

## Feasibility of a randomised controlled trial to evaluate home-based virtual reality therapy in children with Cerebral Palsy

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### **Abstract**

**Purpose:** Evidence is increasing for effective virtual reality therapy for motor rehabilitation for children with Cerebral Palsy. We assessed the feasibility of a virtual reality therapy mode of intervention, appropriateness of measures, and potential cost-effectiveness.

**Methods:** A 12-week, 2-group, parallel-feasibility trial (ISRCT 17624388) using Nintendo Wii Fit™ at home. Children aged 5–16, with ambulatory Cerebral Palsy, who were able to follow simple instructions were randomised to two groups; one supported by physiotherapists (individualised activity programme), the other unsupported with children having free choice (control). Children were assessed in clinic at baseline, week 6, and week 12 by blinded assessors. Feasibility of the intervention was assessed via recruitment, adherence, and usefulness of measurement tools.

**Results:** Forty-four children were eligible (out of 48 approached): 31 consented, 30 were randomised, 21 completed the study; 10 in the supported group and 11 in

32 the unsupported group. Nine children discontinued from tiredness, after-school  
33 activities, homework, surgery, technical difficulties or negative system feedback.  
34 The supported group completed 19 of 36 (IQR 5-35) possible sessions; the  
35 unsupported group 24 of 36 sessions (IQR 8-36). Gross Motor Function Measure  
36 scores varied by Cerebral Palsy severity after the intervention. There were no  
37 adverse events.  
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40 **Conclusion:** Virtual reality therapy offers potential as a therapeutic adjunct for  
41 children with Cerebral Palsy, warranting substantive confirmatory study. Gross  
42 Motor Function Measure, with modifications to improve sensitivity, appeared  
43 appropriate as a primary measure, with Timed up and Go test secondary. The  
44 intervention was inexpensive costing £20 per child. An explanatory trial to  
45 evaluate the clinical/cost-effectiveness of commercial system virtual reality  
46 therapy is feasible with minor methodological adaptation.  
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53 **Keywords:** Child; Cerebral Palsy; Randomised Controlled Trial; Physical  
54 therapy modalities; Therapy, Computer Assisted; Exercise Therapy  
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## Introduction

Cerebral Palsy (CP) is an umbrella term for a collection of disorders that occur as a result of primary non-progressive damage to the developing foetal or infant brain, occurring at a rate of approximately 2 per 1000 live births in the UK or 254,000 live births per annum, globally [1]. The impairment of the developing brain affects muscle tone and strength, which limits movement and physical activity. Co-morbidity [2] can cause further disturbances of sensation, perception, cognition, communication and behaviour, with conditions such as autism, epilepsy, and secondary musculoskeletal problems [3].

In the UK, children with CP experience a decline in the amount of therapy time they receive as they age, from 12 hours per year for 0 - 6 year olds, to seven hours for 12 - 18 year olds [4]. Further, a reduction in therapeutic exercise is exacerbated by general resistance to home-based physical activity [4-6]. Children with more severe and complex impairments receive the most therapeutic input, leaving ambulatory and older children with CP to receive as little as two hours of therapy per year [5, 6].

New approaches are needed to counteract this poor access to therapy. To be practicable, new home and school-based interventions need to be low-cost, easily deployable, flexible and acceptable. Whilst motor learning theory supports intensive task focused therapies for CP, poor motivation has been observed in current therapies with insufficient applicability to daily function [7-11]. Therapeutic modes need to be both motivating and responsive to the needs of families and be developed with direct input from families of children with CP to ensure greater alignment and applicability to daily function. Home-based therapies delivered by parents are showing some promise as well as challenges for some families [12, 13]. Virtual reality therapy (VR therapy)

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2  
3 carried out in the home may be one potential avenue for increasing children's  
4  
5 engagement with therapy and improving outcomes.  
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### 8 9 *Virtual Reality Therapy*

10  
11 As digital technology becomes more prevalent and pervasive for the current millennial  
12  
13 generation(s) of 'digital natives' [14], there has been a parallel and unprecedented  
14  
15 growth in assistive and rehabilitation digital technology for children with additional  
16  
17 needs [15]. However, practical frameworks that align technology to clinical need remain  
18  
19 elusive [15]. In particular; pragmatic questions remain regarding issues of acceptability,  
20  
21 feasibility, and patient data security for physical activity with smartphones, global  
22  
23 positioning systems, and use of large-scale patient data sets [16]. Scrutiny is required to  
24  
25 ensure digital healthcare services are provided that are appropriately evidence-based,  
26  
27 cost-effective, and fit for purpose. Voices of dissent even suggest in the title of journal  
28  
29 articles that digital technology may be more 'hype than hope' [17].  
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35 One avenue for digitized patient care is in the use of Virtual Reality (VR)  
36  
37 therapy that uses motion capture digital technology to assist as part of a therapeutic  
38  
39 treatment programme [18, 19]. A recent study by this research team identified the  
40  
41 potential of VR therapy in the home as supportive to active therapy intervention, and is  
42  
43 welcomed by children and families but a clearer understanding of the potential impact is  
44  
45 needed [20]. Commercial systems such as the Nintendo Wii Fit™, Xbox Kinect™, or  
46  
47 bespoke systems such as Mitii™ have all been tested to date with varying success in  
48  
49 stroke rehabilitation, dementia, children with developmental coordination disorder,  
50  
51 acquired brain injury and CP [21-23]. Recent results suggest that therapy with the Wii  
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53 Fit in-clinic may be more effective than standard physiotherapy intervention [24].  
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57 However, published studies are often beset with problems of inadequate sample size  
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3 [25, 26], non-standardisation of measurement tools [27], lack of adherence, unclear  
4 dosage within programmes of therapy, lack of clarity for the role of the therapist, and  
5 alignment of aims with daily life skills [28]. For example, James et al. [23] demonstrate  
6 the ‘Move it to improve it’ (Mitii™) VR system is partially effective for improving  
7 activities of daily living in children with unilateral CP over a 20 week period, but  
8 problems were still experienced in sustaining the novelty of the intervention after the  
9 first 20 hours of therapy.  
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18  
19 One in four children is reported to have a video game console such as the  
20 Nintendo Wii or Sony PlayStation [17], or more recently the Xbox Kinect in the home.  
21 A recently published survey in England suggests this number may be far higher, with  
22 97% of families in possession of a commercial games console, with active gaming  
23 consoles such as the Xbox Kinect making up 68% of total ownership [20]. Families of  
24 children with CP reported that 28 of 61 (48%) survey respondents already used or had  
25 attempted to use the Wii Fit™ for therapeutic purposes [20]. This raises the possibility  
26 of an additional motivating tool in the home which may be supported by physiotherapy  
27 directed activities, and enhance patient adherence for home-based exercise regimes.  
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40 The prohibitively high costs of bespoke VR systems for physiotherapy  
41 interventions takes access to such technologies beyond the reach of most patients and  
42 services [23]. To address this issue our focus is on identifying affordable options, with  
43 the most likely candidate technology being modified entertainment and exercise  
44 systems that are commercially available. There is “great opportunity to use interactive  
45 technology as a holistic intervention to address broad ranges of impairments” [p15, 29].  
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54 Health inequality could also be reduced by allowing individuals to carry out the  
55 intervention at home, with their family, and at a time of their choosing [28], alongside  
56 personal goal setting, which is paramount in rehabilitation practice [28, 30]. As the gap  
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3 between research and practice is narrowing, work is more gradually focusing on the  
4 integration of VR and serious games into therapy according to three key elements;  
5  
6 prevention, participation and neural plasticity [31]. Our work here focuses on assessing  
7  
8 the feasibility of using low-cost VR therapy in the home.  
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10

11 Before embarking on a definitive trial, we have undertaken a feasibility study to  
12  
13 see if VR therapy, using commercially available systems, may be one avenue to  
14  
15 increasing therapeutic engagement with children with CP.  
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## 19 **Study Aims**

20  
21 The primary aim was to explore the feasibility of a future multicentre randomised  
22  
23 controlled trial (RCT), testing the clinical effectiveness of our chosen methods and  
24  
25 measures, and the cost effectiveness of a commercially available console for virtual  
26  
27 reality therapy in children with ambulatory CP. Therefore we sought to investigate:  
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31

- 32 • Whether procedures for recruitment attracted sufficient participants
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- 34 • If children adhered to the recommended programme and
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- 36 • Whether proposed measurement tools, methods of analysis, and resource
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- 38 implications/costs were appropriate in relation to outcomes
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45 We aimed to estimate the precision of group differences for our five main outcome  
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47 measures, to begin to gain greater clarity of the sensitivity of these measures to detect  
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49 relevant change for the potential utility of these measures in a definitive RCT.  
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53 Additionally, we investigated cost-effectiveness of whether the treatment can be  
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55 offered through physiotherapy services in the UK National Health Service (NHS), if  
56  
57 there is fidelity to the delivery of the treatment, what outcomes are important to  
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3 measure, and the profile of children for whom the treatment may be effective and  
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5 ineffective.  
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## 7 8 **Method** 9

