

An integrated VR-based tele-rehabilitation platform to support RECOVERY and maintenance of FUNctional abilities among seniors: A usability and acceptability study protocol

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Abstract

The aging of the population leads to an increase in disability implying a strong effect on health care systems and the lives of caregivers. As example, stroke is a major cause of very common disease and is one of the leading causes of disability in older adults. Rehabilitation is the most effective intervention to counteract patient disability and at the same time reduce the burden of caregivers. In particular, repetitive and task-specific training seems to be the most effective intervention in post-stroke rehabilitation. Virtual reality (VR) is a very useful tool to provide this type of intervention making it fun through gamification. This paper aimed to present the protocol that will be used to evaluate the acceptability and usability of an upper limb rehabilitation solution based on VR. In fact, the RecoveryFun tele-rehabilitation system consists of a VR headset, a wearable sensor, a caregiver application and a clinical platform. A total of 15 patients fulfilling the inclusion and exclusion criteria will be recruited in 3 recruitment centres, 5 from each site. The system will be given to patients and they will be free to use it when they prefer at their home, with or without caregiver help, following the clinical session set by the physiotherapist. At least 20 minutes of use per week is requested. The physical therapist will be able to remotely monitor the progress of the therapy and increase the difficulty and repetitions of the exergames, also considering patient's fatigue and stress levels. The system will be held by the patients for 4 weeks, and there will be several meetings and phone call supervision by the therapist. The main dimensions investigated will be system usability and acceptability. Upper limb function and patient's quality of life as well as caregiver's perceived stress will also be assessed as secondary outcomes. The trial will start in May 2024 and end in June 2024. The aim of the study is to propose and evaluate a new telemedicine system that would allow greater adherence to therapy without moving from home, reducing the burden on the caregiver. The system could also be used in rehabilitation centres by complementing traditional rehabilitation. Finally, with the calibration system enabling the therapist to create customized clinical sessions for the patient, the system could be versatile and fun for a wide range of patients.

The study was approved by the Ethics Committee of the IRCCS INRCA. It was recorded in ClinicalTrials.gov on the number NCT06640452. The study findings will be used for publication in peer-reviewed scientific journals and presentations in scientific meetings.

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Abstract

Background: The aging of the population leads to an increase in disability implying a strong effect on health care systems and the lives of caregivers. As example, stroke is a major cause of very common disease and is one of the leading causes of disability in older adults. Rehabilitation is the most effective intervention to counteract patient disability and at the same time reduce the burden of caregivers. In particular, repetitive and task-specific training seems to be the most effective intervention in post-stroke rehabilitation. Virtual reality (VR) is a very useful tool to provide this type of intervention making it fun through gamification.

Objective: This paper aimed to present the protocol that will be used to evaluate the acceptability and usability of an upper limb rehabilitation solution based on VR. In fact, the RecoveryFun tele-rehabilitation system consists of a VR headset, a wearable sensor, a caregiver application and a clinical platform.

Methods: A total of 15 patients fulfilling the inclusion and exclusion criteria will be recruited in 3 recruitment centres, 5 from each site. The system will be given to patients and they will be free to use it when they prefer at their home, with or without caregiver help, following the clinical session set by the physiotherapist. At least 20 minutes of use per week is requested. The physical therapist will be able to remotely monitor the progress of the therapy and increase the difficulty and repetitions of the exergames, also considering patient's fatigue and stress levels. The system will be held by the patients for 4 weeks, and there will be several meetings and phone call supervision by the therapist. The main dimensions investigated will be system usability and acceptability. Upper limb function and patient's quality of life as well as caregiver's perceived stress will also be assessed as secondary outcomes. The trial will start in May 2024 and end in June 2024.

Conclusions: The aim of the study is to propose and evaluate a new telemedicine system that would allow greater adherence to therapy without moving from home, reducing the burden on the caregiver. The system could also be used in rehabilitation centres by complementing traditional rehabilitation. Finally, with the calibration system enabling the therapist to create customized clinical sessions for the patient, the system could be versatile and fun for a wide range of patients

Trial Registration: The study was approved by the Ethics Committee of the IRCCS INRCA. It was recorded in ClinicalTrials.gov on the number NCT06640452. The study findings will be used for publication in peer-reviewed scientific journals and presentations in scientific meetings.

Keywords: older adult; tele-rehabilitation; virtual reality; upper limb; technology for elderly; digital health; e-health; innovation in healthcare

Introduction

Ageing is characterized by a progressive decline in physiological integrity, leading to an impaired functional ability and ultimately increased mortality [1]. The decline in physiological integrity with ageing is partially linked by an increased risk for chronic diseases, including e.g. cardiovascular diseases, diabetes, neurological diseases and cancer. Furthermore, patients with chronic diseases, such as multiple sclerosis, are also exposed to the decline in physiological integrity in ageing. Also, age-related musculoskeletal disorders like arthritis, osteoporosis or

frailty are associated with pain, mobility disorders, increased risk of falls and fractures, and impaired ability or even disability to perform activities of daily living [2].

Age-related diseases not only cause health loss and disability for individuals, they can also have a great impact on the life of the caregivers, increasing their stress due to an increased care burden [3]. Moreover, age-related diseases also represent a burden to healthcare systems and economies through loss of productivity and high healthcare costs [4][5][6]. Thus, ageing population is challenging healthcare systems by ensuring rehabilitation in the long term for patients [7].

In particular, the global prevalence of neurological diseases has risen sharply in recent years with the significant ageing of the global population [8]. Notably, stroke is the third leading cause for long-term disability in most countries and can result in paralysis, speech impairment, loss of memory and reasoning ability, coma or even death [9]. But also acquired brain injuries such as traumatic brain injury can lead to similar long-term disabilities like balance and motor impairments, as well as cognitive complaints related to memory and concentration, and chronic headache [10].

The most commonly reported impairment after suffering from stroke or acquired brain injury is the complete or partial loss of motor function in an Upper Extremity (UE), which can hinder the performance of activities of daily living (ADL) and significantly undermine the quality of life (QOL) of patients [9].

However, recent neuroplasticity studies indicate that highly repetitive and task-specific training may induce changes in the brain to regain motor function, and this response can be optimised if the task is challenging enough [11]. Hence, Virtual Reality (VR) Exergaming gained interest in rehabilitation, as it may be advantageous in comparison to conventional rehabilitation, since VR exergaming has the potential to better provide the key elements of neuroplasticity (i.e., feedback, repetition, intensity, and tasks specific training), which are helpful to speed up the recovery of motor function in UEs [12].

