ISRCTN54463720 https://doi.org/10.1186/ISRCTN54463720

Body weight support treadmill training on children with ataxia

Submission date
17/01/2021

Recruitment status
No longer recruiting

Registration date
27/01/2021

Overall study status
Completed

Last Edited
10/04/2025

Condition category
Nervous System Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Ataxia is a term for a group of disorders that affect co-ordination, balance and speech. Any part of the body can be affected, but people with ataxia often have difficulties with: balance and walking, speaking, swallowing, tasks that require a high degree of control, such as writing and eating, vision.
The present project aims to design a functional intensive rehabilitation program for children ataxia and propose feasible in clinical practice and goal directed approaches for promoting functional rehabilitation. The proposed program will utilize partial body weight support strategies and motor dual task training using a treadmill.

Who can participate:
Children aged 8-18 years old with ataxia as a result of congenital, acquired or genetic damage, with GMFCS II-IV

What does this study involve?
This study will last approximately 3 months. In this period children will need to be assessed in terms of motor and functional skills in 3 different periods. According to the allocated group, children will either continue their regular therapeutic program or will combine their regular therapeutic program with a functional 4-week PBWSTT program.

What are the possible benefits and risks of participating?
Participation will be voluntary so there will be no financial benefit since this research is not funded. However, the information we will get from this research will be for the future benefit of children with ataxia disorder. This contribution will help improve clinical evaluation and design of effective therapeutic interventions. This research involves minimal risk or danger. All measurements from the scales and assessment tools are valid and reliable, safe to use and all tests are always performed under the supervision and instructions of the physiotherapist. The same applies to physiotherapy intervention that involves activities, which will always be performed under the supervision of a physiotherapist.

Where is the study run from?
Department of Physiotherapy of the University of West Attica (UniWA) (Greece)

When is the study starting and how long is it expected to run for?
February 2020 to March 2023

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Alexandra Lepoura, alepoura@uniwa.gr

Contact information

Type(s)
Scientific

Contact name
Mrs Alexandra Lepoura

ORCID ID
https://orcid.org/0000-0002-3353-0388

Contact details
67 Pentelis Str
Kinitro kai Kinisi
Marousi - Athens
Greece
15126
+30 6948620233
alepoura@uniwa.gr

Type(s)
Public

Contact name
Prof Vasiliki Sakellari

ORCID ID
https://orcid.org/0000-0002-9481-996X

Contact details
Physiotherapy Department
University of West Attica
Egaleo
Greece
12243
+30 6979033952
vsakellari@uniwa.gr

Type(s)
Public

Contact name
Dr Sofia Lampropoulou

ORCID ID
http://orcid.org/0000-0002-2095-5184

Contact details
Department of Physiotherapy
School of Health Rehabilitation Science
University of Patras
Psaron 6, Myrtia
Aigio
Greece
25100
+30 6946749576
szlampropoulou@gmail.com

Type(s)
Public

Contact name
Dr Marianna Papadopoulou

ORCID ID
https://orcid.org/0000-0002-0163-7455

Contact details
Physiotherapy Department, University of West Attica
Agiou Spiridonos 28
Egaleo
Greece
12243
+30 210 5387485
mpapad@uniwa.gr

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
The effectiveness of a Functional Partial Body Weight Support Treadmill Training (FPBWSTT) on motor and functional skills of children with ataxia

Acronym
FPBWSTT and Child Ataxia

Study objectives
Current hypothesis as of 29/12/2021:
A great heterogeneity characterizes the pediatric population with ataxia, which has been studied poorly, in terms of both evaluation and intervention. The lack of postural control and coordination, in addition with features of the 'ataxic' gait are linked with functional limitations. Studies on physiotherapy interventions for children with ataxia are highly needed for identifying optimal training strategies for improving motor and functional related skills.
The primary objective of the proposed protocol is to evaluate the effect of the proposed 4-week intensive therapeutic program on motor tasks and functional skills related to standing and gait. We hypothesize that the suggested therapeutic functional program is more effective than typical physiotherapy in improving gross motor function in standing and walking when applied in children with ataxia, aged 8 to 18 years.
Secondary objectives include evaluating the effect from the application of the proposed program on functional skills in balance, self-selected cadence, dynamic balance control, physical condition and endurance, ataxia features and gait analysis characteristics. Further objectives of the study refer to the long-term effect of the 4week therapeutic program in a time period of 2 months and to understand the effect of such intervention and clinically interpret its results for future therapeutic purposes.