10  
11 The study procedures were approved by the Lancaster National Research Ethics  
12  
13 Committee (NW1499), International Standard RCT number 17624388.  
14

### 15 16 17 ***Recruitment and Consent*** 18

19  
20 Children with CP were identified from Community NHS Trust Child Development  
21  
22 Teams in South-East England (see Figure 1, process of informed consent). Families  
23  
24 were provided with information about the study by their regular clinician during  
25  
26 appointments or by mail. The opportunity to take part in the trial was advertised through  
27  
28 posters, or flyers distributed to clinicians at local study days, study presentations to  
29  
30 Child Development Teams or through local clinical research networks. Participants  
31  
32 were also able to self-refer to the research team who checked suitability with the child's  
33  
34 care team. After participants registered their interest in the study to their clinical team or  
35  
36 through self-referral there was a 24-hour cooling off period. Participants were then  
37  
38 approached by a research assistant to book an appointment to check eligibility and  
39  
40 obtain written consent. A record of participation interest and consent was made on  
41  
42 clinical notes so as not to duplicate contact with families, and of families not wanting to  
43  
44 take part, to determine the likely size of population needed to run a definitive RCT  
45  
46 (Figure 2). Recruitment took place between 27/7/2015 and 10/5/2016 and follow-up  
47  
48 ended on 2/8/2016. Based on local population size and prevalence predictions we  
49  
50 anticipated that by recruiting children of school age (i.e. 5 to 16 years) we would be  
51  
52 able to reach a target of 30 children, assuming a 40% positive response rate. Julious [32]  
53  
54 recommends that a pilot trial should have at least 12 participants per group for the  
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3 analysis, therefore allowing a drop out of 20% post randomization.  
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5 *Insert figure 1 here*  
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7

### 8 ***Inclusion criteria*** 9

10  
11 Ambulatory children aged 5 to 16 years with bilateral or unilateral CP were invited to  
12 take part in the study. Children were included and classified using Gross Motor  
13 Function Classification System (GMFCS) levels I and II [33]. At GMFCS I and II  
14 children are able to walk independently over short distances without the use of walking  
15 aids. Children had to be able to follow task instructions.  
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### 23 ***Exclusion criteria*** 24

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26 Children with epilepsy who were photosensitive or had had a seizure within the  
27 previous year or were taking anticonvulsant medication were excluded.  
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### 32 ***Randomisation*** 33

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35 Participants were randomised with Minimpy [34] using minimisation [35]. This gives a  
36 70% probability of a group allocation which minimises imbalance on variables that  
37 could influence the outcome, namely gender, type of CP (unilateral or bilateral), and  
38 age group (primary school age (under 11 years) or secondary school age (over 11  
39 years)). Table 2 shows the balance of minimisation.  
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### 48 ***Randomised Groups*** 49

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51 Children were allocated to either a physiotherapist supported group with prescribed  
52 games (SG) or an unsupported group with freedom over game choice, the control group  
53 (USG). The SG was given a structured home-therapy programme. The USG had free  
54 use of their console in order to control for the Hawthorne effect [36] and further, it was  
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3 considered unethical to withdraw families' own consoles for the 12-weeks of the study.  
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### 6 7 **Measurement tools**

#### 8 9 10 *Study Outcome measures*

11  
12 Five measurement tools were employed, and considered for their measurement  
13 properties, suitability for detecting change, and potential to support the estimation of a  
14 sample size of a future RCT. Clinical measurement were taken by a physiotherapist  
15 blind to allocation at baseline, 6 weeks, and 12 weeks.  
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22  
23 The **Gross Motor Function Measure-66** (GMFM-66) is a clinical measure  
24 designed to evaluate change in gross motor function in children with CP. This could  
25 potentially be a primary measure in future studies as it is already the *de facto* gold  
26 standard [e.g. see 37 for details] for measuring impact on motor function for children  
27 with CP.  
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35 There are five dimensions to assessment; lying and rolling, sitting, crawling and  
36 kneeling, standing, and walking, running and jumping [37]. This tool has a strong track  
37 record of use in studies with children with CP and VRT [31, 38-39]. Although GMFM-  
38 66 is considered to be better clinically than the longer GMFM-88, it has been shown to  
39 report changes more slowly postoperatively in gross motor function compared to  
40 GMFM-88 [40-41]. For work with assisted technologies, GMFM-66 is considered to be  
41 a sensitive tool capable of detecting gross motor improvement in children with CP [33].  
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54 The **Timed up and Go test (TUG)** measures mobility, and active and static  
55 balance. It involves recording the time taken to get up from a chair, walk three metres,  
56 walk back to the chair and then sit down. It is conducted using the normal mobility aids  
57 an individual may need. This tool has a track record of use in studies with children with  
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3 CP and VRT [33, 42-43] and has high detection rates for functional mobility [44]. The  
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5 test has high reliability within session (intra class correlation of 0.99) and test re-test of  
6  
7 the same level [45]. Whereas the GMFM measures gross motor skills, the TUG has  
8  
9 been found to show accompanying changes in movement speed [46].  
10

11  
12 **Bruininks-Oseretsky test of motor proficiency-2<sup>nd</sup> Edition** – short form,  
13  
14 Balance subscale, and Running, Speed and Agility subscale (BOT2) [47]. This tool was  
15  
16 included because of its effective sensitivity to change in motor proficiency conducted  
17  
18 during our own pilot study with children with developmental coordination disorder [21].  
19  
20 We also wished to consider whether VRT had any impact on aspects of upper-limb  
21  
22 function [48-49]. Additionally we are unsure of ceiling effects of the GMFM-66, which  
23  
24 this feasibility RCT study assessed.  
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31 **Goal Attainment Scale (GAS)** scores patient's individual goals, is particularly  
32  
33 sensitive to change, and encourages patient intervention [50]. This tool has been used in  
34  
35 studies with children with CP and VRT, and has been included because of its effective  
36  
37 prior use in establishing and maintaining interest in patient intervention [30].  
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41 Three of the four tools have been used in previous studies of VRT in children  
42  
43 with CP (GMFM, TUG, GAS) whilst BOT-2 scores are untested with VRT and CP. The  
44  
45 present feasibility study investigated how appropriate these measurements would be for  
46  
47 gathering data from which effectiveness could be assessed. We also assess what the  
48  
49 primary outcome measure might be, and how the four measurement tools work together,  
50  
51 if at all, if they potentially cause fatigue and/or pain, and whether they are useful  
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53 clinically for showing changes in functional balance and secondary effects following  
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55 VRT in children with CP.  
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3 Psychosocial outcomes were measured through recorded diaries (see  
4  
5 supplementary material S1) of the child and parental experience of using VRT. The  
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7 **Strengths and Difficulties Questionnaire (SDQ)** which reflects, in this instance,  
8  
9 parent report of social and emotional behaviour was also administered at the start and  
10  
11 end of the study to assess potential broader impacts [51].  
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14  
15 **The Edinburgh handedness inventory** [52-53] is a short four item  
16  
17 questionnaire asking whether a child uses one hand predominantly for certain tasks such  
18  
19 as writing, throwing, using a toothbrush ('always', 'usually', 'both equally') and  
20  
21 produces a laterality quotient of either left, right or mixed handed. This measurement  
22  
23 was used as children and parents were often unsure which hand was predominant if the  
24  
25 child had bilateral CP.  
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30 Diaries of games undertaken were utilised to provide information of subjective  
31  
32 ratings of acceptability and enjoyment. Participants also took part in a postal  
33  
34 questionnaire on physical activity and participation in daily tasks.  
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### 37 38 ***Public and Patient Involvement (PPI)***

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40 Reporting of patient and public involvement in this trial uses the GRIPP2 (table 1)  
41  
42 reporting checklist [54].  
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### 45 46 *Table 1 about here*

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48  
49 Two parallel streams of public and patient involvement in Sussex and Devon  
50  
51 informed the research. Parents in both groups agreed that getting children to do regular  
52  
53 therapy exercises is a struggle. Parents perceived that using Wii Fit™ active computer  
54  
55 games would be popular with children and families, and improve adherence to therapy  
56  
57 programmes. Initial work on this project involved testing out not only the Nintendo Wii  
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3 Fit™, but also the use of Microsoft Kinect technology. We held a parent consultation  
4  
5 day in Sussex and our two co-applicants/authors emerged from this and expressed  
6  
7 interest in taking part in the study.  
8  
9

