XoSoft balance belt testing * Testing the feasibility and user experience of a balance orthesis during gait and balance tasks

Published: 14-11-2019
Last updated: 12-04-2024

The main question this research tries to answer is: How does this balance belt affect balance and gait during walking? Secondary research question: How do participants experience this belt in terms of usability?

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

Summary

ID

NL-OMON48007

Source
ToetsingOnline

Brief title
XoSoft balance belt testing

Condition

- Other condition

Synonym
balance, equilibrium

Health condition

evenwichtsproblemen door ouderdom (evenwichtsorgaan, spierzwakte, slechter zicht)

Research involving

Human

Sponsors and support

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

Intervention

Keyword: balance, feedback, fit elderly, gait

Outcome measures

Primary outcome

The difference in quantitative gait and balance measures between the feedback

and no-feedback circuits.

Secondary outcome

Quantitative usability assessment with the UMUX-LITE, but especially the

qualitative feedback in response to this questionnaire (leading to

recommendations for improvement of the orthesis)

Study description

Background summary

A prevalent problem in elderly (and all XoSoft primary user groups) is an impaired sense of balance. The XoSoft system itself will not be able to keep the primary user in balance, but with external feedback, the user herself may be able to correct the situation. A balance orthesis has been developed in the form of a belt to provide intuitive, helpful feedback on mediolateral (left-right) upper body tilt during walking, which may help improve posture and motion and prevent falls.

Study objective

The main question this research tries to answer is: How does this balance belt affect balance and gait during walking? Secondary research question: How do

participants experience this belt in terms of usability?

Study design

A cross-over study, where no-feedback and feedback phases will be alternated (ABAB) in order to address learning effects and participant fatigue.

Intervention

Each participant executes a gait and balance task circuit repeatedly with and without external feedback from the balance belt.

Study burden and risks

BURDEN: Participants visit the lab only once for a duration of 1h30, during which they will be exposed to a series of gait and balance tasks. As participants will be locals, there is only a minimal burden of travel time. During the experiment, participants wear low-heeled shoes and a t-shirt or something similar to provide a thin layer of fabric between the belt and the skin.
At the start there will be one questionnaire for general patient information, a semi-structured interview to assess fall history based on Freiberger & Vreede (2011), and Short FES-I questionnaire to assess fear of falling. At the end there is an UMUX-LITE questionnaire combined with an open dialog to assess the usability of the balance belt.
During the experiment, the participant will wear various sensors for measurement and the balance belt which contains one sensor (XSens MTW Awinda IMU) to determine mediolateral upper-body tilt and a string of vibration motors (Elitac Science Suit) to provide feedback.
RISK: Because feedback will be provided on balance during gait there is a certain risk for loss of balance if this feedback is incorrect or if the participant is startled by the feedback (risk reduced by a balance belt training session as part of the protocol). For safety, a researcher will be walking next to the participant. Safety grips attached to the participant's waist allow the researcher to respond quickly if necessary. Participants can verbally express their discomfort and wish to pause or discontinue at any time.
BENEFIT: The vibration feedback might lead to adjustment of upper body sway during walking, which in turn could result in an improved dynamic balance. The focus of this experiment, however, is to see whether there is an effect at all and to evaluate the usability of the orthesis. Evaluating the effect and usability of this balance orthesis is a necessary step in the development process of this orthesis, in making it available for home use in the future, and the burden and risks for the participants are small.
RELATEDNESS: Balance problems are a prevalent problem in elderly. The proposed balance feedback might be helpful for elderly who are otherwise fit and able to

walk independently without the need for mobility aids.

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

- Age: 60-90 years old
- Community-dwelling * living independently at home
- Able to walk independently without walking aids on even and uneven surfaces
- Able to stand independently for 10 minutes
- Self-perception of minor balance problems [14], such as a light fear of falling
(actual balance problems further assessed through the Fear of Falling and Fall history questionnaires)
- Able to sit and have their joints (arms, legs, ankles, hip) bent in natural

angles (for calibration of the IMU sensors)
- Able to wear the balance belt around the waist or the additional sensors on arms, legs and torso.
- Able to read and understand patient information forms, understand questions and able to execute commands
- Able and willing to participate in the study
- Signed Informed Consent

Exclusion criteria

- Neurological or orthopedic impairment that would limit their ability to stand or walk, such as Parkinson's disease or polyneuropathy

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	14-01-2020
Enrollment:	12
Type:	Anticipated

Ethics review

Approved WMO

Date:	14-11-2019
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL67633.044.18