Moreover, growing evidence has revealed that VR exergaming can be used in the context of tele-rehabilitation, as VR exergaming offers the possibility to generate individualised, safe and multimodal simulations that have the potential to create a location-independent, effective rehabilitation environment [13]. The utilization of VR exergaming in a tele-rehabilitation context therefore allows patients to transfer a part of their rehabilitation services from the clinical setting to their home environment [14]. This brings the advantage of making rehabilitation programs more adaptable to patients' schedules, partially relieving therapists of their time-constrained schedules, reaching locally isolated areas where clinical facilities are not available, and saving costs (e.g. by reducing the number of travels to the rehabilitation clinic or home-visits) [15] [16].

However, although the advantages of such systems are well-known, there are currently almost no such systems on the market. Our aim was to develop such a VR tele-rehabilitation solution and to investigate the usability and acceptance of this VR system (prototype) by potential end

users (patients, caregivers, health professionals), focusing on practical functional testing of the system, the games and a so-called caregiver app.

Methods

The RecoveryFun system

The RecoveryFun system is represented by a series of integrated components, which will be deeply presented in this section.

The patient is provided with:

- A virtual reality (VR) headset with the exergames VR application, to perform his/her training session;
- A wearable sensor, which connects to the Network through a gateway, to monitor physical parameters during training sessions;
- A tablet, to have remote support by the clinical staff;
- A router, to provide the Internet connection.

The informal carer is able to monitor, support and motivate the patient activity by using the mobile carer app. He/she also has the possibility to use the tablet to visualize the VR environment in which the patient is playing.

The professionals (carer, therapist and management staff) rely on the clinical platform to manage the clinical session settings and to monitor the patient's data, with a dedicated decision support system (DSS) service.

RecoveryFun system architecture is represented in Figure 1.

VR Headset

The RecoveryFun exergames application developed for rehabilitation purposes is implemented on the PICO 4 VR headset (Fig. 2).

The device represented the latest version provided on the market by PICO at the time of system development. In addition to eye tracking, this VR headset is embedded with hand tracking functionality, which makes it easily usable by patients wearing bio-sensors during the training session.

Exergames

A set of Exergames is implemented in the RecoveryFun application for rehabilitation purposes. In particular, they are designed to improve and maintain upper limbs functionality and to stimulate cognitive exercise. They are developed with special attention to spatial anchoring of the patients, as a measure to increase acceptance and reduce risk of dizziness. For each exergame, the motion parameters are based on the measurements evaluated in the calibration phase performed during the first session with the physiotherapist. In particular, the dimensions investigated concern: the hand motricity, the space that can be explored by the upper limb and the reaction time.

The system includes seven different exergames:

- *Escape from Alpatraz* (Fig. 3), in which the patient has to grab the alpaca and drag it to the final line of the maze. The game stimulates eye motor coordination skills and offers a cognitive exercise in which the patient will have to perform forced movements to reach the target. Motor control and proprioception of the upper limb will be trained. This exercise improves the endurance of the muscles, leading the patient to keep the arm elevated throughout the length of the line. In addition, in the most difficult level of the game, the patient must be able to recognize the correct line.
- *Clapping hands* (Fig. 4), in which the person has to imitate the gesture he/she sees and then pushes the hand towards the image. The game stimulates the skills to reproduce the same gesture that the patient sees. All joints of the upper limb will be trained. This exercise can be useful also if the patient suffers from ideomotor apraxia.
- *Memory* (Fig. 5), in which the person has to find pairs of similar images. It stimulates the memory of the user. The patient has to move all the upper limbs. Since this exercise requires precise movements, patients suffering from dysmetria may benefit from it.
- *Whack a mole* (Fig. 6), in which the person has to hit moles with the hand and avoid the penguins. The game stimulates the reaction time of the patient, who would flex the shoulder and extend the elbow to reach the target. The patient has to be able to differentiate the penguins and moles in a short time.
- *Groceries* (Fig. 7), in which the person has to put into the shopping cart only the products on the shopping list. At the start of the game, a shopping list is shown and the person has to memorize it. The game trains some skills: spatial exploration (the patient has to move head to find all items) and memory. This exercise is repetitive and task oriented which provides an effective approach in case of stroke recovery [12].
- *Basket* (Fig. 8), in which the person has to close his/her hand in a fist to charge the power of the shot (loading bar). When the patient has loaded the bar fully, he/she has to open the hand to score. The game trains finger flexion and coordination
- *Table trouble* (Fig.9), in which the person has to throw specific objects into the water. The game stimulates the patient to move the arm on the all field of view and on all space plans. This exercise can be useful especially for patients suffering from associative agnosia.

Wearable sensor

A biosensing wireless sensor (wristband), shown in Figure 10, is integrated in the Internet of Things (IoT) connected ecosystem to measure physiological parameters (Photoplethysmography (PPG) and Galvanic Skin Response (GSR) data) of end users during the rehabilitation session. The collected data are then processed by an appropriate algorithm to derive measures of stress and fatigue for the clinicians.

Caregiver application

The informal carer has access (only) to the secured mobile caregiver app installed on his/her smartphone (Fig. 11). Its main goal is to give the possibility to the caregiver to motivate and support the end user in the therapy adherence.

No medical data is presented in the caregiver app. Moreover, motivational messages sent by the caregiver from this application are visible by the patient in the RecoveryFun VR application's home.

Using the app a carer has the possibility to:

- Monitor the training adherence of the patient;
- Send motivational messages to the patient, who will see them in the RecoveryFun VR application's home.
- Consult support material on the use of the system (explanatory videos and faq section) to help the patient in using the devices, acting as a 1st level assistance.

Clinical platform

The clinical personnel have access to the Clinical platform provided as a secured web app (Fig. 12). The system administrator can differentiate access rights to each clinical user group (e.g. doctors, physiotherapists, nurses).

In the Clinical Platform an authorized clinician can:

- Edit the clinical/administrative data of the assigned patients;
- Manage the VR devices and assign them to a specific patient;
- Associate the caregiver with the correspondent patient;
- Create rehabilitation plans for specific patients;
- Monitor the activity of the patients (i.e., observe the progress of the rehabilitation sessions executed, see the number and the duration of training sessions executed, evaluating compliance to the rehabilitation plan);
- Connect to a secured video channel to see the patient's activities in the VR environment.

Smart services

The platform in the future will also include the presence of smart services, actually under development. This component of the system aims at improving clinician's activity, allowing a further customization of the rehabilitation experience for the patient and providing a DSS for the clinical staff.