_____

Previous hypothesis:
Functional based PBWSTT improves motor and functional skills more than a conventional physiotherapy program in children with ataxia.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 14/04/2020, University General Hospital Attikon- Scientific Council (1 Str Rimini, Chaidari, 12462, Athens, Greece; +30210-5831693/+30210-5831698; no email contact), ref: Γ ΠΑΙΔ, ΕΒΔ 149/20-03-2020
2. Approved 26/04/2021, Ethics Committee of University of West Attica (University of West Attica
Agiou Spiridonos 28, 12243 Egaleo, Athens, Greece, Tel.: +302105387294; ethics@uniwa.gr), ref: 14η/26-04-2021

Study design
Interventional stratified randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details below to request a participant information sheet in Greek language

Health condition(s) or problem(s) studied
Physiotherapy intervention for children with ataxia

Interventions
Current intervention as of 29/12/2021:
The recruitment of the population will be carried out by private and public therapeutic areas. A group of children with ataxia, aged 8 to 18 years, will participate.

An information sheet and consent form will be provided to all participants. After obtaining a signed consent form, subjects will be randomly assigned to either intervention group (functional PBWSTT) or control group (conventional physiotherapy).

Assessment will be obtained in three time periods: prior to the experiment, after the experiment and 2 months after the experiment. For the anthropometric data acquisition, precision equipment will be used. Gait training will be performed using a Lite Gait LGI 200Psystem accompanied by a Gait keeper Treadmill system with a low start walking speed (0.1 m/h) and built-in sensors for data recording. Gait Sens 2000 and BiSymSoftware will be used. Gait and posture biomechanical data will be acquired by 10 Vicon Cameras (6MXT10 and 4 Verov2.2) at 100 Hz and 2 Basler (Pentaxlenses) digital video cameras 50 Hz. ViconNexus 2.9.1 recording software for the 16 passive reflective markers gap-filling and data filtering will be used. Further processing and extraction of data will be made through Vicon Polygon 3.5.1 software.

Functional based PBWSTT Intervention:
The proposed protocol will be based on the implementation of the protocol of Bjornson et al. (2019) with modifications based on the findings of the literature, alongside functional dual-task activities. All the phases of the protocol will be administered in PBWS. The suspension will be set to <40% of body weight. Twenty 45-minute sessions will be completed over a period of 4 weeks (5 days per week). The period of 45 min will be composed of two phases:
1. Phase 1: Walking training on the treadmill. The treadmill gait training through short burst interval PBWSTT will last 30 total minutes. The speed of the treadmill will be individualized for each participant, employing baseline self-selected and fast walking speed over ground (10-m walk test), thus standardizing the dosing of training speeds for high and low-speed walking levels. Starting tread speeds for high and low walking treadmill speed will be 75% of each participant’s baseline walking over-ground levels. High-speed and low-speed intervals will be alternated every 30 sec. High speed will be gradually increased by 5% between sessions, while low speed remains constant throughout the protocol. The child will be informed of the speed intervals during the gait. In the 30 minutes of gait training there will be short breaks, whenever needed during which the child will stand upright in a physical position. The goal is to achieve a total of 20 minutes of walking. The handles will not be used throughout the gait training to enhance the reciprocal arm swing as much as possible.
2. Phase 2: Functional activities - dual task. The Functional dual training will last 15 total minutes

and will be delivered during constant low-speed gait on the treadmill (treadmill pace step). Functional exercises during gait will simulate the needs of daily life and they will consist of walking in different directions, steps to the side, back steps, walking and crossing obstacles, walking and catching and throwing a ball. In each session, 3 of the 6 activities will be applied in a rotating cycle, each of which will last 5 minutes. In each session, the performance of each participant will be recorded and the physiotherapist will encourage the gradual improvement of the motor performance in each activity with verbal and visual guidance.

