

Please cite the Published Version

Levac, D, McCormick, A, Levin, MF, Brien, M, Mills, R, Miller, E and Sveistrup, H (2018) Active Video Gaming for Children with Cerebral Palsy: Does a Clinic-Based Virtual Reality Component Offer an Additive Benefit? A Pilot Study. *Physical and Occupational Therapy in Pediatrics*, 38 (1). pp. 74-87. ISSN 0194-2638

DOI: <https://doi.org/10.1080/01942638.2017.1287810>

Publisher: Taylor & Francis

Version: Accepted Version

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Abstract (200 words):

Aims: To compare changes in gross motor skills and functional mobility between ambulatory children with cerebral palsy who underwent a 1-week clinic-based virtual reality intervention (VR) followed by a 6-week, therapist-monitored home active video gaming (AVG) program and children who completed only the 6-week home AVG program.

Methods: Pilot non-randomized controlled trial. Five children received 1 hour of VR training for 5 days followed by a 6-week home AVG program, supervised online by a physical therapist. Six children completed only the 6-week AVG program. The Gross Motor Function Measure Challenge Module (GMFM-CM) and Six Minute Walk Test (6MWT) were used to evaluate change.

Results: There were no significant differences between groups. The AVG-only group demonstrated a statistically and clinically significant improvement in GMFM-CM scores following the 6-week AVG intervention (median difference 4.5 points, interquartile range [IQR] 4.75, $p = 0.042$). The VR + AVG group demonstrated a statistically and clinically significant decrease in 6MWT distance following the intervention (median decrease 68.2m, IQR 39.7m, $p = 0.043$). All 6MWT scores returned to baseline at 2 months post-intervention.

Conclusion: Neither intervention improved outcomes in this small sample. Online mechanisms to support therapist-child communication for exercise progression were insufficient to individualize exercise challenge.

Keywords: cerebral palsy, active video games, virtual reality, home exercise programs

INTRODUCTION

Children with cerebral palsy (CP) whose abilities are classified at Levels I and II of the Gross Motor Function Classification System (GMFCS) have balance and gross motor skill impairments (Pavao et al., 2014) that can limit participation in physical activities (Lauruschkus et al., 2013; Mitchell et al., 2015; Shikako-Thomas et al., 2013). Interventions incorporating virtual reality (VR) systems in which children use body movements to interact with objects in a virtual environment can improve balance and gross motor skills (Dewar et al., 2015; Fehlings et al., 2013; Weiss et al., 2014). VR systems offer standardization of task practice conditions, presentation of visual and auditory feedback supporting error detection (Biddiss, 2012; Levin, 2011), and an enriched environment that may motivate users to practice more frequently (Tatla et al., 2013). Compared to VR systems that are designed specifically for rehabilitation, off-the-shelf active video games (AVGs) that use similar motion-capture technology have significantly less capacity to individualize task difficulty parameters and capture therapeutically-relevant performance metrics (Biddiss, 2012; Levac & Galvin, 2012). However, AVGs are less expensive, more accessible for home use and have a wider game variety.

The evidence for AVG use to improve gross motor skills in children with CP has primarily been reported for Nintendo's Wii and WiiFit, systems in which interaction with the game is via a hand-held controller or a force platform (e.g., Chiu et al., 2014; Do et al., 2016). Full body movement is the medium for game interaction in Microsoft's Xbox360 Kinect motion-capture sensor games. Two studies in children with CP have found improvements in upper limb function (Luna-Oliva et al., 2013), walking endurance and gross motor skills (Zoccolillo et al., 2015) following 8-week Kinect AVG interventions. In contrast, more evidence supports use of

GestureTek Health's rehabilitation-specific, clinic-based motion-capture Interactive Rehabilitation Exercise System (IREX). There is strong level III evidence (AACPD; www. for IREX-training to improve functional balance and mobility outcomes in children with CP (Glegg et al., 2014; Weiss et al., 2009). In a single subject research design, we demonstrated that an intensive 1-week IREX intervention can improve short-term balance and functional mobility in four adolescents with CP at GMFCS Level I (Brien & Sveistrup, 2011).

Access to clinic-based VR systems can be challenging for busy families. Instead, AVGs offer a promising option for home exercise programming. Adherence to traditional home exercise programs is often poor for children with CP (Peplow & Carpenter, 2013). AVGs are recommended for home use because of their potential to motivate children to increase practice dosage (Biddiss, 2012). Children with CP are motivated to participate in short-term VR-based exercise (Bryanton et al., 2006; Tatla et al., 2013). However, previous research has shown that sustaining motivation over a lengthy (i.e., multiple weeks) AVG home intervention program can be problematic (Golomb et al., 2010; James et al., 2015).

