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RESEARCH PROTOCOL

Evolution of Gait Biomechanical Parameters in Toddlers with Unilateral Cerebral Palsy

SPONSOR	National Clinical Center of Neuropsychomotor Recovery for Children "Dr. N. Robanescu" (NCCNRC)
ACRONYM	BB-AQM 2
COMPLETE TITLE	Evolution of Gait Biomechanical Parameters in Toddlers with Unilateral Cerebral Palsy During the First 18 Months of Independent Walking: A Comparison with Typically Developing Peers
PRINCIPAL INVESTIGATOR	Dr. Anca Irina Grigoriu Str. Dumitru Minca 44, Sector 4, Bucharest, Romania an_ir_ra@yahoo.fr
PROTOCOL VERSION	V2.0 Consolidated English version incorporating the approved amendment
DOCUMENT DATE	16/10/2026
ORIGINAL DOCUMENT DATE	9/02/2022
ORIGINAL ETHICS COMMITTEE APPROVAL	10/03/2022/ No. 4708
AMENDMENTS APPROVAL DATE	20/09/2023/ No. 8143
STUDY DESIGN	Longitudinal observational controlled study
STUDY SITE	National Clinical Center of Neuropsychomotor Recovery for Children "Dr. N. Robanescu", Str. Dumitru Minca 44, sector 4, 041408,Bucharest, Romania

Data-processing agreement: An agreement between National Clinical Center of Neuropsychomotor Recovery for Children "Dr. N. Robanescu", Bucharest, Romania and Brest University Hospital (CHRU de Brest), France, was signed on 29/11/2024 concerning the transfer and processing of study data.

PROTOCOL HISTORY

Document History and Ethics Committee Approval

This document is a consolidated English version of the original research protocol, incorporating the subsequent amendment approved by the Ethics Committee. The original protocol and the amendment were prepared and reviewed at different times during the study's development. The consolidated version is intended to provide a coherent description of the study and its approved modifications.

Document/version	Date	Description
Original protocol — Version 1.0	9/02/2022	Original research protocol submitted to the Ethics Committee
Ethics Committee approval	10/03/2022	Approval of the original research protocol
Protocol amendment — Version 1.1	17/08/2023	Amendment concerning recruitment and eligibility criteria for the typically developing control group
Amendment approval	20/09/2023	Ethics Committee approval of the amendment
Consolidated English version — Version 2.0	16/10/2026	English version incorporating the approved amendment

Summary of the Amendment

The original protocol planned a second gait analysis assessment of the typically developing (TD) control group. However, it was not possible to complete the planned second assessment in all TD participants. Consequently, an amendment was introduced to modify the recruitment strategy for the TD control group. An additional group of typically developing children, with maximum 42 months of age and with 12–24 months of independent walking experience, was recruited and assessed to serve as the control group for the UCP children for the second gait analysis.

The amendment modified the recruitment strategy for the TD control group, but it didn’t modify the objectives and hypothesis of the study. The objective of comparing gait biomechanics between children with unilateral cerebral palsy and typically developing children was retained.

Administrative note: The dates and descriptions above should be completed and checked against the original protocol, the formal amendment, and the corresponding Ethics Committee decisions. The consolidated English document does not imply that this exact consolidated version was separately approved by the Ethics Committee.

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ORIGINAL RESEARCH PROTOCOL

1. General Information

1.1. Title

Evolution of Gait Biomechanical Parameters in Toddlers with Unilateral Cerebral Palsy During the First 18 Months of Independent Walking: A Comparison with Typically Developing Peers

Short title: BB AQM 2

1.2. Principal Investigator

Dr. Anca Irina Grigoriu, MD, PhD

National Clinical Center of Neuropsychomotor Recovery for Children “Dr. N. Robanescu”, Str. Dumitru Minca 44, Sector 4, 041408, Bucharest, Romania

1.3. Study Coordination and Monitoring

Dr. Anca Irina Grigoriu, MD, PhD

National Clinical Center of Neuropsychomotor Recovery for Children “Dr. N. Robanescu”, Str. Dumitru Minca 44, Sector 4, 041408, Bucharest, Romania

1.4. Institutional Support and Administrative Oversight

The study will be conducted at National Clinical Center of Neuropsychomotor Recovery for Children “Dr. N. Robanescu”, with the authorization of the institution's management. The institutional management will provide administrative support, as appropriate, to facilitate the conduct of the study in accordance with institutional policies and applicable ethical requirements. Scientific responsibility for the study will remain with the principal investigator.

