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## **Title page**

A pilot single-blind multicentre randomised controlled trial to evaluate the potential benefits of computer-assisted arm rehabilitation gaming technology on arm function of children with spastic cerebral palsy.

**Run-on subtitle:** Computer-assisted arm rehabilitation

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# **A pilot single-blind multicentre randomised controlled trial to evaluate the potential benefits of computer-assisted arm rehabilitation gaming technology on arm function of children with spastic cerebral palsy.**

## **Abstract**

**Objective:** To evaluate the potential benefits of computer-assisted arm rehabilitation gaming technology on arm function of children with spastic cerebral palsy.

**Design:** a single-blind randomised controlled trial design. Power calculations indicated that 58 children would be required to demonstrate a clinically important difference.

**Setting:** Intervention was home-based; recruitment took place in regional spasticity clinics.

**Participants:** Fifteen children with cerebral palsy aged five to twelve years were recruited; eight to the device group.

**Interventions:** Both study groups received 'usual follow up treatment' following spasticity treatment with botulinum toxin; the intervention group also received a rehabilitation gaming device.

**Main measures:** ABILHAND-kids and Canadian Occupational Performance Measure were performed by blinded assessors at baseline, six and twelve weeks.

**Results:** An ANCOVA showed no group differences in mean ABILHAND-kids scores between time points. A non-parametric ANOVA on Canadian Occupational Performance Measure scores showed a statistically significant improvement across time points ( $\chi^2(2,15)=6.778, p=0.031$ ) but this improvement did not reach minimal clinically important difference. Mean daily device use was seven minutes. Recruitment did not reach target due to unanticipated staff shortages in clinical services. Feedback from children and their families indicated that the games were not sufficiently engaging to promote sufficient use that was likely to result in functional benefits.

**Conclusion:** This study suggests that computer-assisted arm rehabilitation gaming does not benefit arm function but a Type II error cannot be ruled out.

## **Clinical messages:**

- The use of assistive gaming technology for less than eight minutes per day in non-collaborative and non-competitive game play does not benefit upper limb activity limitation of children with cerebral palsy.

## **Keywords**

Cerebral palsy, activity limitation, upper limb, assistive technology, rehabilitation gaming technology

# **A pilot single-blind multicentre randomised controlled trial to evaluate the potential benefits of computer-assisted arm rehabilitation gaming technology on the arm function of children with spastic cerebral palsy.**

## **Introduction**

Virtual reality and computer gaming e.g. the Nintendo Wii or custom-built rehabilitation technology has been the focus of recent research to increase engagement and participation of children with cerebral palsy in rehabilitation programmes<sup>1-3</sup>. Rehabilitation programmes that target arm function of children with cerebral palsy are based on principles of motor learning, which involves repetitive and intensive training<sup>4-6</sup>. The intensity of practice and number of repetitions which appear to be the essential components have been the central component of experimental approaches such as Constraint Induced Movement Therapy or bilateral training that show promising results,<sup>5,7</sup> but they prove challenging for children and their families to maintain<sup>7-9</sup>. Virtual reality and computer gaming therefore offer a potential opportunity to engage children and improve participation in intensive, repetitive arm rehabilitation.

However, commercially available technology and games (e.g. Nintendo Wii<sup>10</sup>) are not designed to target and support the movements of disabled children<sup>11</sup>. Conversely, customised technologies such as assistive robotic devices that facilitate movements of the child to participate in the computer or functional activity are expensive and time-consuming to produce<sup>11</sup>. Studies into the use of these technologies in children with cerebral palsy are limited mainly to case studies and feasibility studies<sup>1,3,12</sup>, or do not focus on improving function<sup>13</sup>. Our own feasibility studies of customised computer-assisted arm rehabilitation gaming technology, initially in children's own homes<sup>14</sup> and then, following a period of redesign and development, in children's schools<sup>15</sup>, suggested the potential for assistive gaming technology to reduce arm function of children with cerebral palsy and improve arm kinematics.

