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Implementation of COGNIVITRA, an Information- and Communications-Technology-Based Solution for Dual-Task Training, in Patients at Risk of Cognitive Impairment

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Abstract: Mild cognitive impairment (MCI) is characterized by a modest decline in cognitive function that, while noticeable, does not severely impact daily life, allowing individuals to maintain their independence—a key factor distinguishing it from dementia. Currently, there are no treatments available that can modify the course of the disease, although cognitive and physical activities have shown potential in slowing its progression. In response to the need for more accessible cognitive care, COGNIVITRA, an information- and communications-technology-based solution, was developed to extend cognitive training into the home environment. This platform not only facilitates communication between patients and care providers but also holds promise for enhancing cognitive care accessibility and potentially influencing the economic aspects of healthcare institutions. To evaluate the usability, impact, and effectiveness of COGNIVITRA, a 12-week (6 mandatory + 6 voluntary) multicenter study was conducted, with an expected total sample size of 20 professionals, 90 patients and 20 caregivers and involving two settings (clinical and home settings) and the collection of various data types at baseline and after 6 or 12 weeks of training, including sociodemographic information, cognitive assessments, and usability metrics. These metrics included the System Usability Scale (SUS), the International Classification of Functioning-Based Usability Scales (ICF-US I and II), the Unified Theory of Acceptance and Use of Technology (UTAUT), health-related quality of life measures such as the EQ-5D-5L, cognitive domain assessments via the Montreal Cognitive Assessment (MoCA), and physical assessments such as the Timed 25-Foot Walk (T25-FW) test. The study included 22 patients, 2 caregivers, and 24 professionals. The usability evaluation revealed that patients, particularly those participating in the home study, showed improved SUS scores, suggesting an enhanced user experience with the platform. The ICF-US I results further supported this finding by indicating that COGNIVITRA was particularly effective as a supportive tool in terms of satisfaction and ease of learning. Despite a higher incidence of errors during the home study, the observational grid questionnaire demonstrated high success rates for task completion. Professionals involved in the study also reported high SUS scores and provided positive feedback regarding device usability. Overall, the participants expressed increased satisfaction with the platform, as reflected in their responses. The UTAUT analysis confirmed a generally positive attitude toward the use of COGNIVITRA. However,

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when assessing effectiveness, the analysis revealed a noninferiority positive trend in the EQ-5D-5L, T25-FW, and MoCA scores, indicating that while there were positive changes, they were not statistically significant.

Keywords: effectiveness; information and communications technology; mild cognitive impairment; rehabilitation telehealth; usability

1. Introduction

Mild cognitive impairment (MCI) is a mild neurocognitive disorder characterized by a subjective and objective decline from a previous level of functioning in one or more of the six cognitive domains that does not substantially interfere with the instrumental activities of daily living and does not occur in the context of delirium or other psychological disorders [1]. The key criteria that distinguish MCI from dementia are preservation of independence in functional abilities and lack of significant impairment in social or occupational functioning. In addition, MCI subtypes are sometimes defined on the basis of the presence or absence of memory difficulties and the number of affected cognitive domains [2]. The estimated prevalence of MCI ranges from 18.8% to 28.3% in people over 60 years of age, with people affected by this condition being at greater risk of developing dementia than the general population and with annual progression rates between 10% and 15% [3–5].

There are several risk factors that increase the probability of developing MCI. While age is the strongest risk factor, other well-established factors include male sex; the presence of the apolipoprotein E allele; a family history of cognitive impairment; and vascular risk factors such as hypertension, hyperlipidemia, coronary artery disease, stroke, and other chronic medical conditions, such as chronic obstructive pulmonary disease, depression, and diabetes mellitus [6–8]. Currently, there are no available disease-modifying therapies for MCI, although symptomatic and supportive treatments have proven to be valuable [9]. In fact, among the risk factors, sedentary behavior and low physical activity might play a role in the transition from MCI to dementia. Physical activity and exercise have been shown to improve not only global cognition but also several noncognitive outcomes, such as disability, falls, and neuropsychiatric symptoms, in participants affected by dementia [10,11].

In this context, COGNIVITRA is an information and communications technology (ICT)-based solution that targets people $\geq$50 years old at risk for cognitive impairment, at risk of worsening cognitive impairment or with MCI [12,13]. Its aim is to support cognitive vitality training at home, extending cognitive and physical stimulation programs performed in hospital or clinical environments to a community setting (e.g., home care center or patient home). It integrates both supporting cognitive and physical exercises (dual-task training) [14] through web-based tools and movement sensors, building a centralized platform that facilitates the interface and communication between patients and care providers. The objective of the present study was to determine the implementation of this dual-task training system and analyze its usability, the impact of its implementation strategy on the population's access to specialized cognitive care, and its economic impact.

2. Materials and Methods

COGNIVITRA is an application aimed at delaying cognitive decline through active engagement in mental, physical, and social activities. Its primary goal is to improve cognitive performance and physical well-being in individuals at risk of cognitive impairment. Unlike traditional programs that require commuting, COGNIVITRA eliminates the need for extensive travel, reducing the burden on both patients and caregivers. The application integrates cognitive and physical exercises, featuring a user-friendly interface with a virtual coach for a seamless user experience. Building on the success of the Cogweb project [15], COGNIVITRA includes more than 100 cognitive training exercises tested for usability across diverse age groups and disease models. Additionally, it introduces new content

for cognitive and proprioceptive stimulation, incorporating features such as automatic hit/miss rate detection and adaptive exercise difficulty. COGNIVITRA utilizes an interface and advanced natural interaction (IANI)-friendly interface, emphasizing embodied conversational agents, environment-based interaction modalities, and multimodal interaction strategies. Overall, it represents a comprehensive solution to enhance cognitive health and physical well-being in individuals vulnerable to cognitive decline [13].

2.1. Study Design

The inclusion criteria were people living independently; aged ≥50 years; being either at risk for cognitive impairment or worsening cognitive impairment or with MCI, which was measured with the Mini Mental State Examination (MMSE); and having both digital literacy and internet access. The exclusion criteria included taking drugs that could affect cognition within the previous three months; alcohol or substance abuse in the previous two years; and having any other condition that, in the opinion of the investigator, might have affected the study. All participants provided informed consent, the study was approved by the Ethics Committee of Fundació Sant Joan de Déu, and all procedures were performed in accordance with the Declaration of Helsinki and its later amendments.

The intervention plan took place through the deployment of a multicenter study with a total duration of 12 weeks (6 mandatory + 6 voluntary), with an expected total sample size of 20 professionals, 90 patients and 20 caregivers. The study consisted of the following two settings: a clinical setting and a home setting. While the clinical setting sessions included the activities conducted at the clinical institutions that were supervised by a therapist, the home sessions were individual sessions in which COGNIVITRA was used at home without supervision while doing the session (Figure 1). Within these studies, the usability and user experience (UX), workflow and impact, and overall effectiveness were evaluated. With respect to the usability and UX, the interaction between the users and the COGNIVITRA interface was analyzed, considering the parameters of the user interface, UX and overall usability of the system. In the case of the workflow and impact, tests of the utility and impact of the system in users' lives were carried out, focusing on the workflow of the professional when handling and supervising activities, as well as its impact on both patients and caregivers. Finally, overall effectiveness was used to analyze the global effectiveness of the COGNIVITRA program, which was centered on the impact of the use of the system at both the institutional and public health levels. The schedule is summarized in Table 1.

