Motor trajectories of children born <30 weeks' gestation from birth to five years: early predictors and functional implications - protocol for a prospective cohort study

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Introduction
Due to advances in medical care, younger and more vulnerable children born preterm are surviving.\textsuperscript{1} The earlier a baby is born the greater the risk of long-term consequences, with over 50\% of children born <30 weeks facing motor, cognitive and behavioural impairments.\textsuperscript{2-4} The neurodevelopmental deficits resulting from early birth may compromise academic achievement, physical function and other health outcomes.\textsuperscript{1,5} Motor difficulties in children born <30 weeks are a particular concern, and can range from a mild impairment to the most severe developmental motor impairment of childhood, cerebral palsy (CP).\textsuperscript{6} A recent systematic review reported the rate of CP to be approximately 15\% for children born <28 weeks and 6\% for those born between 28-31 weeks, which is in stark contrast to expected rates of 0.1\% in term-born children.\textsuperscript{7} Deficits in gross and fine motor control, balance and coordination in preterm children without CP are even more common and occur in up to 50\% of children born <30 weeks.\textsuperscript{8}

A recent Cochrane review by our group of early developmental interventions for preterm infants demonstrated the importance of intervening early to improve cognitive and motor outcomes.\textsuperscript{9} However, current interventions have failed to improve long-term motor outcome
at school age. The reasons for this are likely to be multifactorial, including: (a) a lack of understanding of the trajectory of motor impairment, i.e. whether early motor delay is associated with long-term motor impairment; (b) inability to detect possible motor deficits in the neonatal intensive care unit (NICU), which means intervention is not commenced during this key period of brain plasticity and musculoskeletal development; (c) poor understanding of the nature and consequences of motor deficits, i.e. whether the target of intervention should focus on general gross motor skills, gait training, postural control, muscle strengthening, or a combination, or on other functional limitations; and (d) a lack of knowledge of co-morbidities, i.e. the extent to which particular motor deficits are related to cognitive or behavioural problems and other non-motor difficulties.

Determining the trajectory of motor development in preterm children will help differentiate developmental delay from impairment in the clinical setting, which has traditionally been difficult. There are considerable clinical implications from knowing early in life which children are likely to: 1) have persistent motor impairments; 2) catch-up and be free of later motor impairment; and 3) develop later motor impairment. Unfortunately, there is limited understanding about the evolution of motor difficulties up to school age, due to the lack of prospective longitudinal studies with an adequate sample size. Our research team has been pivotal in revealing the strong associations between early motor assessments in the first year post-term equivalent age and later motor functioning in preterm children. However, identifying children most at risk earlier in their NICU course is crucial to ensure interventions are targeted to children most in need and to optimise the benefits of early intervention during a time of maximal brain plasticity and musculoskeletal development.

A substantial evidence base has been established for the risk factors, causal pathways and neurological mechanisms for CP, but there has been little research into the non-CP motor impairments, which affect a much larger number of preterm children. Whilst early measures of motor functioning in the neonatal period offer opportunities for early detection of motor impairment, combining these assessments with magnetic resonance imaging (MRI) at term equivalent age offers a unique opportunity to strengthen our prediction and understanding of the development of motor impairment. Our group has used MRI to identify how brain injury and altered brain development relates to motor impairment in children born preterm, such as changes in brain tissue volumes and structures and white matter microstructure. The
neuroimaging field is expanding rapidly, with many exciting technological advancements occurring in the past few years that provide us with the opportunity to better understand large-scale (whole-brain network) to small-scale (microstructural) brain characteristics. Thus, these new MRI analytic techniques may hold the key to a more comprehensive understanding of the brain abnormalities leading to motor dysfunction in preterm populations.

To address these issues, we are extending our prospective longitudinal cohort of preterm children born <30 weeks and term-born controls already recruited for a study examining brain development and neurobehavioural impairments from birth to two years,\(^{15}\) and will comprehensively re-assess the children at five years of age. This study will utilise: (a) detailed motor assessments collected from birth to two years; (b) novel advanced brain MRI techniques to analyse previously collected neonatal images; (c) comprehensive motor assessments including novel measures of gait and postural control at five years; and (d) measures of physical activity, cognitive and learning ability, and emotional and behavioural status at five years.

The specific aims are:

**Aim 1:** To compare the prevalence of motor impairment from birth to five years of age between children born <30 weeks and term-born children, and examine whether abnormal motor assessments in the newborn period among those born <30 weeks predict abnormal motor functioning at age five years.

**Aim 2:** To determine whether there are novel early MRI biomarkers detectable in the neonatal period that can predict motor impairments at five years, and whether these relationships differ between children born <30 weeks and those born at term.