1.5. Associated Scientists

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Department of Physical Medicine and Rehabilitation

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Mathieu LEMPEREUR, Engineer

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1.6. Associated Technical Facilities

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1.7. Methodologist – Biostatistician

Mathieu LEMPEREUR, Engineer

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Department of Physical Medicine and Rehabilitation

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A formal collaboration agreement will be signed between the two institutions (the National Clinical Center of Neuropsychomotor Recovery for Children "Dr. N. Robanescu", Bucharest, and CHRU Brest) prior to data processing, specifying the respective responsibilities of each party and the arrangements for data processing and analysis.

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2. Background and Rationale

Cerebral palsy (CP) is a group of permanent disorders affecting the development of movement and posture, causing activity limitations that are attributed to non-progressive disturbances occurring in the developing fetal or infant brain [1]. Unilateral cerebral palsy (UCP) represents a specific clinical phenotype in which motor impairment predominantly affects one side of the body. Although children with UCP may acquire independent walking relatively early compared with children with more severe bilateral motor involvement, gait abnormalities may already be present during the first months of independent walking [2,3]. These abnormalities may involve temporal and spatial gait organization, pelvic orientation, lower-limb kinematics, and inter-limb coordination.

The first months following the acquisition of independent walking represent an important period of rapid locomotor development. In typically developing (TD) children, gait undergoes substantial maturation during this period, including changes in walking speed, cadence, step and stride characteristics, support phases, and lower-limb joint kinematics [4-9]. In children with UCP, however, the trajectory of gait development during this early period remains insufficiently characterized.

Three-dimensional gait analysis (3DGA) provides objective quantitative information about gait kinematics and spatiotemporal parameters. Previous research has described gait abnormalities in children with CP using 3DGA [2,10], but longitudinal studies specifically addressing the early development of gait in toddlers with UCP after the acquisition of independent walking remain limited. A better understanding of gait biomechanics during this critical developmental period may help distinguish delayed maturation from persistent pathological patterns and may contribute to the optimization of early rehabilitation strategies.

The main aim of this study was to analyze the evolution of the biomechanical parameters (lower-limb kinematics and spatiotemporal parameters) of toddlers with UCP, who received standard therapeutic care, during the first 18 months after the acquisition of independent walking, and to compare their gait with that of typically developing (TD) toddlers with the same walking experience, by using a 3D motion analysis system.

Children with UCP received standard rehabilitation care according to their individual clinical needs during the study period. These treatments were not assigned by the research protocol and were not considered experimental interventions. The purpose of the study was to describe the natural longitudinal evolution of gait under usual clinical care rather than to evaluate the efficacy of a specific rehabilitation intervention.

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3. Research Question

How do lower-limb kinematics and spatiotemporal gait parameters evolve during the first 18 months following acquisition of independent walking in toddlers with UCP, and how does this evolution compare with typically developing peers?

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4. Objectives

4.1. Primary objective

To investigate the longitudinal evolution of lower-limb kinematics and spatiotemporal gait parameters in toddlers with unilateral cerebral palsy during the first 18 months following acquisition of independent walking.

4.2. Secondary objectives

1. To compare gait parameters of toddlers with UCP with those of TD toddlers during the first 6 months of independent walking and explore how the differences between groups evolve after 12–18 months of additional walking experience.

2. To characterize the evolution of global gait deviation using the Gait Profile Score within the UCP group and between the UCP and the TD groups at both time assessments.

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5. Hypotheses

The study hypothesizes that children with UCP would demonstrate significant differences in spatiotemporal gait parameters and lower-limb kinematics compared with TD peers during the early stages of independent walking and these differences would change during the first 18 months after the independent walking onset.

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6. Study Design

This will be a prospective longitudinal observational controlled study.

Two groups of children will be considered:

- a group of children with unilateral cerebral palsy (UCP);
- a comparison group of typically developing (TD) children.

