findings, recruitment of a 574 more targeted population may have resulted in different 575 outcomes. As the games were designed to be applicable 576 across a range of post-stroke abilities, it was therefore 577 not expected that all levels of the games could be 578 completed by all participants. Indeed, the inclusion of 579 individuals with poor physical function impacted on the 580 ability of these participants to complete the full study 581 protocol. Several participants were unable to partake in 582 the higher game levels and could not perform the activ-583 ities in a standing position. The relatively prolonged 584 concentration and attention required, as well as the 585 repetition of one type of physical task, may have also 586 been too demanding for some participants. This is con-587 sistent with findings presented by Galna et al. (2014), 588 who found that people with Parkinson's disease strug-589 gled with some of the physical and cognitive challenges 590 presented in their Kinect-based game intervention [28]. 591 However, participants with significant impairments in 592 the current study were able to successfully engage in at 593 least the lower levels of the games, and while it was 594 challenging, it would be expected to become less so as 595 they improved. 596

Conversely, several highly functioning participants 597 felt they weren't being challenged enough by the 598 games and this may have led to boredom with repeti-599 tive practice. Arguably, these participants may have 600 been better suited to using commercial games such as 601 the Nintendo Wii, or other systems which provide a 602 greater level of physical or cognitive challenge. How-603 ever, the study protocol used allowed the researchers 604 to develop a clearer understanding of the likely re-605 sponse and progression that could be expected in 606 people with different levels of post-stroke disability to 607 these games. 608

Acceptability of the game-based intervention was gen-609 erally high. This is consistent with previous studies of 610 Wii-based interventions following stroke [17, 18, 40] 611 and Kinect-based interventions in other neurological 612 populations [28, 41]. Although most participants found 613 the games to be enjoyable and potentially helpful for 614 their recovery, it would be valuable to investigate longer-615 term acceptability and adherence. Indeed most previous 616 research has evaluated game-based interventions of two to 617 618 six weeks duration in people after stroke [12, 16-18, 40]. Acceptability in this study appeared to be lower in the 619 most highly or poorly functioning participants. Accept-620 ability may have been affected by the study design, par-621 ticularly in Phase 1, as participants were asked to perform 622 one game activity only and progress through all levels of 623 difficulty in seated and standing positions. Greater indi-624 vidual adaptation was included in Phase 2 from sessions 625 3 to 8, where participants were asked to choose, in col-626 laboration with the therapist, the number of games, 627 time spent on each game and level of difficulty. Accept-628 ability of the game-based intervention may have been 629 enhanced through the provision of a larger range of ac-630 tivities, more engaging and varied interfaces, aligning 631 632 the tasks more closely to participant goals, and enabling individuals to work at their optimal level of challenge. 633

No major adverse safety events occurred within the 634 study sessions; however, the incidences of pain reported 635 in this study imply that this should be carefully monitored 636 and activities adapted where appropriate. It is difficult to 637 determine whether the pain reported in this study was 638 significantly different from what was experienced during 639 participants' usual therapy sessions as this was not re-640 corded. Furthermore, the incidence of pain in post-stroke 641 642 populations has been reported as high [42] and the validity of using pain scales in this population has been questioned 643 [36]. However, given the repetitive nature of the activities 644 performed, and the possibility of individuals ignoring pain 645 symptoms due to high levels of engagement and motiv-646 647 ation [43], these findings suggest caution and close monitoring during implementation. It may also be advisable to 648 increase the variability and graduate the intensity and 649 duration of practice. 650