**Aim 3:** To investigate the association between motor impairments and concurrent deficits in body function and structure at five years of age using a combination of standardised and innovative tests of gait, postural control and strength, and determine whether these relationships differ between children born <30 weeks and those born at term.

**Aim 4:** Explore how motor impairments at five years, including abnormalities of gait, postural control and strength, are related to concurrent functional outcomes including physical activity, cognitive and learning ability, behavioural and emotional problems, and whether these relationships differ between children born <30 weeks and those born at term.
Methods

Design

Prospective follow-up of a longitudinal cohort study of children born <30 weeks and term-born children recruited at birth from the Royal Women’s Hospital, Melbourne, Australia at five years of age.

Participants and Setting

Over a three-year period between 1/1/2011 to 31/12/2013 we recruited 150 preterm children (born <30 weeks) and 151 term-born children (born >36 completed weeks’ gestation and weighing ≥2500 g).15 Inclusion criteria: infants admitted to the Royal Women’s Hospital. Exclusion criteria: (i) infants with congenital abnormalities known to affect neurodevelopment; (ii) infants with non-English speaking parents due to questionnaires needing to be completed in English; and additionally for term-born infants only (iii) any admission to a neonatal intensive or special care nursery. Of the preterm children, six died in the neonatal period and one was diagnosed with Down’s Syndrome and was later excluded.

Motor assessments from birth to two years

All children in this study have had comprehensive motor assessments from birth to two years of age as previously described15 as part of a longitudinal prospective cohort study. To summarise, infants born <30 weeks had weekly assessments from shortly after birth to 32 weeks’ post menstrual age, followed by fortnightly assessments until discharge from the Royal Women’s Hospital and/or term equivalent age. At term equivalent age and at one and two years corrected age, infants from both groups attended an assessment at the Murdoch Childrens Research Institute, The Royal Women’s Hospital, or a had a home visit if unable to attend an outpatient appointment. This assessment was performed by an independent, blinded assessor, masked to previous assessment results and medical history (including preterm birth).

Procedure for five-year follow-up

The five-year follow-up will consist of a single visit to the Murdoch Childrens Research Institute at the Royal Children’s Hospital, Melbourne. Age will be corrected for prematurity
to avoid a known bias in cognitive test scores if age is not corrected. The assessment will take approximately three to four hours and be conducted by an experienced physiotherapist, psychologist/research assistant and exercise scientist who will be blinded to clinical history and previous assessment results. Parents will be asked to complete a questionnaire on demographics, physical activity, activities of daily living, behaviour and additional therapy (e.g. physiotherapy, occupational therapy) . Questionnaires will be sent to the primary caregiver prior to the assessment where possible, via email using REDcap. Further assessments that are not able to administered via REDcap will be administered with the caregiver during the assessment. When the child is unable to attend the hospital for follow-up, an appointment will be offered at home.

**Measurements**

Assessment measures to be collected at 5 years were selected in accordance with the World Health Organization's International Classification of Function, Health, and Disability (known as the ICF) and are described below. The primary outcome is motor impairment at five years.

**Measures of Activity:** Motor development will be assessed with the: *i) Movement Assessment Battery for Children – Second edition (MABC-2)* which consists of three subscales: manual dexterity, aiming and catching, and balance, which are summed to give a total motor score. It is reliable and valid in assessing motor development of children from three to sixteen years of age and considered the ‘gold standard’ outcome measure of motor impairment. *ii) A CP diagnosis* will be made by the child’s paediatrician and confirmed by the assessing physiotherapist on the basis of loss of motor function and abnormal tone and tendon reflexes at five years. The five-level *Gross Motor Function Classification System (GMFCS)* will used to further classify motor function for children with CP.

**Measures of Body Structure and Function:** We will use a combination of clinically validated measures and new techniques to measure balance, gait and functional strength including:
i) *Anthropometric measures* will be recorded for each child. These measures include weight, height, head circumference, lower limb length and shoe size. Lower limb length will be measured from the anterior superior iliac spine to the medial malleolus in a supine position.

ii) The *GAITRite*® Walkway (CIR Systems Inc., Clifton, NJ) – a 16 foot electronic carpet walkway consisting of an instrumented walking surface with an array of embedded pressure-sensitive switches used to measure gait. As a participant walks, the switches close, enabling the calculation of timing and spatial measures of the gait pattern. *Key spatiotemporal variables* will be extracted including, but not limited to, gait speed, cadence, step length, step width, and step time, and step-to-step variation of associated variables.