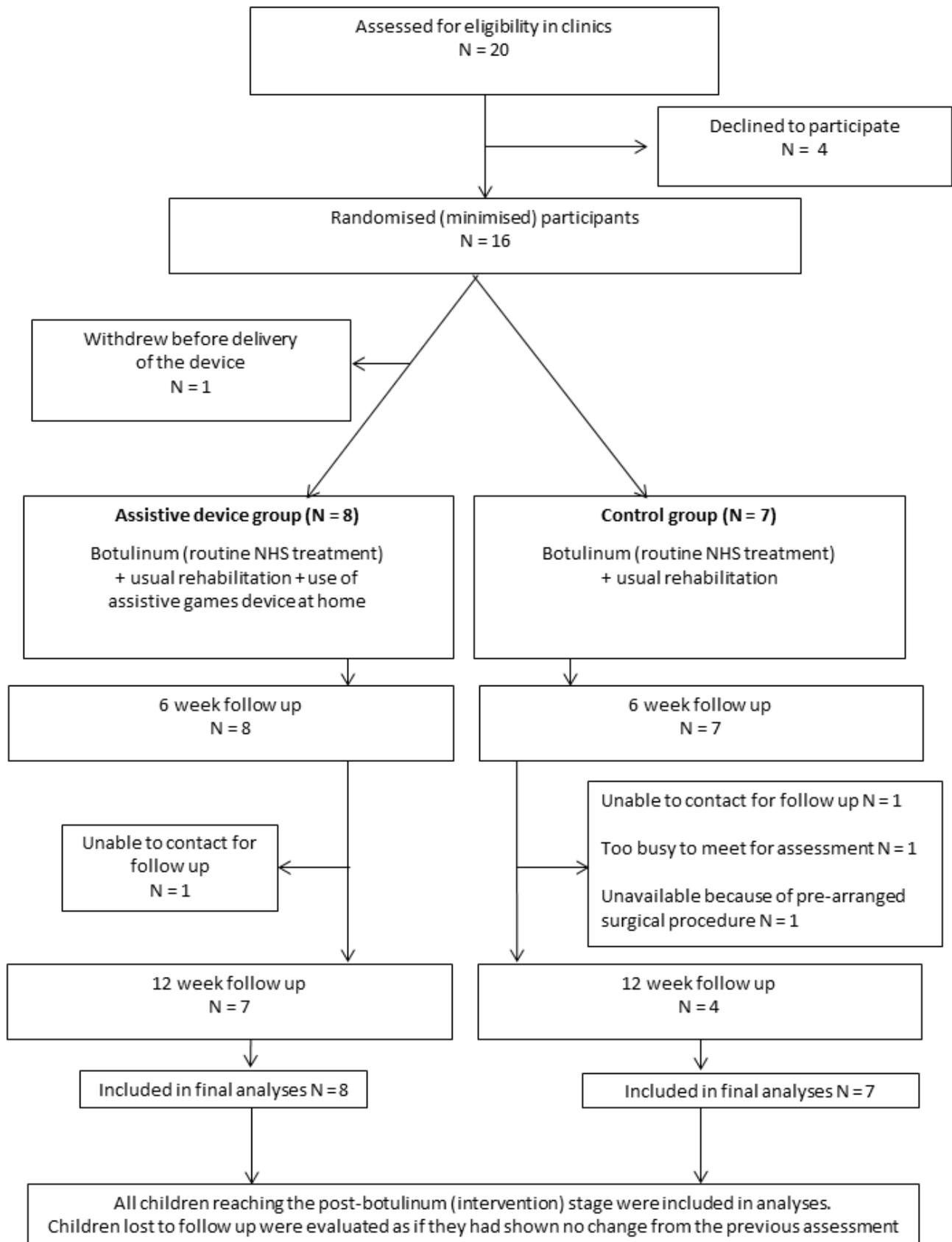
The aim of this study was to investigate the benefits of computer-assisted arm rehabilitation gaming technology on arm function of children with cerebral palsy.

