

Investigation into the effect on automatic change of seating posture with the *Fit-form Vario Zorgfauteuils* on the skin vitality.

Published: 12-01-2016

Last updated: 19-04-2024

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON42349

Source

ToetsingOnline

Brief title

Effect of automatic change in seating posture.

Condition

- Other condition
- Skin vascular abnormalities

Synonym

skin blood flow, Skin vitality

Health condition

Algehele mobiliteit van patient, met name huid vitaliteit

Research involving

Human

Sponsors and support

Primary sponsor: Revalidatiecentrum Het Roessingh

Source(s) of monetary or material Support: Bedrijven, Revalidatiecentrum Het Roessingh, Wellco International BV.

Intervention

Keyword: Interface pressure, Posture, Seating, Skin vitality

Outcome measures

Primary outcome

Changes in oxygensaturation, blood flow, interface pressure and comfort during the various test-modules.

Secondary outcome

not applicable

Study description

Background summary

The Dutch population is aging, and due to all changes people are supposed to live longer independently and at home. New technology can help in staying independent and keep healthy and mobile. Already chairs are on the market that can help elderly with sit-to-stand, and thereby decrease the risk of falling. It is well known that sitting still for a long time and other forms of inactivity have detrimental effects on the body and can lead to morbidity. Staying active and mobile is thus very important. Furthermore, sitting still for a long time can also result in a decreased skin vitality and eventually lead to a pressure ulcer.

Study objective

With this study we want to test two new modules of a chair specialised for elderly and test whether these new modules improve skin vitality and do not disturb the users comfort. The new modules apply automatic changes in seating

posture after a certain time. With the study we will test what change is effective (or not) en how disturbing these changes are.

Study design

Experimental, non-randomised intervention study in which multiple tests are performed with different parameters of automatic change in seating posture.

Intervention

automatic change in seating posture

Study burden and risks

The risks for the subjects are limite. In theory prolonged sitting can lead to tissue damage, but the seating times during this research are well within the guidelines, and therefore is the expected risk minimal. The burder for the participants is the investment of time (3 hours).

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 between 18 and 35 OR 60 years or older
- Considered to be healthy
- Caucasian/white skin colour. This is essential for the measurement device *Oxygen to See*.

Exclusion criteria

- Known diseases such as: heart diseases, respiratory diseases, diabetes, other diseases to microcirculation.
- Skin colour deviations at site of measurement.
- Surgery at the area of measurement (bottom).
- Pregnancy
- Unable of sitting still for 2 hours.
- Body mass index below 20 (underweight) or above 30 (obese).
- Body length below 1.60m or above 1.90m. The current measurement chair cannot correctly be adjusted for these body lengths)
- Not able to stand up without assistance from a chair.

Study design

Design

Study type: Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Prevention

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 10-02-2016

Enrollment: 15
Type: Actual

Medical products/devices used

Generic name: Vario Fitvorm chair
Registration: Yes - CE intended use

Ethics review

Approved WMO
Date: 12-01-2016
Application type: First submission
Review commission: METC Twente (Enschede)

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
Other	Aangemeld bij NTR, nummer nog niet bekend.
CCMO	NL55766.044.15