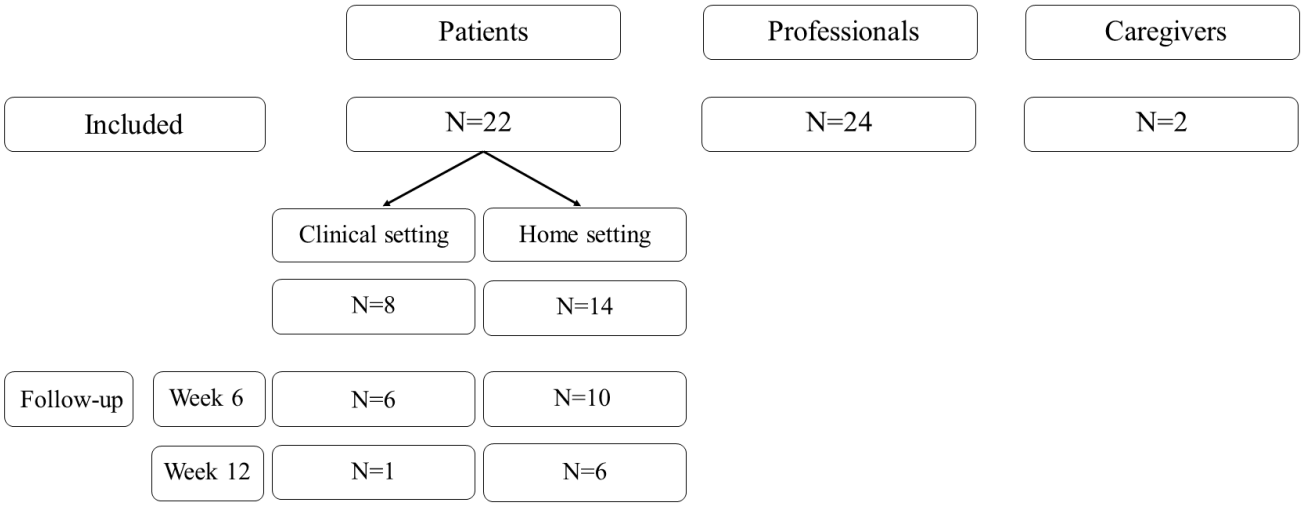

Figure 1. Study flowchart.

Table 1. Assessment schedule and the instruments used for evaluation.

Evaluation Phase/ Timeline	Participants	Instruments	Purpose
Baseline/First contact with COGNIVITRA	Patients	Informed consent, Study information sheet, Checklist of conditions for participation in home study, Sociodemographic questionnaire, Session script, MMSE, SUS, Overall satisfaction rating question, Weekly registration forms, MoCA, EQ-5D-5L, T25-FW, ICF-US I and II, Log files, Critical incident log sheet, and Observation grid	Collect baseline data on participants' demographics, initial usability impressions, and system interaction.
	Professionals	Informed consent, Study Information sheet, Sociodemographic questionnaire, Session script, Observation grid, Log files, and Critical incident log sheet	
Weeks 1–12/Every week throughout the study	Patients	Log files, and Weekly registration forms	Monitor continuous usage, track performance, and document any issues or patterns in system interaction.
Week 6/Midpoint of the study	Patients	SUS, Overall satisfaction rating question, MoCA, EQ-5D-5L, T25-FW, Log files, Critical incident log sheet, and Weekly registration forms	Evaluate mid-term usability, user satisfaction, and overall experience with the COGNIVITRA system.
Week 12/End of the study	Patients	Overall satisfaction rating question, MoCA, EQ-5D-5L, T25-FW, Log files	Assess final usability, user satisfaction, impact on cognitive function, physical health, and overall quality of life.
	Professionals	SUS, UTAUT, ICF-US I and II, Log files, Overall Satisfaction rating question	
	Patients, caregivers, and professionals	Focus Group	Gather qualitative feedback on the system's utility, its impact on daily activities, and any suggestions for improvement.

2.2. Study Variables and Data Collection

The main objective was the implementation of a system for a dual-task training program (COGNIVITRA). The secondary objectives included the assessment of the usability and UX of the system's features among the major subgroups of target users, the impact of its implementation strategy on the population's access to specialized cognitive care, and the economic impact at the institutional level.

The data collected included sociodemographic data from the participants. Regarding the usability and UX evaluation, a test with a session script was delivered to the user in which they had to perform the tasks described in it while their performance in the observation grid (number of errors, task execution time, and success/failure) and the occurrence of unforeseen events in the critical incident log sheet performance were recorded. In addition, the System Usability Scale (SUS), the International Classification of Functionality-based Usability Scale (ICF-US), and the Unified Theory of Acceptance and Use of Technology (UTAUT) were used to measure intention of use after the test was performed. Finally, user satisfaction was recorded through general satisfaction assessment questions. In the case of the workflow and impact, patients were asked about topics such as the utility of the COGNIVITRA system, impact on both patients and caregivers, and functionalities that could be changed or enhanced. In terms of the overall effectiveness, instruments such as the EQ-5D-5L questionnaire for the assessment of patients' quality of life, the Timed 25-Foot Walk (T25-FW), and a dual-task activity consisting of the repetition of the T25-FW counting backward from 100, and the Montreal Cognitive Assessment Scale (MoCA) were used. Data were gathered at baseline and after 6 and 12 weeks from the start of the trial, although in the latter case, only the overall satisfaction questionnaire was assessed.

The SUS is a generic usability rating scale that consists of a 10-item questionnaire scored on a 5-point Likert scale, with the final score ranging from 0 to 100, where higher values indicate better usability. While scores of $\geq$68 are considered above average, values under that value are considered below average [16]. The ICF-US is a usability assessment scale that is based on the opinion of the observer and consists of two subscales. The first subscale, the ICF-US I, allows for a comprehensive usability assessment, whereas the second subscale, the ICF-US II, allows for the classification of the application components as barriers and facilitators, identifying the application's strengths and weaknesses. The ICF-US I scores all items from -3 to 3, representing the most and least positive answers, respectively. The score ranges between -30 and 30, and whenever a user scores below 10, there is room for improvement, and the ICF-US II should be applied. The ICF-US II scale is composed of items that identify different application components (e.g., menu navigation, image, or interaction), consisting of three parts (i.e., application components, detailed usability, and overall assessment) that are classified as either barriers or facilitators. Whenever a component is classified as a barrier, the evaluator must identify the characteristic that is causing the component to be classified as a barrier, allowing the identification of which items require more work to improve the application [17,18]. The UTAUT, whose values range from 1 to 7, was only applied to the professional's group and is a technology acceptance model formulated from the conceptual and empirical integration of eight previously developed models. This model assesses the intention to use and effective use of technological solutions, enabling the identification of key aspects to improve the solution to increase exploitation by potential users. It consists of a set of items that are scored on a 7-point Likert scale, with a value of 1 corresponding to "strongly disagree" and a value of 7 corresponding to "strongly agree" [19]. The EQ-5D-5L is a questionnaire for the assessment of patients' quality of life, consisting of a descriptive system (EQ-5D) and a visual analog scale (EQ-VAS). The first part, the EQ-5D, comprises five dimensions (mobility, self-care, usual activities, pain/discomfort and anxiety/depression), with each one having five levels (no problems, slight problems, moderate problems, severe problems and extreme problems). The score for each item ranges from 1 to 5, in which 1 represents "no problems" and 5 represents "extreme problems", whereas the "index value" ranges from 0 to 1 [20]. The second part, the EQ-VAS, measures health outcomes according to

