The Influence of Vestibular and Muscle-Tendon Capacities on Locomotor Stability, Plasticity and Falls Incidence

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Primary Objective: • To determine the adaptation potential of the reactive stepping response following repeated mechanical perturbations while walking.Secondary Objective(s): • To determine and compare the initial recovery response to a mechanical...

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

Summary

ID

NL-OMON52987

Source
ToetsingOnline

Brief title
Vestibular and Muscle-Tendon Influences on Locomotion

Condition

- Other condition

Synonym
falls, imbalance

Health condition

ageing and falls risk

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: age, falls, locomotion, muscle

Outcome measures

Primary outcome

The reactive adaptation potential measured during the locomotor plasticity assessment protocol with the CAREN will be the main parameter of the study. This will be calculated as the magnitude of change in the margin of stability at touchdown of the first step after the perturbation before and after repetition of the perturbation.

Secondary outcome

• Margins of stability, step width, length and cadence at touchdown of the first and following recovery steps after each perturbation

• Various characteristics (e.g. local divergent exponent) of unperturbed walking at various speeds

• For the young subject group: difference at each step and perturbation after 1 month (calculated as a percentage) in order to calculate locomotor retention

• For the older group: falls incidence, type and cause of falls, and fear of falling from questionnaire data

Study description

Background summary

Humans over 50 years old are at an increased falls risk and deficiencies in dynamic gait stability can be observed as early as 40 years of age. Dynamic gait stability refers to the ability to control one*s center of mass appropriately during motion so that forward progress during walking or running continues without the loss of balance in any direction. Falls most commonly occur during walking and are often attributed to age-related neuromuscular deficiencies, for example reduced muscle strength, power and leg muscle asymmetry and a slower reaction time to perturbations. Walking is a complex motor task, which requires frequent adjustments of body and limb positions. Two important sets of systems in humans are those that assess and process the external environment (the sensory systems) and those that produce the required movements for the given external environment (the musculoskeletal systems). If the systems that control these adjustments do not function normally, falls can be a likely outcome. For older people, the injury risk and the threat to quality of life that falls present are of great concern. Aside from the injury risk to individuals, fall occurrence is a major concern for European countries with growing elderly populations, due to the associated healthcare demands of falls. The physical, psychological and potentially financial harm that can be caused by falls represent valid reasons for a detailed study of the underlying contributing factors.
The ability to react and take a large, balance recovery step following perturbations (such as a trip, slip or stumble) is a key factor in recovering from mechanical perturbations. However, recovery stepping responses are diminished in older subjects and vestibular disorder patients. That being said, locomotor adaptation to repetitive locomotor tasks has been shown in a number of subject groups and therefore, targeted physical exercise or other types of interventions to reduce falls risk and improve the plasticity of locomotion in these subject groups are of importance. Adaptation to external gait perturbations is not currently well understood. The observed differences between healthy subjects and those with mild neuromuscular deficiencies in association with ageing and more severe neurological disorders such as vestibulopathy are relatively recent and the extent to which the adaptation and plasticity of human gait is influenced by neuromuscular factors has not been thoroughly analyzed. Therefore, the challenging and perturbing conditions that can be provided by the CAREN system (Motek Medical, Amsterdam), lend themselves well to answering these questions.

Study objective

Primary Objective:
• To determine the adaptation potential of the reactive stepping response following repeated mechanical perturbations while walking.
Secondary Objective(s):
• To determine and compare the initial recovery response to a mechanical perturbation while walking in healthy young and older adults.
• To analyze the magnitude of limb to limb transfer and retention over time of adaptations in the reactive stepping response to mechanical perturbations while

walking in healthy subjects.
• To determine how biomechanical features of non-perturbed, normal walking affect stability control of gait both during walking and during recovery from perturbations.
• To determine how performance on the locomotor plasticity assessment protocol (Adaptation potential, limb to limb transfer of adaptations, initial recovery response) is related to fall incidence and fear of falling in older subjects over a 1 year period.

Study design

Setting: University Hospital Maastricht:
CAREN Measurements: CAREN Lab, Dept of Physical Therapy
Type: Observational, cross-sectional study
The groups will consist of a healthy young group, a healthy older group.

Study burden and risks

In general, there is very little risk associated with participation in this study. Some minor muscle soreness may be experienced for a few days following the muscle-tendon assessments and a dizziness sensation may be experienced during the clinical vestibular assessments but this will be made clear to the subjects before obtaining informed consent. Given the potential benefits discussed above of this research to these at-risk groups, these small chances of acute discomfort are considered negligible.

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

Young healthy adults:
• Between 20 and 30 years old
• No known musculoskeletal disease, condition or injury that could negatively affect walking or balance ability
• No history of balance problems, dizziness or walking difficulties
• No participation in elite level competitive sports
• Must be able to walk at a comfortable speed for 30 minutes without stopping
• Informed consent given
Older healthy adults:
• Between 65 and 80 years old
• No known musculoskeletal disease, condition or injury that could negatively affect walking or balance ability
• No history of balance problems, dizziness or walking difficulties
• Must be able to walk at a comfortable speed for 30 minutes without stopping
• Informed consent given

Exclusion criteria

• Not being able or willing to undergo the CAREN measurements following briefing and/or familiarization with the system and protocol
• Incapacitated patients
• Not being able to stop medication against anxiety or depression, if taken (after consulting their general practitioner)
• Not wanting to be informed about any incidental findings (e.g. potential vestibulopathy detected in healthy subjects)
• Is, or in the course of the study becomes, pregnant

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	30-05-2017
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO

Date:	03-05-2017
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date:	11-08-2022
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL58205.068.16