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Does a 10-week physiotherapy programme, using interactive exercise equipment, improve balance and walking in children with cerebral palsy aged 4-18 years when compared to usual care?

Submission date
08/01/2021

Recruitment status
No longer recruiting

Registration date
11/01/2021

Overall study status
Completed

Last Edited
16/10/2023

Condition category
Nervous System Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Children with cerebral palsy (CP) frequently have difficulties walking. Walking can be very tiring and difficulties with balance make everyday tasks much harder. This can affect a child's self-confidence and how children interact with other peers.
Home exercise programmes are designed to help with such problems but children often do not want to do these exercises. When a child's muscles get stiff and tight they may need costly and burdensome surgery to lengthen the muscles. Where there are several problems that affect movement, it can be difficult for physiotherapists to develop effective home-based treatments. A novel piece of equipment, similar to a cross-trainer, has been developed that allows the child to do therapy by playing motivating computer games using their leg movement. The device supports the child in a standing position while they work on improving standing posture, balance, strength and mobility in a fun and motivating way. The device uses motors at the ankles and knees to assist or resist the movements that children have difficulties performing. It allows children to carry out precise movements to control a series of interactive, fun computer games. A small study suggested that using the interactive trainer intensively over a 10-week period results in some improvement in children's walking. This study aims to carry out preliminary work to find out if it is possible to undertake a major study to test the effectiveness of this intervention.

Who can participate?
Children with cerebral palsy (CP) aged 4-18 who are able to walk

What does the study involve?
In the study, children with CP will be allocated at random using a computer to either a group using the interactive trainer or usual physiotherapy management. This will ensure both groups are similar in terms of the age and level of physical impairment at the start of the trial. Twenty

children will use the interactive trainer and twenty children will have usual care. The interactive trainer will be based at either home, local school or physiotherapy department and will be set up to the individual child's training needs by their physiotherapist. Children will then train three times per week, helped by their physiotherapy or teaching assistant. The 'usual care' group will undertake home-based exercises. The content of the usual care exercises will be defined and based on current guidelines and the consensus opinion of ten expert physiotherapists.
Training in both groups will take place over 10 weeks. Children will be assessed at the beginning of the study, after 10 weeks of therapy, and 3 months after finishing the training. Measures will include walking and balance ability, and other factors such as strength and overall satisfaction. Finally, participants' views will be sought on whether the novel intervention and the usual care exercises were comfortable and motivating. Six children and their parents from each group will be selected and invited to be interviewed. These children will receive an electronic tablet and will be asked to indicate daily how they found the training and how they felt. Over the 10-week training period they will be asked to take 5-20 photos that they feel represent their experiences of their exercise programme. The photos will guide the discussion during an interview to gain a deeper knowledge of their experiences. Parents will also be interviewed about the impact of the exercise programme on family life as well as the feasibility of this study. The researchers will interview a group of physiotherapists about their experiences of the study. The results of this study will be brought together to determine how to design future clinical trials.

What are the possible benefits and risks of taking part?
The results of this study will show whether it is feasible to run a large trial to test whether the interactive trainer is more effective than usual care. Children may benefit from treatments in either group. Children may find the tests tiring to complete. They may feel some fatigue or muscle soreness following strength training.

Where is the study run from?
University of Plymouth (UK)

When is the study starting and how long does it go on for?
September 2019 to August 2022

Who is funding the study?
National Institute for Health Research (NIHR) (UK), ref. ICA-CDRF-2017-03-041

Who is the main contact?
Rachel Rapson
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Study website
https://www.plymouth.ac.uk/research/a-novel-interactive-training-device-to-improve-walking-ability-and-quality-of-life-for-children-with-cerebral-palsy-trial-accept-study

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
269948

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
ACCEPT Study protocol version 2_11.09.2020, IRAS 269948, CPMS 44763

Study information

Scientific Title
A multi-centre feasibility randomised control trial of a physiotherapy programme using interactive exercise equipment to improve balance in ambulant children with cerebral palsy

