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Everyday walking and crouch gait in children with cerebral palsy

Submission date	Recruitment status	[X] Prospectively registered
22/06/2022	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
07/07/2022	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
09/01/2024	Nervous System Diseases	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Cerebral palsy (CP) is a group of disorders that affect a person's ability to move and maintain balance and posture. Crouch gait is one of the most common walking problems affecting children and young people with bilateral cerebral palsy (affecting both sides of the body). Crouch gait is a tiring walking pattern, characterized by excessive knee bend when walking and if left untreated may lead to chronic knee pain and difficulty with walking. The cause of crouch gait is unclear, with potential factors including, knee muscle weakness, knee muscle tightness and difficulties selectively moving joints independently of one another. The aim of this study is to find out how factors such as knee muscle strength impact crouch gait during everyday walking activities where children and young people encounter, slopes and steps.
To do this children with cerebral palsy and typically developing children will be recruited for a one-off study appointment, where measures of knee extensor strength, knee flexor strength and stiffness and a measure of their ability to move joints in the leg independently of one another will be assessed. They will then complete six everyday walking tasks; walking up and down a slope, up and down three steps and along a level walkway at a fast and self-selected speed. At the same time the degree of knee bend will be assessed using wearable motion sensors.
Data will then be explored to see if there is a relationship between the degree of knee bend and measures of knee muscle strength, stiffness and selective joint movement across the six walking tasks.
It is hoped that this research will enable the development of new treatment approaches for young people with cerebral palsy and crouch gait, which target real-life difficulties they may experience daily when walking outside.

Who can participate?
Children aged between 6-18 years old and have cerebral palsy and are able to walk with or without a walker up and down a slope and able to complete 3 steps with a rail.

What does the study involve?
The researcher will arrange a convenient time to discuss the study over the phone or via a video call and to screen whether the child is eligible to participate in the study. The researcher will invite participants for a one-off study assessment at the University of Plymouth, Human

Movement and Function Lab, based in the School of Allied Health Professions.
During this assessment, the researcher will measure the child's knee muscle strength and stiffness using a device called a dynamometer. This will involve pushing or pulling against a strap placed around their leg and having the leg moved at different speeds by the dynamometer. None of these leg measurements will hurt or overstretch the muscles. At the same time small sticky pads will be placed on the child's legs to measure muscle activity.
The researcher will also measure the child's range of motion at the knee and ankle using a goniometer and measure selective motor control. During the assessment the child will be asked to move different joints independently of one another and this will be video recorded to enable the researcher to score their selective motor control ability.
Lastly the child will be asked to complete six everyday walking tasks in bare feet, with or without their walking frame (depending on preference and walking ability), wearing a small motion sensor box on the ankle, hip and knee, of their most affected leg. The everyday walking tasks are as follows.
1. Walking along a 5-metre level walkway at a self-selected (with or without a walker)
2. Walking along a 5-metre level walkway at a fast speed (with or without a walker)
3. Walking up a slope with railings (with or without a walker)
4. Walking down a slope with railings (with or without a walker)
5. Walking up three steps with railings
6. Walking down three steps with railings

This study will all be carried out during a one-off assessment, which will take about 90 minutes in total. Participants will be reimbursed for any reasonable travel expenses incurred as a result of participating in the study.

What are the benefits and risks of participating?
Participating will help to improve the researchers' understanding of crouch gait during everyday walking activities and help to shape future treatment options for children and young people with cerebral palsy. The child may find the tests tiring to complete. There is the possibility that their muscles may feel tired and a bit sore the next day. The researchers will provide rest periods between measurements and stop tests if they cause any discomfort.

When is the study starting and how long is it expected to run for?
October 2021 to March 2024

Who is funding the study?
Torbay Medical Research Fund (UK)

Who is the main contact?
Harriet Hughes, harriet.hughes-5@postgrad.plymouth.ac.uk

Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
313063

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 313063

Study information

Scientific Title
How does selective motor control and knee extensor strength impact crouch gait in children with cerebral palsy during an everyday walking circuit? The RAINCOAT study

Acronym
RAINCOAT

Study objectives
Selective motor control and knee extensor strength have an impact on knee flexion angle during midstance of gait in children with cerebral palsy when carrying out an everyday walking circuit.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 13/02/2023, West Midlands - Black Country Research Ethics Committee (Meeting held by video-conference via Zoom; +44 (0)207 104 8010, (0)207 104 8141; blackcountry.rec@hra.nhs.uk), ref: 22/WM/0268

Study design
Observation cross-sectional study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)

Hospital

Study type(s)
Other

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Cerebral palsy

Interventions
The participant will arrive at the University Of Plymouth; Human Movement and Function Lab. The study will be outlined using the previously supplied information sheets and videos as a guide. Consent will be obtained to participate in the study from parents/guardians. Time will be given for the participants and/or parent/legal guardian to ask questions. Prior to initiating any measures, the researchers will obtain assent from children under the age of 16 years old. Throughout the measures of impairment, the child or young person will be given the opportunity to take comfort breaks. They will also 'check in' with the child during each measure, to ensure they are comfortable, to ask whether they may need a drink or a snack or the opportunity to go to the toilet as well as to check that they are happy to continue with the study. The researchers will inform the child and young person that they can withdraw their participation at any point during the study.