## **Methods**

### *Study design*

This single blind randomised controlled trial is outlined in Figure 1 and is described using the CONSORT guidelines for parallel group randomised trials<sup>16</sup>. Favourable opinions were given by the Leeds West National Health Service Research Ethics Committee (11/YH/0276) and the Medicines and Healthcare products Regulatory Agency (CI/2012/0005). The study was registered on the International Standard Randomised Controlled Trial Number Register (ISRCTN26206379).

**Figure 1. Trial profile for consent, participation and follow up.**



### *Recruitment*

To reduce the impact of spasticity on the children's use of the gaming technology, we invited children who were receiving botulinum toxin treatment to reduce arm spasticity in four regional spasticity clinics in the north of England to participate in this study. Inclusion criteria for this study were:

- children aged five to twelve years with a diagnosis of cerebral palsy who were to receive botulinum toxin treatment for arm spasticity;
- manual ability graded as Manual Ability Classification System levels II-IV
- sufficient cognitive ability to play simple computer games
- arm capability sufficient to manipulate the handle of the robotic arm and vision sufficient to view the computer screen and follow on-screen movements

We excluded children who had arm surgery within the previous six months. Potential participants at each clinic were initially approached by the clinical staff. The lead investigator (NP) was available at each spasticity clinic to meet families who indicated their interest in the study. Written informed consent was obtained from parents and children aged 12 years. Written assent was recorded for children under 12 years old.

### *Sample size*

Due to the lack of published data regarding the effect sizes of outcome measures in children with cerebral palsy, we calculated sample sizes using published psychometric properties of the primary outcome measure, the ABILHAND-kids. Using this information, we aimed to recruit 58 children (29 per group) to detect a large effect at 5% level of significance with 80% power. This number of participants would also allow collection of information about feasibility and trial fidelity issues for a future, larger scale study.

### *Baseline assessments and outcome measures*

All baseline assessments were performed by the lead investigator in the spasticity clinic before the children's treatment with botulinum toxin and randomisation, so that blinding at baseline was achieved. The primary outcome measure was the ABILHAND-kids.

*ABILHAND-kids:* The ABILHAND-kids is a Rasch-derived, parent-completed questionnaire of 21 unilateral and bilateral activities. Each item is graded as easy, difficult or impossible for the child to achieve. Its responsiveness has yet to be established<sup>17,18</sup>. There is no established minimum clinically significant difference for the ABILHAND-kids so a change greater than the standard error (mean SE = 0.44) was deemed to be clinically significant.

*The Canadian Occupational Performance Measure:* The Canadian Occupational Performance Measure is validated for use with children with cerebral palsy<sup>19, 20</sup>. At baseline, parents defined up to five arm activities in which the child's function was limited. The child's performance at each activity was then graded out of 10, with one being the poorest level of performance (unable to achieve activity at all), and 10 indicating full capability. The Canadian Occupational Performance Measure outcome score for each child was calculated as a mean of the scores for the activities. Although evidence suggests that outcome measures that produce ordinal outcome scores lack responsiveness<sup>21</sup>, the Canadian Occupational Performance Measure has reports of good responsiveness in clinical trials<sup>22</sup>. An individual change score of two or greater represents a clinically significant change.

### *Randomisation*

Once baseline measurements were completed, stratified randomisation using minimisation<sup>23</sup> was performed to balance the groups for age, gender, manual ability and ownership of commercial computer games systems. Minimisation was performed using a bespoke computer programme, and carried out at the spasticity clinics. Parents and children were informed of the allocation and arrangements made for follow-up as appropriate for each group.

