2021 43rd Annual International Conference of the
IEEE Engineering in Medicine & Biology Society (EMBC)
Oct 31 - Nov 4, 2021. Virtual Conference

Exploring the Acceptability and Feasibility of Providing a Balance Tele-Rehabilitation Programme to Older Adults at Risk for Falls: An Initial Assessment

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***Abstract*— Falls are a major health concern. The HOLOBALANCE tele-rehabilitation system was developed to deliver an evidence based, multi-sensory balance rehabilitation programme, to the elderly at risk of falls. The system delivers a series of balance physiotherapy exercises and cognitive and auditory training tasks prescribed by an expert balance physiotherapist following an initial balance assessment. The HOLOBALANCE system uses augmented reality (AR) to deliver exercises and games, and records task performance via a combination of body worn sensors and a depth camera. The HOLOBALANCE tele-rehabilitation system provides feedback to the supervising clinical team regarding task performance, participant usage and user feedback. Herewith we present the findings from the first 25 study participants regarding the feasibility and acceptability of the proposed system. The results of the clinical study indicate that the system is acceptable by the end users and also feasible for using in hospital and home environments.**

I. Introduction

Recently, various virtual reality (VR) platforms were proposed, aiming at the monitoring and treatment of certain diseases [1-6]. VR technology is considered a suitable way of handling issues that require training on a daily basis [7-10]. A study assessed key differences between conventional training and virtual coaching training in a population consisting of people suffering from Chronic unilateral vestibular loss [11]. No obvious differences were reported as far as symptom training is concerned, but the study showed that subjects' attitude was way more positive towards the technology, and participants were satisfied using it for their routine rehabilitation program. Another three-dimensional VR solution was developed and evaluated for patients with Meniere's disease, and chronic imbalance problems [12]. It provided specific training types for balance improvement (eye, head, extension, and coordination exercises). There was significant improvement in the symptoms of the patients that were trained with the VR vestibular rehabilitation exercise protocol compared to participants in the controlled group. This platform created a step-wise, interactive, dynamic, three-dimensional, and interesting rehabilitation environment, helping patients improve their center of gravity sway and trajectory excursion in the mediolateral direction. Regarding AR technology, a pilot study using a prototype tele-rehabilitation system (Ghostman) [13], that allowed both the clinician and the patient to interact visibly with each other in an AR environment, assessed the training of novel motor function skills with this technology in comparison with conventional training. Results showed that this AR system is successful for motor training and learning, since a reduction of errors in this learning technique was noticed, and also there were positive outcomes in the required duration of various learning activities execution, in comparison with conventional training. Another AR tele-rehabilitation system (ARTESH) [14], was used in a pilot study, to assess the useful interaction between the clinician and the patient, regarding remote Musculoskeletal examination. The outcome suggested that a real time session is possible between the end users, allowing both to receive information through image, audio and also via haptic feedback, making use of haptics and depth camera technologies. The participants were positive towards this technology but showed a preference in conventional face to face evaluation.

HOLOBALANCE is a novel, AR platform, aiming at the rehabilitation of community dwelling citizens with balance disorders [15]. It makes use of AR technology in the form of a surrogate virtual coach physiotherapist. AR was preferred over VR because some of the studies have reported that VR technology may provoke symptoms like dizziness or nausea [16][17]. The acceptability of AR for elderly population, in which balance problems are more frequent, was already assessed in a previous study and the majority of testers accepted it very well and even perceived the simulated coach as an alive and friendly human [18]. In this paper we present

*This work has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No [769574].

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the preliminary results regarding the feasibility of the proposed system, which includes a multisensory, Internet of Things (IoT) component and two different modes of AR interaction, to provide coaching for balance physiotherapy exercises and exergames [19], as well as key findings for the technical aspects, from the ongoing clinical study in two clinical sites (Freiburg, Germany and Athens, Greece), both at hospital and home environments.

II. METHODS

A. Study Design

HOLOBALANCE runs a multi-centre, assessor-blinded, randomised proof of concept study to explore the acceptability and feasibility of providing a home-based balance tele-rehabilitation programme to older adults at risk for falls. When completed, it will: 1) compare acceptability of the tele-health programme (e.g. compliance, drop-out rate) to an established home exercise programme (the OTAGO HEP), currently considered as standard care, and 2) explore trends for effectiveness across a number of validated outcome measures to explore whether a future trial is warranted, and if so to provide data for a sample size estimate [20]. In this paper we will focus only on acceptability and feasibility, as well as in technical aspects, based on the findings from 25 patients of the intervention group.