Initially the researchers will measure the participants' height and weight. If the child and young person is happy to do so, they will then ask them to change into shorts. They will then sit on the edge of a plinth, whilst sitting they will then ask them to kick a ball with their preferred leg. This is to establish leg dominance in both the typically developing and CP participants.
The children and young people with CP will then be asked to lie down on a plinth. The study coordinator (SC Hughes) will then carry out manual muscle testing of knee extensor strength using the Medical Research Council Manual Muscle Testing scale (MRC Muscle Scale) and the Ashworth Scale of the knee flexors bilaterally to establish their most affected leg.

Following this, the participant will be positioned comfortably on the Dynamometer (Biodex system 2, UK) chair with the support of the SC. The SC will then explain how the Biodex Dynanometer works and will also show them the Electromyography (EMG) device. The participant will then be given the opportunity to ask questions about the equipment and given reassurance before any measures are taken. EMG stick on surface electrodes will then be applied to the most affected limb (quadriceps, hamstrings and gastrocnemius) and attached via leads to a transmitter attached around the waist.

Measures of knee, extensor and flexor strength and stiffness will be taken using the dynamometer (Biodex system 2, UK). Torque, position, velocity and EMG signals will be analog-to-digital converted at 2 KHz (power 1401, Cambridge electronic design (CED) UK) and recorded using spike 2 software (CED, UK). The participant will then be repositioned supine on a plinth. The SC will then explain the clinical measures before measures of SMC and passive range of motion at the ankle and knee are carried out. The SMC will be measured alongside EMG recordings and the assessment videoed to allow offline assessment of muscle activation and SCALE rating.

Once completed, a Promove device (inertia technologies, Netherlands) will be placed around the ankle, knee and hip of the participant's most affected leg. EMG recordings using spike 2 software (CED, UK) will be synchronised to the Promove recordings. With bare feet the participant will then complete six everyday walking tasks (EWTs). The study is then complete, and the participant will be given the opportunity for debrief.

Strength (A)
Knee extensor and flexor strength will be measured by a dynamometer (Biodex system 2, Uk). Participants will be sat on an adjustable chair with hips at 85 degrees and the axis of the knee aligned to the axis of the motor. The lower leg will be supported by the dynanometer with the foot fixed in an ankle-foot orthosis, set at 45 degrees plantarflexion and fastened with a figure of 8 strap. Trunk and Thigh straps will be used to stabilise proximal joints and safety features will include software and hardware stops to prevent excessive joint movement and participants are provided with an emergency cut-off switch, to stop the trial at any time. The following strength tests will be undertaken:

A1 Maximal isometric strength
For the knee extensor this will be assessed with the knee at 90 degrees (outer range) and 30 degrees knee flexion (inner range). For the knee flexors this will be assessed with the knee at 30 degrees flexion only (outer range).

A2 Maximal isokinetic strength
Isokinetic knee extensors strength will be measured through the available range, starting at 90 degrees extension and moving at a peak speed of 40 degrees per second. This is based on the average knee velocity during loading and midstance as measured in previous work with children with CP (Compton MPhil University of Plymouth Unpublished observations).
Both maximum isometric and isokinetic strength will be measured offline using Spike 2 software (Cambridge Electronic Design, UK). The ratio of the knee extensor strength in the inner and outer range will also be determined and the degree of EMG co-contraction assessed (percentage activation of quadriceps and hamstrings relative to baseline, resting EMG levels).

Stiffness (B)
B.1 Passive stiffness
Knee flexor passive stiffness will be assessed with the Biodex system, using six, 15-degree amplitude stretches, from a starting position of 90 degrees knee flexion and at a speed of 5 degrees per second. Stretches will be separated by between 2-5 seconds, to allow the muscle to relax between each stretch. EMG monitoring will ensure that the muscle is relaxed before a stretch is applied.