The children in each group received botulinum toxin treatment following clinical assessment by their regional spasticity centres' medical teams. Follow up rehabilitation by therapists after botulinum toxin treatment was carried out independently of this study, but typically consists of appropriate splinting, antagonist muscle training of the treated muscles and task-oriented training of activities previously limited by spasticity and muscle weakness. Therefore both groups were treated identically apart from allocation of the computer-assisted arm rehabilitation gaming technology to the computer-assisted arm rehabilitation gaming technology group. We controlled for differences in follow-up rehabilitation by providing parents with weekly therapy diary sheets.

### *Blinded assessment at follow-up*

Follow-up assessments were carried out by a trained assessor blinded to the children's allocation at a location convenient for the children and their parents, usually the participants' homes.

### *Intervention*

The computer-assisted arm rehabilitation gaming technology was delivered within one week of botulinum toxin treatment and collected six weeks later. After delivery to the children's

homes, the computer-assisted arm rehabilitation gaming technology was quickly tested in situ, with the parents practising device set-up. Parents were asked to encourage their children to use the gaming technology for thirty minutes a day. The control group did not receive a matching visit for delivery or collection of the device. A visit to check the gaming technology at the participants' home was carried out after three weeks. The purpose of the visit was to offer encouragement to the children and to check the gaming technology system. To maintain balance between the groups, a visit was also carried out to the control group. The control group children were offered similar encouragement about any rehabilitation exercise that they had been given. Besides the delivery, presence, use and collection of the gaming technology in the intervention group, there was no difference between the groups

At six and 12 weeks the blinded assessor arranged visits to participants' homes to perform follow-up assessments. The device was always removed from the house before the blinded assessor visited the child at six weeks. We intended to always remove the device within seven weeks of the botulinum treatment, and within six weeks of delivery; we therefore gave the contact details of the family to the assessor on the first day of the sixth week following treatment. This ensured that the device was not present when the assessor visited and the assessor was always given the details at the same time post botulinum treatment to prevent any possible clues as to allocation of the child. The assessor always attempted to visit as soon as possible after the child's contact details were provided. Children were reminded that their part in the study was a secret from the assessor until after the study had been completed. We encouraged families not to discuss their part in the study with the blinded assessor, and to contact the research team with any enquiries or problems. Prior to collection, we wrote to the families requesting that they completed their diary describing the rehabilitation exercises performed daily, use of commercial computer games and any other activities. We included a questionnaire to gather feedback about use of the gaming system, their engagement with the games and about their participation in the study.

The Canadian Occupational Performance Measure goals taken at baseline were provided for the assessor without the scores given by parents at the baseline assessment.

### *Statistical analyses*

Primary analysis was on an 'intention-to-treat' basis. The ABILHAND-kids raw scores were transformed into interval level data and parametric statistical analyses were performed on ABILHAND-kids scores using a mixed-design ANCOVA<sup>24</sup>, adjusting for child covariates. The ANCOVA was used to determine differences between groups at each time point and within

groups across time points with Bonferroni adjustment. Appropriate post-hoc testing explored any differences revealed by the ANCOVA.

Canadian Occupational Performance Measure outcome scores are ordinal data and were analysed using the non-parametric Friedman's Test and Kruskal-Wallis Test for within-groups and between-groups analyses respectively. Further *post hoc* evaluations were performed using appropriate testing if indicated.

All statistical analyses were performed using IBM® SPSS® Statistics Version 21 Release 21.0.0.0 64 bit edition.

## Results

### *Participants*

Twenty children were identified as potentially eligible and approached for participation in the study. Sixteen children from three participating sites were allocated to the two groups over a period of 21 months. One child was withdrawn from the study after consent and randomisation, but before taking delivery of the computer-assisted arm rehabilitation gaming technology. The parent cited a lack of room for the device once we arrived to install it. This participant was not included in any statistical analyses, and their stratifying factors were removed from the minimisation programme files to prevent the data influencing allocation of future participants. Eight children were allocated to the intervention group and seven to the control group. Allocation of children to groups was revealed to the blinded assessor on two occasions. Of the other thirteen children, the blinded assessor did not know the allocation at any time but correctly guessed the allocation of six children (46%). A binomial test of proportions with significance set at 0.05 produces a confidence interval of 34% and 58%, suggesting that blinding was successful. If the two children that revealed their allocation were included in the binomial test of proportions, the blinded assessor correctly identified the allocation of eight children (53%). The confidence interval was 42% to 64%, suggesting that successful blinding of assessments was achieved even with the two revealed allocations.

