UNIVERSITY OF BRESCIA

PhD Program
in
TECHNOLOGY FOR HEALTH

A novel technology-based care concept for an accessible and personalized cognitive-motor therapy to counteract frailty and promote health: The PROHEALTH project

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Background

A steep growth in the number of people aged 60 years and over is expected by the end of the 21st century. Age-related declines in physical and cognitive functioning and the associated adverse outcomes such as restricted mobility, cognitive impairment, and falls ultimately result in a decrease in the quality of life of older adults. A common strategy to promote healthy aging is to engage in physical activity. Previous research has shown that physical activity has a number of positive effects on physical and psychological health outcomes as well as on cognition in older adults (Kramer & Colcombe, 2018). Furthermore, it has been demonstrated that older adults benefit similarly from cognitive training targeting various cognitive functions such as memory, executive functions, attention, visuo-spatial skills, and information processing speed (Reijnders et al., 2013). Given the comprehensive positive effects of physical activity and cognitive training, it has been suggested that a combination of both might be promising. Indeed, previous studies have revealed that simultaneous motor and cognitive training may be equally or even more effective than separate or sequential training of both functions (Herold et al., 2018). In fact, simultaneous motor-cognitive training can lead to improvements in various physical functions such as balance (Morat et al., 2019), aspects of gait, e.g., gait initiation (Swanenburg et al., 2018), as well as in cognitive functions such as executive control and processing speed (Stanmore et al., 2017), exercise enjoyment (Franco et al., 2012), decreased depressive symptoms, and an increased mental health-related quality of life (Rosenberg et al., 2010). However, several issues are limiting the success of such training programs and recommendations. For instance, many people/patients suffer in general from low training motivation, therapy might not be personalized and progressive, and most physical and/or cognitive training programs are provided face-to-face, and accessibility is a major concern for older adults due to potential mobility limitations, transportation issues, or a lack of facilities in their nearby community. Furthermore, demographic changes are increasing the need for long-term care/treatment (Eurostat., 2020) and pose financial, time, and personnel challenges to the health-care systems. As a result, training interventions can often not be provided long enough, thus, preventing geriatric patients from reaching their full recovery potential and/or from leading an active and healthy lifestyle (Tillou et al., 2014). A solution to the aforementioned obstacles is offered by information and communication technologies (ICTs) which can support the provision of care through telerehabilitation. Telerehabilitation is a broad term and can be defined as the remote provision of rehabilitation services/home-based therapy (Russell, 2009). Home-based training has a number of advantages compared to conventional face-to-face rehabilitation such as better self-management, higher accessibility, lower costs, convenience, and easier integration in everyday life (Collado-Mateo et al., 2021) while at the same time it is equally effective (Suso-Martí et al., 2021). In addition, telerehabilitation is especially important during lockdown periods, such as the recent COVID-19 pandemic. Moreover, ICTs allow technology-based exergame training. Exergames are a promising option to provide simultaneous motor-cognitive training. They can be described as interactive whole-body movement, game-based training approaches which efficiently connect motor and cognitive tasks (Huber et al., 2022). Due to their game features, exergames are created to enhance enjoyment and engagement (Johnson et al., 2016) which in turn might have a positive effect on adherence rates (Valenzuela et al., 2018) and thus also health and wellbeing (Johnson et al., 2016). In the past 10 years, the EU and other funders have devoted billions for ICT-related Research and Development (R&D) projects for active and healthy aging. Yet, many project outcomes failed to get traction in the market and/or healthcare system. One reason for this is that health technology developers often failed to incorporate a user- centered development and design process while developing their products. Another reason is that “proven” interventions are often not tested in the real world. Research on health systems, such as implementation research, is crucial to meeting that challenge, providing a basis for the context-specific, evidence-informed decision- making needed to make what is possible in theory a reality in practice. The World Health Organization (WHO) has advocated for greater embedding of research into decision making and called for more demand-driven implementation research (Peters et al., 2013). Therefore, in order to ensure their integration into the healthcare system, any innovative approaches need to be tested in pragmatic trials first.