Both groups will undergo two 3D gait-analysis assessments:

- **T1:** within the first 6 months following acquisition of independent walking;
- **T2:** 12–18 months after T1, corresponding to approximately 12–18 months of additional walking experience.

The longitudinal comparison will be performed within the UCP group, while cross-sectional comparisons will be performed between the UCP and TD groups at each assessment stage.

The study will not assign or modify rehabilitation treatment. Children with UCP will continue to receive standard clinical care according to their individual needs.

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7. Study Setting and Period

The study will be conducted at the Motion Analysis Laboratory of the National Clinical Center of Neuropsychomotor Recovery for Children “Dr. N. Robanescu”, Bucharest, Romania.

The study period is extended for approximately 30 months after the approval of the Ethics Committee of the hospital.

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8. Participants

8.1. UCP group

3DGA is routinely performed on children of all ages who present with a gait disorder. It is a non-invasive, painless examination with no risks identified in the literature, and it is recognized as the gold standard for the study of gait [11]. Currently, 3DGA is part of the standard medical care for cerebral palsy from a very early age. Young children with cerebral palsy who have less than 6 months of walking experience are recruited through existing

physical medicine and rehabilitation (PMR) clinics. Children with a clinical diagnosis of unilateral cerebral palsy will be eligible for participation.

8.2. Typically developing group

TD toddlers will be recruited from siblings of children with UCP and from children known to the investigators.

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9. Eligibility Criteria

9.1. Inclusion criteria

Participants are eligible if they meet the following criteria:

1. age up to 3 years;
2. no more than 6 months of independent walking experience at recruitment/T1;
3. ability to walk independently for at least 5 m without falling or external support;
4. parental/legal guardian informed consent;
5. for children with UCP, a right or left hemiparesis and a medical history compatible with cerebral palsy (e.g., prematurity, prenatal or perinatal stroke, foetal distress/birth hypoxia, or cerebral malformations);
6. For the TD group, a typical psychomotor development and acquisition of independent walking before 18 months of age.

Independent walking onset is defined as the ability to perform at least three consecutive unaided steps.

9.2. Exclusion criteria

1. previous lower-limb surgery;
2. lower-limb trauma within the preceding 6 months;
3. known allergy to adhesive materials.
4. lower-limb botulinum toxin injections within the previous 3 months for the UCP group;
5. presence of neurological and/or orthopaedic disorders for the TD group.

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10. Recruitment and Consent

Children with UCP will be recruited from patients attending the National Clinical Center of Neuropsychomotor Recovery for Children “Dr. N. Robanescu”, Bucharest, Romania, including inpatient and outpatient services.

Typically developing children will be recruited from siblings of children with UCP and from children known to the investigators.

Parents or legal guardians will receive information regarding the study procedures, objectives, potential risks and benefits, and the voluntary nature of participation.

Written informed consent will be obtained before participation.

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11. Rehabilitation and Usual Care

During the study period, children with UCP will continue to receive standard rehabilitation care according to their individual clinical needs.

Usual care could include physical therapy, botulinum toxin treatment, and orthotic management.

These treatments will not be assigned by the study protocol and will not be administered for research purposes. The study doesn't evaluate the efficacy of any specific rehabilitation intervention and doesn't prescribe a standardized therapeutic program.

The longitudinal observations therefore intend to describe gait development occurring within the context of usual clinical care.

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12. Study Procedures

Demographic and anthropometric data will be collected for all participants. Relevant perinatal history will be documented in both groups. Psychomotor development will be evaluated using the Denver Developmental Screening Test [12]. In the UCP group, information regarding the presumed aetiology of cerebral palsy and Gross Motor Function Classification System (GMFCS) levels will also be recorded. Clinical examination includes assessment of joint range of motion, bimalleolar axis, and spine alignment. Lower-limb spasticity, evaluated using the Modified Ashworth Scale, will additionally be assessed in children with UCP.

Participants will undergo 3DGA using the standardized laboratory gait-analysis protocol. At each assessment, participants will be allowed sufficient time to become familiar with the laboratory environment and walking task.