B. Study Population

All study participants are in risk of falls or having experienced a fall or suffer from some kind of balance disorder. The age range is 65-80 years old. They all are community dwelling older adults, living independently and not taking part in any rehabilitation program regarding falls or cognitive training. The recruited subjects didn't have any significant comorbidities (neurological conditions, acute musculo-skeletal injuries, depression) or cognitive impairments. Home broadband connection is a technical requirement so that the IoT based platform can operate efficiently on the participants' homes [21]. This analysis includes 25 study participants that have completed their training in Athens and Freiburg clinical sites or in-home environments.

C. Ethical Approvals

This study has received institutional ethical approvals in Germany (reference: 265/19), Greece (reference: 9769/24-6-2019) and the UK (reference: 19/LO/1908). TRIAL REGISTRATION NUMBER: NCT04053829. PROTOCOL VERSION: V.2, 20 January 2020.

D. The HOLOBALANCE Platform

A. HOLOBALANCE System

HOLOBALANCE is a telerehabilitation platform, which stimulates users and helps them overcome or improve their balance problems, by challenging their physical and cognitive abilities [15]. This outcome is achieved with the AR technology that the system makes use of, with the form of a virtual physiotherapist [22][23]. The HOLOBALANCE platform displays the prescribed physiotherapy exercises, exergames and cognitive games and the intervention varies

Figure 1. HOLOBALANCE architecture.

from user to user to address the specific condition that needs to be trained. The level of difficulty (progressions) is also adjusted for each exercise according to the patient's ability to complete the exercise properly and with low or no symptoms. Fig. 1 describes the basic HOLOBALANCE architecture.

The main architecture components on hardware level include an IoT-based multi-sensory and motion capture module, the main data processing module-Edge computing unit, and finally the augmented reality generation unit, that is the head mounted device with the embedded smartphone to project the AR hologram. The interconnection between these different parts of the system is achieved through the open source FIWARE-ORION module, that is enhancing the communication between these different components [24].

The sensory module is composed of 5 devices: a pair of smart, pressure insoles, two inertial measurement units (IMUs), and a depth camera. The technologies and protocols implemented are based heavily on wireless communications, and for each sensor, different configurations are implemented to focus on capturing efficiently the raw data and after, processing the required body movements. Data collection and processing takes place with edge computing approaches [24][25].

The EDGE computer, which is the main component of the platform, has two main functionalities: 1) provide real time guidance, through the holographic coach, to the patient by assessing the correctness of the captured movements and 2) calculate intelligent analytics which include scoring the study participants' performance, assess their stress and frustration and suggest modifications in the plan. This information is available to clinicians through their dashboard and enables them to make informed, data driven decisions about the personalized, rehabilitation regime [25].

The dashboard is the web-based application that the clinicians use in order to: register new patients in the system and import their data and other evaluations, define the rehabilitation plan, view and analyse patient's performance in exercise execution and other tasks (i.e. cognitive and auditory training), and adjust the rehabilitation plan as needed.

The interaction is provided by the AR coach who is responsible for demonstrating the correct exercise execution as well as for guiding, correcting, stopping or progressing the participant during the training session. The human-like hologram is able to interact with the patient in a natural way, by greeting and motivating the participants [18][23].

HOLOBALANCE also includes AR cognitive games, aiming at training tasks such as attention and working memory, and exergames that basically are gamified versions, also with AR, of the physiotherapy exercises. Moreover, the platform offers auditory training tasks which aim at improving patients' speech perception and auditory memory.

B. *Training With the Holobox Version*

Holobox is the version of the interaction that can be used in controlled environments such as clinics and private practices. Holobox uses a metallic construction with an integrated projector and a foil, where the virtual coach is being projected in front of the participant. Holobox is presented in Fig. 2. The training with the holobox system is being held twice a week for a total of 8 weeks for each participant, with the supervision and guidance of the responsible physiotherapist. The clinician is following closely the progress of each patient and refines the weekly exercise program of the system according to each individual and their needs in training. Holobox training includes physical exercises, exergames and cognitive games. Physical exercises are implemented first, and then the games follow by implementing cognitive on week 3 and exergames on week 4 [21]. The physiotherapist is registering the patients scoring on a variety of variables, and also his symptom triggering of each exercise and plans accordingly the following week's training program.