Usual/typical care:
Participants both in the experimental and control group will continue receiving their usual typical care, formed by physiotherapy and any other form of therapy that the child requires, such as occupational therapy, speech therapy etc. It is anticipated that typical physiotherapy (alongside with hydrotherapy or horse riding) will constitute only 1-3 days per week sessions, otherwise it can be considered as an intensive physiotherapy program.

———

Previous intervention:
The recruitment of the population will be carried out by private and public therapeutic areas. A group of children with ataxia, aged 8 to 18 years will participate.

Information sheet and consent form will be provided to all participants. After obtaining a signed consent form, subjects will be randomly assigned to either intervention group (functional PBWSTT) or control group (conventional physiotherapy).

Assessment will be obtained in three-time periods: prior to the experiment, after the experiment and 2 months after the experiment. For the anthropometric data acquisition precision equipment will be used. Gait training will be performed using aLite Gait LGI 200Psystem accompanied by a Gait keeper Treadmill system with a low start walking speed (0.1m /h) and built-in sensors for data recording. Gait Sens 2000 and BiSymSoftware will be used. Gait and posture biomechanical data will be acquired by 10 Vicon Cameras (6MXT10 and 4 Verov2.2) at 100 Hz and 2 Basler (Pentaxlenses) digital video cameras 50 Hz. ViconNexus 2.9.1 recording software for the 16 passive reflective markers gap-filling and data filtering will be used. Further processing and extraction of data will be made through Vicon Polygon 3.5.1 software.

Functional based PBWSTT Intervention
The proposed protocol will be based on the implementation of the protocol of Bjornson et al. (2019) with modifications based on the findings of the literature, alongside functional dual-task activities. All the phases of the protocol will be administered in PBWS. The suspension will be set to <40% of body weight. Twenty 45-minute sessions will be completed over a period of 4-weeks (5 days per week). The period of 45 min will be composed of two phases:
1. Phase 1 (Gait treadmill training phase with PBWS). The treadmill gait training through short burst interval PBWSTT will last 30 total minutes. The speed of the treadmill will be individualized for each participant, employing baseline self-selected and fast walking speed over ground (10-m walk test), thus standardizing the dosing of training speeds for high and low-speed walking levels. Starting tread speeds for high and low walking treadmill speed will be 75-80% of each participant’s baseline walking over-ground levels. High-speed and low-speed intervals will be alternated every 30 sec. High speed will be gradually increased by 5-10% within and between sessions, while low speed remains constant throughout the protocol. The child will be informed of the speed intervals during the gait.
2. Phase 2 (Functional dual kinetic training with PBWS). The Functional dual kinetic training will last 15 total minutes and will be delivered during constant low-speed gait on the treadmill

(treadmill pace step). Functional exercises during gait will simulate the needs of daily life and they will consist of walking in different directions, steps to the side, back steps, walking and crossing obstacles, walking and catching and throwing a ball.

Subjects in the intervention group will continue their regular therapeutic program, alongside the control group.

Intervention Type
Behavioural

Primary outcome measure
Current primary outcome measure as of 29/12/2021:
For the primary outcome measure there will be a first baseline assessment prior to the 4-week intervention period (pre), a 4-week post-assessment conducted by the end of the 4-week intervention period (4-week post) and a final 2-month post-assessment, conducted 2 months after the end of the 4-week intervention period (follow-up).
1. The Gross Motor Function Measure (GMFM-88) dimension D/E, will be expressed as percentage score (%) for assessment of the motor performance and functional ability in standing, walking, running and jumping. GMFM is considered the primary outcome measure, as this has been examined widely in pediatric population and can be affected positively after a therapeutic intervention. The change from pre to 4-week post of GMDF -D will be used as the primary endpoint for calculating the effect size, as this measure is more likely to be mostly affected.