the patient's own judgment on a vertical VAS, where the endpoints range from "The best health you can imagine" to "the worst health you can imagine", with scores ranging from 0 to 100. The T25-FW is the most commonly used standalone measure of physical activity and is based on a timed 25-foot walk, measuring the time needed to complete the task. The patient is instructed to walk as fast and as safely as possible across a clearly marked, linear 25-foot course, with the task immediately administered again by having the patient walk the same distance while counting backward from 100. The T25-FW score is the average (in seconds) of the two successive trials [21]. Finally, the MoCA is a brief screening tool for mild cognitive impairment that assesses different cognitive domains (executive function; visuospatial capacity; memory; attention and concentration; working memory; language; and both temporal and spatial orientation), and its score varies between zero and 30 [22].

2.3. Statistical Analysis

While continuous variables are represented as the means and standard deviations (SDs), categorical variables are depicted as percentages. Either a chi-square test or Fisher test was used to compare the categorical variables between groups, and the Student's *t* test for independent samples or the Mann-Whitney U test was used to compare the continuous variables between groups. Changes in week 6 from baseline were analyzed according to the group via paired samples t tests or Wilcoxon tests if applicable. Statistical significance was established at $p \leq 0.05$, and statistical analyses were performed with SAS 9.4 software.

3. Results

A total of 22 patients, 2 caregivers, and 24 professionals were included in the trial. The baseline characteristics are summarized in Table 2.

Table 2. Baseline characteristics of the patients.

	Overall (n = 22)	Home Study (n = 14)	Clinical Setting Study (n = 8)
Patients			
Age, mean years (SD)	63.4 (10.2)	63.4 (9.9)	63.4 (11.4)
Digital literacy, n (%)			
Use of internet	17 (77.3)	12 (85.7)	5 (62.5)
Computer	14 (63.6)	10 (71.4)	4 (50.0)
Smartphone	21 (95.5)	14 (100.0)	7 (87.5)
Tablet	7 (31.8)	4 (28.6)	3 (37.5)
TV	19 (86.4)	13 (92.9)	6 (75.0)
Education, mean years completed (SD)	11.8 (4.0)	12.0 (4.0)	11.4 (4.3)
Retired, n (%)	10 (45.5)	6 (42.9)	4 (50.0)
Retirement age, mean years (SD)	56.7 (14.0)	60.9 (6.4)	49.5 (21.4)
MMSE, mean score (SD)	28.6 (1.4)	29.1 (1.1)	27.9 (1.5)
EQ-5D-5L, mean score (SD)			
Mobility	1.7 (0.8)	1.4 (0.7)	2.0 (0.9)
Self-care	1.2 (0.6)	1.2 (0.6)	1.3 (0.7)
Usual activities	1.3 (0.6)	1.3 (0.6)	1.3 (0.7)
Pain/discomfort	2.0 (0.9)	1.9 (0.9)	2.1 (0.8)
Anxiety/depression	1.8 (0.9)	1.9 (0.9)	1.6 (0.7)
General health (VAS scale)	68.6 (17.5)	71.1 (15.5)	64.4 (21.1)
Index value	0.8 (0.2)	0.8 (0.2)	0.8 (0.1)

Table 2. *Cont.*

	Overall (n = 22)	Home Study (n = 14)	Clinical Setting Study (n = 8)
Timed 25-Foot Walk, mean seconds (SD)			
One task	6.5 (2.2)	7.1 (2.7)	5.8 (1.3)
Two tasks	7.7 (3.2)	6.7 (1.8)	8.6 (4.0)
MoCA, mean score (SD)	24.1 (3.2)	25.0 (2.9)	23.1 (3.4)

Note: MMSE: Mini Mental State Examination; MoCA: Montreal Cognitive Assessment Scale; SD: standard deviation.

3.1. Usability and User Experience Evaluation

In terms of usability, overall, higher SUS scores, which ranged from 0 to 100, were obtained among patients after 6 weeks compared to those at baseline, although the differences were not statistically significant (66.1 ± 12.2 vs. 72.3 ± 17.2, $p = 0.061$). However, these changes were different between the participants in the home study and clinical setting study. While significantly greater values were obtained in the former at 6 weeks than at baseline (65.0 ± 14.9 vs. 79.0 ± 10.9, $p = 0.001$), nonsignificant differences were reported in the clinical setting study participants (67.9 ± 6.6 vs. 61.3 ± 20.8, $p = 0.545$). Overall, after 6 weeks, higher values were reported for items such as ease of use of COGNIVITRA (2.9 ± 1.5 vs. 3.9 ± 1.0) and confidence in using the device (3.6 ± 1.2 vs. 4.0 ± 1.2), although significant differences were only obtained for the ease of use in the overall study ($p = 0.041$) and home study ($p = 0.004$) but not in the clinical setting study ($p = 0.611$). On the other hand, overall values regarding difficulties in using COGNIVITRA, such as its complexity (2.4 ± 1.3 vs. 2.2 ± 1.3) or needing assistance (2.6 ± 1.5 vs. 2.0 ± 1.3) and the need to learn lots of things before using it (2.3 ± 1.1 vs. 1.7 ± 0.9), were lower (which means less difficulties using COGNIVITRA) after the 6-week period (Table 3). In the case of healthcare professionals, an overall SUS score of 68.9 ± 12.2 was obtained, with these participants indicating the likelihood of frequent use of the device (4.1 ± 0.8), noting its ease of use (3.7 ± 1.3), ease of quickly learning how to use the tool, and confidence while using the product (3.6 ± 1.1 for both; Table 4).

For the ICF-US-I, in which the overall values ranged from −30 to 30, an overall score of 15.5 ± 9.3 was obtained among all patients (Table 5). The items, which ranged from −3 to 3, concerning satisfaction with the use of the tool (1.9 ± 0.8), ease of learning how to use it (1.8 ± 1.1), how the application responded to the user's actions (1.8 ± 1.1), and overall satisfaction (1.8 ± 1.2), showed higher mean values. Overall, the ICF-US I scores were similar between participants from the home study and those from the clinical setting study (15.5 ± 7.3 vs. 15.4 ± 12.8), although some differences were observed among the items for which higher scores were obtained. In the home study, achieving the expected results (2.0 ± 1.2), overall satisfaction (1.9 ± 0.7), and the application's responsiveness (1.8 ± 1.4) showed higher scores, whereas the participants in the clinical setting study primarily appreciated the application's use (2.3 ± 0.7), responsiveness (1.9 ± 0.6), and similarity in the operational mode of the different tasks (1.7 ± 1.3). Among healthcare providers, overall satisfaction (1.8 ± 0.8) and satisfaction with the use of the tool (1.7 ± 1.2) scored the highest, with an overall ICF-US I score of 13.4 ± 7.1 (Table 5). The ICF-US II was applied to three patients and five professionals.