C. *Training With the Home-Based HOLOBALANCE Version*

The study participant is required to wear the head mounted display (HMD) every time he/she wishes to train [15][18]. The AR virtual trainer is generated by an application on the smartphone that is fixed on the HMD and also a head sensor is placed in it, so head movements can be efficiently measured. The home based system is presented in Fig. 3.

The users are able and should train daily with the home-based system for the most effective improvement of the symptoms, in the 8 week rehabilitation program. After the end of each session, the finalised analytics and data are sent to the dashboard, along with patient's symptoms, recorded by speech recognition algorithms, and an indication of how well the exercise was executed (knowledge based motor score) [25]. The responsible clinician is then able to monitor users' progress and adjust the weekly program accordingly to best suit the needs of the trainee.

During the 8-week rehabilitation regime, an IT expert is

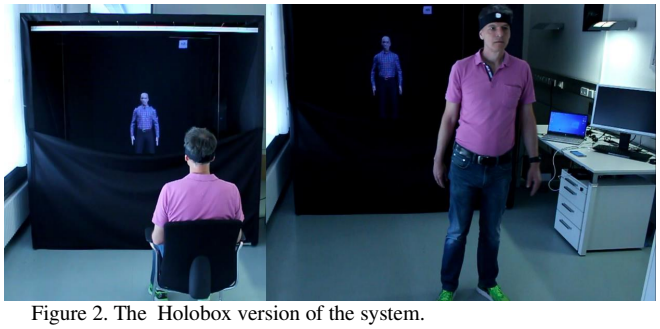

Figure 2. The Holobox version of the system.

Figure 3. Home-based HOLOBALANCE system.

available for supporting both the participants and clinicians, by guiding the user on correct handling, gathering useful information and improving the system for future use, solving system errors and bugs, and being in a direct communication with the responsible clinician in order to obtain the best data quality, and offer an optimal user experience.

III. OUTCOMES DEFINITION

Feasibility, including availability, reliability, fault tolerance, recoverability and technical feasibility is evaluated with the following methods [20]:

- the Dropout rate in the 8-week program
- a Qualitative interview at the end of the program
- the Monitoring of Adverse and Serious Adverse Events
- the Monitoring for deviations from study protocol
- the Program Compliance which is the percentage of training sessions against the number of prescribed sessions (system operability)
- the percentage of completed or near completed sessions (by the intervals 0-25%, 25-50% etc.).

The training sessions executed refer to sessions that at least one or more exercises were completed successfully. These consist only of attempted sessions (at least trying to open the system, with success or not), meaning that times when participants didn't open the system because of personal issues or because of reasons that didn't include the HOLOBALANCE platform, aren't considered as prescribed. The percentages of completed sessions suggest intervals of success in training sessions. The exit interview was conducted with the form of 12 questions to the participants, and VADER (a lexicon and rule-based sentiment analysis tool) was used [26]. VADER is used for sentiment text analysis, and is able to extract (by classification and quantification), positive, neutral and negative emotions or opinions and their magnitude.

TABLE I. CLINICAL STUDY RESULTS - FEASIBILITY METRICS

Feasibility Metrics	PATIENTS																				
	FREIBURG												*ATHENS*								
	HOLOBOX					*HOME-BASED HOLOBALANCE SYSTEM*							*HOLOBOX*					*HOME-BASED HOLOBALANCE SYSTEM*				
	ROUND ONE					*ROUND ONE*			*ROUND TWO*				*ROUND ONE*					*ROUND ONE*				
	1	*2*	*3*	*4*	*5*	*6*	*7*	*8*	*9*	*10*	*11*	*12*	*1*	*2*	*3*	*4*	*5*	*6*	*7*	*8*	*9*	*10*
operability	100	100	100	100	100	68.42	97,96	66.67	92.86	92.45	81.82	100	100	100	100	100	100	96	98.25	83.33	100	93.62
0%-25%	0	6.25	0	0	0	13.33	6.25	13.33	0	0	4.08	0	0	0	0	0	0	2.08	0	5	0	2.27
25-50%	0	0	7.14	25	0	13.33	2.08	6.67	2.22	2.85	0	0	6.25	0	0	0	6.67	2.08	3.57	0	0	0
50-75%	18.75	18.75	28.57	12.5	9.09	6.67	12.5	33.33	11.11	5.71	6.12	0	25	0	0	12.5	6.67	2.08	3.57	10	5.26	0
75-99%	25	12.5	7.14	31.25	45.45	20	33.33	23.33	33.33	37.14	40.82	43.48	6.25	35.71	16.67	37.5	33.33	29.17	12.5	30	8.77	6.82
100%	56.25	62.5	57.14	21.25	45.45	46.67	45.82	23.33	53.33	54.29	48.98	56.52	62.5	64.29	83.33	50	53.33	64.58	80.36	55	85.96	90.91

