

# Limbs Alive: Use of video games to provide motivating, child centred therapy to improve bimanual skills for children with hemiplegic cerebral palsy

<b>Submission date</b> 28/11/2012	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 29/11/2012	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 25/11/2019	<b>Condition category</b> Nervous System Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

## Secondary identifying numbers

11138

# Study information

## Scientific Title

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

## Study objectives

The aim of this study is to find out whether bespoke video games can improve bimanual function in children with hemiplegic cerebral palsy.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

21/04/2011, ref: 11-NE-0027

## Study design

Randomised interventional trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Not specified

## Study type(s)

Treatment

## Participant information sheet

## Health condition(s) or problem(s) studied

Hemiplegic cerebral palsy

## Interventions

70 children with hemiplegia will be randomly allocated to intervention or placebo groups, stratified for sex and severity. The children and families will be told only that computer games are being evaluated for therapy. The research team will be blinded to group allocation. Both groups will be given the same computer games. Intervention group: successful playing will require increasing bimanual dexterity. Placebo group: increasing skill will be required of only the non-affected hand. The date, time, duration of play and score will be recorded automatically.

The Intervention Group The initial grade of difficulty of the task for the paretic hand will be set to make use of their maximum skill. Bimanual dexterity will be required and the task difficulties will be interactively adjusted as part of the game to take account of increasing skill in bimanual hand use.

Clinical assessments of upper limb function will be carried out at baseline, 1, 3 and 6 months by an experienced therapist.

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome measure**

Melbourne Unilateral Upper Limb Assessment at 1 month, 3 months and 6 months

**Secondary outcome measures**

1. Assisting Hand Assessment at 1 month, 3months and 6 months
2. Beery-Buktenica Developmental Test of Visual-Motor Integration at 1 month, 3 months and 6 months
3. Canadian Occupational Performance Measure at 1 month, 3months and 6 months
4. Kidscreen at 1 month and 6 months

**Overall study start date**

01/04/2012

**Completion date**

30/12/2012

## Eligibility

**Key inclusion criteria**

1. Hemiplegic cerebral palsy
2. Able to actively grasp the game controller with the paretic hand, though grasp need not be maintained.
3. Male & Female, age 7-15 years

**Participant type(s)**

Patient

**Age group**

Child

**Lower age limit**

7 Years

**Upper age limit**

15 Years

**Sex**

Both

**Target number of participants**

Planned Sample Size: 70; UK Sample Size: 70

**Key exclusion criteria**

1. IQ less than 70
2. Severe behavioural problems
3. Severe visual impairment
4. Severe fixed contractures of the wrist or elbow
5. Epilepsy induced by the flicker frequency of a computer screen

**Date of first enrolment**

01/04/2012

**Date of final enrolment**

30/12/2012

**Locations****Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Sir James Spence Institute**

4th Floor

Newcastle upon Tyne

United Kingdom

NE1 4LP

**Sponsor information****Organisation**

Newcastle upon Tyne Hospitals NHS Foundation Trust (UK)

**Sponsor details**

Northern Centre for Cancer Care

Freeman Road

High Heaton

Newcastle upon Tyne

England  
United Kingdom  
NE7 7DN

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.newcastle-hospitals.org.uk>

**ROR**

<https://ror.org/05p40t847>

## **Funder(s)**

**Funder type**

Government

**Funder Name**

National Institute for Health Research (NIHR) (UK) - Research for Patient Benefit (RfPB)

## **Results and Publications**

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**

Not provided at time of registration