Table 3. System Usability Scale (SUS) scores obtained from the patients.

	Overall (n = 16)		Home Study (n = 10)		Clinical Setting Study (n = 6)	
	Mean (SD)	***p***	**Mean (SD)**	***p***	**Mean (SD)**	***p***
I think that I would like to use this website frequently						
Baseline	4.1 (1.0)	0.494	4.0 (1.2)	0.716	4.2 (0.8)	0.289
Week 6	3.6 (1.2)		3.8 (1.1)		3.3 (1.4)	
I found this product unnecessarily complex						
Baseline	2.4 (1.3)	0.508	2.2 (1.3)	0.063	2.7 (1.2)	0.363
Week 6	2.2 (1.3)		1.7 (1.1)		3.0 (1.4)	
I thought this product was easy to use						
Baseline	2.9 (1.5)	0.041 *	2.2 (1.2)	0.004 *	4.0 (1.1)	0.611
Week 6	3.9 (1.0)		4.0 (0.9)		3.7 (1.0)	
I think that I would need assistance to be able to use this product						
Baseline	2.6 (1.5)	0.133	2.2 (1.5)	0.125	3.3 (1.5)	0.403
Week 6	2.0 (1.3)		1.8 (1.1)		2.3 (1.5)	
I found the various functions in this product were well integrated						
Baseline	4.3 (0.9)	0.391	4.4 (0.8)	1.000	4.2 (1.2)	0.203
Week 6	3.9 (1.3)		4.4 (0.7)		3.2 (1.8)	
I thought there was too much inconsistency in this product						
Baseline	2.4 (1.3)	0.828	2.9 (1.4)	0.125	1.5 (0.5)	0.224
Week 6	2.3 (1.3)		2.2 (1.4)		2.3 (1.2)	
I would imagine that most people could learn to use this product very quickly						
Baseline	3.4 (1.2)	0.388	3.3 (1.3)	0.138	3.5 (1.0)	0.771
Week 6	3.6 (1.1)		3.8 (1.1)		3.3 (1.0)	
I found this product very cumbersome/awkward to use						
Baseline	2.1 (1.3)	0.795	2.3 (1.6)	0.438	1.8 (0.4)	0.444
Week 6	2.0 (1.4)		1.7 (1.3)		2.5 (1.6)	
I felt very confident using this product						
Baseline	3.6 (1.2)	0.375	3.5 (1.4)	0.125	3.7 (1.0)	0.842
Week 6	4.0 (1.2)		4.3 (0.8)		3.5 (1.5)	
I needed to learn a lot of things before I could get going with this product						
Baseline	2.3 (1.1)	0.125	1.8 (0.6)	0.138	3.0 (1.4)	0.501
Week 6	1.7 (0.9)		1.3 (0.7)		2.3 (1.0)	
System Usability Scale total						
Baseline	66.1 (12.2)	0.061	65.0 (14.9)	0.001 *	67.9 (6.6)	0.545
Week 6	72.3 (17.2)		79.0 (10.9)		61.3 (20.8)	

Note: Total values range from 0 to 100, with values for each item being scored on a 5-point Likert scale. The asterisk (*) indicates statistical significance ($p < 0.05$).

Table 4. System Usability Scale (SUS) scores obtained from the healthcare professionals.

	n	Mean (SD)
I think that I would like to use this website frequently	24	4.1 (0.8)
I found this product unnecessarily complex	24	2.4 (1.0)
I thought this product was easy to use	24	3.7 (1.3)
I think that I would need assistance to be able to use this product	24	2.5 (1.2)
I found the various functions in this product were well integrated	24	4.5 (0.7)
I thought there was too much inconsistency in this product	24	3.3 (1.1)
I would imagine that most people could learn to use this product very quickly	24	3.6 (1.1)
I found this product very cumbersome/awkward to use	23	1.8 (0.9)
I felt very confident using this product	24	3.6 (1.1)
I needed to learn a lot of things before I could get going with this product	24	2.6 (1.4)
System Usability Scale total	23	68.9 (12.2)

Total values range from 0 to 100, with values for each item being scored on a 5-point Likert scale.

Table 5. International Classification of Functioning-Based Usability Scale (ICF-US I) scores obtained from the patients and professionals.

	Patients			Professionals (n = 24)
	Overall (n = 22)	Home Study (n = 14)	Clinical Setting Study (n = 8)	
Ease of use	1.3 (1.2)	1.1 (1.4)	1.6 (0.7)	1.4 (1.2)
Satisfaction with its use	1.9 (0.8)	1.7 (0.8)	2.3 (0.7)	1.7 (1.2)
Learning ease	1.8 (1.1)	1.9 (0.5)	1.6 (1.8)	1.5 (0.9)
Achievement of expected results (e.g., wanted to write a text and did it)	1.7 (1.4)	2.0 (1.2)	1.3 (1.6)	1.5 (1.1)
Similarity in the operation mode in the different tasks (such the way to confirm an action always being the same)	1.6 (1.1)	1.5 (1.1)	1.7 (1.3)	0.8 (1.6)
Possibility of interacting in various ways (e.g., keyboard, touch, or voice)	0.7 (1.8)	0.7 (1.8)	0.6 (1.9)	1.4 (1.4)
Understanding of the messages presented (e.g., written or sound)	1.5 (1.4)	1.6 (1.1)	1.4 (2.0)	0.6 (1.6)
The application's responsiveness to your actions	1.8 (1.1)	1.8 (1.4)	1.9 (0.6)	1.5 (1.3)
Knowledge of what was happening in the application during use	1.5 (1.5)	1.5 (1.0)	1.5 (2.3)	1.6 (0.5)
Overall satisfaction	1.8 (1.2)	1.9 (0.7)	1.5 (1.7)	1.8 (0.8)
Total ICF-US I	15.5 (9.3)	15.5 (7.3)	15.4 (12.8)	13.4 (7.1)

Total ICF-US I values range from −30 to 30, with each item ranging from −3 to 3.

While analyzing the observational grid results from the patients, a success rate higher than 70% was achieved in all the tasks, with the task involving turning on the box obtaining the highest percentage of success (Task 1; 95.5%) (Figure 2A). Although the execution times varied among the different tasks, ranging from 17 s to 163 s (Figure 2B), overall, there were few errors, with no errors detected in some of the tasks (Figure 2C). The percentage of patients who needed help to perform the tasks ranged from 5 to 25% (Figure 2D). In the case of the healthcare professionals, the success rates were greater than 90% in all the included tasks (Figure 3A), with execution times ranging from 2 s for saving the data (Task 4) to almost 400 s for selecting the exercises to prescribe and the type of action required (Task 7) (Figure 3B). The task in which more errors were identified was the one involving opening

the "Add new patient" menu on the dashboard and creating a new patient profile (Task 3) (Figure 3C). Finally, professionals needed different degrees of help depending on the task while performing it (Figure 3D).

