

# The effect of walking with and without music on executive functions and gait in children aged 8 to 16 years old and adults over 40 years old with mild cerebral palsy

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<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Congenital and peripartum neurological conditions
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON56174

### Source

ToetsingOnline

### Brief title

Moving, Music & CP

### Condition

- Congenital and peripartum neurological conditions

### Synonym

Brain damage, spastic paralysis

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Vrije Universiteit

**Source(s) of monetary or material Support:** CP Nederland (voorheen BOSK) actie September. Zadelhoff.

## Intervention

**Keyword:** Cerebral Palsy, Executive functions, Gait, Music

## Outcome measures

### Primary outcome

The main outcome measure is executive functioning. Neurocognitive functioning (inhibition, attention/switching and processing speed) will be assessed with three short neuropsychological tests. Used tests:

Children: 'Opposite worlds' and 'Creature counting' from the TEA-CH (Test of Everyday Attention for Children); 'Coding&Symbol Search' from the WISC-V.

Adults: Stroop Color and Word test; 'Visual elevator' from the TEA (Test of Everyday Attention for Adults); 'Coding&Symbol Search' from the WAIS-IV.

### Secondary outcome

Secondary outcome measures are endurance and temporal spatial gait parameters (stride length, step length, velocity, symmetry and cadence). Endurance will be measured with the 2-minute walk test. Temporal-spatial gait parameters will be measured with the GAITRite system and accelerometer.

## Study description

## **Background summary**

Due to early onset problems with movement and posture, children and later as they become adults with cerebral palsy (CP) lead more sedentary lives than their able peers. The early brain damage which causes motor problems, can also cause cognitive deficits. Numerous studies point to a positive relation between physical exercise and executive functions (EF). However, only a few have studied the effect of physical exercise on cognitive functioning in people with CP. Motor movement and endurance could be supported by listening to music during walking. When listening to music makes walking less strenuous, it is expected cognitive functioning will also improve.

## **Study objective**

The main objective of this study is to investigate the acute beneficial effect of moderate intensive exercise (defined as walking) on neurocognitive functioning in healthy children and adults with mild CP, GMFCS I and II and if this effect is larger when music is added during walking. The secondary objective is to investigate the effect of music on gait pattern and endurance.

## **Study design**

The study is designed as a Randomized Controlled Trial. In this design we include three groups: two experimental groups and one control group.

## **Intervention**

In this study, one experimental condition consists of a child-group and an adult-group walking with music during an interval of 10 to maximal 20 minutes. The other experimental condition consists of a child-group and an adult-group walking without music during an interval of 10 to maximal 20 minutes. The control condition consists of a child-group and an adult-group who remain inactive during 20 minutes. Neurocognitive functioning will be measured once before and twice after the described intervention with a set of three short neuropsychological tests. A third measurement will take place after a 20 minutes brake. Gait pattern and endurance will be measured once before and during the walking interval in the experimental conditions.

## **Study burden and risks**

All participants in the experimental conditions undergo the walking intervention, which is expected to be beneficial for neurocognitive functioning for most participants. Participants who walk with music are also expected to improve on endurance and gait pattern. The effects are expected to be transient effects, not lasting effects. The burdening of walking does not exceed the burdening of regular gait training most participants receive during

rehabilitation. The duration of walking can be adjusted to the capabilities of the participants and can be less than 20 minutes. There are no extra risks associated with participating in this study. The activities during the intervention resemble normal activities during school time and/or daily life. The duration of the whole intervention (including the intake) is 150 minutes. This can be experienced as long, especially by young children. It is also possible participants will feel tired after the intervention and may experience some muscle pain afterwards.

Because children with CP are still developing their gait pattern and neurocognitive functioning, it is important to include them in our study. Results from the child-group can be used in therapy and education to optimize their development. The results that will be obtained from the adult-group with CP are not representative for the child-group, because the adult gait pattern and neurocognitive functioning has already developed. For this group, results could be used as an easy and non-invasive manner to ease walking and prevent a decline in walking ability and neurocognitive functioning.

## Contacts

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

## Age

Adolescents (12-15 years)  
Adolescents (16-17 years)  
Adults (18-64 years)  
Children (2-11 years)  
Elderly (65 years and older)

## Inclusion criteria

Cerebral palsy  
8-16 year  
40 year or older  
GMFCS level I-II  
MACS level I-II or being able to perform the tests manually  
Being able to walk independently

## Exclusion criteria

Deafness  
Contra-indication to perform moderate physical exercise  
Uncontrolled seizure disorder  
Recent lower limb surgery  
Severe visual difficulties  
Mentally incompetence

# Study design

## Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

## Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	14-11-2022
Enrollment:	156
Type:	Actual

## Ethics review

Approved WMO	
Date:	07-10-2021
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	19-10-2023
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	13-06-2024
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	03-04-2025
Application type:	Amendment
Review commission:	METC Amsterdam UMC

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

No registrations found.

**In other registers**

Register	ID
CCMO	NL74253.029.20