Fatigue scores varied considerably in this study; how-651 ever, the overall mean increase was below what may be 652 considered as clinically significant [35]. Calculated from 653 the findings by Tseng et al. 2010, the standard error of 654 measurement (SEM) and minimal detectable change 655 (MDC) scores for post-exercise fatigue change using a 656 657 VAS in individuals with stroke are estimated as 1.2 and 3.4 points respectively. Although the fatigue scale used 658 was not able to differentiate the type of fatigue reported, 659 660 a number of participants commented on feeling greater cognitive than physical fatigue. This was also reflected in 661 662 the informal participant feedback and comments during the game-based sessions and would be an interesting 663 area for further research. Perceived exertion in both 664 Phases of the study was rated as "fairly light". This 665 finding is consistent with previous research investigating 666 the use of the Nintendo Wii in individuals with stroke 667 [16, 18]. The level of fatigue and exertion experience 668 may affect an individual's focus of attention and sub-669 sequent motor learning. It has been suggested that an 670 external focus of attention (such as that encouraged by 671 video game use) is beneficial for motor learning and also 672 may reduce internal sensations of fatigue and exertion; 673 however, as exertion increases it will tend to dominate 674 an individual's attention [44]. The clinical significance of 675 increases in fatigue or exertion and the subsequent 676 impact on an individual's attention and motor learning is 677 relatively unexplored and an important area for future 678 research. 679

This feasibility study was not designed to detect signifi-680 cant changes in functional outcomes, rather we wanted to 681 explore the utility of a range of measures related to the 682 trained task (i.e. primarily standing based activity and 683 balance). However, the findings indicated greater changes 684 in mobility outcomes including the FIM (transfers and 685 mobility) and the 6-min walk test in the intervention 686 group. Although these findings must be interpreted with 687 caution, the games could have resulted in improvements 688 in these measures due to training which was primarily 689 focused on weight-shifting and endurance in standing ac-690 tivities. Interestingly, the Functional Reach did not show 691 significant changes despite the games challenging trunk 692 control and upper extremity movement. This result may 693 have been influenced by ceiling effects of this outcome 694 measure. Single leg balance and upper limb activities were 695 not highly trained by the game activities, which may be 696 why other outcomes did not see significant changes. 697

Surprisingly, many of the outcomes did not signifi-698 cantly change within the groups over the four weeks 699 despite participants also undertaking standard inpatient 700 or outpatient therapy during that time. This may be ex-701 plained by several factors. Phase 2 of the study recruited 702 a relatively small number of participants with varying 703 impairments and at different times following stroke. The 704 type of training provided may not have provided an ad-705 equate level of challenge to allow for functional improve-706 ments in some participants. Concurrent therapy ranged 707 from multiple sessions per day in more acute participants, 708 to weekly in those who were in the chronic post-stroke 709 phase. Although the usual therapy provided did not sig-710 nificantly differ between study groups, the type and 711 amount of concurrent therapy received likely impacted on 712 functional gains. The Phase 2 game-based intervention 713 was relatively short and it has been suggested that at least 714 16 h of additional therapy is required to demonstrate 715 functional gains after stroke [45]. Additionally, the type 716

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and amount of game-based activities varied between 717 participants from sessions 3 to 8. However, it was 718 noted that participants in Phase 2 completed on aver-719 age an additional 20 min of standing activity during 720 each 26 min treatment session. Therefore, this type of 721 intervention shows potential as an effective means to 722 increase engagement in physical activity, found to be 723 724 particularly low in hospital settings following stroke 725 [10]. Furthermore, consistent with previous research on game-based interventions [13], participants were seen 726 to engage in a relatively high number of movement repeti-727 tions during each session. 728

Although the outcome measures were selected as 729 potentially sensitive measures, which approximate the 730 task demands of the game intervention, the use of other 731 outcomes may have resulted in different findings. Several 732 of the measures suffered from floor and ceiling effects, 733 thereby reducing potential responsiveness within certain 734 participant groups. For example, a large number of par-735 ticipants were unable to perform the 6-min walk test at 736 baseline, and the Step Test at either baseline or after 737 four weeks. Conversely, scores for the Functional Reach 738 suffered from ceiling effects as they were generally 739 740 within the range of normative values. Furthermore, separating the Functional Independence Measure into single 741 item subcomponents has not been validated; however, 742 assessing the full scale was not feasible for the purposes 743 of this study. As the game-based intervention typically 744 encouraged trunk and weight-shifting activities over a 745 fixed base of support in a seated or standing position, al-746 ternative measures, such as the Trunk Impairment Scale 747 [46], Fugl-Meyer Assessment [47] or Postural Assess-748 ment Scale for Stroke [48], may have been more respon-749 750 sive in lower functioning participants. A specific upper limb measure, such as the Wolf Motor Function Test 751 [49], may also have been more appropriate for detecting 752 any changes resulting from the upper limb training com-753 ponent. These would be recommended for future effi-754 755 cacy studies.