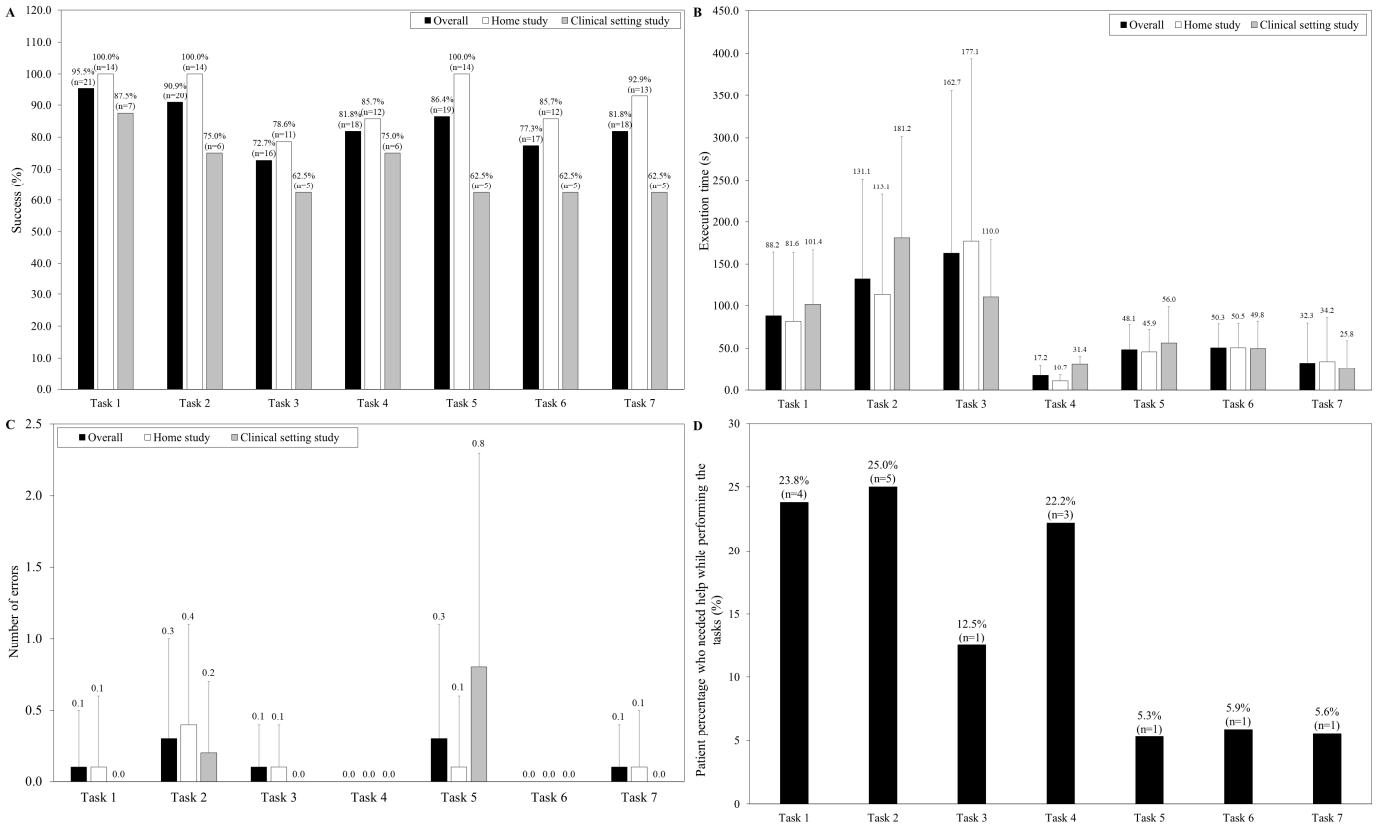

Figure 2. Patient observation grid results. The success percentages (**A**); execution times in seconds (**B**); number of errors (**C**); and percentage of patients who needed help (**D**) for each task are depicted. Task 1: connect CogniViTra (turn on the box using the power button); Task 2: log in as a patient using the following data; Task 3: Read the welcome notes and click start; Task 4: start the exercise session and perform the dual-task training session; Task 5: pause the game, read the instructions for the exercise again, then resume and continue the exercise; Task 6: once you finish the programed session, consult the results; Task 7: exit the session by clicking on "Exit".

Finally, regarding usability, a total of 8.1 ± 3.7 training weeks were performed, with higher values in the home setting than in the clinical setting (8.8 ± 4.2 vs. 6.9 ± 2.5 weeks). Notably, only the first six weeks were mandatory, with the following six weeks being optional. The percentage of completed weeks was 60.9 ± 23.4 (55.5 ± 19.6 and 70.23 ± 27.7 for the home study and clinical setting study, respectively), in which a total of 14.5 ± 11.9 total accesses were performed (17.4 ± 14.0 for the home study and 9.5 ± 4.4 for the clinical setting study, respectively), with four patients (18.2%) having accessed the application more than two times per week, all of whom were enrolled in the home study. Overall, a total of 296.6 ± 244.7 h of activity on the application were logged (318.3 ± 304.5 and 258.7 ± 70.0 h in the home study and clinical setting study, respectively), and 172.1 ± 126.1 exercises were performed (185.3 ± 155.1 in the home study vs. 148.9 ± 50.0 in the clinical setting study). The values for each of the exercise types are summarized in Table 6.