The field trial

The field trial will be conducted as a pre-post approach, with a group of patients receiving the system and data collection before and after the installation and use of the technical solution. The study will last 4 weeks, during which each participant will follow an individualized rehabilitation plan of at least two rehabilitation sessions ranging from a minimum of 10 minutes to a maximum of 30 minutes

per week. Each rehabilitation session will be planned and scheduled by the therapist remotely via the dedicated clinical platform. The physiotherapist, by monitoring performance and adherence data regarding previous sessions, will be able to create sessions customized to the patient by choosing the most useful level and exergames according to the rehabilitation goals. The patient will be able to perform more sessions at will if he/she wishes.

The field trial procedure will be divided into different phases, as described in Textbox 1:

Textbox 1. Field trial phases.

1. *Recruitment, baseline evaluation and education sessions*: This phase will involve the recruitment assessment to assure that the patient meets the inclusion and exclusion criteria, the baseline assessment with the patient and caregiver to collect data, and the execution of the education session. This session will aim to show the operation of the system and its proper use to the patient and caregiver. The number of education sessions will be then planned in relation to the degree of confidence of the patient and caregiver in using the system independently at home.
2. *System installation and use*: After the conclusion of the education sessions, the system will be installed at home and the patient will begin rehabilitation sessions, with the support of the informal caregiver. The physiotherapist will constantly monitor the treatment progress through the clinical platform available to him/her.
3. *Monitoring (at the end of each week)*: The clinician will call the patient weekly to ask how he/she is doing, how the sessions are going, whether there are any difficulties and/or technical problems. If the problem can not be solved remotely, a meeting will be scheduled at home or in the hospital.
4. *Final evaluation (after four weeks of use)*: The aim of this phase will be to assess the usability and acceptability of the system and detect any critical issues by the patient, to evaluate the perceived stress and usability of the system by the informal caregiver and, finally, to collect information on the impact and usability of the system according to the professional.

Recruitment

The population selected for the trial in the RecoveryFun project will concern a patient who has overcome an acute event and completed intensive inpatient rehabilitation. The patient we are referring to has already returned home and needs to maintain the goals achieved or increase functionality.

In order for the patient to be able to use the system properly (to date), specific physical/cognitive requirements are needed: the patient has to have good trunk control and be able to maintain a sitting position for at least 30 minutes without feeling fatigue; (s)he must have good upper limb function (gross and fine hand motor skills). Even if the work space of the games will be defined according to patient characteristics during the calibration phase, the shoulder range of movement must be wide enough to be able to reach the boundary of the minimum definable work space. Moreover, the patient

has to be able to transfer the load into the pelvis.

In addition, the patient should have a caregiver that, if necessary, can assist him or her during the game session (wearing, initiating and stimulating him/her).

There will be three centers of recruitment: IRCCS INRCA (Italy), TRAINM (Belgium) and ZURZACH Care (Switzerland). In each center will be recruited 5 patients with the caregiver. A total of 30 participants will take part in the trial, excluding the physiotherapists.

The following activities will be carried out during recruitment:

- Patient and caregiver information and informed consent;
- Verification of inclusion/exclusion criteria;
- Medical history;
- Objective examination;
- Administration of rating scales and collection of socio-demographic data of the patient and caregiver

Patient

Once the informed consent will be obtained in duplicate, the compliance with the criteria of inclusion and exclusion of the study will be verified and the baseline evaluation will be carried out with the questionnaires and clinical trials provided by the study design.

Patient inclusion criteria are:

- Age ≥ 60 years;
- No more than 12 months from acute event (e.g. stroke or brain injury);
- Trunk Impairment Scale (TIS) score ≥ 20 ;
- Fugl-Meyer Assessment (FMA) Upper Extremities:
Motor function for upper extremities (section A-D): a minimum Score of ≥ 33 is requested for the inclusion.
In addition to this general cut-off score, specific items were defined that a participant must fulfil in order to play the games and thus be included in the field trials. These are:
 - Section A.II. Volitional movement: value 1 or 2 for items: Shoulder elevation, abduction (90°) and external rotation; Elbow flexion and extension; Forearm pronation;
 - Section B. Wrist: value 1 or 2 for items stability at 15° dorsiflexion (elbow at 90° and at 0°);
 - Section C. Hand: value 1 or 2 for items C. pincer grasp, opposition and D. cylinder grasp;
 - Section D. Coordination/speed: 1 or 2 for item tremor;
 - Section H. Sensation, J. Passive joint motion and J. Joint pain will not be considered as these parameters don't have an influence on the participants capacity to participate in the intervention;
- Presence of a caregiver available to participate in the study.

Instead, patient exclusion criteria are the following:

- Participant is unable to give his/her informed written consent;
- Technical Requirements based on the safety manual of the PICO headset:
 - Ocular pathologies such as cataracts, glaucoma, and diabetic retinopathy;

- Binocular vision abnormalities;
- High degree of myopia, astigmatism or far-sightedness;
- Presence of corrective glasses not fitting below the VR headset;
- Allergy to plastic, PU or fabric;
- Pacemakers;
- Implanted defibrillators;
- Cochlear implants and other hearing aids;
- Participants who are not able to put on the VR goggles independently;
- Presence of pathology that could impact on the ability of using VR system or can be worsened by the use of VR system:
 - Epilepsy;
 - Migraine especially with aura and tension headache;
 - Vertigo or cyber-sickness;
 - Trigeminal neuralgia;
 - Pressure sensitivity and hyperalgesia in the face;
 - Psychotic disorders;
 - Severe cardiac or pulmonary conditions;
 - Open wounds, injuries to the head, skin infections and dermatological issues that won't allow the participant to wear the headset;
 - Tremor or Severe fatigue and exhaustion: the participant is unable to concentrate or stay awake/attentive enough for participating in the intervention for 20min;
 - Various phobias (e.g. Claustrophobia);
 - Visual neglect;
- Presence of cognitive impairment: Montreal Cognitive Assessment (MoCA) score <24 [24].

Outcomes

The field trials aim to assess the usability and acceptance of the RecoveryFun system and the adherence to therapy, as described in Textbox 5.

Textbox 5. Primary outcomes of the study.

1. Usability perceived by the patient through System Usability Scale (SUS) [17] and User Experience Questionnaire (UEQ) [18];
2. Usability perceived by the informal caregiver through SUS [17];
3. Acceptance perceived by the patient through Quebec User Evaluation of Satisfaction with Assistive Technology (QUEST) 2.0[19];

Then, the field trials also focus on the impact of the RecoveryFun system, as shown in Textbox 6.

Textbox 6. Secondary outcomes of the study.

1. Impact of the system on patient quality of life, measured with the World Health Organization Quality of Life Bref (WHOQOL-BREF) [20], and functional ability with the FMA [21];
2. Stress perceived by the caregiver through Perceived Stress Scale (PSS)[22] and an

ad-hoc questionnaire;

3. Patient interest to use and the attitude to pay using an ad hoc questionnaire;
4. Impact of the system on the caregiver to understand whether it is a helpful and supportive tool or causes additional difficulty through an ad hoc questionnaire.

