Protocol Trial

Title of the project Wearable Robotic Upper Body Exoskeleton for Workers (Exo4Work)

Objective of the study

The overall objective of the Exo4Work project is to design, develop and validate a smart modular exoskeleton for spinal, torso and upper limb support to assist workers, to reduce the physical load on workers, keep older workers active for a longer period of time, increase quality of work, reduce fatigue, and prevent injuries.

The objective of this study is to assess physical and mental load of industrial work in laboratory conditions.

Investigator(s)

Prof. Dr. Romain Meeusen (PI, MFYS-VUB) – Romain.Meeusen@vub.be – responsible head of the research group
Dr. Kevin De Pauw (MFYS-VUB) – Kevin.De.Pauw@vub.be
Drs. Sander De Bock (MFYS-VUB) – Sander.De.Bock@vub.be
Bert Pluym (MFYS-VUB) – Bert.Pluym@vub.be

Departments/laboratories involved in the study

Research group Human Physiology (MFYS-VUB) – 02/629 22 22
Pleinlaan 2, 1050 Brussel

Introduction

It is acknowledged that industrial workers face high risks of musculoskeletal injuries, such as lower back pain, since they work in small places and non-ergonomical postures. Besides providing preventive evidence-based practical guidelines to support occupational safety and health, a potential solution can be found in the research field of Human-Centered Robotics, i.e. the implementation of exoskeletons. An exoskeleton is a wearable, external mechanical structure that assists the operator during human movement.

Companies gain increasing interest in the implementation of exoskeletons in the working environment with the aim to improve work efficiency and reduce work-related injuries. The research field about the implementation of exoskeletons in field conditions is novel. After an observational, ergonomic evaluation of work postures during different industrial tasks in an earlier stage of the project, the current study will simulate industrial work in laboratory settings. The outcome will be an ergonomic evaluation of postures of industrial work using physiological and biomechanical data.

Study design

The design of the study is interventional, cross-over (in laboratory conditions).

The subjects

Number of subjects

During this experiment twelve healthy subjects will be recruited. Experiments wherein industrial work will be simulated in laboratory settings will be conducted. These experimental trials will take place at VUB (climate chamber, research group MFYS).

Inclusion criteria

Healthy males between 18-65 yrs

Exclusion criteria

Injuries

Replacement of subjects

New subjects will be recruited in case of drop out.

Restrictions and prohibitions for the subjects

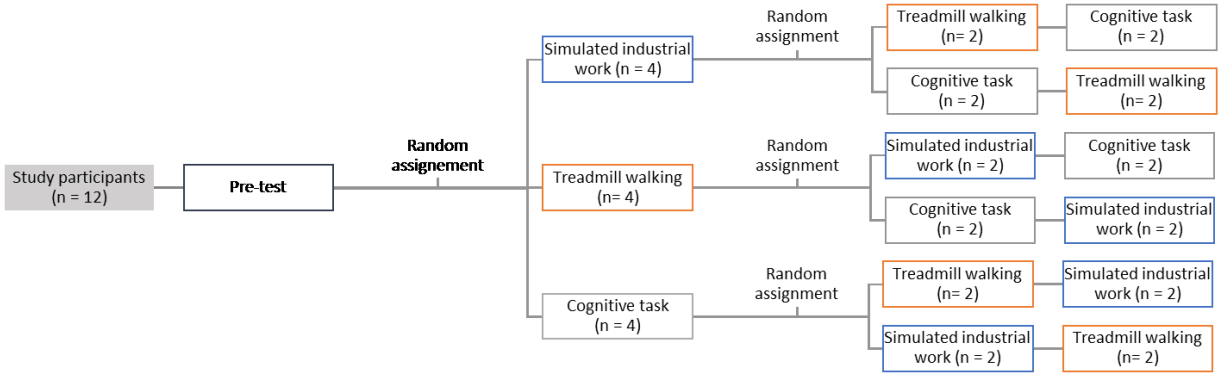
/

Procedures

The physical and mental load of simulated industrial work will be investigated in laboratory conditions. Each subject will perform a pre-test and three lab trials. The pre-test (1h) will include basic biometric measurements, simple motor tasks (e.g. squatting), a dual-task walking task using the cognitive Stroop task to determine reaction time and accuracy during walking (Arcelin et al., 1998) and a familiarization trial of the simulated industrial task (described further down this protocol).
A first lab trial will include a cognitive task (90 min, 2-back task (Massar et al., 2010) (cognitive component). During a second trial a 90 minute walking task will be performed (physical component). The third trial will exist out of a simulated industrial task (physical and cognitive component). The simulated industrial task will be a 90 minute task during which boxes (max 15 kg) will be moved from one place to another (0.05 Hz) while also performing a cognitive task (2-back task). Before and after the cognitive, physical or simulated industrial task a 10 minute Stroop task will be performed.
In the laboratory the ergospirometric device K5 (Cosmed) will be attached to the subject to measure oxygen consumption (via a mask) and indirectly energy expenditure. A heart frequency monitor (Polar) will be attached using a chest belt. The non-invasive electro-encaphalography (EEG) and electro-myography (EMG) electrodes will be placed on the subjects head using non-invasive EEGcap and EMG surface electrodes, respectively. Furthermore, different questionnaires will be used, i.e. the Rating of Perceived Exertion (RPE), the Profile of Mood States (POMS), the Local Discomfort Scale, the Visual Analogue Scale (VAS) for fatigue, Nasa TLX, heat scores and Need for Recovery scale. In simulated industrial settings oxygen consumption and heart rates will be determined, as well as following questionnaires: RPE, POMS, Local Discomfort Scale, VAS for fatigue, Nasa TLX, heat scores and Need for Recovery scale.