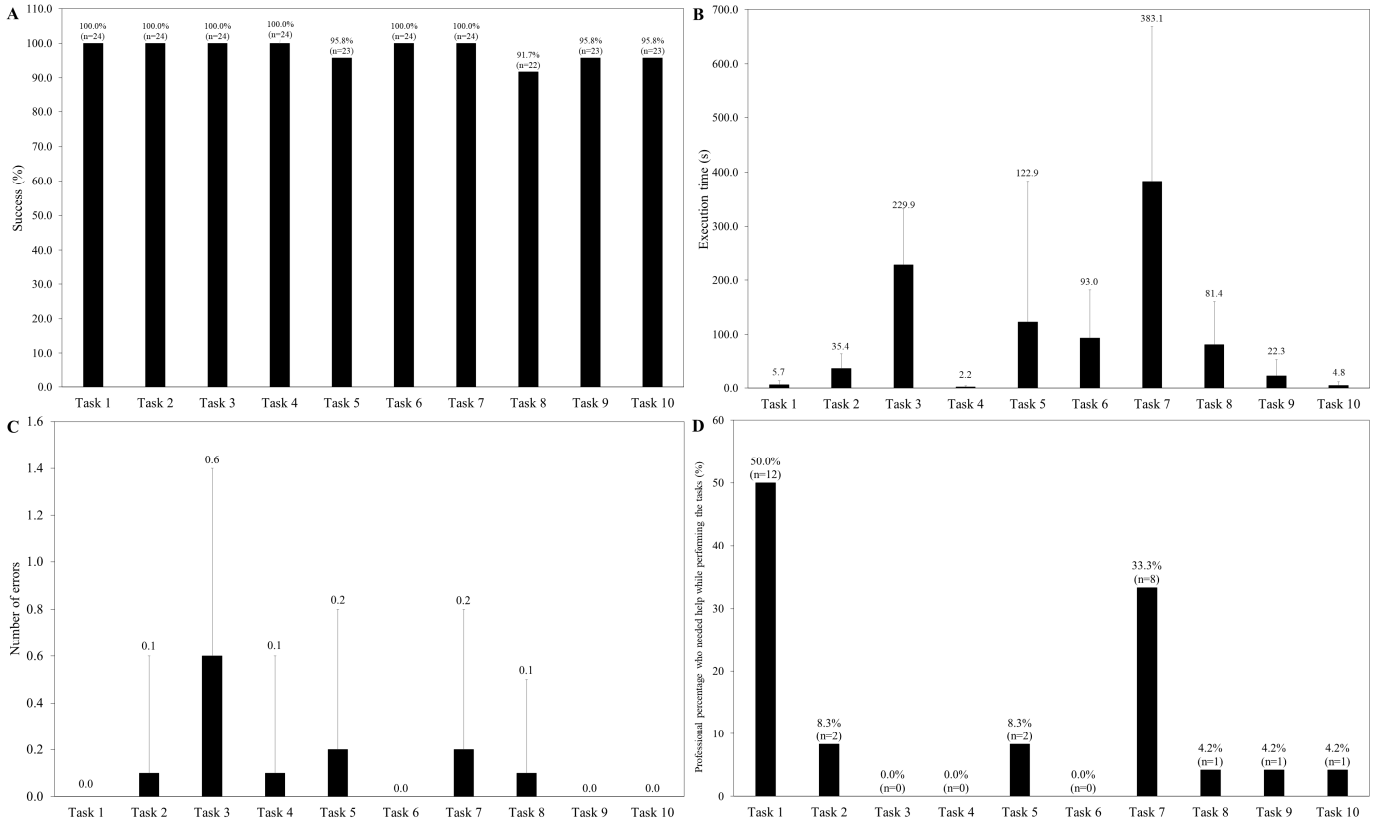

Figure 3. Professional observation grid results. The success percentages (**A**); execution times in seconds (**B**); number of errors (**C**); and percentage of professionals who needed help (**D**) for each task are depicted. Task 1: Access Cognivitra; Task 2: Log in as a professional; Task 3: On the dashboard, open the "Add new patient" menu and create a new patient; Task 4: Save the data; Task 5: On the dashboard, open the "schedule session" icon and select "add"; Task 6: Choose the "advanced" schedule type and select 2 days of training per week; Task 7: Select the exercises to prescribe and the type of action needed; Task 8: Set the starting level and duration of each exercise; Task 9: Check the structure of the scheduled sessions and save the data; Task 10: Exit the session by clicking on "Exit".

Table 6. Log files. All values are depicted as means and standard deviations.

	Overall (n = 22)	**Home Study (n = 14)**	**Clinical Setting Study (n = 8)**
General			
Training weeks, n (SD)	8.1 (3.7)	8.8 (4.2)	6.9 (2.5)
Percentage of completed weeks, % (SD)	60.9 (23.4)	55.5 (19.6)	70.23 (27.7)
Total accesses completed, n (SD)	14.5 (11.9)	17.4 (14.0)	9.5 (4.4)
Total accesses completed/week, n (SD)	1.7 (0.9)	1.9 (1.0)	1.4 (0.4)
Patients with more than 2 accesses/week, n (%)	4 (18.2)	4 (28.6)	0 (0.0)
Total time realized (min)	296.6 (244.7)	318.3 (304.5)	258.7 (70.0)
Time realized (min/week)	36.4 (18.4)	34.9 (22.4)	39.0 (8.6)
% patients with >40 min/week	7 (31.8)	5 (35.7)	2 (25.0)
Total games played, n (SD)	172.1 (126.7)	185.3 (155.1)	148.9 (50.0)
Total errors, n (SD)	32.9 (22.7)	33.7 (24.6)	31.50 (20.6)
Errors/min, n (SD)	0.1 (0.1)	0.1 (0.1)	0.1 (0.1)

Table 6. *Cont.*

	Overall (n = 22)	Home Study (n = 14)	Clinical Setting Study (n = 8)
By cognitive area and exercise (duringthe entirestudy)			
Attention			
Attention			
Time realized, min (SD)	66.5 (46.7)	71.8 (56.5)	57.1 (21.5)
Total games played, n (SD)	44.2 (27.0)	48.29 (33.2)	37.00 (7.7)
Total errors, n (SD)	5.7 (5.7)	5.9 (6.7)	5.5 (3.6)
Errors/min, n (SD)	0.4 (0.3)	0.3 (0.3)	0.5 (0.3)
Equal or different v1			
Time realized, min (SD)	11.4 (7.7)	11.0 (9.3)	12.3 (2.8)
Total games played, n (SD)	9.9 (5.6)	10.4 (6.6)	9.3 (3.8)
Total errors, n (SD)	0.5 (1.3)	0.0 (0.0)	1.3 (2.0)
Errors/min, n (SD)	0.0 (0.1)	0.0 (0.0)	0.1 (0.2)
Equal or different v2			
Time realized, min (SD)	16.9 (12.8)	16.7 (14.0)	17.4 (11.4)
Total games played, n (SD)	14.8 (6.9)	15.3 (7.8)	14.0 (5.6)
Total errors, n (SD)	1.4 (1.9)	1.2 (1.8)	1.9 (2.1)
Errors/min, n (SD)	0.1 (0.1)	0.1 (0.1)	0.1 (0.1)
Equal or different v3			
Time realized, min (SD)	15.8 (17.0)	16.9 (18.3)	14.1 (15.9)
Total games played, n (SD)	14.7 (7.9)	16.9 (9.5)	11.6 (3.9)
Total errors, n (SD)	1.7 (2.9)	2.4 (3.6)	0.6 (0.9)
Errors/min, n (SD)	0.1 (0.1)	0.1 (0.1)	0.0 (0.0)
Pages			
Time realized, min (SD)	17.3 (16.0)	22.0 (19.3)	10.2 (4.3)
Total games played, n (SD)	11.7 (8.4)	14.8 (9.5)	7.0 (3.1)
Total errors, n (SD)	2.2 (2.8)	2.3 (3.3)	1.9 (1.9)
Errors/min, n (SD)	0.2 (0.2)	0.1 (0.1)	0.2 (0.3)
Tiles			
Time realized, min (SD)	11.0 (12.7)	12.0 (13.9)	8.6 (10.1)
Total games played, n (SD)	7.2 (5.2)	7.5 (5.9)	6.3 (1.2)
Total errors, n (SD)	1.9 (2.4)	2.1 (2.7)	1.3 (0.6)
Errors/min, n (SD)	0.2 (0.3)	0.2 (0.4)	0.1 (0.0)
Calculations			
Calculous			
Time realized, min (SD)	56.8 (53.2)	58.7 (66.1)	53.6 (19.0)
Total games played, n (SD)	30.2 (24.8)	31.3 (29.3)	28.3 (15.6)
Total errors, n (SD)	6.2 (4.9)	6.1 (4.0)	6.3 (6.5)
Errors/min, n (SD)	0.5 (0.3)	0.5 (0.3)	0.5 (0.5)
Math			
Time realized, min (SD)	12.0 (12.9)	9.7 (13.2)	16.6 (11.9)
Total games played, n (SD)	10.8 (5.1)	10.0 (6.4)	12.0 (2.4)
Total errors, n (SD)	1.0 (1.5)	1.0 (1.4)	1.0 (1.7)
Errors/min, n (SD)	0.1 (0.2)	0.1 (0.3)	0.1 (0.1)