Four children were lost to follow-up. One parent reported that being too busy to meet for the final assessment, and it was not possible to contact two parents. The fourth child was recuperating from elective surgery on a pre-existing medical condition, an event of which the research team had been made aware of during the informed consent procedure.

All other participants were allocated to a group through the randomisation process and included in all statistical analyses. Sample and allocated group demographics and clinical details are given in Table 1.

**Table 1. Baseline demographics, clinical details and baseline scores of activity measures.**

| Group                         | Age           | Gender | MACS levels |   |   |   |    | Limb involvement |   | Associated impairment |        | Activity               |               |                  |
|-------------------------------|---------------|--------|-------------|---|---|---|----|------------------|---|-----------------------|--------|------------------------|---------------|------------------|
|                               |               |        |             |   |   |   |    |                  |   | Learning              | Visual | ABILHAND-kids (Logits) |               | COPM Performance |
|                               |               |        |             |   |   |   |    |                  |   |                       |        | Mean (SD) /            | median        |                  |
| All participants<br>(n = 15)  | 9y 2m (2y 5m) | 9/6    | 3           | 5 | 7 | 1 | 14 | 6                | 4 | 0.8084 (1.23) /       | 0.645  | 4                      | (2.4 to 5.0)  |                  |
| Intervention group<br>(n = 8) | 9y 5m (2y 3m) | 4/4    | 2           | 3 | 3 | 1 | 7  | 3                | 2 | 0.86 (0.46) /         | 0.66   | 4.1                    | (2.49 to 5.3) |                  |
| Control group<br>(n = 7)      | 8y 7m (2y 7m) | 5/2    | 1           | 2 | 4 | 0 | 7  | 3                | 2 | 0.75 (0.47) /         | 0.59   | 4                      | (2.33 to 4.2) |                  |

MACS: Manual Ability Classification System;  
M: Male;  
F: Female  
y: years;  
m: months;  
SD: standard deviation

### *Intervention delivered*

The mean number of days that the computer-assisted arm rehabilitation gaming technology was in children's houses was 40 days, and the gaming technology was played on a mean of 14 days. Half of the children used the device for three or fewer of the six weeks, with one child using the gaming technology in the first week only. The mean total use per child was 99 minutes. The mean daily amount of time the gaming technology was played was seven minutes, substantially less than the 30 minutes per day that was suggested to parents. Children 2 and 13 used gaming technology the greatest amount, with a total of over four hours each (daily mean 10min 40s and 8min 20s, playing for 24 and 29 days respectively), while child 7 played the games the least (for a total of six minutes across four days in the first week only).

### *Effect on arm function of treatment*

Table 1 gives baseline scores for the ABILHAND-kids and the Canadian Occupational Performance Measure. Change scores at six and twelve weeks are given in Table 2.