B.2 Stretch mediated stiffness
Knee flexor stretch mediated stiffness will also be assessed with the Biodex system using six, 15-degree amplitude stretches, from a starting position of 90 degrees knee flexion. In order to bring about a stretch reflex-mediated muscle response this stretch will be carried out at a speed of 75 degrees per second. Again, stretches will be separated by between 2-5 seconds, to allow the muscle to relax between each stretch and EMG monitoring applied to ensure the muscle is relaxed before a stretch is applied.

B.3 Total stiffness
Total Stiffness will be determined from the fast stretch, following removal of torque due to the weight of the leg (estimated via anthropometric data). Offline analysis in Matlab™ will determine the average torque and position in the 300 ms prior to the stretch onset and 300 ms period immediately after stretch offset and manipulandum as:

Stiffness = (Change in torque)/(Change in position)

Passive stiffness (assessed following the 5 deg/s stretch) and total stiffness following the fast stretch will be determined. Stretch mediated stiffness will be determined as:
Stretch mediated stiffness = total stiffness (fast stretch) - passive stiffness
Mean EMG amplitude in the hamstrings following the mediated stretch stiffness will be determined. Here the EMG signal will be rectified and the onset and offset of EMG activation determined as the point the signal goes above and below a level (mean baseline period + 4 standard deviations). In total four variables will be assessed (passive stiffness, total stiffness, stretch-mediated stiffness and EMG amplitude).

An exploratory assessment of activation of the gastrocnemius during muscle stretch tests and stretches will be undertaken. Here the amplitude of the EMG activation during each test relative to resting levels will be measured.

Gait kinematics during six everyday walking tasks (EWT)
Gait kinematics will be recorded with children in bare feet using Promove inertial sensors (Promove Inertia Studios Netherlands Ltd). These will be placed on the lateral aspects of the ankle, shank, thigh and lateral aspect of the pelvis (see figure B). EMG recordings using spike 2 software (CED, UK) will be synchronised to the Promove recordings (inertia studio software, Netherlands) using trigger pulses generated via the Promove inertia gateway.

Promove data will be recorded at 200Hz and exported for offline analysis in MatLab. Sagittal plane Euler angles will be determined for the ankle, knee and hip joints and the movement of the pelvis in space will be determined to give an estimate of the centre of mass motion.
Participants will then perform the following six EWT:
EWT 1 - 5-metre level walk: self-selected speed
EWT 2 - 5-metre level walk: fast speed
EWT 3 – 3.6-metre walk slope up (complies fully with Building Regulations Document M for dwellings)
EWT 4 – 3.6-metre walk slope down
EWT 5 - three steps up
EWT 6 - three steps down
For safety handrails will be provided for the slope and steps assessment (https://www.disabledaccessramps.net).
Children requiring the use of a walker will use the rails on the steps and slope test and can use their walker on the level surface. A spotter will also provide supervision throughout the EWT. Up to three trials will be performed per EWT to gather a minimum of five steps per task.
The mean amplitude and variability (determined respectively from the mean and standard deviation of five steps) of knee flexion in midstance (50% stance phase) and at initial contact will be determined in each condition. Exploratory analysis will assess joint inter-coordination using angle-angle plots. Mean rectified EMG amplitude over a 200 ms window centred on each time point (initial contact and midstance) will be assessed

Clinical Measures of Impairment (C)

C.1 Selective Motor Control (SMC)
SMC will be assessed using the validated, Selective Control Assessment of the Lower Extremity (SCALE) tool. This tool was developed by Fowler et al. (2009) for health professionals to clinically assess SMC in the entire lower limb in patients with spastic CP. The SCALE assessment will be completed by the SC with participants positioned on a plinth in sitting, except for the

assessment of the hip, which will be performed in side-lying. The assessment will be filmed using three static cameras set up to give a 3D view and the video footage will be used by the SC and a blinded assessor to calculate the SCALE score for each participant's lower limb. EMG recordings will be simultaneously assessed to provide an exploratory analysis of muscle activation during this test.

C.2 Passive Range of Motion (PROM)

C2 (I) Popliteal Angle
The popliteal angle (assessment of hamstring length) will be obtained from both lower limbs with the participant positioned in supine lying on the plinth. The SC will flex the participant's hip to 90 degrees and extend the knee, the research assistant will then record the popliteal angle using a goniometer, in accordance with CPIP measurement guidelines ((APCP, 2017). This will then be repeated three times on each leg, so that an average popliteal angle is obtained for the right and left limb.