IV. RESULTS

Regarding the Dropout rate, all 10 patients, 5 in Athens and 5 in Freiburg, completed the holobox training, at the clinic, training for 8 weeks. This is a strong indication of the system's feasibility in a controlled environment, since no dropouts occurred, and the outcome is that the system can be handled successfully by a trained supervisor, so the system's desired functionality can be achieved. Regarding the home-based HOLOBALANCE system, the results obtained showed that in Freiburg, in round one, 3 out of 5 patients completed successfully the 8-week program, while the other two dropped out in the first day of system usage, because of personal health issues and having difficulty in handling the technology. On the other hand, round one in Athens finished in the most successful way possible, with the 5 patients being actively engaged with the system and most of them participating in sessions daily. Round two in Freiburg was also concluded in positive results, having 4 out of 5 users practicing daily, while the other one abandoned participation in the program, having completed 3 weeks of training and in total 6 sessions. In total we have 3 out of 25 dropouts (12%), all at home environments. Also no adverse and serious adverse events were reported during the study and no deviations from the clinical protocol were implemented.

As far as the Qualitative interview is concerned, data are gathered from 15 participants so far, 10 from Freiburg (holobox and home-based system) and 5 from Athens (holobox system). The participants recruited for using the home based version with the HMD, were more enthusiastic in their enrolment in the study and showed a more positive attitude regarding the whole experience as well as the benefits in their balance. Participants' feedback for the games was pretty much neutral for both interfaces even though their benefits were rated as positive. Participants were also positive towards the hardware used. HMD was associated with more negative sentiments regarding troubleshooting and frustration caused by tasks, however any occurring issue has been resolved and the system has been improved. The Holobox users had some positive proposals for additions in the system while HMD users did not propose anything. Regarding changes, HMD users had more positive feedback. Finally, the results about proposing the system to friends were very similar, and reveal that the users would in general suggest the system to other end users. Qualitative interview was conducted with the first version of the system in use, so better results are expected with the second, as it is also confirmed by the rest feasibility metrics.

The Program Compliance (or system operability metric) and also the percentage of completed sessions, is depicted in Table I. In this table these two metrics are gathered for a more profound understanding of the current pilot outcome results. Taking into consideration the system operability, which shows the system's percentage of achieving flawless functionality, we can observe clearly, that while the system was being used in hospital environments (holobox), both in Freiburg and Athens, the system worked 100% percent of the times, with the handling of the physiotherapist and support when necessary from the technical team. This is again an important indicator of the system's feasibility in a controlled environment.

As far as the home-based HOLOBALANCE system is concerned, we can distinguish a variation in system operability in round one and two in Freiburg, Germany, and also between round one in Freiburg and Athens. This is due to the fact that round one in Freiburg was conducted first, with the first version of the HOLOBALANCE system, and then round one in Athens and round two in Freiburg took place, with the improved system, which addressed issues gathered from user feedback, and improved user adherence.

The outcome clearly shows the improvements that came with the second version, and strengthens the practicability of the system on home environments too, that is the most important outcome of the study so far - individual users being able to handle the system on their own with no technical help. In addition, we can conclude at the same results observing the percentages of completed sessions, both in Freiburg and Athens. While in Freiburg's round one clinic and home trainings, we see that the percentages of completed sessions of the trainings are scattered through all five intervals, round two and also round one in Athens, seems to have accomplished more completed sessions, since the last two intervals (75-99%, 100%) are containing most of the training sessions. This can be clearly noticed, in round one Athens home pilot. Lastly, we can also notice that most of the trainings that took place are completed or near completed and this conclusion comes to complement the result taken from the system operability metric, that the system is technically feasible for using both in hospital and home environments.

V. CONCLUSION - FUTURE WORK

In this paper, an overview and the preliminary results of the HOLOBALANCE clinical trial were presented. The outcome indicates that hologram guided balance rehabilitation is feasible both at home and the clinic, with the HOLOBALANCE system, since the Primary Outcome Measures are all satisfied as described in the results section. Feasibility and acceptability will be further confirmed with the recruitment and inclusion of more patients in the study. In total, up to 55 more consenting subjects are expected to be recruited in Athens, Freiburg and London.

ACKNOWLEDGMENT

This work has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No [769574].

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