For these reasons, the protocol includes study specific questions on demographics and attitudes to technology from both the patient and informal caregiver. In addition, questions related to subjective health and social support are also explored with the patient.

The tables below (Table 2 to Table 5) summarize the different tools adopted with each end-user group, in all the phases of the study:

Table 2. Tools and dimensions of the patient protocol.

Dimension	Tool	R	T0	T1
Functional ability	FMA [21]	X		X
Trunk stability	TIS [23]	X		
Cognitive status	MoCA[24]	X		
Socio-demographic characteristics; Subjective health assessment; Social support	Ad hoc questionnaire		X	
Attitude to technology	MPT-SOTU-C [25]		X	
Quality of life	WHOQOL-BREF [20]		X	X
Acceptance	QUEST 2.0 [19]			X
Usability	SUS [17]			X
Usability	UEQ [18]			X
Intention to pay	Ad hoc questionnaire			X

R= recruitment; T0= baseline; T1= final evaluation; FMA= Fugl-Meyer Assessment; TIS= Trunk Impairment Scale; MoCA= Montreal Cognitive Assessment; MPT-SOTU-C= Matching Person and Technology-Survey of Technology Use-Consumer; WHOQOL-BREF= World Health Organization Quality of Life Bref; QUEST 2.0= Quebec User Evaluation of Satisfaction with Assistive Technology; SUS= System Usability Scale; UEQ= User Experience Questionnaire.

Table 5. Tools and dimensions of the informal caregiver protocol.

Dimension	Tool	R	T0	T1
Socio-demographic characteristic	Ad-hoc questionnaire		X	
Attitude to technology	MPT-SOTU-C [25]		X	
Perceived stress	PSS [22]		X	X
Perceived stress	Ad-hoc questionnaire			X
Usability	SUS [17]			X
Impact of the system	Ad-hoc questionnaire			X

R= recruitment; T0= baseline; T1= final evaluation; MPT-SOTU-C= Matching Person and Technology-Survey of Technology Use-Consumer; PSS= Perceived Stress Scale; SUS= System Usability Scale.

Statistical Analysis

The first step of the data analysis will deal with the description of the sample. Continuous variables will be reported as either mean and standard deviation or median and interquartile range on the basis of their distribution (assessed using Kolmogorov-Smirnov test). Categorical variables will be expressed as an absolute number and percentage. The Trial comparison between pre- and post-conditions will be evaluated by paired t test (for normal distribution), Mann-Whitney U tests (for non-normal distribution), or Chi-Square tests (for categorical variables). Moreover, a linear regression model on the outcome variation between baseline and follow-up will be estimated in order to evaluate measure variation.

Discussion

In the face of an aging population we will inevitably see an increase in acute events in the coming years, which are among the leading causes of disability in Europe [26]. Moreover, we will see an increase in the population's demand for health care services [27]. This will result into an increased care burden on the part of families. Taking these facts into account, interventions are needed to be able to relieve families of these burdens and try to ensure the highest possible level of care even in the long term.

In this regard, the main treatment following cerebrovascular events is physiotherapy, which allows to pursue the hospitals' primary goal: regaining balance and standing in order to reduce the workload and ensure basic daily ADLs for the patient.

In particular, rehabilitation of the upper limb needs more time as the required movements are finer and more complex [27].

Within this framework, RecoveryFun project aims to offer an answer to these growing needs. RecoveryFun makes use of VR as it is now recognized to be effective and helpful during upper limb rehabilitation in the stroke patient [28]. In fact, the system is designed to provide personalized and fun upper limb tele-rehabilitation for patients. In addition, the professional, through his/her dedicated portal, can constantly remotely monitor the patient and stimulate him/her to perform the exercises, resulting in more efficient work.

All phases of the project were focused on the needs of the user and his or her caregiver in order for the system to be usable at home without the presence of the professional. Prior to the start of the experimentation, several tests were performed, during the co-creation phase, that helped to make a system as responsive as possible to the needs of the end user. These tests were performed with both potential patients and professionals in the field.

In fact, while some of the devices used were already on the market, such as the visor used Pico 4 Enterprise, the sensor on the other hand was a prototype model that was not yet marketable. The games, platform and dedicated caregiver application were developed for the project and were optimized for the goal. The calibration of the viewer, which then conditions the professional's choice of games, required special work by the technical partners as it was not initially planned but was requested by the clinical partners because they wanted to avoid as much as possible potential

frustration in use by the patient.

Pilot tests were also carried out prior to the start of the trial to test the system with the patient and collect any critical issues that the user might encounter.

The design of the study, described in this paper, allows the solution to be tested for a period of only one month, which is a sufficient period to evaluate the usability and acceptability of the system. In fact, the study includes a final evaluation in which both quantitative and qualitative instruments will be administered, in addition, during the month, weekly feedback will be collected via phone calls or messages.

The main challenges of this study are to investigate whether the patient, even with low familiarity with technology, will use the system consistently throughout the month-long trial and whether motivation will be created.

To make sure to provide the system to patients who are able to use it, the choice of inclusion criteria took much time and thought within the consortium. In fact, the use of immersive VR as tele-rehabilitation is completely innovative and, according to the state of the art, still has never been used. The main concern of the researchers was not to generate frustration in the patient so there were identified criteria that would lead to the selection of patients with good upper limb function, excellent trunk control and physiological or mild cognitive impairment.

Although the study was of usability, the consortium decided to redo the FMA and WHOQOL-BREF also at the end of the test to collect more data and see if there was a change in upper limb function and quality of life for patients. The choice was also made because of the evidence that debates of improved upper limb function in gross motor skills examined by FMA [29]. Similarly, caregivers were given the PSS again to assess any changes in perceived stress. This would be useful data for a potential future study on the effectiveness of the system.

In fact, the system has great potential for future development and could be of great help to rehabilitation centres, even during hospitalization to supplement traditional rehabilitation. This use in a “protected” environment could make patients feel more confident in using the system, thus motivating the patients to use the system even once they return home to receive motor and cognitive stimulation.

A limitation of the system is that the patients who can use it must have very specific requirements that significantly reduce the eligible population. However, the system, being extremely versatile, could also find developments in other areas and in the treatment of other diseases while maintaining the tele-rehabilitation mode.

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The project website is available on the internet [31].

Conflicts of Interest

None declared.

