Smart device for clinically validated MOVEment assessment and monitoring at home and in the clinic (SMOVE) PART 1: Feasibility and exploratory study in healthy adults

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

Summary

ID

NL-OMON48471

Source
ToetsingOnline

Brief title
SMOVE - healthy adults

Condition

- Other condition

Synonym
motor problems

Health condition

bewegingsproblemen

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: InterReg V-A programma. het InterReg V-A programma is een door de Europese Unie gefinancierd programma om samenwerking in grensregio's te versterken ten einde de bedrijvigheid in de regio te stimuleren;op zo'n manier dat dit de lokale bevolking ten goede komt. Zie ook https://interreg.eu/.

Intervention

Keyword: accelerometer, electromyography, gyroscope, movement monitoring

Outcome measures

Primary outcome

To classify activities we will use time and frequency domain accelerometry

based parameters. To determine intensity of movement (movement quantity), we

will use accelerometry and gyroscope based parameters, as well as ECG-based

heart rate. To determine movement quality, we will use accelerometry and

gyroscope, as well as EMG based parameters

Secondary outcome

NA

Study description

Background summary

Monitoring and quantifying the physical activity and their intensity patterns gives general insight into the intensity and type of activity people perform. The qualitative aspects of movements (how are movements performed) can provide detailed knowledge of specific biomarkers related to motor impairments. These assessments are typically done in the controlled environment of the lab or clinic. However, laboratory based analysis may not fully reflect individual free-living motor capabilities while monitoring people in their home

environment, can provide more valid information about a person*s functioning, and allows monitoring of interventions outside the clinic.
Wearable sensors, like (3D) accelerometers, gyroscopes and surface electromyography make home monitoring possible. In the SMOVE project (Smart device for clinically validated MOVEment assessment and monitoring at home and in the clinic; INTERREG EU financed),
we aim to develop a *hybrid sensor system* for automatic, continuous monitoring of specific movement features in the laboratory and especially in free living-like conditions. In the present study we will first examine the feasibility and test algorithms in a healthy population before examining patient groups in the future.

Study objective

The primary objective in the first phase is to test the feasibility of recording hybrid IMU/EMG based movement/muscle activity parameters during different movements in the lab and at home.
The primary objectives in the second exploratory phase are 1) to apply and assess the performance of *best evidence* algorithms to automatically analyse quantitative and qualitative aspects of movement in a supervised laboratory setting (*living lab*), and 2) to test and when necessary adjust the above laboratory based algorithms in the unsupervised free-living (@home) situation.

The secondary objectives in the second exploratory phase are 1) to determine differences in biomarkers of movement between the young and old groups as part of the performance assessment process, 2) to determine the added value of EMG-based compared to IMU-based biomarkers to determine quantity and quality of movement, 3) to determine the added value of using gyroscopes in comparison to only accelerometers to determine quantity and quality of movement, 4) to determine the added value of a heart rate measurement using an electrocardiogram (ECG) sensor to determine intensity of movement, 5) to determine the minimal number of sensors needed to extract the most important movement biomarkers for the primary objectives, and 6) to determine the test-retest reliability of those movement biomarkers for which no reliability information is available from the literature.

Study design

Cross-sectional, observational study. Assessment of different types of movement in the laboratory and in the free living situation (@home). Participants will wear a portable device that allows hybrid EMG, ECG and accelerometry measurements (SAGA from tMSI, Enschede, the Netherlands).

Study burden and risks

There are no risks or benefits, and the burden is limited to the time invested

in the test (approximately 2 hours in the lab, with breaks, and 8 hours of observation at home). Video will be recorded of the participants throughout the experiment, which will be anonymized in the post-processing.

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

- Healthy (self-reported)
- Age (in years) between 18-30 (young adults) or 65-85 (older adults; overlapping in age with majority of future patients)
- Able to walk independently (self-reported)
- Able to perform activities of daily living without assistance (self-reported)
- Written informed consent

Exclusion criteria

- current orthopaedic, neurological, and/or psychiatric disorders (self-reported)
- medication use that might affect motor performance (mobility, gait, balance)
- Older adults only: Mini Mental State Examination (MMSE) score < 26 to exclude low task performance due to cognitive disabilities

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-09-2020
Enrollment:	65
Type:	Actual

Ethics review

Approved WMO

Date:	09-12-2019
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL71796.042.19