Given that therapists cannot remotely access Kinect Xbox360 game play parameters, we created an interactive website for children and families to record adherence to their AVG home program, communicate with therapists and respond to weekly questions about motivation and challenge levels. The website was designed to inform therapists' decisions about AVG exercise program progression. While our goal was to evaluate the effectiveness of the 6-week Kinect home AVG program, we questioned whether beginning the program with an evidence-based (Brien &

Sveistrup, 2011) 1-week intensive clinic-based VR '*jump-start*' might offer a benefit. Specifically, we expected this benefit to be twofold. Firstly, participants would derive exercise benefits from an intense VR intervention, and secondly, they would be exposed to a more sophisticated clinic-based VR system under the direct supervision of a physiotherapist who could reinforce optimal movement during game interaction and enhance participants' motivation to adhere to the home-based AVG program. This would in turn translate to improved outcomes as compared to the AVG-only group. As such, the purpose of this study was to compare changes in gross motor skills and functional mobility between children with CP at GMFCS levels I or II who underwent a 1-week intensive clinic-based VR intervention followed by a therapist-monitored 6-week home AVG program to children who completed only the 6-week therapist-monitored home AVG program. We hypothesized that outcomes immediately following the AVG intervention and at 1 and 2 months post-intervention would improve more so for children who completed the combined VR + AVG program as compared to those who completed the AVG program alone.

METHODS

Study design

Pilot non-randomized controlled trial. Ethics approval was obtained from the University of Ottawa Research Ethics Board and the Ottawa Children's Treatment Center (OCTC) Research Ethics Committee. Informed consent and assent were obtained from parents and children.

Participants

Children and youth between the ages of 7 and 18 years with a confirmed diagnosis of CP at GMFCS levels I or II were invited to participate. Inclusion criteria were the ability to follow directions on standardized testing in English or French (as determined by parent), Internet access at home; and access to a television at home in a space suitable for Kinect play. Exclusion criteria were visual, cognitive or auditory impairment that would interfere with game play, orthopedic surgery or lower extremity BOTOX injections in the past 12 months; and regular past use of an AVG system at home (defined as greater than 1 hour/week for more than 4 weeks in the past year). Children were recruited via study information letters mailed from the OCTC and disseminated in schools by physical and occupational therapists via the Community Care Access Centre.

Sample size justification

We did not undertake power analyses for this pilot study because our goal was to generate effect size and variability estimates to power a subsequent trial.

Setting

IREX interventions took place in the OCTC's VR-based therapy room. AVG exercise programs took place in participants' homes.

Exercise program development

Kinect AVG programs:

The PI (XX) and 3 physical therapists (XX, XX and XX) developed the exercise programs. We selected the following discs with games that incorporated full body movements: Big League Sports, Adventures, Sports Season 2, Just Dance Kids 2, Dance Central 2, Motion Sports, and

Motion Sports Adrenaline. We undertook a task analysis within game play sessions in which we categorized games according to movements elicited (e.g. weight-shifting inside base of support, weight-shifting outside of base of support, jumping, squatting, and reaching). We classified each game as activity- or sport-based. Finally, we ranked games with respect to physical (e.g. extent of cardiovascular challenge, number and range of movements elicited) and cognitive (e.g. amount of competing visual and auditory stimuli, amount and speed of decisions required about movements and obstacle avoidance) challenges when played at the easiest level. We then developed Easy and Hard Activity- and Sports-based programs. In the easy version, the physical challenge level was lower in terms of game requirements, difficulty level, speed and nature of suggested progressions. Each program included progressions across the 6 weeks and alternative game play suggestions, including use of hand weights or balance board, or different ways to play the game (e.g., while standing on 1 foot). Each day's exercise program included a 'free choice' game that the child could select him/herself.

IREX VR program:

We played each of the 9 IREX games and undertook a task analysis using the same body movement requirements as previously described. The games (Birds n' Balls, Drums, Conveyor, Formula Racing, Gravball, Shark Bait, Soccer, Snowboard, and Zebra Crossing) were then ranked as 'Easy', 'Medium' or 'Hard' on the basis of their physical and cognitive challenge when played using the lowest game parameters. Three 5-day exercise programs were developed (Easy, Medium, and Hard) which provided suggested games, challenge parameters and progressions across the 5 days.