Abbreviations

NCT: National Clinical Trial

VR: Virtual Reality

UE: Upper Extremity

ADL: Activities of Daily Living

QOL: Quality of Life

DSS: Decision Support System

IoT: Internet of Things

PPG: Photoplethysmography

GSR: Galvanic Skin Response

TIS: Trunk Impairment Scale

FMA: Fugl-Meyer Assessment

MOCA: Montreal Cognitive Assessment

SUS: System Usability System

UEQ: User Experience Questionnaire

QUEST: Quebec User Evaluation of Satisfaction with Assistive Technology

WHOQOL-BREF: World Health Organization Quality Of Life Bref

PSS: Perceived Stress Scale

MPT-SOTU-C: Matching Person and Technology Survey of Technology

R: Recruitment

T0: Baseline

T1: Final evaluation

References

- 1) Cai, Y., Song, W., Li, J., Jing, Y., Liang, C., Zhang, L., Zhang, X., Zhang, W., Liu, B., An, Y., Li, J., Tang, B., Pei, S., Wu, X., Liu, Y., Zhuang, C. L., Ying, Y., Dou, X., Chen, Y., Xiao, F. H., ... Liu, G. H. (2022). The landscape of aging. *Science China. Life sciences*, 65(12), 2354–2454. <https://doi.org/10.1007/s11427-022-2161-3>
- 2) Minetto, M. A., Giannini, A., McConnell, R., Busso, C., Torre, G., & Massazza, G. (2020). Common Musculoskeletal Disorders in the Elderly: The Star Triad. *Journal of clinical*

- medicine*, 9(4), 1216. <https://doi.org/10.3390/jcm9041216>
- 3) Garlo, K., O'Leary, J. R., Van Ness, P. H., & Fried, T. R. (2010). Burden in caregivers of older adults with advanced illness. *Journal of the American Geriatrics Society*, 58(12), 2315–2322. <https://doi.org/10.1111/j.1532-5415.2010.03177.x>
 - 4) Akhtar, S., Mohanty, S. K., Singh, R. R., & Sen, S. (2022). Chronic diseases and productivity loss among middle-aged and elderly in India. *BMC public health*, 22(1), 2356. <https://doi.org/10.1186/s12889-022-14813-2>
 - 5) Atella, V., Piano Mortari, A., Kopinska, J., Belotti, F., Lapi, F., Cricelli, C., & Fontana, L. (2019). Trends in age-related disease burden and healthcare utilization. *Aging cell*, 18(1), e12861. <https://doi.org/10.1111/acer.12861>
 - 6) Blakely, T., Sigglekow, F., Irfan, M., Mizdrak, A., Dieleman, J., Bablani, L., Clarke, P., & Wilson, N. (2021). Disease-related income and economic productivity loss in New Zealand: A longitudinal analysis of linked individual-level data. *PLoS medicine*, 18(11), e1003848. <https://doi.org/10.1371/journal.pmed.1003848>
 - 7) World Health Organization [WHO]. (2015). *World report on ageing and health*. WHO Press.
 - 8) Dumurgier, J., & Tzourio, C. (2020). Epidemiology of neurological diseases in older adults. *Revue neurologique*, 176(9), 642–648. <https://doi.org/10.1016/j.neurol.2020.01.356>
 - 9) Huang, X., Naghdy, F., Naghdy, G., & Du, H. (2017). Clinical effectiveness of combined virtual reality and robot assisted fine hand motion rehabilitation in subacute stroke patients. *2017 International Conference on Rehabilitation Robotics (ICORR)*, 511–515. <https://doi.org/10.1109/ICORR.2017.8009299>
 - 10) Ruet, A., Bayen, E., Jourdan, C., Ghout, I., Meaude, L., Lalanne, A., Pradat-Diehl, P., Nelson, G., Charanton, J., Aegerter, P., Vallat-Azouvi, C., & Azouvi, P. (2019). A Detailed Overview of Long-Term Outcomes in Severe Traumatic Brain Injury Eight Years Post-injury. *Frontiers in neurology*, 10, 120. <https://doi.org/10.3389/fneur.2019.00120>
 - 11) Dimyan, M. A., & Cohen, L. G. (2011). Neuroplasticity in the context of motor rehabilitation after stroke. *Nature reviews. Neurology*, 7(2), 76–85. <https://doi.org/10.1038/nrneurol.2010.200>
 - 12) Laver, K. E., Lange, B., George, S., Deutsch, J. E., Saposnik, G., & Crotty, M. (2017). Virtual reality for stroke rehabilitation. *The Cochrane database of systematic reviews*, 11(11), CD008349. <https://doi.org/10.1002/14651858.CD008349.pub4>
 - 13) Mekbib, D. B., Debeli, D. K., Zhang, L., Fang, S., Shao, Y., Yang, W., Han, J., Jiang, H., Zhu, J., Zhao, Z., Cheng, R., Ye, X., Zhang, J., & Xu, D. (2021). A novel fully immersive virtual reality environment for upper extremity rehabilitation in patients with stroke. *Annals of the New York Academy of Sciences*, 1493(1), 75–89. <https://doi.org/10.1111/nyas.14554>
 - 14) Schröder, J., van Criekinge, T., Embrechts, E., Celis, X., Van Schuppen, J., Truijen, S., & Saeys, W. (2019). Combining the benefits of tele-rehabilitation and virtual reality-based balance

