VIRTUES - Virtual reality training for upper extremity in subacute stroke
Study protocol of a randomized controlled multicenter trial

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Introduction
Approximately two thirds of patients with stroke experience impaired arm motor function, which compromises independence in activities of daily living, occupational areas and quality of life. High intensity training of challenging tasks with many repetitions is a key factor for regaining motor function after stroke. Novel virtual reality (VR) rehabilitation systems provide the potential to increase intensity and offer challenging and motivating tasks. The efficacy of VR systems has not been demonstrated yet in sufficiently powered studies. The objective of this randomized controlled multicenter trial is to study the effectiveness and acceptance of a novel VR training approach.

Methods
In this study 120 patients 1-12 weeks post stroke will be recruited in 5 participating Norwegian, Danish and Belgian rehabilitation institutions. The patients are randomized to either a group receiving VR training in addition to conventional arm training, or a group receiving dose-matched and therapist attention-matched conventional arm-training. During a period of 4 weeks the patients are offered additional 4-5 training sessions weekly of 45-60 minutes duration by a physiotherapist or an occupational therapist. In both groups a therapist chooses exercises tailored to the patients’ needs. Arm motor function, dexterity and independence in daily life activities are evaluated at baseline, post and 3 months follow-up assessments. The primary outcome measure is the Action Research Arm Test; secondary outcome measures comprise Box and Blocks Test, Functional Independence Measure and questionnaires for patients and therapists.

The VR system: The YouGrabber (YouRehab Ltd., Switzerland) allows different therapy modes such as unilateral and bilateral exercises, mirrored movements of the unimpaired arm and observation of movements with the intention to imitate. The movements of the patient’s arms are mapped and transferred to virtual arms. The patient then observes his/her virtual arms from a first person view on a screen. Real movements can be virtually enhanced and the system also provides the possibility for partly automating and quantifying therapy procedures. If a certain level of dexterity is reached, the difficulty of the training can be increased by e.g. higher speed, more target objects or another gaming alternative.

The VIRTUES trial is organized and coordinated by the University of Bergen, Norway, Department of Global Public Health and Primary Care in collaboration with the Haukeland University Hospital and Sunnaas Rehabilitation Hospital in Norway, Hammel Neurocenter and Skive Neurorehabilitation in Denmark, Rehabilitation Campus Sint-Ursula, Jessa Hospitals and KU Leuven, University of Leuven, Department of Rehabilitation Sciences in Belgium.

Discussion
VR training is a promising approach for upper extremity rehabilitation after stroke. This international multi-center study will lead to acquisition of new knowledge regarding the efficacy of a novel technology-based rehabilitation approach for patients with paresis of an arm after stroke. The study will also provide an opportunity to assess cost-effectiveness of this novel approach as compared to conventional rehabilitation and to evaluate the implementation of virtual reality-based rehabilitation from therapists’ and patients’ points of view. The results will be of relevance for patients, health professionals and health economists.