Project title: Limbs Alive: Use of computer games to provide motivating, child centred therapy to improve bimanual skills for children with hemiplegic cerebral palsy.

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Plain language summary
Together with children who have hemiplegia, we have designed computer games requiring two-handed control. The aim of the research was to find out if children will play these games regularly over a 3 month period and if this leads to increased skill in two-handed activities of everyday life.

74 children with hemiplegia were randomly sorted into two groups; 16 children failed to complete the 3 month study - 8 from each group. 29 children in each group completed the study. The children in both groups received the same initial games; for one group (placebo) the games relied primarily on use of the less affected hand with only simple moves required of their affected hand. For the other group (treatment group) the games progressed to require more and more skillful use of their affected hand and arm. The children and their families were told we are simply evaluating computer games. The research team did know which group each child was in. The total time the children spent making the therapy moves embedded in the games was recorded automatically by the computer. The ability of children in each group to perform two-handed tasks was assessed at the start and at 1, 3 and 6 months.

The children completed on average 177 minutes (Sd 144 minutes) of actually attempting the therapy moves (i.e. performing the therapy exercises). There was no difference in the time the children played the games between groups. Unfortunately there was also no difference between groups in the games the children played. Those in the experimental group did not progress past the simplest games, which were also played by the placebo group. When you combined the data from both groups there was however a significant relationship between the number of minutes children performed the therapeutic moves within the games over the 3 month period and improvement in their upper limb function at both 3 and 6 months. The association may be explained by reverse causality i.e that those with better hand performance play more games. However the relationship was independent of initial severity of hand function and of age.

Keywords
hemiplegia, cerebral palsy, video games, upper limb dose response
Summary of research findings
Background
Hemiplegic cerebral palsy is common affecting 1 in 1,300 births. The children grow-up using their unaffected hand almost exclusively and neglect their impaired hand. Development of the sensorimotor cortex controlling the affected limb is suppressed and they do not develop effective motor programmes for bimanual activities. Many activities of daily living require two hands and children with hemiplegia often do not develop sufficiently skilful bimanual dexterity to be fully independent in adulthood. The term “never-learned-to-use” (NLTU) is used to describe this common situation. If NLTU is addressed during childhood, by increasing use of the affected arm and hand in bimanual activities, it is preventable or reversible.

Well designed computer games provide all the elements for effective motor learning, namely interactivity, repetition, multi-sensory stimulation, immediate feedback and motivation. Flexibility to change interactively task difficulty according to the patients’ initial capabilities, their rate of learning and the therapeutic goals, are additional advantages of using computer games for therapy. Together with children who have hemiplegia, we have designed and piloted computer based video games requiring two hands to be played.

Aims
Our aims are (1) to conduct a randomised doubled blinded and controlled trial to assess in children with hemiplegic cerebral palsy whether specifically designed, computer-based video games requiring two handed control, improve significantly the functional use of their affected arm and hand. (2) to conduct an economic evaluation

Subjects: Inclusion criteria: i). Hemiplegic cerebral palsy ii) Melbourne Score for their affected side of between 30 and 85. (2). Age 7-15 years. Exclusion criteria: i). IQ less than 70. ii) Severe behavioural problems iii). Severe visual impairment iv) Severe fixed contractures of the wrist or elbow. 74 children with hemiplegia were randomly allocated to intervention or placebo groups, stratified for sex and severity of hemiplegia. All members of the research team were blinded to subject allocation. The children and the families were blinded to the purpose of the study and told simply that we are assessing the value of computer games in therapy. We were careful to avoid contamination of the families by ensuring they do not meet in relation to the trial before or during therapy. Contamination at school did not occur since no two subjects went to the same school.

Methods
The children received a laptop with the same range of computer games, which they were asked to play at home for 3 months. In the learning phase of the game both groups started with games where the task difficulty for their affected hand was simple.

The Intervention. In the intervention group the task difficulties for their paretic hand will be interactively adjusted as part of the game to take account of increasing skill in bimanual hand use. Therefore to change levels within the game and to achieve points, as the child becomes more skilful with their affected hand and arm, more challenging tasks will be asked of both hands working together.
The Placebo Group. The task difficulty for the affected hand and arm remained simple. The control of the game will not interactively adapt to changing skills in the paretic hand, rather a fixed and relatively low level of skill will be demanded at all levels of the game. These children provided controls for the effects of: training of their non-affected hand, clinical assessments and advice from the occupational therapist and for the effects of the introduction of a novel and interesting therapy (i.e. attention control).