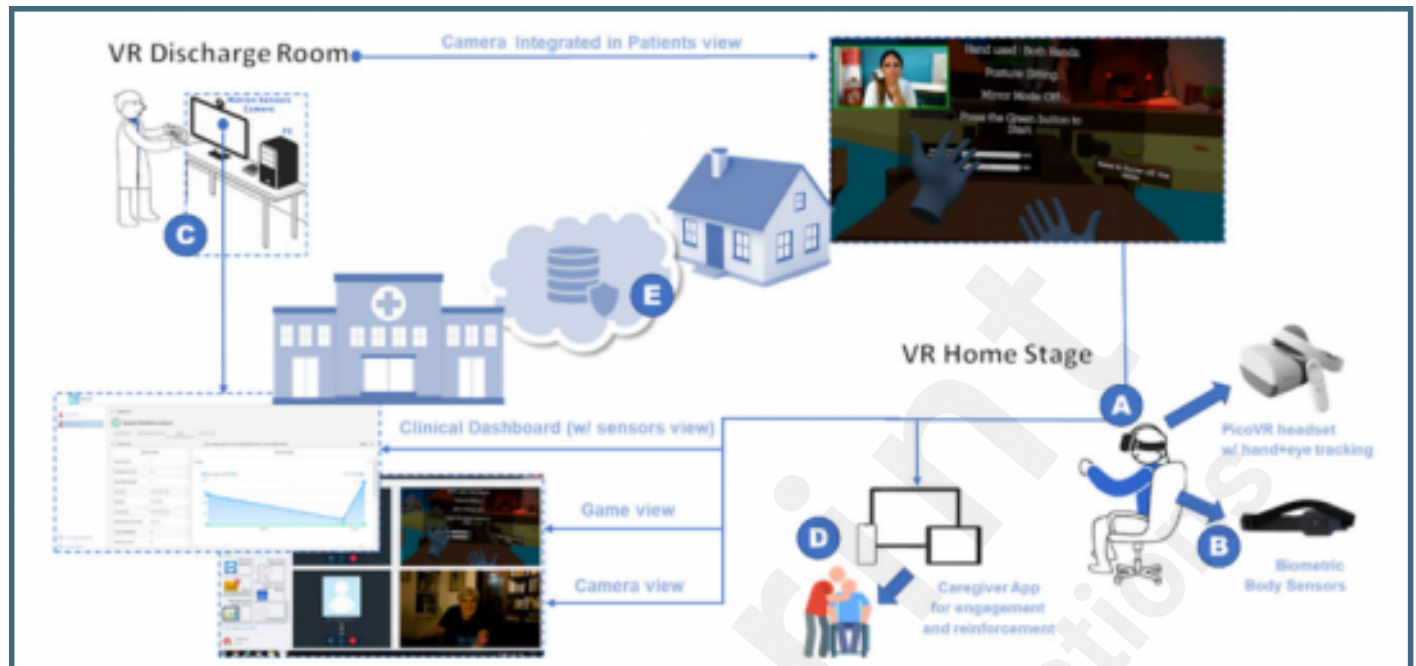
- training: a systematic review on feasibility and effectiveness. *Disability and Rehabilitation: Assistive Technology*, 14(1), 2–11. <https://doi.org/10.1080/17483107.2018.1503738>
- 15) Laver, K. E., Adey-Wakeling, Z., Crotty, M., Lannin, N. A., George, S., & Sherrington, C. (2020). Telerehabilitation services for stroke. *Cochrane Database of Systematic Reviews*, 2020(1). <https://doi.org/10.1002/14651858.CD010255.pub3>
 - 16) Lloréns, R., Noé, E., Colomer, C., & Alcañiz, M. (2015). Effectiveness, usability, and cost-benefit of a virtual reality-based telerehabilitation program for balance recovery after stroke: A randomized controlled trial. *Archives of Physical Medicine and Rehabilitation*, 96(3), 418-425.e2. <https://doi.org/10.1016/j.apmr.2014.10.019>
 - 17) Brooke, J. (1996). SUS: A quick and dirty usability scale. In P. W. Jordan, B. Thomas, B. A. Weerdmeester & I.L. McClelland (eds) *Usability Evaluation in Industry* (pp.189-194). Taylor and Francis.
 - 18) Laugwitz, B., Held, T., Schrepp, M. (2008). Construction and Evaluation of a User Experience Questionnaire. In: Holzinger, A. (eds) *HCI and Usability for Education and Work USAB 2008* (pp.63-77) . Lecture Notes in Computer Science, vol 5298. Springer.
 - 19) Demers L, Weiss-Lambrou R, Ska B. Item analysis of the Quebec User Evaluation of Satisfaction with Assistive Technology (QUEST). *Assist Technol.* 2000;12(2):96-105. doi:10.1080/10400435.2000.10132015
 - 20) World Health Organization. (1996). *WHOQOL-BREF: Introduction, administration, scoring and generic version of the assessment. Field trial version.* Programme on Mental Health WHO, Geneva.
 - 21) AR, Jääskö L, Leyman I, Olsson S, Steglind S. The post-stroke hemiplegic patient. 1. a method for evaluation of physical performance. *Scandinavian journal of rehabilitation medicine.* 1975;7(1):13-31.
 - 22) Cohen, S., Kamarck, T., and Mermelstein, R. (1983). A global measure of perceived stress. *Journal of Health and Social Behavior*, 24, 386-396. <https://doi.org/10.2307/2136404>
 - 23) Verheyden, G., Nieuwboer, A., Mertin, J., Preger, R., Kiekens, C., & De Weerd, W. (2004). The Trunk Impairment Scale: a new tool to measure motor impairment of the trunk after stroke. *Clinical rehabilitation*, 18(3), 326-334.
 - 24) Nasreddine, Z. S., Phillips, N. A., Bédirian, V., Charbonneau, S., Whitehead, V., Collin, I., et al. (2005). The Montreal Cognitive Assessment, MoCA: A Brief Screening Tool For Mild Cognitive Impairment. *Journal of the American Geriatrics Society*, 53(4), 695-699. <https://doi.org/10.1111/j.1532-5415.2005.53221.x>
 - 25) Scherer, M. J. (1998). *Matching Person & Technology (MPT) Model Manual and Accompanying Assessments*, Third Edition. Webster, NY: Institute for Matching Person & Technology, Inc. 1998
 - 26) Kwakkel G, Stinear C, Essers B, Munoz-Novoa M, Branscheidt M, Cabanas-Valdés R, Lakičević S, Lampropoulou S, Luft AR, Marque P, Moore SA, Solomon JM, Swinnen E, Turolla A, Alt Murphy M, Verheyden G. Motor rehabilitation after stroke: European Stroke Organisation

- (ESO) consensus-based definition and guiding framework. *Eur Stroke J*. 2023 Dec;8(4):880-894. doi: 10.1177/23969873231191304. Epub 2023 Aug 7. PMID: 37548025; PMCID: PMC10683740.
- 27) Wafa HA, Wolfe CDA, Emmett E, Roth GA, Johnson CO, Wang Y. Burden of Stroke in Europe: Thirty-Year Projections of Incidence, Prevalence, Deaths, and Disability-Adjusted Life Years. *Stroke*. 2020 Aug;51(8):2418-2427. doi: 10.1161/STROKEAHA.120.029606. Epub 2020 Jul 10. PMID: 32646325; PMCID: PMC7382540.
- 28) Wu J, Zeng A, Chen Z, Wei Y, Huang K, Chen J, Ren Z. Effects of Virtual Reality Training on Upper Limb Function and Balance in Stroke Patients: Systematic Review and Meta-Meta-Analysis. *J Med Internet Res*. 2021 Oct 12;23(10):e31051. doi: 10.2196/31051. PMID: 34636735; PMCID: PMC8548971.
- 29) Chen J, Or CK, Chen T. Effectiveness of Using Virtual Reality-Supported Exercise Therapy for Upper Extremity Motor Rehabilitation in Patients With Stroke: Systematic Review and Meta-analysis of Randomized Controlled Trials. *J Med Internet Res*. 2022 Jun 20;24(6):e24111. doi: 10.2196/24111. PMID: 35723907; PMCID: PMC9253973.
- 30) Ageing well in the digital world. Active Assisted Living Programme. URL: www.aal-europe.eu [accessed 2024-11-04]
- 31) RecoveryFun. Active Assisted Living Programme. URL: <https://recoveryfun.eu/> [accessed 2024-11-04]

Supplementary Files

Figures

RecoveryFun system architecture - A: VR Headset; B: Wearable sensor; C: Clinical platform; D: Caregiver App; E: Smart services.