Objectives

As mentioned before, the PROHEALTH project will make use of technology that was developed within the scope of the AAL project COCARE. The COCARE system comprises of a portable exergame device that is designed for home use, a stationary exergame device with an integrated ICT-based assessment system that delivers information about the user`s cognitive and motor functioning status and a rehabilitation cockpit which allows therapists to assign training content to all users and users to contact them in case they have any questions or face any problems during training. The first objective of the PROHEALTH project is to improve the (automated) personalization and progression of therapy provided by the software. Assessment results should be linked to individual training recommendations following a progressive adaptation. Optimal training challenge should increase effectiveness. The second and most crucial objective is to evaluate the effectiveness of the proposed telerehabilitation concept in reducing both physical and cognitive frailty while improving fall-risk factors among frail adults who have multiple comorbidities. By conducting a comprehensive assessment of the intervention's impact, we aim to provide concrete evidence of its efficacy, thereby bolstering its acceptance and integration into the healthcare system and clinical practice. To ensure the successful adoption of our proposed concept, we also plan to examine the cost and benefit relationship associated with its implementation using a Value-Based Healthcare (VBH) perspective. Assessing the economic implications and advantages of the telerehabilitation approach will be paramount in determining its feasibility and potential for wider implementation within healthcare systems. By expanding our understanding of the effectiveness and economic implications, we can pave the way for the integration of this innovative telerehabilitation concept into routine clinical practice, thus benefiting frail adults with multiple comorbidities and ultimately improving their overall well-being.

Methodologies

- Study Design: Pragmatic RCT - Project Duration: 36 months - Aim: To reduce physical and cognitive frailty and to improve fall-risk factors in frail adults - Primary Outcome: Fall-risk (as measured by the Timed Up-and-Go test in dual-task or the Berg Balance Scale) - Secondary Outcomes: (Instrumented) Motor Tests, e.g. balance/gait speed; cognitive Tests, e.g. attention/psychomotor speed/memory; Psychological Tests, e.g. gait efficacy/fear of falling/quality of life; Number of Falls; Cost-Benefit - Sample Size: The exact sample size calculation will be performed based on the results of the ongoing pilot study using the same device for exergame-based telerehabiliation training. However, based on current literature of cognitive-motor, exergame-based training we expect medium effect sizes (ca. 0.4-0.5). For alpha=0.05 and power of 80% we would need a sample size of 124-272 participants (62-136 per group). Accounting for a 20% drop- out rate, we plan to conduct our study with at least a total of 326 participants (163 per group). - Inclusion Criteria: Any person/admitted patient, of any age, with any (controlled) comorbidities, that can benefit from cognitive-motor training and/or falls prevention training (e.g. multiple sclerosis, Parkinson`s, stroke, osteoarthritis); Internet connection at home and TV with an HDMI port; Presense of physical and or cognitive frailty according to: Fried Frailty Phenotype (at least one criterion met) OR Mini Mental State Examination Score between 20-25 - Exclusion Criteria: Persons with severe/uncontrolled/acute health conditions; Persons unable and unsafe to use the SensoFlex - Screening: In additional to checking for all the rest of the criteria, therapists will let participants play 3 exergames (1.5 minutes each) on the Senso Flex and evaluate whether they are able to conduct the training safely at home (subjective report) - Control Group: Usual Care - Intervention Group: 12 weeks personalized and progressive exergame-based cognitive- motor training using the SensoFlex - Follow-Up: 12 weeks Pre-Assessments will take place at the clinics and will include (instrumented) motor and cognitive assessments conducted e.g. on the Senso; (the stationary device aimed for supervised training in therapy center). The results of those assessments will be used to generate personalized training plans. Participants of the intervention group will then receive a portable exergame device (SensoFlex) (a foldable pressure sensitive mat that is connected to a TV) and will be asked to follow the training plan generated by the system`s “Rehabilitation Cockpit” for 12 weeks. The control group will continue receiving their usual care. After those 12 weeks, all participants will return to the clinic for the post- assessments. After another 12 weeks of follow-up, another assessment session will take place. The project aims to evaluate the cost-effectiveness of the developed solution in a Value-Based Healthcare (VBH) perspective. This involves assessing the additional value of treatments delivered with the innovative model compared to usual care, considering the improvement in clinical outcomes and associated costs. A specific VBH model will be developed to determine if the SensoFlex-based model provides greater value compared to usual care. Real-world data from the clinical trial, including clinical scale scores and instrumental data from the SensoFlex solution, will be used to measure clinical outcome improvement. Cost evaluation will be conducted from the perspective of a healthcare provider, considering investments, workflow-associated costs, and sustainability of the innovative care model in different scenarios.