### **Table 2. Change scores in the primary and secondary activity measures.**

**Table 2. Change scores in the primary and secondary activity measures.**

| Primary measure (ABILHAND-kids) change scores, comparisons and statistical results                               |   |                         |               |   |                  |
|--|---|-------------------------|---------------|---|------------------|
|  | Change mean in scores within participants from baseline (range in change score)           |                         | p-value       | Difference between group mean scores  |                  |
|  | AT SIX WEEKS  | AT TWELVE WEEKS         |               | AT SIX WEEKS  | AT TWELVE WEEKS  |
| All participants<br>(n = 15)   | -0.663 (-2.378 to 0.684)  | -0.474 (-2.341 to 1.42) | $p = 0.039^1$ |   |                  |
| intervention group<br>(n = 8)  | -0.48(-2.378 to -0.684)   | -0.61(-2.166 to 0.684)  | $p = 0.462^2$ | -0.51   | 0.19             |
| control group (n = 7)  | -0.88(-2.341 to 0.611)  | -0.31(-2.341 to 1.42)   | $p = 0.699^3$ | $p = 0.861$ (unadjusted between groups ANCOVA) <sup>4</sup> $p = 0.919$ (adjusted between groups ANCOVA) <sup>5</sup> |                  |
| Secondary measure (Canadian Occupational Performance Measure) change scores, comparisons and statistical results |   |                         |               |   |                  |
|  | Change in median scores within participants from baseline (range in median change scores) |                         | p-value       | Difference between group median scores  |                  |
|  | SIX WEEKS   | TWELVE WEEKS            |               | AT SIX WEEKS  | AT TWELVE WEEKS  |
| All participants<br>(n = 15)   | 0.6 (-1 to 3)   | 0.6 (-1.5 to 5)         | $p = 0.031^6$ | 0.9, $p=0.221^8$  | 0.1, $p=0.862^8$ |

- 
- <sup>1</sup> unadjusted p-value of within-participants (repeated-measures) ANCOVA showing significance of comparisons of changes in mean scores between time points.
- <sup>2</sup> p-value of within-participants (repeated-measures) ANCOVA showing significance of comparisons of changes in mean scores between time points, adjusted for covariates of age, gender, MACS, use of commercial home games systems.
- <sup>3</sup> p-value of within-participants (repeated-measures) ANCOVA investigating the interaction of participant allocation and time.
- <sup>4</sup> unadjusted p-value of between subjects effects (repeated-measures ANCOVA) comparing differences between group means at each time point.
- <sup>5</sup> p-value of between subjects effects (repeated-measures ANCOVA) comparing differences between group means at each time point, adjusted for covariates of age, gender, Manual Ability Classification System, use of commercial home games systems.
- <sup>6</sup> p-value of within-participants non-parametric repeated-measures ANOVA (Friedman's Test) comparing differences between participants' median scores at each time point.
- <sup>7</sup> p-value of Wilcoxon Signed Ranks Test comparing difference between participants' median scores at baseline to median scores at six weeks (significant at the Bonferroni-adjusted level of significance of 0.025).
- <sup>8</sup> p-value of non-parametric between-groups ANOVA (Kruskal-Wallis Test) to test for differences between group medians at six and twelve weeks.

*ABILHAND-Kids*: There was no difference between the control and the computer-assisted arm rehabilitation gaming technology groups at baseline (mean (SE) = 0.75 (0.47) and 0.86 (0.46)) respectively ( $t(13) = -0.160, p=0.875$ ). ABILHAND-kids scores decreased in both groups at six weeks; at 12 weeks the gaming technology group had deteriorated further, but the control group had improved, although not to the baseline level. A clinically significant improvement was observed in two children, one from the control group and one from the gaming technology group. However, nine children showed a clinically significant deterioration in activity performance, five in the control group and four in the gaming technology group. Twelve children did not show any improvement in function.

The repeated-measures ABILHAND-kids mean scores for the control group at baseline, six weeks and twelve weeks were 0.75, -0.13 and 0.44 respectively. The scores for the computer-assisted arm rehabilitation gaming technology group were 0.86, 0.38 and 0.24. The between-participants ANCOVA revealed that there was no difference between groups at each time point  $F(1,8)=0.011, p=0.919$ . This suggests that use of the gaming device had no impact on the gaming technology group's arm function.