For all trials, children will walk between ‘goal posts’ placed two metres from each end of the *GAITRite*® Walkway, to ensure steady-state speed is captured and to minimise acceleration or deceleration phases. All assessments will be completed in bare feet, unless unsafe to do so. Gait aids or orthoses will be used, and recorded, if required for safety. A verbal and a visual demonstration, as well as a practice trial, will precede each walking condition. Six walking trials will be captured during each condition in the following sequence: (1) preferred walking speed, (2) a dual cognitive task, (3) a dual motor task, (4) a tandem line-walk and (5) running.

Dual task conditions have been shown to affect gait in both preterm and full term born children.\(^{20}\) The cognitive dual task involves walking at preferred speed while providing verbal answers within a specified category. The participant is instructed to state as many answers as possible, with the number of items recorded. Example categories for this condition include; ‘animals’, ‘things you can eat or drink’, or ‘things you can wear’.\(^{21}\) The dual motor task requires the participant to walk while balancing four table tennis balls on a 20 cm diameter plate,\(^{20}\) with the number of dropped balls recorded. In the tandem line-walk condition, participants will walk placing one foot in front of the other on a 5 cm wide non-slip line placed over the walkway, with occasions of loss of balance recorded. The running condition involves six continuous laps without stopping, at preferred running pace. Prior to the running condition, we will record resting heart rate, oxygen saturation and perceived rate of exertion using the Children’s OMNI Scale of Perceived Exertion for walking and running.\(^{22}\) These measures will be recorded again immediately after completion of the six laps.
iii) A *Microsoft Kinect®* will be used to track reflective markers placed on the sacrum and posterior calcaneus in three dimensional (3D) space during all walking and running conditions. The Kinect® includes an infrared camera (514x424) and light source used to track the location of the markers, and a depth sensing (514x424) and video camera (1920x1080) to track the body surface around the marker to allow for representation of the anatomical landmark in 3D space. The variables derived from the Kinect® at 30Hz will include (but not be limited to) those acquired from the GAITRite® and additional measures of trunk movement including vertical and medial-lateral centre of mass displacement. These trunk measures may be important, as they are known to be affected in children born preterm.23 The participant will also complete three vertical jumps with Kinect® monitoring, with the primary outcome measure being maximum vertical jump height.

iv) *Hand grip strength* (force in kilograms) will be measured using a grip strength dynamometer in a seated position, with the shoulder adducted and neutrally rotated, elbow flexed at 90° and the forearm and wrist in a neutral position.24 Children will be instructed to squeeze the dynamometer as hard as possible with verbal encouragement throughout each trial. A practice trial will be provided to ensure the child understands the contraction required. Three unilateral trials on each arm will be recorded. Three additional trials of bilateral grip strength will be performed with the participant in the same position as the unilateral test but with the shoulders internally rotated to allow the dynamometer to be positioned at the midline of the body

**Measures of Participation:** i) A small Axivity AX3 tri-axial accelerometer-based activity monitor will be worn on the ankle over a consecutive seven day period to obtain information about the number of steps taken per day and sedentary behaviour patterns. The child and caregiver will be educated on wearing the device, and the child will wear it 24 hours a day for seven days before returning it in a pre-paid envelope.

ii) A *physical activity questionnaire* will accompany the activity monitor and will be completed by parents during the same seven-day period that the monitor is worn. This questionnaire will provide more detailed information regarding the sedentary behaviours, screen time and the types of physical activities completed by participants. This questionnaire was developed for use in this study, and is included in Appendix 1.
iii) The PEDI-CAT (Pediatric Evaluation of Disability Inventory)\textsuperscript{25} is a questionnaire that will be used to assess abilities in three functional domains: Daily Activities (e.g. dressing, feeding), Mobility (e.g. transfers, steps and inclines, running and playing) and Social/Cognitive (e.g. interaction, communication, self-management). It provides standard and scaled scores based on normative and disability samples, and is validated for children with a range of physical and behavioural conditions, including children who use mobility devices. Caregivers will complete the PEDI-CAT on an iPad during their child’s assessment.

iv) The PedsQL 4.0\textsuperscript{26} is a 23 item questionnaire that will be used to assess child health-related quality of life. It will be completed by parents, and measures domains of physical health, emotional and social functioning.

v) The Little Developmental Coordination Disorder Questionnaire (Little DCD)\textsuperscript{27} is a parent-completed measure which is designed to identify subtle motor problems in children. This questionnaire has been revised to be appropriate for use by parents of children aged five to seven years of age and its concurrent validity has been established with the MABC-2.\textsuperscript{28}