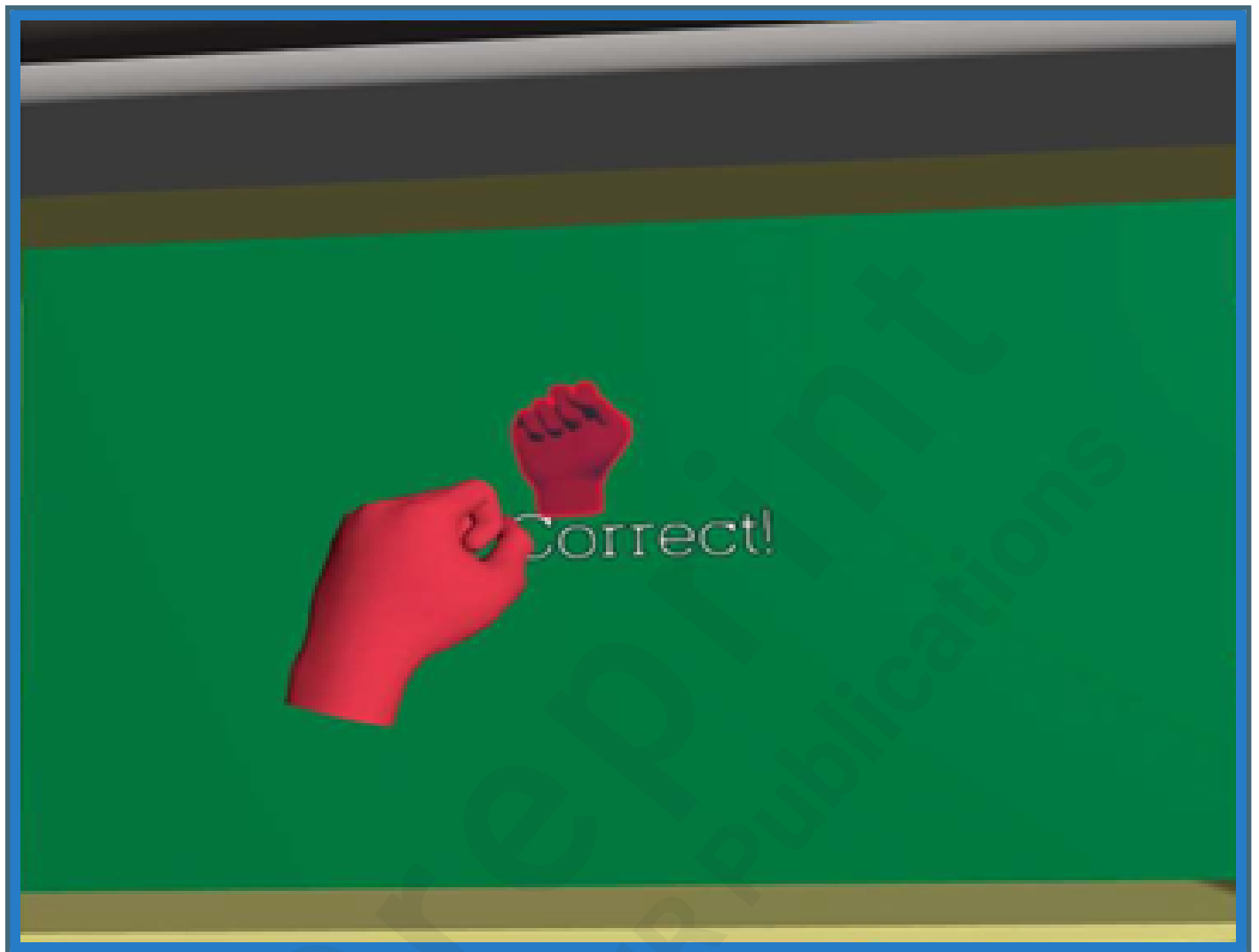
VR headset.



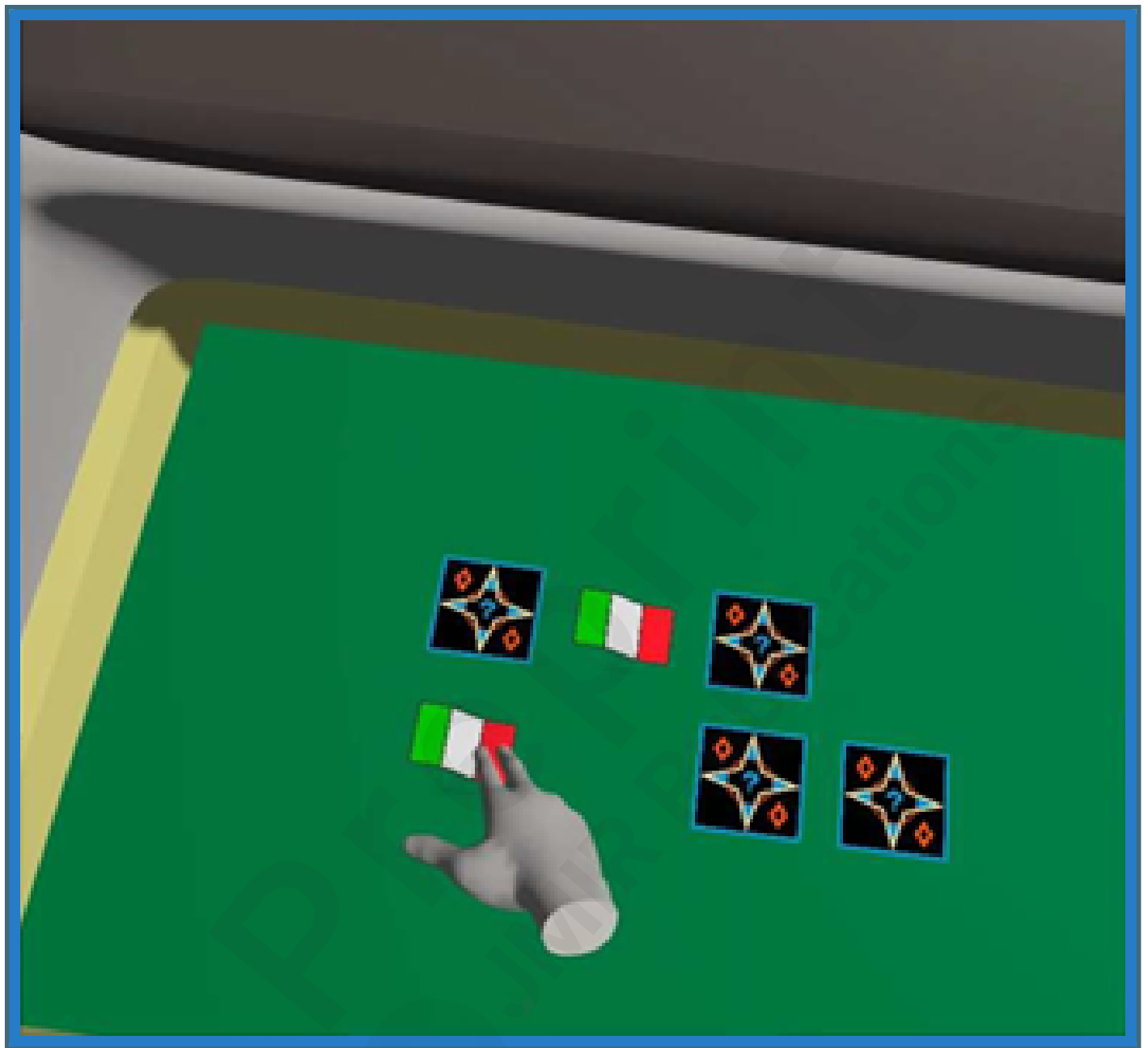
Escape from Alpatraz exergame.