Acronym
ACCEPT

Study objectives
Training on the Happy Rehab™ interactive device improves outcomes of dynamic balance when compared to usual physiotherapy care.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 03/02/2020, North of Scotland Research Ethics Committee (Summerfield House, 2 Eday Road, Aberdeen, AB15 6RE, United Kingdom; +44 (0)1224 558458; nosres@nhs.net), ref: 20/NS/0018

Study design
Mixed methods feasibility randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Treatment

Participant information sheet
https://www.plymouth.ac.uk/research/a-novel-interactive-training-device-to-improve-walking-ability-and-quality-of-life-for-children-with-cerebral-palsy-trial-accept-study

Health condition(s) or problem(s) studied
Ambulant children with cerebral palsy GMFCS I-III

Interventions
The objective of the trial is to assess the feasibility of conducting an RCT evaluating the effect of interactive exercise equipment on balance and walking for children with cerebral palsy, the feasibility of the intervention and investigate participant views of taking part in the trial. Participants will be randomised on a 1:1 using minimisation criteria based on age and gross motor function classification to either the intervention or usual physiotherapy care. The intervention is 20 minutes training using a Happy Rehab™ interactive training device for 20 minutes, 3 times per week for 10 weeks. The device will be used in the home and set up by the usual treating physiotherapist.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Happy Rehab™

Primary outcome measure
Balance measured by two potential primary outcome measures at 0, 10 and 20 weeks:
1. Next step test of dynamic balance, specifically the medio-lateral and antero-posteriori movement of the centre of mass and stepping error
2. Pediatric Balance Scale

Secondary outcome measures
1. Walking kinematics measured using CODAmotion gait analysis at 0, 10 and 20 weeks
2. Muscle strength of quadriceps, hamstrings, and gastrocnemius and hip abductors measured

using a handheld dynamometer (three measurements) at 0, 10 and 20 weeks
3. Passive range of movement and spasticity measured using the modified Tardieu scale of quadriceps, hamstrings, gastrocnemius and hip adductors using a goniometer (three measurements) at 0, 10 and 20 weeks
4. Participation measured using the Canadian Occupational Performance Measure (COPM) at 0, 10 and 20 weeks
5. Quality of life measured using CHU-9D at 0, 10 and 20 weeks

Overall study start date
01/09/2019

Completion date
01/08/2022

Eligibility

Key inclusion criteria
1. Diagnosis of cerebral palsy Gross Motor Function Classification Scale (GMFCS) I-III
2. Aged 4-18 years
3. Leg weakness (≤4/5 on the MRC muscle strength rating scale) in at least one muscle group
4. Leg hypertonia (≥1 on the Tardieu scale fast stretch) in at least one muscle group
5. Ability to interact with a computer game using a mouse or joystick

Participant type(s)
Patient

Age group
Child

Lower age limit
4 Years

Upper age limit
18 Years

Sex
Both

Target number of participants
20

Total final enrolment
16

Key exclusion criteria
1. Selective dorsal rhizotomy or multi-level orthopaedic surgery within the last 12 months
2. Soft tissue surgery in lower limbs in the last 6 months
3. Anti-spasticity botulinum toxin injections within the previous 3 months
4. Training with the Happy Rehab™ in the last 4 months

Date of first enrolment
25/01/2021

Date of final enrolment
31/12/2021

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Torbay and South Devon NHS Foundation Trust
John Parkes Unit
Newton Road
Torquay
United Kingdom
TQ2 7BA

Study participating centre
University Hospitals Plymouth NHS Trust
Plymouth Child Development Centre
Scott Business Park
Deacon Park Road
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PL2 2PQ

Sponsor information

Organisation
Plymouth University

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Sponsor type
University/education

Website
https://www.plymouth.ac.uk/

ROR
https://ror.org/008n7pv89

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in Child Health and Development

Intention to publish date
01/05/2023

Individual participant data (IPD) sharing plan
The participant-level data will be anonymised and available for access via PEARL at the University of Plymouth after study close down. Participants will be asked for their consent to share this anonymised data. Interested parties can contact Rachel.rapson@plymouth.ac.uk or access it via the PEARL repository.

IPD sharing plan summary

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version V2	11/09/2020	11/01/2021	No	No
Protocol article		30/05/2022	08/06/2022	Yes	No
HRA research summary			28/06/2023	No	No