Sensorimotor adaptation and learning in the control of human standing balance in cerebellar ataxia patients

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Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON51486

Source
ToetsingOnline

Brief title
Cerebellar ataxia and balance learning

Condition

- Other condition

Synonym
balance instability and motor control problems

Health condition

sensorimotor learning for standing balance in cerebellar patients

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: NWO - VIDI project

Intervention

Keyword: balance, cerebellum, control, motor learning

Outcome measures

Primary outcome

The main study parameters are measures of standing balance behaviour (whole body kinematics and kinetics) and evoked balance responses (probed with sensory and/or mechanical stimuli).

Secondary outcome

Healthy controls and cerebellar patient participants will be asked to visit the Department of Neuroscience at Erasmus at least one time for the selected experiment. During the visit, they will perform tasks specific to each experiment. The robotic balance simulator does not present significant discomfort or risk for the participants.

Study description

Background summary

Recent studies have provided insights into the capabilities and mechanisms of sensorimotor adaptation and learning in human standing balance. These include establishing the underlying mechanisms for the nervous system to recalibrate to novel sensory feedback, adjust control when sensory-motor relationships change, and learn to maintain standing under conditions which are initially destabilizing. However, it remains largely unclear which neural structures are responsible for these adaptive learning processes. A candidate brain region is the cerebellum, given its roles in multisensory integration and sensorimotor prediction, though several questions regarding its involvement in adaptive

learning remain unanswered. What types of adaptive processes in standing balance control does the cerebellum contribute to? If cerebellar function is compromised, can other parts of the nervous system accommodate for the dysfunction and facilitate sensorimotor learning? And if possible, under what sensorimotor conditions can this be achieved? With the research proposed here, we seek to understand whether compromised cerebellar function impairs sensorimotor adaptation and learning in human standing balance. Furthermore, we seek to determine what sensory feedback conditions are optimal for cerebellar patients to adapt and learn new balance tasks.

Study objective

The primary objective of this study is to establish whether cerebellar patient populations can adapt and learn to maintain standing balance when sensory-motor relationships of balance are modified. By comparing patient behavior with age-matched control participants, we will determine whether disrupted cerebellar function impedes the sensorimotor learning processes involved in standing balance.

Study design

All experiments will involve healthy controls and cerebellar patients performing standing balance experiments on a robotic balance simulator. This simulator is used to control, replicate, and modify the mechanics and sensory-motor relationships for ongoing standing.

Study burden and risks

Healthy participants will visit the Erasmus MC at least once (up to 2 times) and an experiment will last for a maximum of 2 hours. The total time spent testing a subject will be limited to 4 hours regardless of experimental protocol. In this study, the safety measures are applied as described in recent human balance and sensory stimulation reviews. There are no serious risks associated with this study. The discomfort and risks associated with the experiments described in this proposal are minor but vary according to the methods used for each experiment. The risks/discomfort for the various techniques used are provided below.

Robotic balance simulator
Standing in the robotic balance simulator may cause vertigo and nausea for participants who are particularly subject to those complaints. When a subject indicates vertigo and/or nausea during any experiment and indicates that they wish to end the experiment, this request will be granted immediately.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

For healthy controls:
• In overall good health
• Age: 18 - 90 years old

For patients:
• Adults between the age of 18 - 90 years old who have been diagnosed with a cerebellar lesion.
• Patients will be invited to participate in the study within 3-12 months after their initial diagnosis.

Exclusion criteria

For healthy controls:
• History of neurological or psychiatric disorders
• Taking acute or chronic psychoactive drugs
• Alcoholism
• History of balance problems
• Pregnant women or women currently breastfeeding
• A prior neuromuscular injury (regardless of source)
• Incompetence to give informed consent

For patients:
• Unable to walk 10 metres unaided
• Unable to stand freely for 10 seconds with the eyes closed
• Diagnosed with polyneuropathy
• Taking acute or chronic psychoactive drugs
• Alcoholism
• Pregnant women or women currently breastfeeding
• Incompetence to give informed consent

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Other

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2022
Enrollment:	260
Type:	Anticipated

Ethics review

Approved WMO Date:	06-09-2022
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	06-12-2022
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	28-02-2023
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL81081.078.22