The results of the repeated-measures (within-participants) ANCOVA indicated that the differences in ABILHAND-kids scores between time points are non-significant  $F(2,18) = 0.807, p=0.462$ , adjusting for the covariates. The ANCOVA results suggest an interaction between age and time points ( $F(4.01(2,18))=4.01, p=0.036$ ). Planned contrasts examining the effects of age on changes in arm function between baseline and six weeks, and baseline and twelve weeks, were both non-significant ( $F(1,9)=0.646, p=0.442$ ;  $F(1,9)=2.619, p=0.14$  respectively).

*Secondary outcome arm function measure*: Canadian Occupational Performance Measure scores of four children showed a clinically significant improvement at six weeks, two in each group. Two had maintained their improvement at twelve weeks, and a fifth (from the gaming technology group) had achieved a clinically significant improvement by twelve weeks.

A Kruskal-Wallis Test<sup>24, 25</sup> for differences between groups at each time point revealed no difference in scores between groups: difference at baseline = 0.1 ( $\chi^2(1, n=15) = 1.638, p=0.201$ ), at six weeks = 0.9 ( $\chi^2(1, n=15) = 1.495, p=0.221$ ), and at twelve weeks = 0.1 ( $\chi^2(1, n=15) = 0.03, p=0.862$ ), suggesting that use of the computer-assisted arm rehabilitation gaming technology did not influence any changes to arm function.

The Friedman Test<sup>25</sup> demonstrated a significant difference ( $\chi^2(2, 15) = 6.778, p=0.031$ ) between scores of all participants across time points (4.0 at baseline, 4.6 at six weeks and 4.6 at 12 weeks). The median scores suggest that these statistically-significant findings apply between the baseline score (median = 4.0) and six week scores (median = 4.6), and between the baseline and 12-week score (median = 4.6). To evaluate this, a *post hoc* non-parametric within-groups Wilcoxon Signed Ranks Test revealed an increase in scores at six weeks (median = 4.6) compared to baseline (median = 4.0,  $z=-2.199, p=0.013$ ) but the effect size is small ( $r = 0.4$ )<sup>24</sup> and less than clinical significance. At 12 weeks (median = 4.6), the scores were still significantly above the baseline scores  $z=-2.608, p=0.003$ , and the effect size was still small ( $r = 0.48$ ).

### *Adverse events*

No adverse events were reported. A malfunctioning castor on the frame that supports the computer-assisted arm rehabilitation gaming technology was noted by the researchers following the return of a device to the University of Leeds' laboratory. Difficulties were experienced during the installation of the device into the home of one child, when final testing of the device blew the main fuse in the house. The device was replaced the following day, and no further problems were experienced. The device did not malfunction when tested at the University of Leeds laboratory, and no further problems were experienced.

## **Discussion**

The results of this RCT suggest that arm function in children with cerebral palsy does not improve after using computer-assisted arm rehabilitation gaming technology at home. This contrasts with our earlier work looking at this technology in children's homes<sup>14</sup> and in their schools<sup>15</sup>.

We achieved satisfactory blinding of the outcome measures. The randomisation (minimisation) process satisfactorily balanced the groups on the stratifying factors with 15 participants using a bespoke computer programme that addressed criticism of minimisation as a randomisation procedure<sup>26</sup>. Our statistical analyses were thorough, and took into account the nature of the data in terms of its type and distribution, prognostic covariates and multiple testing.

However, our own study included some important limitations. The study was underpowered by a large margin, suggesting the possibility of a Type II error. Although recruitment was initially satisfactory, recruitment slowed when staffing levels at the largest regional

spasticity clinic were reduced through unforeseen circumstances; overall, the study recruited only a quarter of the necessary sample to achieve adequate power. Any positive findings in the results, such as those suggested by the secondary outcome measure, should be interpreted with caution and can only be applied to children who have been treated with botulinum toxin.

An additional barrier to recruitment was that patient confidentiality prevented inclusion of academic research staff in clinics and other situations where they can approach potential participants; this is a previously recognised obstacle<sup>27</sup>. Potentially, therefore, many potentially eligible children might not have been invited to participate. Finally, some potential participants were unable to accommodate the device in their homes.