Flowchart

Twelve subjects will be included to conduct experiments in laboratory conditions. Three experimental trials per subject will be planned. One trial will include a simulated industrial task during which boxes are moved while walking on a treadmill. The intensity of the task will be determined based on the results of an ongoing observational study which ergonomically evaluates industrial work (approximated max 15 kg, lifting frequency of 0.05 Hz). During the second trial, a 90 minute normal walking task on a treadmill will be executed. The third trial will include a 90 minute cognitive task (2-back task). Before and after each trial a 10 minute Stroop task will be performed in order to analyse the cognitive performance of the subject. The total duration of one experimental trial is 3 hours.



Randomisation/blinding

The order of the executed trials will be randomly assigned to avoid possible sequence effects. No blinding occurs.

Prior and concomitant therapy

Before the subjects start their first experimental trial, the health status of the subjects will be checked (Par-Q).

Study analysis

Sample size calculation
Twelve subjects will be recruited to perform laboratory tests in a cross-over design. This amount of subjects is similar to the cohort size used in an earlier cross-over mental fatigue studie concering exercise (Martin et al., 2015).

Analysis of the samples
Physiological data gathering and analysis will be conducted by a PhD student of MFYS, Sander De Bock (Sander.De.Bock@vub.be). Ergospirometrical data will be gathered with the ergospirometrical device K5 from Cosmed and extracted to an Excel file using the program Omnia (Cosmed). Heart rate monitoring using Polar is a wireless and continuous process. Electro-physiological data (EXG, such as EMG, EEG) will be collected using Brain Vision Recorder (BrainProducts) and analysed using Brain Vision Analyzer (BrainProducts).

Statistical analysis
The physiological data will be statistically analysed with IBM SPSS statistics 25. Normality tests (Shapiro-Wilk normality testing) will precede parametric or non-parametric testing. Data

analysis of electro-physiological data will be conducted using Brain Vision Analyzer, wherein data will be pre-processed (signal filtering, re-referencing, artefact removal) and processed (power spectral analysis, coherence and non-invasive brain imaging). From Brain Vision Analyzer files will be extracted and inserted in standardized Low Resolution Brain Electromagnetic Tomography or sLORETA. The statistical analysis performed in sLORETA is Statistical non-parametric mapping or SnPM using the Fisher's permutation test that relies on a Bootstrap method with 5000 randomizations. Sander De Bock (Sander.De.Bock@vub.be) is responsible for the physiological data analyses.

Quality control and quality assurance

To ensure data quality (heart rate and oxygen consumption) outliers will be detected and removed. Preceding the determination of oxygen uptake using the mobile ergospirometric device K5 the device will be calibrated to obtain accurate data. Additionally, a well fit mask will be used per individual (mask sizes range from extra-small, small, medium, large to extra-large). The latter will avoid leakage of air from the mask to the ambient air.

EEG electrodes are embedded in an EEGcap (different sizes from 54 to 60 (cm) according to head size). The electrical signal will be optimized using a gel between the electrodes and the skin of the subjects' head. Raw data will be recorded, but during recording the electrode impedance (indicator of signal quality) needs to be always kept below 10kΩ. Furthermore, during recording basic noise-reducing filters can be applied to allow the focus on the EEG frequency range of interest. The post-hoc pre-processing (basic filters and artefact removal) steps are performed by one researcher (Sander De Bock) and state-of-the-art pre-processing steps (such as Independent Component Analysis) are conducted to assure data quality.

Data management

Questionnaires filled out during the experiment will be scanned in and digitalized. Physiological data will be measured by specific devices and stored locally on laboratory computers. After each experiment, the data will be restored on the investigators personal computer or external hard drive. The laboratory computer, as well as the investigators personal computer are embedded in a back-up loop which backs up twice a day to the laboratory's Synology NAS system.

Publication policy

The publication policy of the research group is to publish papers in international peer-reviewed journals (preferably Q1 journals). All authors should have made substantial contributions to (1) the design of the study or acquisition of data or analysis and interpretation of data, (2) drafting the article or revising it critically, (3) final approval of the version to be submitted.

References

Arcelin, R., Delignieres, D., & Brisswalter, J. (1998). Selective Effects of Physical Exercise on Choice Reaction Processes. Perceptual and Motor Skills, 87(1), 175–185. https://doi.org/10.2466/pms.1998.87.1.175

Massar, S. A. A., Wester, A. E., Volkerts, E. R., & Kenemans, J. L. (2010). Manipulation specific effects of mental fatigue: Evidence from novelty processing and simulated driving. Psychophysiology, 47(6), 1119–1126. https://doi.org/10.1111/j.1469-8986.2010.01028.x
Martin, K., Thompson, K. G., Keegan, R., Ball, N., & Rattray, B. (2015). Mental fatigue does not affect maximal anaerobic exercise performance, 715–725. https://doi.org/10.1007/s00421-014-3052-1