Website development

A website was created to provide information about the games, enable participants to record adherence to the exercise programs, communicate with therapists, and allow therapists to specify each week's exercise program. Interfaces for younger children and adolescents differed in presentation but not content. Therapists and children/families could send messages that would be received as emails in their usual email accounts. The website also featured a calendar that the therapist or participant could use to record study visits and Kinect game play days. We did not ask children to report their exact AVG program each day, but rather to record which required and which free choice game they had played most and least often each day that week. Children were also asked to report frequency of daily physical activities. The website required that Kinect game play and physical activity information be entered for 5 of the past 7 days before enabling the weekly questionnaire consisting of questions probing enjoyment, challenge and boredom with that week's program.

Procedures

Participants were assigned to either the VR or the AVG group based on their self-declared ability to come to OCTC to participate in the 1-week VR session. **Figure 1** outlines the study procedures, including timing of outcome measurement.

INSERT FIGURE 1 ABOUT HERE

VR + AVG group

Therapists selected a pre-determined exercise program on Day 1 of the intensive VR intervention, which was progressed or altered based on observation of game play as well as participant report of physical challenge, enjoyment or fatigue. The PT introduced the Kinect in an additional hour following the final session. The research assistant (XX) undertook a home

visit with the child and family to install the Kinect system and familiarize the child and family with the study website. Children then completed the 6-week AVG program as described below.

AVG-only group

In the week prior to the AVG program, children visited the clinic once for 1 hour to meet the therapist who would introduce the Kinect. The RA then undertook a home visit. Children then completed the 6-week AVG program as described below.

6-week AVG program

All participants were instructed to undertake their home exercise program for 30 minutes/day, 5 days per week. They were encouraged to play for a full 30 minutes, not including rest time and time to switch between disks. They were asked to play each game in that day's program at least once, and could select the frequency with which they repeated each game during the session. We felt that it was overly prescriptive to stipulate the exact frequency of game play and that more choice would enhance children's motivation and autonomy.

Therapists followed predetermined suggestions to progress exercise program challenge over the 6-week period by increasing game difficulty, adding therapeutic adaptations (e.g. weights, altered support surface), moving to a more challenging game, and adding a cognitive dual-task. Progressions were made on the basis of information from children's website entries. The website was programmed to send an email reminder to the child or parent if there had been no login for the past 4 days. Therapists were also asked to check the website daily and send gentle email reminders. Therapists responded to any questions posed by the child and or family via emails sent and received through the website.

Outcome measures

Outcome measures were performed in the following order:

1. Postural responses to externally triggered perturbations of a support surface (using the Computer Assisted Rehabilitation Environment [CAREN]; this outcome measure will be reported in a subsequent paper.
2. Six Minute Walk Test (6MWT): Assesses functional capacity for walking a prolonged distance. The 6MWT has excellent test-retest reliability in this population (Maher et al., 2008; Thompson et al., 2008).
3. Gross Motor Function Measure (GMFM) Challenge Module (Glazebrook & Wright, 2014): Tests advanced gross motor skills of balance and postural control, coordination, agility, speed and strength. Test-retest reliability ICC is 0.94 in this population (Wright FV, personal communication). Scores were converted to percentages.
4. Weekly questions related to participant perceptions of the AVG exercise program: participants indicated their agreement with 5 statements about enjoyment, fatigue, ease, difficulty and boredom of the week's Kinect activities using a 7 point Likert Scale (1 Strongly disagree [1] - Strongly agree [7]).

Statistical Analyses

Descriptive analyses summarized participant demographics and exercise program adherence.

SPSS v. 21.0 was used for statistical analysis. Normality testing of the data was undertaken by

examining skewness and kurtosis values and histograms. The data was determined to be non-normal and non-parametric inferential testing using Wilcoxon test for within-group changes and Mann Whitney- U test for between group changes was undertaken. These tests were undertaken for each outcome measure at each assessment point. Qualitative content analysis (Hsieh & Shannon, 2005) was used to analyze the email content. Email content was grouped into categories, which were then tallied in frequency counts.

RESULTS

Participant demographics

Table 1 provides participant details. There were no significant differences between groups in terms of age, baseline GMFM-CM score ($Z = -.366$, $p = .792$) or baseline 6MWT distance ($Z = -1.095$, $p = .329$). Only one child (in the VR+ AVG group) received physical therapy (once weekly) during the intervention and follow up period. One participant in the VR+AVG group did not return for the final 2 assessment occasions.