**Measures of Personal Factors:**

i) General cognitive function will be assessed using the *Wechsler Preschool and Primary Scale of Intelligence (Fourth Edition, Australian and New Zealand Standardised Edition; WPPSI-IV).*\textsuperscript{29} The WPPSI-IV has Australasian norms and is the gold standard measure for assessing general intellectual ability. It provides measures of key cognitive domains: full-scale IQ, verbal comprehension, visual-spatial reasoning, fluid reasoning, working memory, and processing speed.

ii) Children’s emotional symptoms, conduct problems, hyperactivity/inattention, peer problems and prosocial behaviour will be assessed using the well-validated and widely-used parent-report of symptoms, the *Strengths and Difficulties Questionnaire.*\textsuperscript{30}

iv) Psychiatric disorder will also be assessed using the *Developmental and Wellbeing Assessment (DAWBA)*. The DAWBA is a structured evaluation for assigning DSM-V psychiatric diagnoses, and demonstrates good validity and will be completed by parents via an online questionnaire.\textsuperscript{31}

v) Parent report using the validated *Ages and Stages Questionnaire (ASQ-3)* will screen child development in the areas of communication, gross motor skills, fine motor skills, problem solving, and personal-social skills.\textsuperscript{32}
**Measures of Environmental Factors:** The Social Risk Index\(^{33}\) assesses six aspects of social status including family structure, education of the primary caregiver, occupation of the primary income earner, employment status of the primary income earner, language spoken at home, and maternal age at birth. It will be completed by the primary caregiver at five years.

**Predictors of motor impairment**

**Brain MRI:** Between 38 and 44 weeks’ gestational age, MRI was performed at the Royal Children’s Hospital, Melbourne on a 3T Siemens Magnetom Trio, Tim system, as previously described.\(^{15}\) As part of the current proposal, three novel advanced multi-modal MRI analyses will be applied to our previously acquired structural, functional, and diffusion images (n=110 for children born <30 weeks and n=38 for term-born controls):

i) **Infant volumetric analyses.** Morphologically Adaptive Neonatal Tissue Segmentation (MANTiS) will be used to divide \(T_2\) images into white matter, cortical grey matter, cerebrospinal fluid, deep nuclear grey matter, brainstem, hippocampus, amygdala, and cerebellum (Figure 1).\(^{34}\) Further, volumes for 100 brain regions will be quantified, including basal ganglia and thalamus, cerebellar vermis and hemispheres, and 68 cortical brain regions (based on the commonly used Desikan-Killiany adult brain atlas available in FreeSurfer software;\(^{35}\) Figure 1). This will be achieved by applying our recently developed novel infant brain atlas: the Melbourne Children’s Regional Infant Brain (M-CRIB) atlas.

![Figure 1. Morphologically Adaptive Neonatal Tissue Segmentation (MANTiS) brain tissue segmentation (A) and Melbourne Children’s Regional Infant Brain (M-CRIB) atlas infant](image-url)
brain sub-regional parcellation including basal ganglia and thalamus, cerebellar vermis and hemispheres, and cortical regions (B).

ii) Connectivity analyses. Graph theoretical methods will be applied to understand the complex large-scale network of the brain, allowing the quantification of topological properties including modularity, network integration and network hierarchy. The ‘nodes’ of the graphs will include the cortical and sub-cortical grey matter regions delineated using M-CRIB. The ‘edges’ will be denoted as the white matter fiber tracts from diffusion weighted images in the case of Structural connectivity analyses. Alternatively, Functional connectivity analyses will utilise resting state images, where temporal correlations in spontaneous Blood Oxygen Level Dependent (BOLD) signal oscillations will form the ‘edges’ of the graph.

iii) White matter microstructural organisation. Advanced cutting edge models of water diffusion will be used to glean insight into microstructural characteristics of grey and white matter, including axon density and myelination. In addition to the quantification of grey and white matter complexity, diffusion models will enable the most advanced tractography methods.

Sample Size: The sample size for the study has already been determined by the size of the existing cohort (currently n=143 <30 weeks and n=151 term). Based on our past experience in assessing many similar aged cohorts over several decades, we conservatively estimate a follow-up rate of 88% overall, which will be higher for the preterm than the term group, and hence we expect approximately 130 in each group. With 130 in each group, the study will have 80% power to detect differences in means between the group as small as 0.35 standard deviation (SD), and a reduction in proportions from 50% down to 35%, with a Type-I error of 5%.