Participants will walk barefoot along a walkway at a self-selected comfortable walking speed. Children will be encouraged verbally to walk toward their parents positioned at the opposite end of the corridor while maintaining a straight trajectory. Toys and visual media are occasionally used to maintain attention.

Multiple gait cycles will be recorded to obtain representative gait data.

For children with UCP, the affected and non-affected limbs will be analyzed separately. For TD children, left and right limbs will be averaged to obtain a representative limb for analysis.

13. Three-Dimensional Gait Analysis

Three-dimensional gait analysis will be performed using BTS motion capture system (BTS Bioengineering, Milan, Italy), composed of 12 infrared cameras, 6 force platforms, and a 10-channel electromyography system. Camera acquisition frequency is set at 340 Hz. The "Helen Hayes with medial markers" biomechanical model is used, including medial knee and ankle markers as well as four technical markers.

Straight-line gait cycles are defined as cycles performed within a corridor width not exceeding 60 cm for at least two consecutive cycles. Data will be retained only when a minimum of five gait cycles per limb and per session will be available, with preference given to consecutive cycles. Kinematic data will be filtered and time-normalized to the gait cycle, expressed as a percentage from 0% to 100%.

To reduce anthropometric bias, step length and stride length will be normalized to lower-limb length, and gait velocity according to the method described by Hof [13].

A qualitative inspection will exclude cycles involving running or deviations from straight-line walking. TD participants presenting atypical gait patterns will also also excluded.

For each participant, mean kinematic and spatiotemporal values will be obtained by averaging the selected parameters or vector components for each side. In the TD group, left and right limb data will be averaged to generate a single representative side.

The Gait Profile Score (GPS) will be calculated.

14. Outcome Measures

14.1. Primary outcome

The primary outcome measure will be the longitudinal change of the selected biomechanical parameters (spatiotemporal, lower-limb kinematics) during the first 18 months following acquisition of independent walking within the UCP group.

Kinematic variables include the pelvis, hip, knee, and ankle in the sagittal, frontal, and transverse planes, according to the variables available from the laboratory gait-analysis protocol.

14.2. Secondary outcomes

The secondary outcomes are:

- The differences in the selected biomechanical parameters (spatiotemporal, lower-limb kinematics) between the two groups at two time points. The mean of the biomechanical

parameters of both lower limbs in TD children will be compared with those of both the affected and the unaffected limbs in children with UCP.

- The differences regarding the calculated Gait Profile Score (GPS) between the groups at both time points and between the two time points within the UCP group.

The GPS represents the overall deviation of an individual's gait from typically developing reference gait, with higher values indicating greater gait deviation.

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15. Data processing and storage of research-related documents and data

15.1. Case Data sheet (CDS)

A paper Case data sheet (CDS) will be opened for each patient. All information required by the protocol will be recorded in the CDS. It will contain the various patient data specified in the protocol and include the information necessary to address the protocol's objectives.

The person responsible for completing the CDS is Anca Irina Grigoriu in Bucarest. Any missing data will be noted.

All information required by the protocol will be documented in the paper-based CDS.

The data will subsequently be entered into a database (Excel). If any data are modified, the change must first be made on the paper version, with the reason for the modification documented, dated, and signed.

15.2. Data processing

Clinical data collection will be based on the implementation of a computerized clinical database (Excel), featuring data-entry screens modeled after the CDS, in compliance with the protocol and current regulations.

The structure of the database and the data-entry screens will be developed by Dr. Anca Irina Grigoriu in the Motion Analysis Laboratory at the National Clinical Center of Neuropsychomotor Recovery for Children “Dr. N. Robanescu”, Str. Dumitru Minca 44, Sector 4, Bucharest, Romania, email an_ir_ra@yahoo.fr.

A final quality control check of the data required for statistical analysis will be implemented.

15.3. Data flow

The anonymised data of all participants will be imported to the Movement Analysis Laboratory in Brest via a secure messaging system, ensuring that no data can be accessed by unauthorized parties or used inappropriately (for example, on social media).

A data transfer agreement will be signed between National Clinical Center of Neuropsychomotor Recovery for Children “Dr. N. Robanescu” in Bucharest and the CHRU of Brest. All data from Bucharest will be transmitted to Brest, to Mathieu Lempereur, an engineer at the Movement Analysis Laboratory of the CHRU of Brest.