### 10 11 *Aim of Public and Patient Involvement in the study*

12  
13 Parents were an integral part of the research project supporting consulting of drafts of  
14  
15 documents to be used during the project including information sheets and consent  
16  
17 forms. Parent advice ensured these were informative and accessible. All materials were  
18  
19 written, and appropriately modified with parent advisors and the Peninsula Cerebra  
20  
21 Research Unit (PenCRU) Family Faculty.  
22  
23

### 24 25 26 *Methods used for Public and Patient Involvement in the study*

27  
28  
29 Two parent carer co-applicants of the research project became consultant parent  
30  
31 advisers to the steering committee. There was also support from a parent carers'  
32  
33 working group in the PenCRU Family Faculty at the University of Exeter Medical  
34  
35 School. Trial steering committees were held in person or in teleconference every four  
36  
37 months. Monthly updates of recruitment and study news were sent to all involved in the  
38  
39 study. Four further consultant parent meetings were held over the course of the study to  
40  
41 test run trial method, design of the project logo review documentation, and review the  
42  
43 whole project and discuss next steps after data collection was complete. PenCRU was  
44  
45 consulted during initiation of the trial, and on completion of the trial with results.  
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### 51 52 *Procedures*

#### 53 54 55 *Data Collection*

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58 Data were collected by five senior physiotherapists over a period of 13 months at four  
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3 NHS child development centres across one county in South-East England. All data were  
4  
5 collected utilising clinical rooms. The size of each room, repeat availability for follow-  
6  
7 up, and variety of equipment in each clinic varied across centres.  
8  
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### 10 11 *Schedule for Follow-up*

12  
13 Both groups were given a Nintendo Wii Fit™ package and asked to play certain games  
14  
15 (see supplementary material S2 for programme) for 30 minutes, 3 times per week for 12  
16  
17 weeks, and asked to keep a diary of their activity.  
18  
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20  
21 Children in the SG were supported by a physiotherapist (not the physiotherapist  
22  
23 who carried out measurements) who contacted the parents of the child every two weeks  
24  
25 by telephone to assign games, and subsequently checked how the prescribed programme  
26  
27 of activity was progressing and suggested scaffolding for extension of games and  
28  
29 activities for motor progress, as necessary. In the USG fortnightly phone contact (see  
30  
31 script in supplementary material S3) was offered for general queries e.g. was the system  
32  
33 working? However, no specific advice on games and activity scaling was provided. A  
34  
35 record of the number of calls, duration, voice messages and summary of conversations  
36  
37 was made. No repeat phone calls were made when there was no answer.  
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### 43 *Analyses*

44  
45 Continuous variables were summarised using means and standard deviations, medians  
46  
47 and interquartile ranges, and categorical and binary variables using frequencies and  
48  
49 percentages. Normality of outcomes was not assumed so differences in outcomes  
50  
51 measures between the groups are presented with bootstrapped bias corrected and  
52  
53 accelerated 95% confidence intervals. All analysis was done using Stata software,  
54  
55 version 14.2 [55]. Recorded clinical measurements were quantitative. Data captured  
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57 using health economic reports, and participant diaries produced both qualitative and  
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3 quantitative data. Inferential significance was minimally considered due to the  
4  
5 exploratory, feasibility nature of this study. Thus 95% confidence intervals were stated for  
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7 between-group comparisons and discussion limited in this respect to avoid  
8  
9 misinterpretation.  
10

### 11 12 13 *Health Economics*

14  
15 A health economics analysis at the individual patient level, and taking the NHS  
16  
17 perspective, was conducted alongside the clinical study. The health economics analysis  
18  
19 investigated the proportion of therapists that completed and returned logs, the number of  
20  
21 calls made and completeness of the calling records (relative to the maximum of 6 calls  
22  
23 over the 12 week period), and the amount of therapist time shown as supporting  
24  
25 children in the study. Mean amount of time spent by therapists during phone calls to the  
26  
27 intervention group was calculated. The cost per child was estimated using validated  
28  
29 national unit costs in the UK [56], applied to recorded therapist time input. Data  
30  
31 appertaining to the USG were examined but costs were not calculated since this was the  
32  
33 control condition and researcher contact was for the purposes of maintaining contact  
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35 with participants in the trial, and not to provide therapeutic input.  
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## 43 **Results**

### 44 45 *Feasibility RCT*

#### 46 47 48 49 *Randomisation and Consent*

50  
51 Figure 2 shows the CONSORT diagram of enrolment to analysis throughout the trial.  
52  
53 Randomisation through minimisation was successful (see table 2). Minimisation  
54  
55 achieved a balance between both groups, with only marginal imbalance between female  
56  
57 versus male participants (20 and 33% respectively). Three quarters of participants in  
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3 USG used a study-provided console (75%), compared to just over half (57%) in the SG  
4  
5 (see tables 3 and 4, and supplementary table S1 for intervention strategy).  
6  
7

8  
9 *Insert figure 2 and table 2 here*

#### 10 *Recruitment and drop out*

11  
12 More children were at GMFCS 2 (66%) than 1 (33%). Forty-four children were  
13  
14 assessed for eligibility. 14 were excluded as they were outside the acceptable age range,  
15  
16 1 child with GMFCS III was mistakenly approached by a clinical team. This child was  
17  
18 offered a Wii Fit™ to take home and try, as they were upset when they realised they did  
19  
20 not meet inclusion criteria. This child was not included in the trial. Five children  
21  
22 declined to participate, 4 gave no further response on approach, and 1 was  
23  
24 recruited/consented but not randomised due to a clinical decision that an upcoming  
25  
26 operation placed the child outside the inclusion criteria, and that the study would be a  
27  
28 complicating factor in post-operative recovery. Thirty individuals (68% of those  
29  
30 approached) met the inclusion criteria and consented. It is not known how many  
31  
32 throughout the region may have seen adverts and flyers for the trial out of a total  
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34 GMFCS I-V estimated population of 300, of which approximately 61% or 183 would be  
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36 children with CP in GMFCS I/II [57].  
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43 Ten of the children in the SG (67%) and 11 in the USG (73%) completed the  
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45 trial. There were a variety of reasons for participant dropout, showing that this  
46  
47 population group lead complex lives and are susceptible to a range of problems.  
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50 Children who completed the study experienced tiredness (3 children) as a factor causing  
51  
52 dropout, which also caused reported ‘time off’ from using the Wii Fit™ during the trial.  
53  
54 School was also a factor causing dropout reflected through children’s after-school  
55  
56 activities (1 child), and homework (1 child) where some children found the burden of  
57  
58 the study too much. Additionally, where surgery (1 child), or difficulties with using the  
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3 technology e.g. where the balance board could not ‘read’ the child was standing on it (1  
4  
5 child). This was because for children with unilateral CP the balance board was  
6  
7 frustrating as it was not reactive enough to detect variation in weight bearing between  
8  
9 left and right side. This is limiting where children have unilateral CP as the balance  
10  
11 board requires an equal split in weight to correctly detect activity. Two children also  
12  
13 reported “no time” to carry out the activities. Lastly, one child with a comorbidity of  
14  
15 autism could not adhere to the measurements and so left the study.  
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#### 21 *Willingness of clinicians and to recruit participants*

22  
23 PTs recruited most participants. Occupational therapists and Consultant Paediatricians  
24  
25 also helped to recruit. Trial physiotherapists worked on a casual basis which meant that  
26  
27 team members did not have sufficient “buy-in” to the project and worked as and when  
28  
29 they saw fit. Research team members became responsible for arranging appointments  
30  
31 which did not work effectively alongside clinical caseload pressure which took  
32  
33 precedence.  
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#### 39 *Physiotherapists carrying out measurements*

40  
41 All therapists received a one day training package, but it was not possible – even with  
42  
43 the utilisation of a senior PT as part of the research team – to verify the level and quality  
44  
45 of professional other than National Health Service pay banding. Variation in levels of  
46  
47 experience, and across sites, was noted.  
48  
49  
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51 *Insert table 3 and 4 here*

#### 52 *Adherence to Programme*

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54  
55 The SG (see table 5) completed a mean number of 19/36 sessions (56% adherence)  
56  
57 whilst the USG completed 24/36 (66%). There were no adverse events. Children at  
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3 GMFCS level II completed more sessions than GMFCS I (27 v 20), with higher mean  
4 subjective enjoyment rating of 3.1 v 2.1/5 (see table 6). Total number of minutes varied  
5 considerably across both groups, and whilst the USG spent more time using the Wii  
6 Fit™ (mean 1230 minutes, S.D. 1003) compared to SG (mean 819 minutes, S.D. 634).  
7  
8 Overall adherence was high; mean total minutes spent for SG was 75% of what was  
9 suggested (mean 819 minutes, compared to recommended 1080) whereas the USG  
10 group carried out 96% of suggested activity time. For two cases in the unsupported  
11 group the number of sessions was unreported, but total minutes were extracted from the  
12 Wii Fit™ memory.  
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### *Feasibility of Study Measures*