This feasibility study had a number of limitations. As 756 the games were in the development phase, there were a 757 restricted number of activities to choose from and a 758 relatively narrow scope for variation within each game. 759 Although a reasonable sample of 40 participants was 760 recruited for Phase 1, a small group of 16 participants par-761 ticipated in Phase 2 of the study. Longer-term acceptabil-762 763 ity and feasibility was therefore only evaluated in eight individuals. Investigation of efficacy was not the primary 764 focus of the study and was limited by sample size, parti-765 cipant heterogeneity, use of a control group who did not 766 receive an equivalent amount of additional therapy and 767 768 participant engagement in concurrent therapy.

This study provides important information on the r70 feasibility of using game-based treatment approaches in a rehabilitation setting in people with a range of post- 771 stroke deficits. This information may assist research and 772 development of new stroke rehabilitation-specific games. 773 In future studies the recruitment of a larger sample of 774 participants and testing against an activity-matched con- 775 trol group should be considered. We recommend that 776 the games used should promote functional movements 777 and provide an optimal level of challenge that is tailored 778 to the individual. Our findings suggest that the difficulty 779 levels of the games may need to be extended as to suit 780 individuals who are either lower or higher functioning. 781 Studies should investigate which activities are most 782 suited to particular sub-groups of participants and what 783 outcome measures will best reflect any functional im- 784 provements made. Important aspects of feasibility, in-785 cluding participant acceptability, motivation, adherence, 786 and safety, should continue to be explored. The evalu-787 ation of longer term and home-based use of this type of 788 intervention is also critical to adequately inform feasibility, 789 efficacy and cost-effectiveness. 790

Conclusions

Training using interactive motion-controlled games 792 appears largely feasible and acceptable for use across 793 post-stroke individuals with a broad range of abilities. 794 However, modifications to this approach are suggested 795 and future intervention studies with larger samples are 796 recommended to further explore longer-term feasibility, 797 safety and clinical efficacy for improving physical out-798 comes in people with stroke. 799

Abbreviations

3D: Three-dimensional; FIM: Functional independence measure; VAS: Visual analogue scale; ANOVA: Analysis of variance; SD: Standard deviation; IQR: Interquartile range.	801 802 803
Competing interests The authors declare that they have no competing interests.	804 805
Authors' contributions	806

All authors contributed to the study design. KB, JL and JB designed the807study. YL and PS developed the games based on input from KB, JL and JB.808KB and JL assisted with data collection and data entry. KB and AG performed809the statistical analyses. KB drafted the initial manuscript. All authors810contributed to the revision of the manuscript and have read and approved811the final version.812

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Q5	Table "2" was received; however, no citation was provided in the manuscript. Please provide the location of where to insert the citation in the main body of the text. Otherwise, kindly advise us on how to proceed. Please note that tables should be cited in ascending numerical order in the main body of the text.	
Q6	Table "3" was mentioned in the manuscript; however, no corresponding table body was provided. Please supply. Otherwise, kindly advise us on how to proceed. Please note that all figures or tables referring to elements of a separate manuscript must be spelt out rather than in numeric form to avoid confusion with in-text citations of tables within the manuscript.	
Q7	References 1, 5, 7, 8, 16, 17, 20, 21, 26, 28, 36, 41, 42, 45, 46 and 49: Citations in the reference list should include all named authors, up to the first 6 before adding 'et al.'.	
Q8	Citation details for Reference [35] is incomplete. Please supply the "volume number and page range" of this reference. Otherwise, kindly advise us on how to proceed.	