15.4. Identification of data collected in the CDS

Data collection includes clinical and functional data, as well as gait data derived from 3D gait analysis. The data available in the database that will be analyzed include:

1. For the UCP group

- Demographic and anthropometric information (sex, age, weight, height, lower limb length)
- Ante- and perinatal history
- General information regarding the origin of the CP and the date of diagnosis
- Age at onset of independent walking
- Surgical history
- Rehabilitation/therapy history/ botulinum toxin injections/ orthosis
- GMFCS score
- Psychomotor development scale (Denver)
- Spasticity of the lower limbs (Ashworth and high-velocity Tardieu scales)
- Passive range of motion of the lower limbs (hip, knee, and ankle for both limbs)
- Assessment of bone morphology (lower limb length discrepancy, femoral anteversion, tibial torsion, scoliosis).

2. For the TD group

- Demographic and anthropometric information (sex, age, weight, height, lower limb length)
- Perinatal history
- Age at onset of independent walking
- Passive range of motion of the lower limbs (hip, knee, and ankle for both limbs)
- Assessment of bone morphology (lower limb length discrepancy, femoral anteversion, tibial torsion, scoliosis).

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16. Statistical Analysis

16.1. Person Responsible for Analysis and Data Storage Location

The software used is Visual 3D, which is available at the Motion Analysis Laboratory in Brest, France. The person responsible for data analysis will be Mathieu Lempereur, Engineer, at the Brest University Hospital (CHRU Brest).

16.2. Method of Statistical Analysis

All data processing and statistical analyzes will be conducted using Python (Python Software Foundation, version 3.7, www.python.org).

Comparisons of clinical variables, spatiotemporal parameters and GPS values between the TD group and the affected and unaffected limbs of the UCP group will be performed using Mann–Whitney U tests. Changes in these parameters between T1 and T2 for the affected and unaffected sides in children with UCP will be analyzed using Wilcoxon signed-rank tests. Statistical significance is set at $p<0.05$.

The method used for the kinematic comparison between groups or between T1 and T2 within the UCP group will be Statistical Parametric Mapping (SPM) [14]. Nine variables representing the principal motion planes of each joint are selected: sagittal plane (X-axis vector) for pelvis, hip, knee, and ankle; frontal plane (Y-axis vector) and transverse plane (Z-axis vector) for pelvis and hip, and foot progression angle. Sidak correction will be applied to maintain a family-wise error rate of $\alpha = 0.05$ across the 9 joint-plane comparisons [14].

For comparisons between UCP and TD groups, the affected and non-affected limbs of the UCP group will be analyzed separately.

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17. Sample Size

The study has exploratory in nature. A minimum target of approximately 10 participants per group will be considered feasible for the study design.

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18. Potential Risks and Benefits

Three-dimensional gait analysis is a non-invasive assessment procedure.

Potential participant burden will be primarily related to walking repeatedly along the laboratory walkway and wearing the equipment required for motion capture. Appropriate rest periods will be provided according to the child's needs.

No experimental treatment will be administered as part of the study.

Participants will not expected to receive a direct therapeutic benefit from participation. However, gait analysis may provide clinically relevant information regarding individual gait characteristics and may contribute to improved understanding of early gait development in UCP.

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19. Data Management and Confidentiality

Participant data will be coded using study-specific identifiers.

Personal identifying information will be kept separate from research data and will be accessible only to authorized study personnel.

Gait-analysis data and clinical information will be stored using the institutional procedures applicable during the study period.

Data will be analyzed in aggregate, and individual participants will not be identifiable in publications or presentations resulting from the study.

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20. Ethical Considerations

The study will be conducted in accordance with the principles of the Declaration of Helsinki.

Ethical approval will be obtained from the Ethics Committee of the National Clinical Center of Neuropsychomotor Recovery for Children “Dr. N. Robanescu” , Bucharest.

Written informed consent will be obtained from the parents or legal guardians of participating children.

Participation is voluntary, and parents/legal guardians can withdraw their child from the study according to the conditions described in the informed-consent documentation.

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21. Dissemination of Results

Study findings will be disseminated through scientific publications and presentations at scientific conferences.