_____

Previous primary outcome measure as of 03/08/2021:
Measured at baseline, 1 month and 3 months. All measurments will be in regards to coordination of movements, upright posture, static and dynamic balance, gait, physical activity and gross functional ability and will include:
1. Gross Motor Function Measure Domain D and E (GMFM-88) for assessing functional skills
2. 10 meters walking test for assessing walking cadence
3. Pediatric Balance Scale

_____

Previous primary outcome measure:
Measured at baseline, 1 month and 3 months. All measurments will be in regards to coordination of movements, upright posture, static and dynamic balance, gait, physical activity and gross functional ability and will include:
1. SARA Scale of Assessing and Rating Ataxia for assessing ataxia
2. Gross Motor Function Measure Domain D and E (GMFM-88) for assessing functional skills
3. 10 meters walking test for assessing walking cadence
4. 6min Walk Test for assessing physical activity-endurance
5. Timed-Up and Go test for assessing walking speed and independent walking ability
6. Biomechanical balance and gait parameters through the equipment mainly specified by gait analysis lab and BiSym and GaitSens software through LiteGait and specific treadmill usage

Secondary outcome measures
Current secondary outcome measures as of 29/12/2021:
Similarly, for secondary outcome measures there will be a first baseline assessment prior to the 4-week intervention period (pre), a 4-week post-assessment, conducted by the end of the 4-

week intervention period (4-week post) and a final 2-months post-assessment, conducted 2 months after the end of the 4-week intervention period (follow-up)
1. Functional balance skills assessed using the Pediatric Balance Scale, with score ranging 0–56 (higher score indicates better balance)
2. Gait speed assessed using the 10-m walk test on the treadmill
3. Dynamic balance control assessed using the Timed Up and Go test
4. Physical condition and endurance assessed using the 6-min walk test
5. Ataxia severity assessed using the Scale for Assessment and Rating Ataxia (SARA), applied in the Greek version, with score range 0–40 (higher score indicates more severe ataxia)
6. Spatiotemporal gait parameters assessed using GaitSens software through LiteGait and specific
treadmill usage
7. Three-dimensional kinematic and kinetic analysis of lower limbs through motion and gait analysis applied with electronic recording of kinematics elements for the pelvis, hip, knee and foot of both lower limbs in the three planes of motion (sagittal, frontal and transverse)

_____

Previous secondary outcome measures as of 03/08/2021:
1. Anthropometric data: age, weight (kg), BMI (kg/m²), height (cm) and data regarding medical records will be assessed at baseline
2. Quality of life measured using the Child quality of Life Questionnaire for child report measured at baseline.
All other measurements will be assessed at baseline, 1 month and 3 months.
3. SARA Scale of Assessing and Rating Ataxia for assessing ataxia
4. 6min Walk Test for assessing physical activity-endurance
5. Timed-Up and Go test for assessing walking speed and independent walking ability
6. Spatiotemporal gait parameters through GaitSens software through LiteGait and specific treadmill usage
7. Three dimensional kinematic and kinetic analysis of lower limbs through motion and gait analysis applied with electronic recording of kinematics elements for the pelvis, hip, knee and foot of both lower limbs in the three planes of motion (sagittal, frontal and transverse).