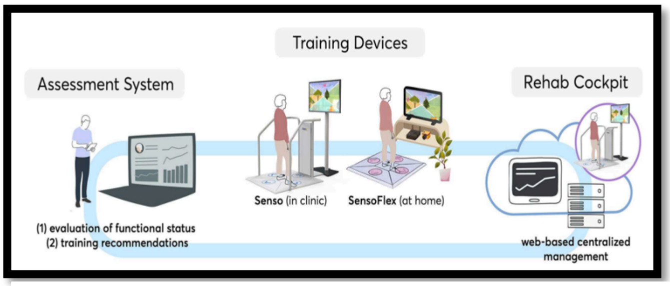

FIGURE 1: THE COCARE SYSTEM

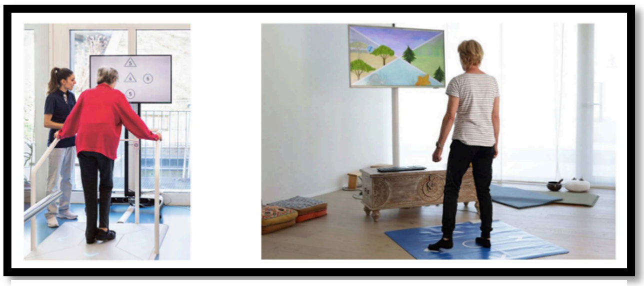

FIGURE 2: TRAINING IN ANINSTITUTION ON A SENSO AND AT HOME ON A SENSO FLEX

Expected Results and Impact

The primary outcomes of PROHEALTH are changes in cognitive/motor performances in frail participants after a 12- week home rehabilitation training using the Dividat Sensoflex device. Secondary outcomes include falls and cost- benefit. If successful, this project addresses important scientific and innovation challenges: 1. Improving autonomy, social participation, and quality of life is crucial for maintaining independent living. The proposed solution offers a continuum of care to a broader population, including those living far from clinical centers. It provides more training sessions to more people, reducing caregiver workload and pressure on healthcare facilities without additional costs. 2. Falls pose a significant health threat to frail individuals, resulting in injuries and high healthcare costs. Multifactorial interventions to prevent falls have been effective but costly. Implementing a new multifactorial intervention, like the one proposed, that is both cost- effective and highly effective in improving cognitive-motor functions presents a scientific research and innovation challenge.

The expected impact and created value of the PROHEALTH project is manifold. Scientific: Cognitive-motor training is already proven to benefit several physical and cognitive functions and thus counteract frailty. Exergaming has the potential to increase enjoyment due to its motivational character and thus to enhance engagement and long-term compliance which in turn will maximize the effects. Moreover, the effects will be further increased due to the automatic personalization of rehabilitation which ensures optimal support of individual needs. While these results come from studies on specific populations, the finding of the present project will add further scientific information about the effect of the proposed training and about cognitive- motor interaction in different cohorts. Societal: As an ICT- based in-home tool with remote monitoring, accessibility to treatment will increase including also individuals with scarce possibilities to access traditional long-term rehabilitation interventions. If the efficacy of the present approach will be demonstrated, a broad population of frail individuals will benefit from the improved motor and cognitive performances due to training, and, consequently, increase their autonomy and social participation, with decreased workload for caregivers and family members. Economic: Given the high health care expenditure for treating fall- related injuries in Europe (nearly 25 billion Euros per year), the large-scale implementation of a multidisciplinary rehabilitation approach which is effective and cost-efficient in reducing fall risk, will have a huge economic impact on health services. Health policy: The results of the pragmatic RCT included in PROHEALTH will inform the healthcare sector with the aim of accelerating the transition from a traditional one-to-one rehabilitation model to a more sustainable and efficient model in which several users carry out their treatments directly at home.