26  
27 Overall, the measurement tools seem appropriate to VR therapy (see tables 7-9). The  
28 GMFM-66 was responsive to use but may have a ceiling effect as some children were  
29 high scoring throughout the study. Children at GMFCS II saw the most change in  
30 GMFM-66 score between baseline and week 12 in the SG, from 67.8 to 75 points  
31 (where the maximum is 100) on the scale whilst doing less activity overall than USG.  
32 Change in SG group was, on average, 6.2 points (75.2 to 81.7) whilst USG group  
33 experienced a change of 3.4 points, from 81.4 to 84.8, but began from a higher average  
34 baseline score.  
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46 The Timed up and Go test (table 7) showed equivalent score change across both  
47 groups. In seconds the SG group got quicker (6.2 to 5.5 seconds) as well as the USG  
48 group (6.6 to 5.7). The USG showed marginally more improvement. The test was easy  
49 to administer, although PTs did find that there was often variation between the style and  
50 height of equipment e.g. chairs or size of available rooms at CDCs.  
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3 The BOT2 short form SG score increased from a mean of 46.5 to 52.3,  
4  
5 compared to USG of 45.8 to 47.7 where the maximum raw score is 88. This is a similar  
6  
7 change to GMFM results. For the balance subscale the difference in means was SG 19.9  
8  
9 to 24.1 and USG 22.4 to 25.1, a change in mean score of 4.2 (SG) and 2.7 (USG).  
10  
11 BOT2 was found to be problematic in taking too much time to record all scores.  
12

13  
14 The GAS showed greatest improvement of all recorded scores, as scores in SG  
15  
16 showed substantial improvement of targeted outcomes from 35.2 to 54.9 (increase of  
17  
18 19.7), with two out of three individualised targets successfully achieved. USG achieved  
19  
20 similar results, with an increase in score from 37.6 to 58.8 (21.2).  
21  
22

23  
24 The Strengths and Difficulties Questionnaire (SDQ) was easy to administer with  
25  
26 the parent often filling in the 16 point questions whilst other measurements were taking  
27  
28 place. Change in children's strengths and difficulties were observed e.g. social  
29  
30 interaction for example in SG 12.5 to 10.9, and USG 12.6 to 9.4 (with a reduction  
31  
32 indicating positive change). The parent-completed SDQ showed both SG and USG  
33  
34 groups to be within the "close to average" category with symptoms marginally  
35  
36 improving.  
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40  
41 *Insert table 5 and 6 here*

42  
43 *Insert table 7 and 8 here*  
44  
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47

48 For a future RCT, measurement tools will need to be significantly streamlined to  
49  
50 include those measures that best detect change in motor function for children with CP  
51  
52 and are easy to use without causing significant burden e.g. stress or anxiety to the child,  
53  
54 family or therapist, and are acceptable to parents and children.  
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3 *Insert table 9 here*

4  
5 *Feasibility of Technology*

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7  
8 The main issue with the use of a commercial console was in the presence of consoles  
9 already in many homes. However, 75% of participants used a project console (table 4),  
10 enabling data retrieval through the SanDisk (SD) card. 25% of participants elected to  
11 use a family owned console, which meant that data could not be collected through SD  
12 cards. SD data on the Wii Fit™ is unreliable: it is unclear which user is active even  
13 when participants were given a pamphlet and talked through the creation of personal  
14 user profiles. The Wii Fit™ cannot isolate the difference between users except in  
15 querying weight change, but where children are close in weight (as happened with a  
16 family with twins) it is impossible to determine who was using the console from Wii  
17 data. Other children were also so light, due to age, and possibly lack of bone mineral  
18 density due to impaired weight-bearing, that the balance board could not detect that they  
19 were on the board, highlighting limitations in the technology. Without the purchase of  
20 SD cards being sent home, potentially invading home gaming privacy, this was lost data  
21 for those who did not use a project console.  
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42 *End of Project Survey*

43 40% of comments in the supported group were positive toward the programme.  
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45 Activities were perceived as generally getting easier over time which was seen as  
46 strength of the intervention across both groups. There was variation in attitude toward  
47 difficulty of the games and in achieving better game scores; some children were  
48 frustrated, whereas others enjoyed the challenge. This was equal across both groups.  
49  
50 Families found the equipment set-up amenable, but the balance board was unable to  
51 detect weight of younger children (e.g. 5 year olds) especially those with hemiplegia.  
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3 *Study results of PPI in the study, including both positive and negative outcomes*  
4  
5

6 Parents enabled drafts of documents to be clear and easily accessible with few errors in  
7 interpretation of documentation. The only error with study documentation was with the  
8 study diary (supplementary table S2) which was perceived to imply “Monday,  
9  
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13 Wednesday Friday” as days when study activity was expected to be conducted. High  
14 recruitment and adherence to the study program is likely to have occurred due to the  
15 input of PenCRU and parent consultants.  
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21 ***Health Economics***  
22

23  
24 The children were monitored during the study by three therapists. Two therapists  
25 supported children in the intervention group (one supported nine children, the other  
26 four). The third therapist supervised all 15 children in the unsupported group. Logs were  
27 returned for 28 children, 13 (87%) in the supported group, 15 (100%) in the  
28 unsupported group.  
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36 Therapists’ logs for the supported group (SG) showed a total of 54 calls (i.e. 4.2  
37 per family) were made (69% of the maximum of 78). Of these 29 (54%) involved a  
38 conversation with a parent. The remainder of calls were not answered or went to voice  
39 mail, or in two cases parents stated they were too busy to speak. The mean time spent  
40 on phone calls, including those with no response, (see supplementary table S3 for phone  
41 call questions) was 35 minutes, ranging from 5 to 55 minutes.  
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51 For the unsupported group (USG), research fellows reported 74 calls (82.2% of  
52 the expected 90), 4.9 per family. Of these 40 (54.1%) were answered. The mean  
53 duration of calls per child was 12.6 minutes, ranging from 2 to 20 minutes. In addition,  
54 the researcher sought advice from the supervising physiotherapist for three children  
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3 whose parents raised particular issues about the use of the Wii. Total therapist time on  
4  
5 these three enquiries was 45 minutes (5, 10 and 30 minutes respectively).  
6  
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8  
9 The cost of a therapist's time over the 12 week intervention was £20.10 per child  
10 in the supported group (A). This is based on an hourly rate for a band 5 physiotherapist  
11 (AfC specialist level) of £37 [56]. The physiotherapists in the study, however, were  
12  
13 band 7 (advanced / team leader) and 8 (principal / consultant). Costs at these higher  
14  
15 levels would be around £30 or £40 per child respectively.  
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## 22 **Discussion**

23  
24 Our primary aim was to determine the feasibility of a future multicentre RCT by testing  
25 the clinical effectiveness of methods and measures, and cost effectiveness of a  
26 commercially available console for VR therapy for children with ambulatory CP in the  
27 home. PPI had a significant impact on study direction (home versus clinical use),  
28 acceptability and preparedness of study documentation, and acceptability of study set-  
29 up (games, set-up of technology, programme of games). It is possible that even more  
30 contact with PPI members would have led to more insight, however it is important not  
31 to burden families and carefully foster of PPI relationships. In a future RCT we would  
32 aim to enable more pro-active and unprompted PPI to occur.  
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46 Recruitment procedures attracted sufficient participants, children adhered to the  
47 recommended programme, measurement tools and methods of analysis were  
48 appropriate, with some exceptions, and resource implications/costs in relation to  
49 outcomes found that the staff cost was low. However, the protocol may not have been  
50 completely acceptable to physiotherapists as therapists' logs for the supported group  
51 showed only 54% of phone calls resulted in a conversation with a parent.  
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3 possible that they did not occur at convenient times for the parent. If arrangements in a  
4  
5 future trial were made to phone only at certain times, this could increase the proportion  
6  
7 of calls that resulted in parent contact.  
8  
9

10  
11 We calculated group differences with 95% confidence intervals for our five  
12  
13 main outcome measures, but the predictive validity of these requires data from future  
14  
15 studies to gain greater clarity of the sensitivity to detect appropriate change as well as  
16  
17 the potential utility of these measures in a definitive RCT.  
18  
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20  
21 This study found that the treatment could be offered through physiotherapy  
22  
23 services in the NHS. The treatment delivery i.e. in the home had fair fidelity in  
24  
25 participants conforming to recommendations of the physiotherapists, and also  
26  
27 potentially in the frequency and duration of sessions undertaken across both groups  
28  
29 (USG and SG). There is some evidence that the novelty of the games wore off at about  
30  
31 the 7<sup>th</sup> week with a tapering off of usage. A future RCT may require participants to use  
32  
33 a project console to ensure complete data capture.  
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### 38 39 *'Active Ingredients'*