_____

Previous secondary outcome measures:
1. Anthropometric data: age, weight (kg), BMI (kg/m²), height (cm) and data regarding medical records will be assessed at baseline
2. Quality of life measured using the Child quality of Life Questionnaire for both child and parents at baseline, 1 month and 3 months
3. Balance measured using The Pediatric Balance Scale at baseline, 1 month and 3 months

Overall study start date
20/02/2020

Completion date
20/03/2023

Eligibility

Key inclusion criteria

Current inclusion criteria as of 29/12/2021:
1. Ataxia as their primary motor disorder, as a result of congenital, acquired or genetic damage
2. Gross Motor Function Classification System (GMFCS) II-IV
3. Aged 8-18 years
4. Attendance of a physiotherapy program in an outpatient or community setting the last 6 months after a relevant medical admission
5. Willingness to participate in the study.

_____

Previous inclusion criteria as of 03/08/2021:
1. Ataxia as their primary motor disorder, as a result of congenital, acquired or genetic damage
2. Gross Motor Function Classification System (GMFCS) II-IV
3. Age 8 - 18 years old
4. Attendance of a physiotherapy program after a relevant medical admission
5. Willingness to participate in the study

_____

Previous inclusion criteria:
1. Aged 8 - 18 years
2. Gross Motor Function Classification System (GMFCS) II-III
3. Ataxia as their primary motor disorder, as a result of congenital, acquired or genetic damage
4. Attendance of a physiotherapy program after a relevant medical admission and
5. Willingness to participate in the study.

Participant type(s)
Patient

Age group
Child

Lower age limit
8 Years

Upper age limit
18 Years

Sex
Both

Target number of participants
The design and analysis of this study has insufficient reference in order to identify with accuracy the sample size estimation. However, we used findings from a recent pilot study on adolescents with ataxia secondary to acquired brain injury and estimated the primary endpoint of GMFM- D domain from baseline to the end of the 4-week intervention period (Peri et al., 2019). It was calculated that a sample size of 13 participants per group is required in order to have an 80% probability of demonstrating a difference between groups of >3% in % change from baseline to 1st month of GMFM-D (Control: 2%±3, Intervention: 5%±3) with a significance of 5% (two tailed test). Sample size estimation was performed using G*Power 3.1.9.2 program. In order to verify the above estimation, when the collection of 5 children per group is completed, the comparison of primary endpoint between groups will be performed and using the results of the analysis,

sample size estimation will be made to determine the final number of the study sample, as this strategy has been suggested by a relevant review on sample size estimation approaches (Serdar et al., 2021) (Updated 09/02/2022, previously: Approximately 30 children with ataxia)

Total final enrolment
21

Key exclusion criteria
Current exclusion criteria as of 29/12/2021:
1. Invasive neurological or orthopedic intervention, such as botox injection, alcohol block, muscle-tendon lengthening, or tendon transfer surgery within 6 months from the study
2. Coexisting degenerative disorders, such as arthrogryposis
3. Significant heart or respiratory disease
4. Lower motor neuron disorder diagnosis, such as spinal muscular atrophy
5. Co-morbid conditions (not related to ataxia diagnosis) such as peripheral vascular disease and diabetic polyneuropathy
6. Coexisting musculoskeletal or rheumatoid disorder that prevents independent walking
7. Deficient ocular alertness
8. Cognitive impairments which restrict them from understanding commands, evidenced by their medical diagnosis or any kind of psychiatric disorder
9. Reluctance of parents to collaborate with the researchers for scheduling the timeframe of evaluations and/or intervention period

———

Previous exclusion criteria as of 03/08/2021:
1. invasive neurological or orthopedic intervention, such as botox injection, alcohol block, muscle-tendon lengthening, or tendon transfer surgery within 6 months from the study
2. coexisting degenerative disorders, such as Spinal Muscular Atrophy
3. significant medical heart or respiratory disease
4. lower motor neurons, such as sciatic nerve paralysis
5. co-morbid conditions such as peripheral vascular disease and diabetic polyneuropathy
6. coexisting musculoskeletal and rheumatoid disorder that prevents independent walking
7. deficient and/or ocular alertness
8. cognitive impairments which restrict them from understanding commands, evidenced by their medical diagnosis or any kind of psychiatric disorder
9. reluctant parents