Table 6. *Cont.*

	Overall (n = 22)	Home Study (n = 14)	Clinical Setting Study (n = 8)
Compare the results			
Time realized, min (SD)	18.6 (20.3)	21.3 (24.4)	13.8 (9.3)
Total games played, n (SD)	9.6 (8.6)	11.2 (10.3)	6.7 (3.0)
Total errors, n (SD)	2.4 (2.5)	2.9 (2.5)	1.6 (2.6)
Errors/min, n (SD)	0.2 (0.2)	0.2 (0.2)	0.1 (0.2)
Complete the math			
Time realized, min (SD)	13.7 (11.0)	12.8 (12.5)	15.0 (9.1)
Total games played, n (SD)	8.2 (3.3)	8.0 (2.7)	8.4 (4.3)
Total errors, n (SD)	2.0 (3.0)	1.5 (2.8)	2.6 (3.4)
Errors/min, n (SD)	0.1 (0.1)	0.1 (0.1)	0.1 (0.2)
Complete the equation			
Time realized, min (SD)	13.5 (17.8)	17.1 (21.2)	7.6 (8.3)
Total games played, n (SD)	12.9 (9.5)	15.4 (10.8)	8.4 (4.6)
Total errors, n (SD)	2.8 (2.5)	3.0 (2.2)	2.4 (3.2)
Errors/min, n (SD)	0.2 (0.2)	0.2 (0.1)	0.2 (0.2)
Find out the result			
Time realized, min (SD)	8.2 (9.1)	6.4 (11.0)	11.4 (1.3)
Total games played, n (SD)	7.1 (5.1)	9.0 (7.7)	5.8 (2.6)
Total errors, n (SD)	1.5 (1.2)	1.5 (0.6)	1.5 (1.5)
Errors/min, n (SD)	0.1 (0.1)	0.1 (0.1)	0.1 (0.1)
Executivefunctioning			
Time realized, min (SD)	25.0 (17.4)	23.5 (19.7)	27.7 (13.1)
Total games played, n (SD)	18.7 (11.4)	17.9 (13.0)	20.0 (8.8)
Total errors, n (SD)	1.7 (2.3)	1.5 (2.1)	1.9 (2.7)
Errors/min, n (SD)	0.1 (0.1)	0.1 (0.1)	0.1 (0.1)
Executive functioning			
Logical mind			
Time realized, min (SD)	15.4 (14.2)	14.6 (14.7)	16.8 (14.3)
Total games played, n (SD)	12.5 (9.4)	11.8 (9.4)	13.7 (9.9)
Total errors, n (SD)	1.1 (1.6)	1.2 (1.9)	0.9 (1.1)
Errors/min, n (SD)	0.1 (0.1)	0.1 (0.1)	0.1 (0.1)
Match the color			
Time realized, min (SD)	10.1 (8.5)	8.9 (9.6)	12.5 (5.5)
Total games played, n (SD)	10.3 (4.6)	11.4 (4.5)	9.1 (4.8)
Total errors, n (SD)	1.0 (1.6)	0.8 (1.0)	1.3 (2.1)
Errors/min, n (SD)	0.1 (0.1)	0.1 (0.1)	0.1 (0.1)
Language			
Language			
Time realized, min (SD)	24.7 (20.6)	26.8 (25.2)	20.9 (8.2)
Total games played, n (SD)	20.5 (11.5)	23.6 (13.5)	15.3 (5.7)
Total errors, n (SD)	2.7 (2.2)	3.6 (2.5)	1.6 (1.1)
Errors/min, n (SD)	0.2 (0.1)	0.2 (0.1)	0.1 (0.1)

Table 6. *Cont.*

	Overall (n = 22)	Home Study (n = 14)	Clinical Setting Study (n = 8)
Antonyms			
Time realized, min (SD)	10.2 (10.2)	11.7 (12.3)	7.8 (5.6)
Total games played, n (SD)	10.9 (6.3)	12.2 (8.0)	9.0 (1.8)
Total errors, n (SD)	1.1 (1.9)	1.4 (2.4)	0.7 (1.0)
Errors/min, n (SD)	0.1 (0.1)	0.1 (0.2)	0.1 (0.1)
Commands			
Time realized, min (SD)	15.7 (12.4)	16.0 (15.1)	15.0 (4.7)
Total games played, n (SD)	12.1 (6.3)	13.6 (7.6)	9.7 (2.1)
Total errors, n (SD)	1.9 (2.0)	2.4 (2.5)	1.3 (1.0)
Errors/min, n (SD)	0.1 (0.1)	0.1 (0.1)	0.1 (0.1)
Memory			
Memory			
Time realized, min (SD)	97.4 (97.5)	107.5 (121.5)	79.8 (23.8)
Total games played, n (SD)	45.6 (45.3)	50.7 (55.9)	36.5 (14.8)
Total errors, n (SD)	12.1 (11.8)	12.5 (13.3)	11.5 (9.7)
Errors/min, n (SD)	0.8 (0.8)	0.7 (0.4)	1.0 (1.2)
Remember the words			
Time realized, min (SD)	10.2 (8.4)	9.7 (10.3)	11.1 (0.8)
Total games played, n (SD)	8.5 (3.7)	10.4 (3.7)	6.3 (2.3)
Total errors, n (SD)	0.8 (1.3)	0.7 (1.1)	0.8 (1.6)
Errors/min, n (SD)	0.1 (0.1)	0.0 (0.1)	0.1 (0.1)
Frames			
Time realized, min (SD)	9.1 (12.9)	7.7 (14.5)	12.0 (9.5)
Total games played, n (SD)	7.3 (4.2)	7.4 (5.2)	7.2 (3.7)
Total errors, n (SD)	0.7 (1.6)	0.2 (0.5)	1.2 (2.2)
Errors/min, n (SD)	0.2 (0.6)	0.1 (0.2)	0.4 (0.8)
Colored letters			
Time realized, min (SD)	11.6 (16.8)	13.4 (20.8)	8.6 (5.6)
Total games played, n (SD)	7.9 (9.0)	9.9 (11.8)	5.3 (1.4)
Total errors, n (SD)	3.1 (2.3)	4.4 (2.1)	1.3 (1.0)
Errors/min, n (SD)	0.2 (0.2)	0.3 (0.3)	0.1 (0.1)
Colored squares			
Time realized, min (SD)	18.2 (21.2)	19.5 (26.4)	16.3 (10.9)
Total games played, n (SD)	9.6 (8.6)	10.9 (10.8)	7.7 (4.1)
Total errors, n (SD)	2.8 (3.0)	2.9 (3.1)	2.7 (3.2)
Errors/min, n (SD)	0.2 (0.3)	0.2 (0.4)	0.1 (0.2)
Canvas			
Time realized, min (SD)	19.1 (21.4)	25.4 (24.6)	9.7 (11.3)
Total games played, n (SD)	13.2 (13.0)	16.4 (14.9)	6.8 (3.7)
Total errors, n (SD)	2.3 (2.2)	2.1 (1.8)	2.8 (3.0)
Errors/min, n (SD)	0.2 (0.3)	0.1 (0.1)	0.4 (0.6)