Clapping hands exergame.



Memory exergame.



Whack a mole exergame.



Groceries exergame.



Basket exergame.



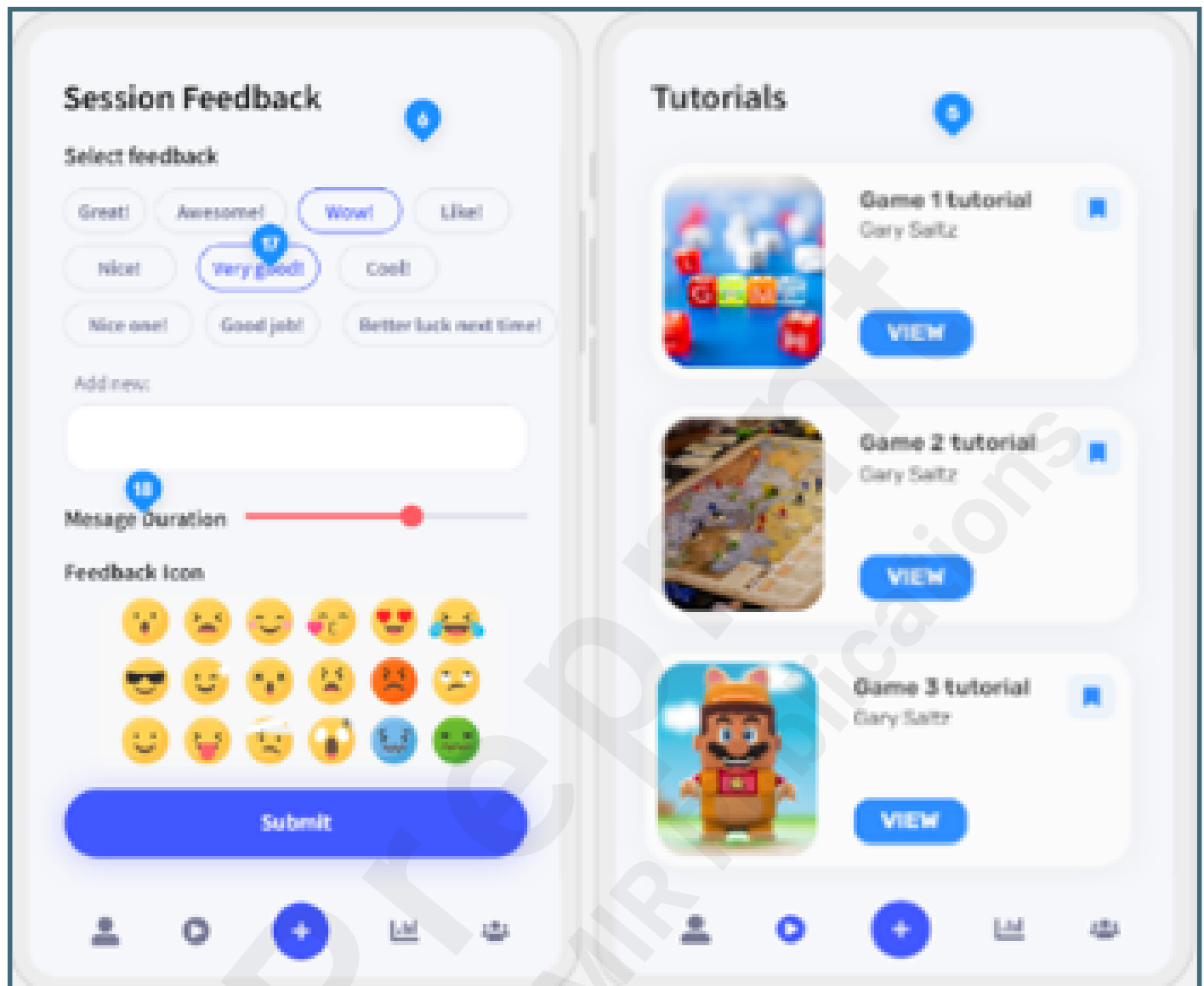
Table trouble exergame.



Wearable sensor.



Caregiver application screens.



Clinical platform screen.

The screenshot displays a clinical platform interface with three tabs: GENERAL INFO, EXERCISE LIST (active), and NOTES. Below the tabs, there are input fields for 'Name of the plan', 'Assessment Left' (a dropdown menu), 'Assessment Right' (a date/time picker showing 24/04/2024 12:08), and 'Maximum duration set at session level' (a numeric input set to 20 minutes). The interface is divided into two main sections: AVAILABLE EXERCISES and ASSIGNED EXERCISES.

AVAILABLE EXERCISES:

- Basket** (Basket game)
- Escape from Alpatraz** (Save the alpatraz)
- Clapping Hands** (Clap your hands)

ASSIGNED EXERCISES:

Exercise	Level	Skippable	Max duration	Affected limb	Action
Basket	Level 1	No	1 minutes	Right hand	[X]
Memory	Level 2	No	1 minutes	Right hand	[X]
Whack a Mole	Level 1	No	1 minutes	Right hand	[X]

At the bottom right, there are 'BACK' and 'PROCEED' buttons.