INSERT TABLE 1 ABOUT HERE

Intervention fidelity

All participants in the AVG-only group completed the 6-week program. One participant in the VR + AVG group completed only the first 5 weeks, and 2 participants in this group took a 1 week break due to previously scheduled vacation activities, returning to complete the final week. Ten of the 11 participants used the website to record adherence and answer the weekly questions; the final participant (in the VR+AVG group) recorded adherence information on

paper. Participants logged in to the website an average of 32.2 times (range 11-84 logins per participant). Each therapist logged in between 32-84 times each and updated exercise programs for each client at least once weekly.

Figure 2 illustrates mean playing time per week for each group for the 6-week AVG home program. The AVG-only group played an average of 42.1 min (SD 4.9min) per day, which is an average of 14.71 (SD 4.85) minutes more per day throughout the six weeks as compared to the VR+AVG group (mean 27.4 min, SD 1.4min). Exercise program adaptations included playing against an opponent (36 times), standing on a different surface (1 time), and changing game rules (9 times).

INSERT FIGURE 2 ABOUT HERE

Email content analyses

An average of 6.2 emails per participant were exchanged. **Figure 3** illustrates the content categories that were covered most and least frequently in emails from therapists and from children/families.

INSERT FIGURE 3 ABOUT HERE

Responses to weekly questions

Figures 4 and 5 illustrate mean participant responses to 5 questions (0 = strongly disagree; 6 = strongly agree) asking agreement about statements of enjoyment, difficulty, boredom and fatigue over the 6-week exercise program. No inferential testing was undertaken. Visual inspection

shows that participants in both groups did not indicate that games were too easy nor too hard or that they were bored or fatigued.

INSERT FIGURE 4 ABOUT HERE

INSERT FIGURE 5 ABOUT HERE

GMFM-CM and 6MWT

The AVG-only group demonstrated a statistically significant improvement in GMFM-CM score following the 6-week intervention (Time 2 to Time 3; median difference 4.5 points, interquartile range [IQR] 4.75, $z = -2.032$, $p = 0.042$). This improvement is greater than the minimum detectable change at a 90% confidence interval (MDC 90) of 4.4 points (Wright FV. personal communication). The VR + AVG group demonstrated a significant decrease in 6MWT distance following the intervention, greater than the minimal detectable change (MDC) of 61.9 m for children at GMFCS Level I (Thompson et al., 2008) [Time 2 to Time 3; median decrease 68.2m, IQR 39.7m, $z = -2.023$, $p = 0.043$], although 6MWT times returned to baseline at 2 months post-intervention (Time 5). There were no significant between group differences at any time point.

Figure 6 illustrates the median GMFM-CM scores (expressed as percentages) for each group at each outcome assessment.

INSERT FIGURE 6 ABOUT HERE

INSERT FIGURE 7 ABOUT HERE

DISCUSSION

Contrary to our hypothesis, children who began a 6-week AVG home exercise program with a 1-week intensive VR intervention did not demonstrate enhanced gross motor skills or functional

mobility as compared to those who undertook a 6-week AVG exercise program alone. Instead, the AVG-only group showed a statistically and clinically significant improvement on the GMFM-CM after the 6-week program. Results may be explained by differences in the dosage received by the two groups. The AVG-only group played an average of 14.7 more minutes daily than did the VR+AVG group. In addition, the VR+AVG group was less consistent: 2 participants had a 1-week interruption during the study intervention, and 1 participant only completed 5 of the 6 weeks of training. As such, the intervention frequency for these participants was lower. In addition, while differences in baseline GMFM-CM or 6MWT scores between the two groups were not statistically significant, Figures 6 and 7 illustrate that the VR+AVG group had higher median scores on both outcome measures at baseline. The VR+AVG group may have had less potential to improve their functioning as a result of the intervention.

Both groups decreased their 6MWT distances immediately following the 6-week AVG program, with the VR + AVG group demonstrating a clinically and statistically significant decrease. These findings cannot be explained by test administration factors, as we followed testing recommendations and standardized testing for time of day, test order and examiner. Notes for these testing sessions do not indicate that any participants reported being unduly fatigued.