Data Management and Analysis:
Data will be collected, entered into a REDCap database, edited, and analysed using Stata, in accordance with the aims as follows:

*Aim 1*: The prevalence of motor impairment from birth to five years will be compared between children born <30 weeks and term-born peers using separate logistic regression models applied at each of the time points (term age, one, two and five years). Results will be
reported as odds ratios for impairment, along with 95% confidence intervals (CI). Persistent motor impairments during the neonatal period will be assessed as a predictor of severity of motor impairment at five years of age in children born <30 weeks using linear regression. All models will be fitted using generalised estimating equations (GEEs) with results reported with robust standard errors, to allow for the clustering of multiple births. Analysis will be repeated adjusting for predictors of motor outcome, including additional therapy, sex, brain injury and chronic lung disease.

**Aim 2:** Logistic regression will be used to investigate the association between neonatal MRI biomarkers and the severity and occurrence of motor impairment at five years, again fitted using GEEs and reported with robust standard errors. Initially univariable models will be fitted for each predictor before combining important predictors into a single multivariable model to investigate independent predictors. Predictor-by-group interactions will be used to explore whether relationships differ in the two birth groups.

**Aim 3:** Linear and logistic regression will be used to investigate the association between gait, posture and strength, and the severity and occurrence of motor impairment respectively. Separate models will be fitted for each predictor using GEEs, with an interaction between each gait, posture and strength variable and group to explore whether these relationships are different in the two birth groups.

**Aim 4:** Linear and logistic regression will investigate the association between severity and occurrence of motor impairment and physical activity, cognitive and learning and behavioural outcomes, applied across all participants in a single model. Separate models will be fitted for each outcome using GEEs, with an interaction between motor impairment and group to explore whether these relationships differ in the two birth groups.

**Discussion/ Significance**

The adverse social and economic impact of the impairments and subsequent health outcomes associated with preterm birth is substantial due to both direct costs (health care and educational support) and lost opportunity costs. Understanding the developmental precursors of motor impairment in children born <30 weeks is essential to minimise the negative effects of preterm birth on motor skill development, and potential secondary impacts on physical activity, participation, academic achievement, and self-esteem. Better understanding of motor skill development will enable targeting of intervention and streamlining of services to the
individuals who are at highest risk of motor impairments. This study will enable the development of clinical practice guidelines, not only for recommendations of early assessment, but also for interventions targeting aspects of motor development, such as strength training if there is underlying weakness identified, or postural control training if balance problems are identified at the body function and structure level. Furthermore, we will be able to advise on the rates of co-morbidities and thus develop recommendations on the role of the multi-disciplinary team in the follow-up of children with motor impairments to ensure appropriate allocation of health resources.

**Conflict of interest declaration:**
The authors have no conflicts of interest to declare.

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References


Motor trajectories of preterm children from 0-5 years: Protocol

Spittle 30/06/2016

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<tr>
<th>Study number:</th>
<th>Day 1 date: ______________</th>
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Please answer the following questions as best as you can for the time your child was with you each day. Estimate any times in hours, including decimals.

**PHYSICAL ACTIVITY DIARY**

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<th></th>
<th>Day 1</th>
<th>Day 2</th>
<th>Day 3</th>
<th>Day 4</th>
<th>Day 5</th>
<th>Day 6</th>
<th>Day 7</th>
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<tr>
<td>Sleep time last night</td>
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<td>Wake time this morning</td>
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<td>Did you child take off the activity monitor today?</td>
<td>Yes/No</td>
<td>Yes/No</td>
<td>Yes/No</td>
<td>Yes/No</td>
<td>Yes/No</td>
<td>Yes/No</td>
<td>Yes/No</td>
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<td>If yes, record time with monitor off (hours)</td>
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<td>Time watching TV/videos/playing computer/video games/playing on smart phones or tablets (hours)</td>
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<td>Time spent in quiet play e.g. reading/being read to/drawing/painting/puzzles/games (hours)</td>
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<td>Did your child attend childcare/kinder/school today?</td>
<td>Yes/No</td>
<td>Yes/No</td>
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<td>If yes, did they travel by active transport?</td>
<td>Walk/Bike / Scooter</td>
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<td>Please circle type of active transport if applicable.</td>
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<td>Time spent participating in active unstructured play e.g. playground, climbing, running, skipping, hula hoops (hours)</td>
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<td>Did your child participate in active <strong>structured</strong> play today?</td>
<td>Yes/No</td>
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<td>If yes, please tick type of activity</td>
<td>Swimming</td>
<td>Football</td>
<td>Dance/Gymnastics</td>
<td>Trampolining</td>
<td>Athletics</td>
<td>Walking (e.g. walking the dog)</td>
<td>Bike riding</td>
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