———

Previous exclusion criteria:
1. Have undertaken invasive neurological or orthopedic intervention, such as botox injection, alcohol block, muscle-tendon lengthening, or tendon transfer surgery within 6 months from the study
2. Have coexisting degenerative disorders, such as Spinal Muscular Atrophy
3. Have significant medical heart or respiratory disease
4. Have Lower Motor Neurons, such as sciatic nerve paralysis
5. Have co-morbid conditions such as peripheral vascular disease and diabetic polyneuropathy
6. Have coexisting any musculoskeletal and rheumatoid disorder that prevents independent walking
7. Have deficient alertness
8. Are unable to understand commands as evidenced by their medical diagnosis or any kind of

psychiatric disorder
9. Parents' are reluctant

Date of first enrolment
15/06/2021

Date of final enrolment
16/12/2022

Locations

Countries of recruitment
Greece

Study participating centre
Alexandra Lepoura
67 Pentelis Str
Kinitro kai Kinisi
Marousi - Athens
Greece
15126

Study participating centre
Elepap
16, Kononos Str
Athens
Greece
11634

Study participating centre
Physiotherapy Lab Uniwa
28, Agiou Spyridonos
Aigaleo
Greece
12243

Sponsor information

Organisation
University of West Attica

Sponsor details
Physiotherapy Department
Agiou Spiridonos 28
Egaleo
Greece
12243
+30 210 5387485
physio@uniwa.gr

Sponsor type
University/education

Website
http://www.uniwa.gr/en/

ROR
https://ror.org/00r2r5k05

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
30/09/2023

Individual participant data (IPD) sharing plan
Current IPD sharing statement as of 29/12/2021:
The datasets generated during and/or analysed during the current study will be available upon request from Alexandra Lepoura (alepoura@uniwa.gr). The individual participant data that underlie the results reported in the published article, after deidentification (text, tables, figures, and appendices), Study Protocol, Statistical Analysis Plan, Informed Consent Form, and Analytic Code will be available beginning 3 months and ending 6 years following article publication to researchers who provide a methodologically sound proposal in order to achieve the aims in the approved proposal. Proposals should be directed to alepoura@uniwa.gr. To gain access, data requestors will need to sign a data access agreement. Data will then be available for 6 years at a third-party website.

Information sheet and consent form will be provided to all participants. Signed consent form should be obtained prior to participants' enrollment to the study. The files with participants' results will be coded and personal data will not be published anywhere. The personal data collected from the experiment will be kept confidential and all data will be stored in the researcher's computer (Alexandra Lepoura) where no unauthorised persons have access. Moreover, the files with the data will be protected by security codes and any data saved in papers will be locked in a special cupboard and only the researchers will have access to them.

Previous IPD sharing statement:
The datasets generated during and/or analysed during the current study are/will be available upon request from Alexandra Lepoura (alepoura@uniwa.gr). the individual participant data that underlie the results reported in this article, after deidentification (text, tables, figures, and appendices), Study Protocol, Statistical Analysis Plan, Informed Consent Form, and Analytic Code will be available beginning 3 months and ending 5 years following article publication to researchers who provide a methodologically sound proposal in order to achieve the aims in the approved proposal. Proposals should be directed to alepoura@uniwa.gr. To gain access, data requestors will need to sign a data access agreement. Data will then be available for 5 years at a third party website.

Information sheet and consent form will be provided to all participants. Signed consent form should be obtained prior to participants' enrollment to the study. The files with participants' results will be coded and personal data will not be published anywhere. The personal data collected of the experiment will be kept confidential and all data will be stored in the researcher's computer (Alexandra Lepoura) where no unauthorised persons have access. Moreover, the files with the data will be protected by security codes and any data saved in papers will be locked in a special cupboard and only the researchers will have access to them.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		25/03/2022	28/03/2022	Yes	No
Results article		06/04/2025	10/04/2025	Yes	No