Results will be reported at the group level, with participant confidentiality maintained.

The study will be reported transparently, including findings that do not reach statistical significance.

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22. Protocol Amendments

Any substantive modification to the study protocol will be documented with the date, nature, and rationale of the amendment.

Where applicable, amendments will be submitted to the relevant ethics committee and reflected in the corresponding study documentation and registry record.

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23. References

[1] Rosenbaum P., Paneth N., Leviton A., Goldstein M., Bax M., Damiano D., Dan B., Jacobsson B., (2007). A report: the definition and classification of cerebral palsy April 2006. Dev Med Child Neurol Suppl, 109, 8-14.

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[8] Hallemans A., De Clercq D., Aerts P., (2006). Changes in 3D joint dynamics during the first 5 months after the onset of independent walking: a longitudinal follow-up study. Gait Posture, 24(3), 270-9.

[9] Bisi M. C., Stagni R., (2015). Evaluation of toddler different strategies during the first six-months of independent walking: a longitudinal study. Gait Posture, 41(2), 574-9.

[10] Grigoriu AI, Brochard S, Sangeux M, et al. Reliability and sources of variability of 3D kinematics and electromyography measurements to assess newly-acquired gait in toddlers with typical developmentand unilateral cerebral palsy. *J Electromyogr Kinesiol* 2021; 58: 102544.

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[13] Hof AL. Scaling gait data to body size. *Gait Posture* 1996; 4: 222–223.

[14] Pataky TC, Robinson MA, Vanrenterghem J. Vector field statistical analysis of kinematic and force trajectories. *J Biomech* 2013; 46: 2394–2401.

PROTOCOL AMENDMENT

Study title: Evolution of Gait Biomechanical Parameters in Toddlers with Unilateral Cerebral Palsy During the First 18 Months of Independent Walking: A Comparison with Typically Developing Peers

Principal Investigator: Dr. Anca Irina Grigoriu; an_ir_ra@yahoo.fr

Institution: National Clinical Center of Neuropsychomotor Recovery for Children "Dr. N. Robanescu" (NCCNRC), Str. Dumitru Minca 44, Sector 4,041408, Bucharest, Romania

Original protocol date: 9/02/2022

Original Ethics Committee approval: 10/03/2022/ No. 4708

Amendment date: 17/08/2023

Amendment approval: 20/09/2023 No. 8143

1. Reason for the Amendment

The original study protocol planned a second gait analysis assessment of the typically developing (TD) control group 12-18 months after the first gait analysis (T1). This seems to be impossible for all the TD children included. Since the beginning of the study and the moment of elaboration of this amendment, we have 5 TD children who were not able to attend the second appointment for gait analysis (T2).

To ensure the availability of a TD control group corresponding to the stage of independent walking experience for the unilateral cerebral palsy group, a modification of the recruitment strategy is proposed.

2. Description of the Amendment

The original protocol planned to reassess the initially recruited typically developing children at T2.

This amended protocol allows the recruitment of an additional group of typically developing children with the next eligibility criteria:

1. age up to 42 months;

2. a typical psychomotor development and acquisition of independent walking before 18 months of age;

3. between 12 and 24 months of independent walking experience;

4. parental/legal guardian informed consent.

Th exclusion criteria for the additional TD group are:

1. previous lower-limb surgery;

2. lower-limb trauma within the preceding 6 months;

3. known allergy to adhesive materials;

4. presence of neurological and/or orthopaedic disorders.

The amendment therefore modifies the recruitment strategy and eligibility criteria for the TD control group.

3. Impact on the Study

The objectives of investigating gait biomechanics evolution in toddlers with unilateral cerebral palsy and the differences with typically developing peers remain unchanged.

The amendment affected the composition and recruitment of the TD control group. Since our objective is not to compare the evolution of the gait biomechanics within the TD group, this changement in recruitment strategy at T2 for the TD group does not affect our outcomes and hypothesis.

All other study procedures remain unchanged, except where explicitly specified in the approved amendment.

4. Ethics Committee Approval

This amendment was submitted to and approved by the Ethics Committee on 20/09/2023, under reference number 8143.

The amendment should be read together with the original research protocol.