C2 (II) Passive Ankle Range of Motion
The participant will be positioned supine on a plinth. The SC will extend the knee and dorsiflex the ankle (assessment of gastrocnemius length), whilst the research assistant measures the degree of ankle dorsiflexion. This will then be repeated with the knee flexed (assessment of soleus length). Both goniometer measurements will be repeated three times, so that an average measure of gastrocnemius and soleus length is obtained for each lower limb

Intervention Type
Other

Primary outcome measure
1. Selective motor control measured using Selective Control Assessment of the Lower Extremity (SCALE) at a single timepoint
2. Maximal isometric and isokinetic knee extensor strength measured using a dynamometer at a single timepoint
3. Knee flexion angle at initial contact and midstance measured using Promove inertial sensors at a single timepoint

Secondary outcome measures
1. Maximal isometric knee flexor strength measured using a dynamometer at a single timepoint
2. Passive Range of motion of the ankle measured using a goniometer at a single timepoint
3. Passive and stretch-mediated stiffness of the knee flexors measured using a dynamometer at a single timepoint
4. Passive range of motion of popliteal angle measured using a goniometer at a single timepoint

Overall study start date
01/10/2021

Completion date
31/03/2024

Eligibility

Key inclusion criteria

1. Typically developing children aged 6-18 years
2. Diagnosis of spastic CP (GMFCS level I-III), affecting one or more muscle groups in both lower limbs
3. The ability to follow simple instructions
4. The ability to be able to travel to the study site at the University of Plymouth (travel expenses will be provided up to a limit of £30)

Participant type(s)
Mixed

Age group
Child

Lower age limit
6 Years

Upper age limit
18 Years

Sex
Both

Target number of participants
40

Key exclusion criteria
1. Dystonic or athetoid CP as the sole presentation (children with dystonia/athetosis co-occurring with a spastic presentation can be included)
2. Selective dorsal rhizotomy or multi-level orthopaedic surgery within the last 6 months
3. Soft tissue surgery in lower limbs in the last 6 months.
4. Anti-spasticity botulinum toxin injections within 3 months
5. Moderate to severe cognitive impairment and/or learning difficulties
6. Typically developing children will be excluded if they have a history of cardiovascular, neurological or musculoskeletal disorders

Date of first enrolment
15/03/2023

Date of final enrolment
31/03/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Torbay and South Devon NHS Foundation Trust
Torbay Hospital
Newton Road
Torquay
United Kingdom
TQ2 7AA

Study participating centre
University Hospitals Plymouth NHS Trust
Derriford Hospital
Derriford Road
Derriford
Plymouth
United Kingdom
PL6 8DH

Study participating centre
Royal Cornwall Hospitals NHS Trust
Royal Cornwall Hospital
Treliske
Truro
United Kingdom
TR1 3LJ

Sponsor information

Organisation
Torbay Hospital

Sponsor details
Newton Rd
Torquay
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United Kingdom
TQ2 7AA
+44 (0)1803 655652
admin.torbaymrf1@nhs.net

Sponsor type
Hospital/treatment centre

Website

https://www.tmrf.info/

ROR
https://ror.org/01vv3y523

Funder(s)

Funder type
Charity

Funder Name
Torbay Medical Research Fund

Alternative Name(s)
TMRF

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The researchers intend to report and disseminate the results of the study through peer-reviewed articles, an internal report and publication on their website. The patient representative of the study will advise on the appropriate dissemination of the results to reach families in the most accessible way.

Intention to publish date
31/01/2025

Individual participant data (IPD) sharing plan
All data will be anonymized and stored electronically using OneDrive and only accessible using password-protected personal computers, in a document file that is also password protected. Data collection for the project will only start after successfully obtaining the ethical approval of the University of Plymouth Faculty of Health Ethics and integrity research committee. University-owned computers will be used for data collection and processing. Microsoft OneDrive, which is governed and securely maintained by the University of Plymouth, will be used to preserve and analyse data. All related paper documents will be stored in a secure and lockable cabinet within the

chief investigator's office and will be processed following the data protection policy guidelines by the University of Plymouth.

Access to the databases will be password protected and limited to staff involved in the study and only for the purpose of quality control, audit or data analysis. The chief investigator will decide which users require read-only and editing access. Remote access will be via the University of Plymouth portal and follow the remote access guidelines set.

This is research data involving human participants. As such it will be retained at the Univeristy of Plymouth for 10 years. Raw data files and data collection sheets will be stored on OneDrive and paper case report files (CRFs) will be stored in a locked cabinet within the principal investigator's office until the completion of studies and publication. It would then be retained at the University of Plymouth for 10 years.

IPD sharing plan summary

Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 4	19/05/2022	28/06/2022	No	Yes
Participant information sheet	version 4	19/05/2022	28/06/2022	No	Yes
Participant information sheet	version 4	19/05/2022	28/06/2022	No	Yes
Protocol file	version 4	19/05/2022	28/06/2022	No	No
HRA research summary			28/06/2023	No	No