40  
41 One of the biggest issues surrounding the use of digital therapeutic intervention is the  
42  
43 identification of 'active ingredients' necessary for VR therapy to be useful to sustain  
44  
45 impact. Our findings are supported by Levac et al [58] who found that active gaming  
46  
47 home-use groups showed significant improvement in GMFM scores, compared to  
48  
49 clinic-based programmes. Deutsch et al [31] suggest that active video gaming (AVG)  
50  
51 research should be primarily aimed at prevention, participation and plasticity; our study  
52  
53 focusses on understanding low-cost therapeutic participation in the home. Levac et al  
54  
55 [19] suggests that therapists should focus on gaining sustained engagement over time  
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60 with the whole family if therapy is to be carried out in the home. Children and families

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3 should be given the opportunity to engage with their own therapy, have autonomy over  
4 choices about activities, and be able to problem solve difficulties [19, 28]. Intrinsic and  
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6  
7  
8 extrinsic motivational factors need to be emphasised so that adherence is high, and  
9  
10 therapies are more likely to be successful. Levac [28] suggests therapists should develop  
11  
12 their role carefully as a facilitator of the technology, by selecting optimal games,  
13  
14  
15 monitoring progress -as attempted here with phone calls- with the assurance that there is  
16  
17 clear alignment between daily activities and motor outcomes that are important to the  
18  
19 patient. For example, one child who was part of this feasibility study had a severe visual  
20  
21 impairment, had extremely motivated parents and therapists were willing and motivated  
22  
23 to make the study accessible for the child. An additional hour was spent by a senior  
24  
25 physiotherapist on the project, acquiring a K-walker for use for the 12 weeks of the  
26  
27 study. The participant subsequently experienced a high change in GMFM score across  
28  
29 the 12 weeks. Children experienced a waning of their interest in the 7<sup>th</sup> week, so  
30  
31 sustaining interest continues to be problematic. However, the deployment of therapists  
32  
33 using focused and personalised scales in clinical conversations such as in the use of  
34  
35 GAS, making phone calls to individuals in lieu of clinical meetings, and asking  
36  
37 participants to keep diaries may help adherence to protocols.  
38  
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43

44 Van Hedel and Aurich [15] go further than Levac and state that rehabilitation  
45  
46 technology should only be used with responsive patient groups, in which case the  
47  
48 identification of patient 'responsiveness' to VR therapy becomes vitally important. If  
49  
50 motivation is related to adherence, which in turn is related to responsiveness then  
51  
52 exploring 'desires', interests, and enjoyment as part of participation makes VR  
53  
54 therapy/AVG as much about psychological attitudes surrounding the technology as well  
55  
56 as actual improvements in motor function. This is reflected in the USG arm of our  
57  
58 study in which participants were free to use the games as they wished; some of whom  
59  
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1  
2  
3 maintained interest and persisted with the use of the VR therapy throughout the 12  
4  
5 weeks with the median total minutes spent playing games was higher than the SG. A  
6  
7 further issue to consider is the transfer of gains made in a 'virtual world' to real-world  
8  
9 actions. Recent research has suggested that upper limb reaching actions may differ in  
10  
11 virtual environments physical environments, emphasising the need for accurate spatial  
12  
13 and temporal resolution of avatars with haptic interfacing to facilitate transfer of gains  
14  
15 made to real-world tasks [64]. The use of the balance board with the Wii Fit™ may  
16  
17 facilitate better transfer of gross balance gains to the physical world with the enhanced  
18  
19 sensory feedback provided. Further investigation is required to identify appropriate  
20  
21 interfacing devices for individual children that mirror real world movements.  
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26  
27 Levac points to therapists who measure client motivation in a standardised way  
28  
29 that can be replicated e.g. Tala et al's (2015) Paediatric Motivation Scale (PMOT) or  
30  
31 the O'Brien and Thomas (2010) User Engagement Scale, which measures novelty and  
32  
33 so captures the potential dropout of participants due to waning interest from  
34  
35 technological innovation. Engaged learners are more likely to have improved outcomes,  
36  
37 such as memory consolidation [28]. Thus, while VR therapy has potential for home-  
38  
39 based use to augment therapy programmes, there is a need to consider factors  
40  
41 influencing uptake and adherence to home-based applications.  
42  
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45

#### 46 47 *Appropriateness of measures*

48  
49 Motor function was acceptably measured by GMFM-66 as children cooperated  
50  
51 with its use, and there appeared to be no floor and ceiling effects. Measurement tools  
52  
53 seemed appropriate to use alongside VR therapy. Timed Up and Go captured change,  
54  
55 but with only marginal a difference between the two groups, which may reflect progress  
56  
57 in functional mobility in both groups associated with the frequency (dose and duration)  
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1  
2  
3 of use of active video games, with or without therapy support. The BOT2 running speed  
4  
5 and agility tool was inappropriate for widespread use as it required a lengthy running  
6  
7 space which was not present in most Child Development Centres and therefore is not  
8  
9 considered feasible for a larger scale study, preventing administration. Furthermore, it  
10  
11 must be noted that BOT2 is primarily used in a clinical context with children with  
12  
13 developmental coordination disorder (DCD) and this was the first attempt to use this  
14  
15 tool with ambulatory CP in this region. Unfortunately applying BOT2 in a population  
16  
17 that has impaired limb mobility is difficult, as recording of dominant side only is  
18  
19 advised. A future study may look at positive change (if any) in the function of the  
20  
21 impaired limb. BOT2 reports only dominant limb change. The short form and balance  
22  
23 subscale detected change, with variation between groups, but was unfamiliar to PTs,  
24  
25 and added to the time taken to complete measurements. Given the recently reported  
26  
27 weak ecological validity of the gross motor subtests of the BOT2 for children with  
28  
29 DCD, its suitability to detect meaningful change in children with CP may also be  
30  
31 restricted [59].  
32  
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36  
37 The Goal Attainment Scale was successfully employed and its use is supported  
38  
39 by Levac [19] and van Hedel and Aurich [15]. One parent pointed out that of all the  
40  
41 tools, GAS enabled the parent and child to engage in a 'body conversation' about those  
42  
43 muscular areas of the body that were engaged during specific activity. This type of  
44  
45 conversation during encounters with patients, opens up points of entry about the  
46  
47 relationship between body structures and functions [60], and can subsequently assist in  
48  
49 fostering a therapeutic environment where capacity for activity and participation  
50  
51 increases [61].  
52  
53

54  
55 SDQ was successfully used and revealed variation in children's social and  
56  
57 emotional behaviours e.g. hyperactivity, pro-sociability, conduct, across both groups so  
58  
59  
60

1  
2  
3 could be employed in a larger trial. As a result of the feasibility RCT, therapists were so  
4  
5 impressed with GAS that it was adopted in the local community NHS trust. However,  
6  
7 the GAS is less helpful as a measure of group changes, unless weighted functions are  
8  
9 incorporated [62] as it is designed to show change for each child individually against  
10  
11 that child's personally set goals, which are different for each child. This may be  
12  
13 appropriate in 'real life' settings, but will not enable group change to be captured in a  
14  
15 trial setting. The Edinburgh handedness inventory was useful when parents and children  
16  
17 were unsure of the child's dominant hand, particularly when there was bilateral upper  
18  
19 limb involvement.  
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### 26 *Limitations/Future adaptations*

27 Treatment fidelity appears to be acceptable however the novelty of the game-based  
28  
29 therapy appeared to have worn off by the 7<sup>th</sup> week. It is essential to find methods to  
30  
31 maintain adherence to 12 weeks until more is known about the optimum treatment  
32  
33 duration.  
34

35  
36  
37       Physiotherapists suggested that too many measurements were used during the  
38  
39 trial, with some children finding 1.5 to 2 hours of assessment a challenge, especially  
40  
41 younger children or children with co-morbidity. The exclusion of BOT-2 may reduce  
42  
43 the time of the measurements to under an hour. Physiotherapists may also have found  
44  
45 the protocol for phone calls challenging as only half of calls resulted in a conversation.  
46  
47 Fewer phone calls but pre-planned timings may be a way forward in future trials.  
48  
49 In a future trial, measurement tools should be streamlined including GMFM as the main  
50  
51 outcome, with the addition of the GMFM challenge outcome module [63] to overcome  
52  
53 concerns of ceiling effect. GAS and Edinburgh Handedness inventory would also be  
54  
55 effective in capturing variation in the therapeutic conversation as well as offer clarity  
56  
57 over children's laterality. A future study would also benefit from the employment of a  
58  
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2  
3 full-time research therapist to avoid management of clinical caseloads interfering with  
4 assessment and data gathering self-direction. Further, dedicated research PTs who have  
5 received training in delivering programme advice for SG would also have periodic  
6 inter-trainer reliability checks. Equipment would also need to be standardised across  
7 clinical environments as is in reality this was often lacking uniformity, relying on  
8 therapists to make notes on e.g. height of chairs, use of orthotics.  
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### 18 *Adjuncts to therapy*