Clinical Assessments
Clinical assessments were undertaken by an experienced occupational therapist blinded to subject allocation and carried out in dedicated assessment areas within the Sir James Spence Institute of Child Health. They were undertaken at baseline (immediately prior to the 3 month intervention) and 1 and 3 months. There was a final assessment 6 months after baseline to assess if any effect continues after the formal period of therapy has been ended. The assessments comprised: i) Melbourne Assessment of Unilateral Upper Limb Function (the primary outcome measure) to give an assessment of the functional skill and quality of movement of the affected hand,ii) Assisting Hand Assessment gives a measure of the child’s spontaneous use of the affected hand in every day activities, iii) The Abilhand -Kids - a parent report which provides a measure of overall manual ability from the parents perspective and vi) Beery-Buktenica Developmental Test of Visual-Motor Integration.

Quantitative assessment of quality of life was performed at baseline and after 6 months using Kidscreen, and at six months semi-structured interview was carried out with the child and with their parents separately to examine positive and negative effects of the intervention.

The economic cost of delivering therapy using video games has been obtained and the analysis is ongoing at present.

Preliminary Analysis of the Results
74 children were recruited 37 to each group. There were no significant differences between groups for age, sex, side or severity of paresis. 16 children failed to complete the study - 8 from each group. 58 children completed the study giving 29 children in each group. There was no difference between groups for age, sex, side or severity of paresis. Children played the games at home on a regular basis. The children achieved a mean time of performing the actual therapeutic moves of - Placebo - 152 minutes (20.5 SD) Intervention 200 minutes (28.6 SD). There was no difference between groups for the duration of game play (p=0.239).

We had anticipated that there would be a difference between groups in the levels of complexity required from the paretic hand - with the intervention group progressing through the games to levels requiring a higher degree of skill. Unfortunately both groups only achieved the same levels of game play over the three months - with the intervention group still only achieving a skill level which required simple moves of the paretic hand and arm. It was therefore not appropriate to compare the outcome between the two groups - since there was no difference in the game play achieved. We therefore pooled the data from the two groups. Analysis of variance revealed a significant positive relationship between the time spent playing the computer games and the improvement in both the Melbourne Unilateral Assessment of Upper Limb Function and the Assisting Hand Assessment at both 3 and 6 months (Melbourne - at 3 months p<0.001; 6 months p<0.01: Assisting Hand Assessment -at 3 months p<0.01; at 6 months p<0.05). This relationship was independent of initial severity of hand function impairment.
Conclusions:
1. Children will play therapeutic video games at home and it is possible to obtain a therapy log which measures the actual time each child spends performing therapeutic moves.
2. There is a positive "dose response relationship" between the improvement in upper limb function and the total duration that a child spends performing the therapeutic moves embedded within the video games. This may reflect a reverse causality effect but the relationship was independent of severity of upper limb function.
3. Children with hemiplegia require longer game play time than 3 months to progress through a therapy programme embedded in a video game. This has implications for game design.

Impact
Children with hemiplegia receive less treatment than other subgroups with cerebral palsy. Current healthcare provision focuses mostly on lower-limb function despite children experiencing progressive decline in upper-limb skills. Games-based therapy could be incorporated immediately within existing NHS services for children with disability. The games can be played within the home and deliver regular and enjoyable therapy without requiring on to one supervision and guidance from a therapist. They are inclusive, allowing parents, siblings and friends to play.

Patient and public involvement
The project was planned and the games designed with input from children and their families. The games were tested during their development by children and their families and their comments and suggested changes informed the games design. This was extremely helpful in achieving games that children and their families enjoyed playing.

We have participated in workshops with hemihelp and demonstrated the games to families and children with hemiplegia.

At the end of the project (January 2015) we held a stakeholders event involving therapy professions and video games development studios as well as NHS England and Academic Health Science Networks to present the results and begin an debate as how to make therapy delivered by video games both scalable and sustainable.

We plan an event involving families and children where we will show case the new games and present the results of the study. We anticipate that this will take place towards the end of 2015.

Data sharing statement
See link [https://www.nihr.ac.uk/documents/nihr-position-on-the-sharing-of-research-data/12253] for the NIHR position of the sharing of research data. The NIHR strongly supports the sharing of data in the most appropriate way, to help deliver research that maximises benefits to patients and the wider public, the health and care system and which contributes to economic growth in the UK. All requests for data should be directed to the award holder and managed by the award holder.
Disclaimer

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This project was carried out between January 2011 and December 2014. This final report has not been peer-reviewed. The report was examined by the Programme Director at the time of submission to assess completeness against the stated aims.