Use of the device was timed for six weeks to take advantage of the optimal period of effectiveness of botulinum toxin<sup>28</sup> and to ensure sufficient quantity of practice and repetition. We reviewed studies of Constraint Induced Movement Therapy and bimanual training to determine the optimal amount of rehabilitation likely to elicit an improvement in arm function, but this has not been established<sup>4</sup> and there is a wide variation in quantity of rehabilitation using these methods. Thirty hours per week<sup>6, 29, 30</sup> is unrealistic for children attending school, and benefits were reported in studies using much less active rehabilitation<sup>9, 31</sup>.

Previous studies have found that 21 minutes per day over 36 to 60 days has the potential to show improvements in arm function<sup>32</sup>, and 12 minutes per day over 13 days only produces kinematic improvement but no changes in arm function<sup>15</sup>. We therefore suggested to parents that 30 minutes per day was desirable, based on the successful outcomes in other studies<sup>9, 31</sup>. However, the children achieved an average of only seven minutes per day, with the most active user achieving less than 11 minutes per day. Previous studies therefore suggest that this is unlikely to be of sufficient intensity to produce improvements in functional ability.

The purpose of the computer-assisted arm rehabilitation gaming technology is to engage children to undertake intensive and repetitive reach-retrieve movements of their impaired arm. There are a number of possible reasons for the disengagement with the games device. Children who participated in a home-based feasibility study<sup>14</sup> expressed a strong desire for a multi-player games system, and this finding was supported by the children who participated in a school-based study<sup>15</sup>. In this trial, children in the gaming technology group and their parents reported to researchers that the children quickly lost interest in the games. This

might have been delayed or prevented if family and friends were able to play the device in competitive and collaborative games.

One suggestion for overcoming this problem is an online network similar to that described by Golomb et al.<sup>32</sup> that provides the facility for participants to play each other in real time. Introducing each game in turn after a set period<sup>15</sup> appears to maintain interest in playing the device for a longer period, resulting in increased game play and therapeutic movement. There is also the potential that over a six week period these four simple games were insufficient to maintain the children's interest, especially when they were competing against commercial games (80% of the gaming technology group children also had commercial games systems), although it is notable that one of the two children without a commercial games system (child 7) used the gaming technology device the least.

This study suggests a number of possible implications for future studies. The difficulty in communicating with parents for follow-up visits and the low return rate of questionnaires and diaries suggests the additional pressure of participation in a study places substantial demands on families. Engagement with the study might have been better had it focused on the gaming system's *rehabilitation* potential that was being evaluated as a supplement to traditional rehabilitation exercises that were essential for the full benefits of botulinum toxin to be realised. That is, suggesting to parents that 30 minutes of playing on the games device would be a much better option for the children than 30 minutes of stretches and standard rehabilitation exercises, and emphasising that active parental encouragement and engagement would be essential for the potential rehabilitation benefits to be realised.

The study produced no evidence to support the hypothesis that use of the computer-assisted arm rehabilitation gaming can improve arm function of children with cerebral palsy. However, use of the gaming technology device was well below the intensity expected to produce beneficial effects, and the small sample size severely limits the strength of any conclusions. Any positive conclusions can only be reasonably applied to children who have been treated with botulinum toxin. Instead, the project provides a useful case study highlighting the difficulties of assessing novel rehabilitation techniques in children with cerebral palsy. The evidence suggests that systems such as computer-assisted arm rehabilitation gaming technology might play a useful role in rehabilitation, and that engagement with the device might be increased if competitive and collaborative play with friends and family is incorporated. But establishing a robust evidence base is very difficult. The inherent difficulties of conducting research in services that are experiencing financial pressures and the restrictions created by regulatory bodies need to be factored into future

studies. The research community may need to show as much innovative flair in testing innovative therapeutic approaches as they show in developing the therapy.

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## **Conflict of interest**

None Declared

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