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21 Virtual reality therapy requires the use of therapists or appropriate professionals to steer  
22 the direction of activity [15, 19, 28, 64]. VR therapy use therefore does not suggest total  
23 automation of therapeutic choices, thereby replacing human and clinical input.  
24  
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### 30 *Full Trial*

31  
32 A full trial appears feasible with adaptations to the intervention, such as reduced  
33 duration or use of other published material to estimate a minimum sample size. The  
34 pooled standard deviation of GMFM-66 at baseline is approximately 12. To detect a 5  
35 point difference between supported and unsupported groups, the effect size (Cohen's D)  
36 would be  $5/12 = 0.41$  (i.e. medium). For 80% power at 5% significance, requires 94  
37 children in each group for the analysis are required. Allowing for attrition of 30% (by  
38 week 6),  $94/0.7 = 134$  children would need to be recruited to each group. It is also  
39 possible that a focus on 6 to 12 year olds may reduce attrition by 30%, as most drop  
40 outs were in children below 6 or over 12 years of age.  
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51  
52 Efficiency of analysis can be increased using analysis of covariance  
53 (ANCOVA). Assuming a correlation of 0.5 between baseline and follow-up GMFM, the  
54 required sample size becomes 71 in each group for the analysis and would require 102  
55  
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57  
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3 children to be recruited per group accounting for attrition. This currently represents a  
4  
5 total sample size of 204.  
6  
7

## 8 9 **Conclusion**

10  
11 This study is the first to use an in-home therapy adjunct alongside low cost commercial  
12  
13 consoles, with a physiotherapist developed package, with the direct purpose of  
14  
15 evaluating participant retention, recruitment and measures. To date, ineffectiveness and  
16  
17 lack of standardisation over measures, sample sizes, bespoke versus low-cost console,  
18  
19 lack of consistency and clarity over dosage and frequency has meant inadequate  
20  
21 outcomes in previous studies. Adding cost-effectiveness –a new element for a feasibility  
22  
23 trial - enables health providers to determine the impact and potential utility of this  
24  
25 approach, and subsequently impact on NICE (National Institute of Health and Care  
26  
27 Excellence) guidelines for care of children with Cerebral Palsy.  
28  
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32

33 There is insufficient evidence to comment on the success of VR therapy,  
34  
35 although trends seen in this study mirror most previous studies suggesting improvement  
36  
37 in motor function. Therapeutic use of Nintendo Wii Fit™ in-home was inexpensive and  
38  
39 acceptable in short periods of around six weeks. Further research is required to compare  
40  
41 effectiveness with standard physiotherapy. Positive change to motor outcomes as a  
42  
43 result of VR therapy will only be confirmed by larger, sufficiently powered, study. A  
44  
45 future trial will be feasible with appropriate modifications to measurement tools,  
46  
47 focusing on GMFM as the primary outcome.  
48  
49

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56  
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59 Social Care.  
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FOR PEER REVIEW

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3 Figure 1 *Process of Informed Consent*

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5 Figure 2 *CONSORT Flow Diagram of Enrolment to Analysis*

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8 *Table 1 GRIPP2 Short form of PPI within this trial*

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Section and topic	Item	Reported on page No
1: Aim	Report the aim of PPI in the study	11
2: Methods	Provide a clear description of the methods used for PPI in the study	11
3: Study results	Outcomes—Report the results of PPI in the study, including both positive and negative outcomes	19
4: Discussion and conclusions	Outcomes—Comment on the extent to which PPI influenced the study overall. Describe positive and negative effects	20
5: Reflections/critical perspective	Comment critically on the study, reflecting on the things that went well and those that did not, so others can learn from this experience	20

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*Table 2 Minimisation Balance*

	Supported		Unsupported	
	n = 15	%	n = 15	%
Female vs. Male	3	20	5	33
Secondary vs. Primary School Age	4	27	4	27
Bilateral vs. unilateral CP	5	33	5	33

FOR PEER REVIEW

*Table 3 Characteristics of Participants*

	Supported n = 15		Unsupported n=14*	
		%		%
GMFCS 2 vs. 1	6	40	3	21
Left side dominant	7	47	5	43
Right side dominant	6	53	4	57
Neither side dominant	2	13	5	36
Left side affected	8	53	8	57
Right side affected	7	47	6	43

\* data missing for one child

FOR PEER REVIEW



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5 *Table 4 Percentage of participants using project versus own console*  
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	Supported group		Unsupported group	
	n	%	n	%
Used project console	8	57	12	75
Used own console	6	43	4	25

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FOR PEER REVIEW

*Table 5 Adherence to Intervention Schedule*

	Supported group					Unsupported group					Difference in means	Bootstrap 95% C.I.* for difference in means
	n	mean	s.d.	median	IQR	n	mean	s.d.	median	IQR		
Number of sessions	11	19	14.6	19	5 to 35	11	24	13.3	30	8 to 36	5	-7.1 to 15.4
Average rating	10	2.4	2	2.1	0.5 to 4.3	8	2.5	1.3	2.6	1.7 to 3.6	0.1	-1.7 to 1.4
Total minutes spent	10	819	634	633	333 to 1065	13	1230	1003	1148	324 to 1547	411	-196 to 1135

C.I.\* bias-corrected and accelerated confidence interval

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*Table 6 Adherence to Intervention Schedule by GMFCS 1 and 2*

	GMFCS 1					GMFCS 2				
	n	mean	s.d.	median	IQR	n	mean	s.d.	median	IQR
Number of sessions	16	19.2	13.8	20	6 to 33	6	27.7	13.3	34.5	24 to 35
Average rating	13	2.1	1.6	2.5	0.6 to 3.4	5	3.1	1.9	4	2.3 to 4.3

For Peer Review

Table 7 Results for Gross Motor Function Measurement 66, Timed up and Go test, Goal Attainment Scale, Strengths and Difficulties

Questionnaire

Outcome measure		Supported group					Unsupported group					Difference in means	Bootstrap 95% C.I.* for difference in means
		n	mean	s.d.	median	IQR	n	mean	s.d.	median	IQR		
Gross Motor Function Measurement-66	baseline	15	75.2	11.1	72.6	68.9 to 79.1	15	81.4	13.1	84	69.6 to 89.7	-6.2	-14.4 to 3.3
	6 weeks	12	79.2	8.5	79.1	71.6 to 85.3	11	82.8	10.4	88	69.2 to 89.7	-3.6	-10.8 to 4.4
	12 weeks	10	81.7	8.4	82.5	73.1 to 88	11	84.8	10.1	83	71.7 to 92.1	-3	-10.6 to 4.5
Timed Up and Go test (in seconds)	baseline	15	6.2	1.6	5.7	4.8 to 8.0	14	6.6	1.8	6.4	5.9 to 6.9	-0.4	-1.8 to 0.7
	6 weeks	12	5.7	1.5	5.5	4.4 to 6.8	11	6.3	1.8	6.2	4.8 to 8.2	-0.6	-1.8 to 0.8
	12 weeks	10	5.5	1.5	5.3	4.1 to 6.5	11	5.7	1.8	5.3	4.3 to 6.0	-0.2	-1.6 to 1.2
Goal attainment scale	baseline	14	35.2	3.6	36.4	33.3 to 37.1	15	37.6	11.7	33.3	31.2 to 36.6	-2.4	-10.8 to 2.6
	12 weeks	10	54.9	15.5	55	40.3 to 63.9	11	58.8	7.1	56.7	52.7 to 63.5	-3.9	-13.8 to 7.5
Strengths and Difficulties Questionnaire	baseline	15	12.5	6.8	11	8 to 18	15	12.6	6.7	10	8 to 18	-0.1	-5.3 to 4.6
	6 weeks	13	9.5	7.4	9	4 to 14	11	9.8	3.5	10	7 to 12	-1.3	-3.0 to 0.3
	12 weeks	10	10.9	6.8	13	5 to 14	11	9.4	3.4	10	7 to 11	0.1	-1.2 to 1.3

C.I.\* bias-corrected and accelerated confidence interval

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Table 8 GMFM-66 results by GMFCS

Gross Motor											
Function Measurement-66 subgroups	Supported group					Unsupported group					
	n	mean	s.d.	median	IQR	n	mean	s.d.	median	IQR	
GMFCS = 1	baseline	9	80.2	11.5	78.3	72.6 to 81.9	11	85.3	11.3	86.5	74.2 to 96
	6 weeks	7	83.6	8.1	84	79.1 to 86.5	8	86.6	8.1	89.7	84.5 to 89.7
	12 weeks	6	86.2	6.6	86.6	80.9 to 89.7	8	88.3	9	90.9	82.5 to 94.1
GMFCS = 2	baseline	6	67.8	4.6	69.7	64.6 to 70.4	3	73.3	15.3	76.8	56.6 to 86.5
	6 weeks	5	73	3.8	73.1	70 to 73.1	3	72.7	9.9	68.9	65.3 to 84
	12 weeks	4	75	6.1	72.9	71.5 to 78.6	3	75.3	6.7	71.7	71.2 to 83