Two possible explanations for the decrease in 6MWT distances may be suggested. Firstly, the time spent playing Kinect each day may have detracted from participants' ability to participate in other physical activities, which may have decreased their cardiovascular endurance. However, children in the VR+AVG group played less than did the AVG-only group, improved their

GMFM-CM scores, and reported that they were participating in other physical activities throughout the 6-week program, so this rationale seems unlikely. 6MWT distances at baseline for the VR+AVG group were higher than reported in other studies (e.g., Nsenga Leunkeu et al., 2012; Thompson et al., 2008), yet this group had a mean GMFM-CM percentage score of 59% (SD 31.8%, range 6.3% to 86.6%), indicating wide variability in terms of advanced gross motor skills. A qualitative assessment of parents and families would help to understand whether the time spent playing the Kinect games took away from time the child would have otherwise been physically active in another capacity.

Secondly, the Kinect exercise program may not have been sufficiently challenging or focused appropriately on specific areas of muscle weakness that would improve functional mobility, such as the hip abductors, knee extensors or ankle dorsiflexors. The games were chosen to challenge balance, strength and endurance, and progressions were suggested to maximize challenge throughout the 6 weeks. However, previous research has demonstrated considerable inter-individual variability in AVG game play among children with CP (Berry et al., 2011), and we can't be sure whether participants played games at recommended intensity. Participants reported playing an average of 34.76 (SD 8.44) minutes per day. A 30-minute game play session, with games lasting 90-120 seconds, interrupted by breaks to change discs, likely did not have sufficient dosage or intensity to elicit functional change.

Therapists were asked to achieve a 'just-right challenge' in this study using information from participants' responses to the 5 weekly questions. For example, they were encouraged to

progress the program challenge if participants reported that it was too easy. Participants and families were encouraged to elaborate on difficulties over email. However only 26% of the emails written by children/families pertained to program clarification. As such, therapists did not have additional information from the emails that would have helped them to build on children's responses to progress the intervention challenge, implying that programs were likely not sufficiently individualized.

Although we evaluated an AVG system with prior evidence of effectiveness in this population (Luna-Oliva et al., 2013) and a VR system with established evidence (Glegg et al., 2014), developed exercise programs with experienced pediatric physical therapists, and used reliable and valid outcome measures, our study had several limitations. The sample size was small and not powered to detect change. Multiple outcome measures in a short time period may have led to fatigue, influencing test performance. A balance-specific outcome measure may have captured more specific training effects related to the intervention; analysis of this measure is currently underway and will be reported in a subsequent publication. We did not measure motivation over the 6 weeks using a standardized outcome measure. Participants only logged in to the website once per week on average, which might have led to recall bias. Self-report means that actual adherence to the AVG program is unknown. Email content analysis showed less frequent discussion of exercise challenge or progression between participants and therapists than anticipated. Therapists could have checked in with families more frequently and could have asked more questions to help further individualize and progress the exercise programs.

Subsequent studies could increase individualization of exercise programs using off-the-shelf AVGs. Participant report may be enhanced by use of a smartphone app rather than website interaction, which would be more feasible for daily reporting. Low-cost rehabilitation-specific AVG systems with tele-rehabilitation monitoring, such as Jintronix (www.jintronix.com) or Mitii (<http://elsassfonden.dk/mitii/english/>) offer individualized parameter settings and allow therapists to remotely monitor adherence and performance. The effectiveness of these systems as home exercise programs could be compared to the Xbox360 in a clinical trial. Finally, subsequent studies will better incorporate principles of the self-determination theory of motivation, which emphasizes competence, autonomy and relatedness (D'Arrigo, Ziviani, Poulsen, Copley, & King, 2016) Although we valued autonomy by letting participants choose games and frequency, subsequent studies could better emphasize competence by providing children with more detailed feedback about their success (such as graphs showing scores increasing over time), and relatedness by pairing participants with age and condition similar peers to focus on competition or teamwork.

CONCLUSIONS

Kinect for Xbox 360 AVG home exercise, supervised remotely by a physiotherapist, did not lead to changes in gross motor skills or functional mobility in this pilot study. There was a significant decrease in 6MWT distance following a 6-week intervention for participants who began with a 1-week VR 'jump-start'. This finding may be related to insufficient AVG intensity or dosage. All participants who showed a decrease in 6MWT distances post-AVG training returned to baseline scores at 2 months post-exercise program completion. Subsequent research will enhance

intervention features to measure motivation and explore mechanisms to individualize commercially-available AVG exercise programs.

Declarations of Interest

The authors report no declarations of interest.

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