Table 9 Results for Bruininks-Oseretsky Test of Motor Proficiency

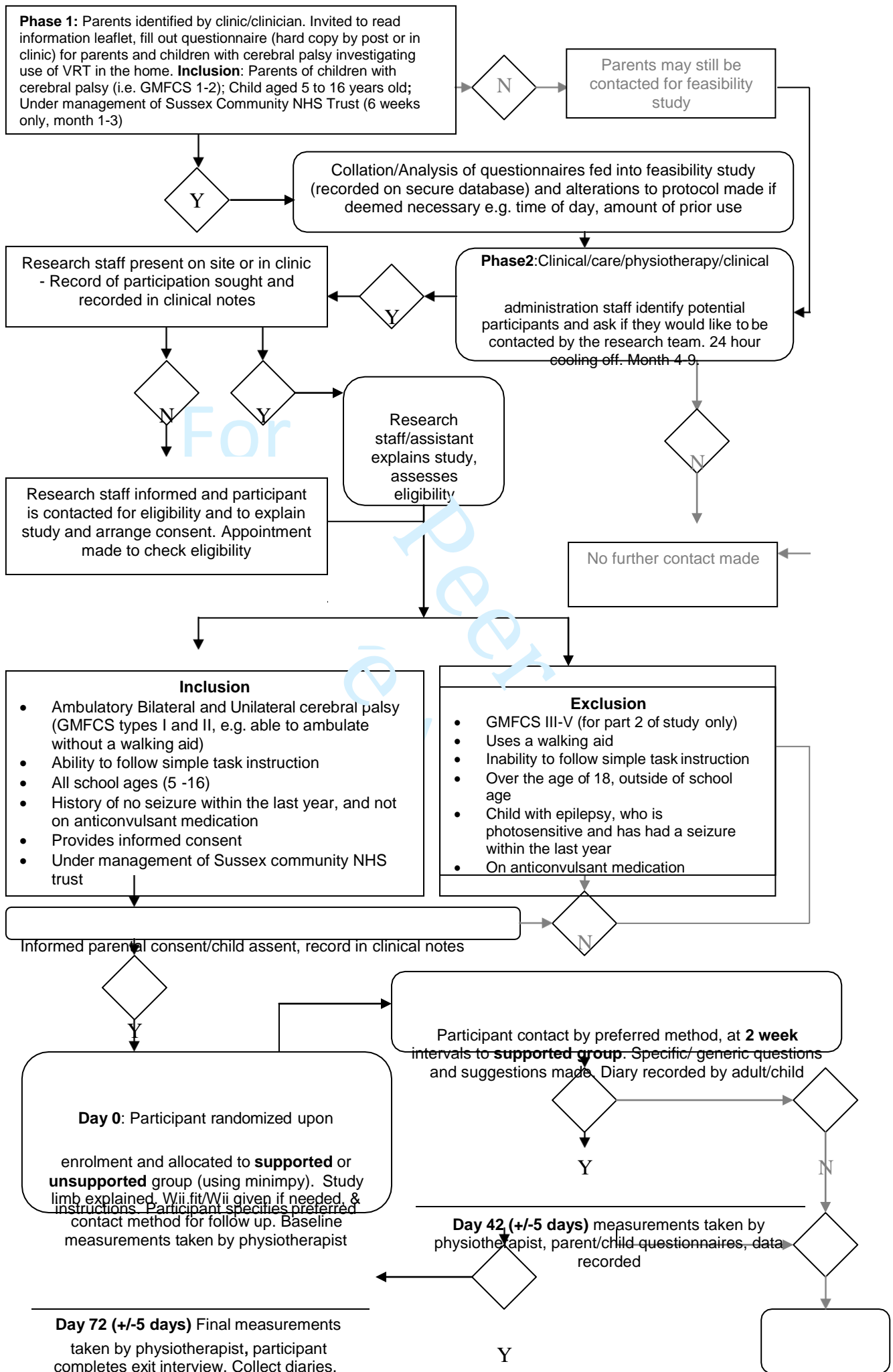
Bruininks-Oseretsky Test		Dominant side											Difference in means	Bootstrap 95% C.I.* for difference in means
		Supported group					Unsupported group							
		n	mean	s.d.	median	IQR	n	mean	s.d.	median	IQR			
BOT-2 short form	baseline	15	46.5	16.9	48	37 to 62	14	45.8	14.7	42.5	38 to 59	0.7	-12.3 to 10.8	
	6 weeks	12	52.2	16.3	57.5	42.5 to 57.5	11	47.4	15.6	50	37 to 65	4.8	-7.7 to 16.7	
	12 weeks	10	52.3	15.2	56	43 to 57	11	47.7	15.0	52	37 to 62	4.6	-9.2 to 16.1	
Balance	baseline	15	19.9	9.6	17	14 to 29	14	22.4	9.3	25	16 to 29	-2.5	-8.6 to 4.9	
	6 weeks	12	22.1	9.9	20	13 to 32	11	25.3	6.6	26	21 to 32	-3.2	-9.1 to 3.8	
	12 weeks	10	24.1	10.1	26.5	19 to 32	11	25.1	8.3	29	22 to 31	-1	-8.4 to 6.9	

C.I.\* bias-corrected and accelerated confidence interval

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FOR PEER REVIEW

Figure 1 Process of Informed Consent





recorded.

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URL: <http://mc.manuscriptcentral.com/dandr> Email: [IDRE-peerreview@journals.tandf.co.uk](mailto:IDRE-peerreview@journals.tandf.co.uk)

Patient lost in  
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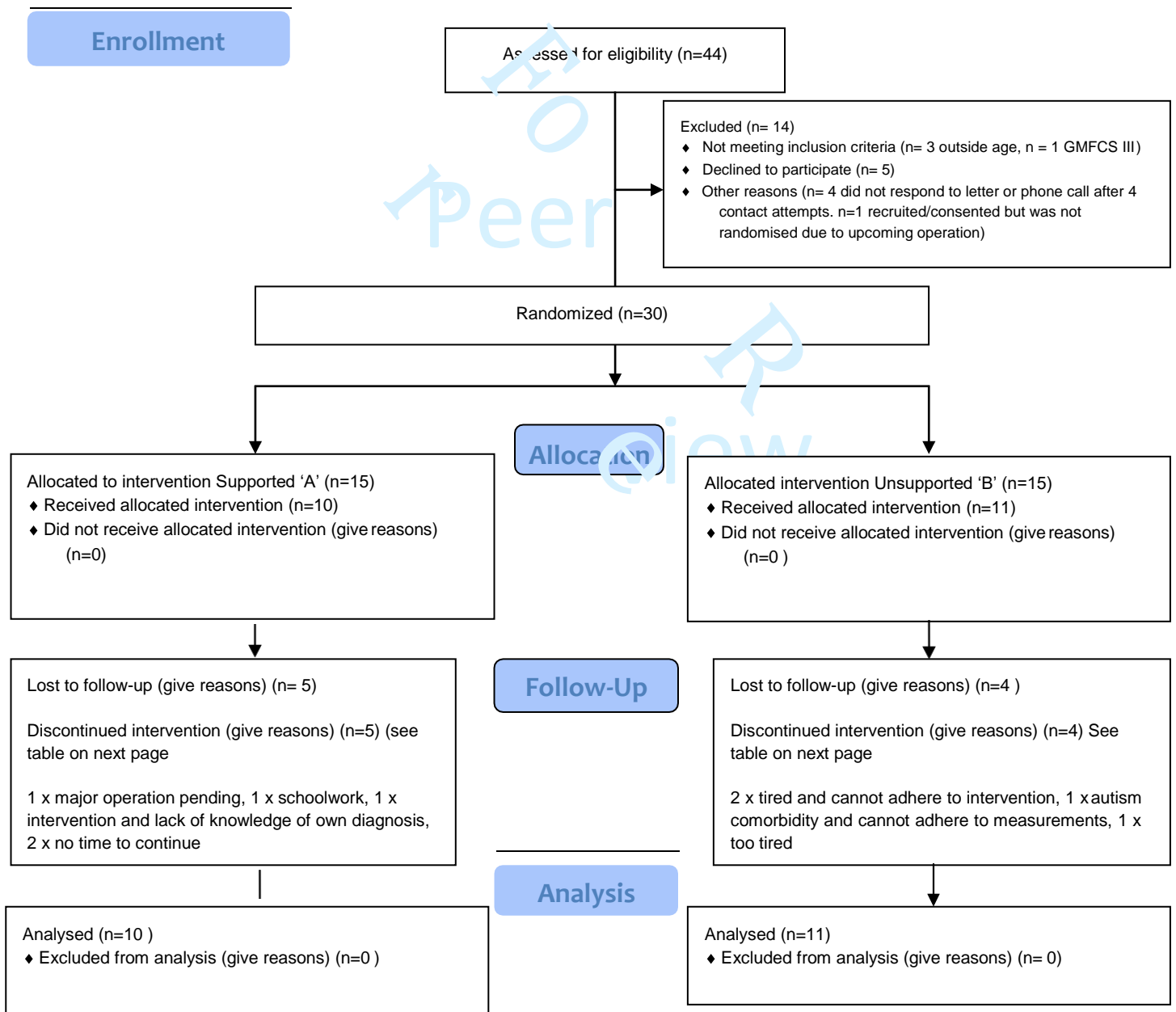
Figure 2 CONSORT Flow Diagram of Enrolment to Analysis



# CONSORT

TRANSPARENT REPORTING of TRIALS

## CONSORT 2010 Flow Diagram







## CONSORT 2010 checklist of information to include when reporting a pilot or feasibility trial\*

Section/Topic	Item No	Checklist item	Reported on page No
<b>Title and abstract</b>			
	1a	Identification as a pilot or feasibility randomised trial in the title	1
	1b	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	1
<b>Introduction</b>			
Background and objectives	2a	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	2-5
	2b	Specific objectives or research questions for pilot trial	5
<b>Methods</b>			
Trial design	3a	Description of pilot trial design (such as parallel, factorial) including allocation ratio	1, 8
	3b	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	n/a
Participants	4a	Eligibility criteria for participants	7
	4b	Settings and locations where the data were collected	6
	4c	How participants were identified and consented	6-7
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	appendix
Outcomes	6a	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	8-10
	6b	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	n/a
	6c	If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial	n/a
Sample size	7a	Rationale for numbers in the pilot trial	6
	7b	When applicable, explanation of any interim analyses and stopping guidelines	n/a
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	7
	8b	Type of randomisation(s); details of any restriction (such as blocking and block size)	7
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	7

Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	7
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	8
	11b	If relevant, description of the similarity of interventions	7-10
Statistical methods	12	Methods used to address each pilot trial objective whether qualitative or quantitative	12/13
<b>Results</b>			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective	Figure 2 (14)
	13b	For each group, losses and exclusions after randomisation, together with reasons	Figure 2 (14)
Recruitment	14a	Dates defining the periods of recruitment and follow-up	6, 12
	14b	Why the pilot trial ended or was stopped	n/a
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 2, 3
Numbers analysed	16	For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group	Figure 2 (14)
Outcomes and estimation	17	For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by randomised group	Table 7, 8, 9
Ancillary analyses	18	Results of any other analyses performed that could be used to inform the future definitive trial	n/a
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	n/a
	19a	If relevant, other important unintended consequences	n/a
<b>Discussion</b>			
Limitations	20	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	25-26
Generalisability	21	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies	24, 27
Interpretation	22	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence	20-26
	22a	Implications for progression from pilot to future definitive trial, including any proposed amendments	24-27
<b>Other information</b>			
Registration	23	Registration number for pilot trial and name of trial registry	1
Protocol	24	Where the pilot trial protocol can be accessed, if available	n/a
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	27
	26	Ethical approval or approval by research review committee, confirmed with reference number	6

1 Citation: Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. BMJ. 2016;355.  
2 \*We strongly recommend reading this statement in conjunction with the CONSORT 2010, extension to randomised pilot and feasibility trials, Explanation and Elaboration for important  
3 clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological  
4 treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see [www.consort-statement.org](http://www.consort-statement.org).  
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For Peer  
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**Supplementary Table S1**

***Participant diary***

**Can we use the Wii Fit to Help Improve Balance and Movement in Children with CP?**

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Patient Identification Number for this trial:

Week No: \_\_\_\_\_

Please complete this diary during your three sessions every week throughout the study. Please be honest. Do not worry if you have missed sessions, as one of the things we want to find out is how well children keep going for a block of virtual reality therapy. Please tell us if you had problems such as the Wii Fit not working, or missed a session, say because you were ill. Please tick the face that shows how much you enjoyed the session using the happy faces scale. Please also use the extra column to record if you have played any extra sessions this week.

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	Session one	Session Two	Session Three	Extra Session
Child and/or Carers: How long did you/your child play for?				
Child and/or Carers: Which games did you/your child play on?				
Parents: Was it stressful or was your child happy to do therapy session?	Stressful OK Happy	Stressful OK Happy	Stressful OK Happy	
Child and/or Carers: Any problems/reasons for not doing session?				
Child: How much did you enjoy session?				

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## Supplementary table S2

*Unsupported group had the freedom to choose from the 15 games that were present in the “Wii Fit Sports” game pack training pack. Six games for the supported group were selected from this set of games*

*Intervention Strategy (supported group) – based on physiotherapist recommended games that focus on particular muscle groups and movement*

Please note that it is important to stick to the following schedule and not allow your child to use any other games on the Wii Fit during their intervention sessions -

Remember every week consists of using the Wii Fit 3 times per week, for 30 minutes per session, and keep a record of how you're doing e.g. what levels are you on, or how fast are you getting?

Week	Game & Duration of play for that session	Believed physiotherapy benefit
1.	Penguin Tilt (15 minutes) Followed by Tilt Table (15 minutes)	Introductory session. Penguin Tilt: Good for all ages, core stability, side-to-side weight transfer Tilt table: Core stability, side-to-side weight transfer, co-ordination
2	Ski Slalom (15 minutes) Followed by Football (15 minutes)	Maintaining previous weeks work on core stability and side-to-side weight transfer. Football: Side-to-side weight transfer,



		balance
3	Snowboard (15 minutes) Followed by Penguin Tilt (15 minutes)	This week whilst still fresh at the start of the session repeat snowboard which you may find challenging, and follow this up with Penguin Tilt from week 1
4	Free choice of the following games: Penguin tilt, Tilt table, Ski Slalom, Snowboard, Football, Balance Bubble. Each chosen game must be played for a minimum of 10 minutes.	This week you can choose any of the games you've been introduced to as a reward as you're halfway through the programme!
5	Ski Slalom (15 minutes) Followed by Tilt Table (15 minutes)	Ski Slalom: Core and quadriceps stability and strength, side-to-side weight transfer Tilt table: Core stability, side-to-side weight transfer, co-ordination
6	Balance Bubble (15 minutes) Followed by Tilt Table (15 minutes)	Balance Bubble: Side-to-side weight transfer, Core and quadriceps stability and strength Tilt table: Core stability, side-to-side weight transfer, co-ordination
7	Football (15 minutes) Followed by	Football: Side-to-side weight transfer, balance

	Snowboard (15 minutes)	Snowboard: Core and quadriceps stability and strength, forward and back weight transfer
8	Free choice of the following games:  Penguin tilt, Tilt table, Ski Slalom, Snowboard, Football, Balance Bubble. Each chosen game must be played for a minimum of 10 minutes.	This week you can choose any of the games you've been introduced to as a reward as you're halfway through the programme!
9	Football (15 minutes)  Followed by  Balance Bubble (15 minutes)	Football: Side-to-side weight transfer, balance  Balance Bubble: Side-to-side weight transfer, Core and quadriceps stability and strength
10	Penguin Tilt (15 minutes)  Followed by  Balance Bubble (15 minutes)	Penguin Tilt: Good for all ages, core stability, side-to-side weight transfer  Balance Bubble: Side-to-side weight transfer, Core and quadriceps stability and strength
11	Snowboard (15 minutes)  Followed by  Ski Slalom (15 minutes)	Snowboard: Core and quadriceps stability and strength, forward and back weight transfer  Ski Slalom: Core and quadriceps

		stability and strength, side-to-side weight transfer
12	Free choice of all games -	This week you can choose any game from the Wii Fit including ones you've not played before as you've finished the programme.

FOR PEER REVIEW

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3 **Supplementary file S3: Specific Phone Call Question for Participants (every 2 weeks)**  
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- 8 1. Did your child require any additional support whilst playing games e.g. holding someone's  
9 hand, having a chair in immediately in front of where you are playing?  
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11 2. Has your child needed additional support reading what is on the screen e.g. your child can  
12 follow instructions verbally but not on the screen?  
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14 3. Did your child need support during the 30-minute session i.e. not at the beginning or at the  
15 end of the session such as "what do I do now"?  
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17 4. How are doing with the games?  
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19 5. Do you think you are getting better with the games?  
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31 **Specific Phone Call Question For non-supported group (every 2 weeks)**  
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