Table 6. *Cont.*

	Overall (n = 22)	Home Study (n = 14)	Clinical Setting Study (n = 8)
Windows			
Time realized, min (SD)	18.3 (13.6)	23.2 (15.3)	11.3 (6.9)
Total games played, n (SD)	9.1 (6.0)	11.2 (6.7)	5.7 (2.4)
Total errors, n (SD)	2.8 (3.0)	3.1 (3.4)	2.3 (2.4)
Errors/min, n (SD)	0.1 (0.1)	0.1 (0.1)	0.2 (0.2)
Trees			
Time realized, min (SD)	13.5 (15.0)	16.0 (17.5)	8.9 (7.8)
Total games played, n (SD)	9.4 (6.0)	10.6 (7.0)	7.0 (2.9)
Total errors, n (SD)	2.7 (3.7)	3.1 (4.3)	1.8 (2.1)
Errors/min, n (SD)	0.1 (0.2)	0.1 (0.2)	0.1 (0.2)
Mixed letters			
Time realized, min (SD)	15.1 (14.1)	15.1 (16.4)	15.1 (10.3)
Total games played, n (SD)	7.9 (3.9)	8.5 (5.1)	7.2 (2.3)
Total errors, n (SD)	4.3 (3.5)	4.7 (3.8)	3.8 (3.6)
Errors/min, n (SD)	0.2 (0.2)	0.2 (0.2)	0.2 (0.2)
Perception			
Perception			
Time realized, min (SD)	28.8 (31.0)	34.9 (38.1)	19.6 (13.2)
Total games played, n (SD)	20.7 (20.8)	27.8 (24.9)	11.9 (9.8)
Total errors, n (SD)	6.0 (4.3)	7.0 (4.3)	4.8 (4.3)
Errors/min, n (SD)	0.4 (0.3)	0.4 (0.3)	0.4 (0.4)
Mirroredcolors			
Time realized, min (SD)	8.7 (12.9)	11.3 (15.2)	4.7 (7.7)
Total games played, n (SD)	11.6 (10.5)	14.3 (11.9)	6.8 (6.2)
Total errors, n (SD)	3.1 (3.4)	3.7 (3.8)	2.0 (2.5)
Errors/min, n (SD)	0.3 (0.3)	0.2 (0.2)	0.4 (0.4)
Mirroredsymbols			
Time realized, min (SD)	21.2 (20.9)	23.6 (26.2)	17.0 (4.8)
Total games played, n (SD)	15.4 (12.7)	19.8 (15.4)	9.7 (4.6)
Total errors, n (SD)	4.6 (3.2)	4.9 (3.6)	4.3 (2.9)
Errors/min, n (SD)	0.3 (0.3)	0.3 (0.3)	0.3 (0.2)

3.2. Satisfaction

Among all participants, an overall satisfaction rating score of 7.8 ± 1.7 (out of ten) was obtained, which increased to 7.9 ± 1.0 and 8.3 ± 0.4 after 6 and 12 weeks, respectively. However, nonsignificant differences were observed during this period. In addition, while the mean values increased in the home study (from 7.5 ± 1.5 to 8.0 ± 1.1 and 8.3 ± 0.4), overall satisfaction among the participants in the clinical setting study decreased during the same time frame (from 8.5 ± 1.9 to 7.8 ± 1.0 and 8.0 ± 0.0; Figure 4).

Analyzing the data gathered via the UTAUT, with scores ranging from 1 to 7 for each item, the usefulness of the device was mainly praised among the performance expectancy items (5.3 ± 1.4), with increases in productivity also resulting in an overall high score (4.5 ± 1.9). With respect to effort expectancy, all the items resulted in good impressions, with the ease of developing the skills necessary to use COGNIVITRA obtaining higher values (6.0 ± 1.5). For the social influence item, the participants thought that the management of the organization would support the use of the device (5.7 ± 1.3), whereas in terms

of facilitating conditions, the participants felt that they had both the necessary resources (6.5 ± 0.9) and knowledge (6.3 ± 1.3) to use the tool. In terms of attitudes toward using the technology, the participants thought that using COGNIVITRA would be a good idea (6.4 ± 1.0) and that working with it would be enjoyable (6.0 ± 1.0), as well as they felt they would have the ability to complete a task using the system if someone taught them how to use it, with this self-efficacy item scoring high (6.1 ± 1.4). In addition, low scores were obtained on both the anxiety/behavioral and security modules of the UTAUT scale among patients, whereas professionals felt that COGNIVITRA was a secure system (6.2 ± 1.0; Table 7).

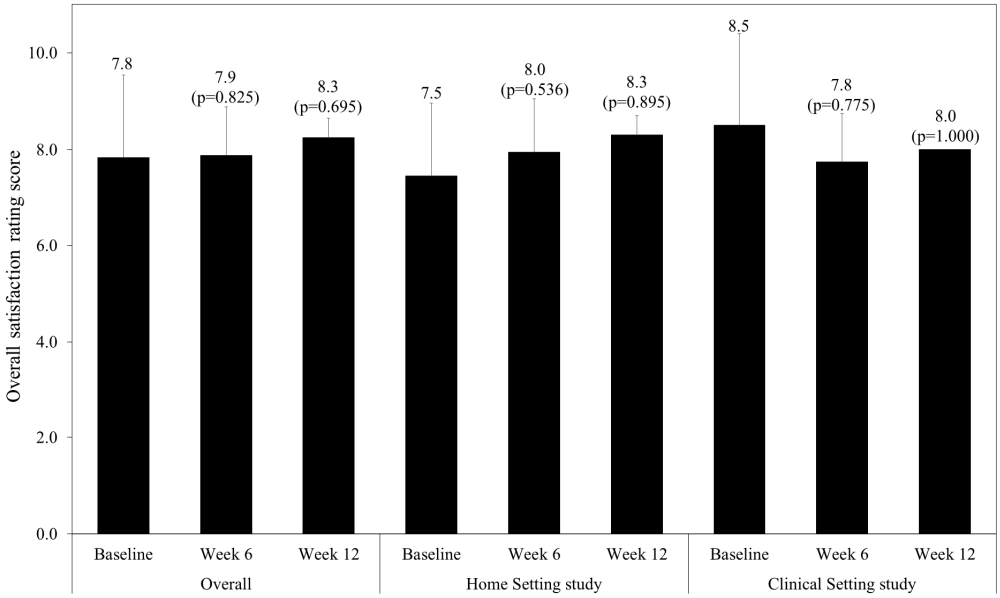

Figure 4. Patient overall satisfaction rating scores at both baseline and after the 6-week and 12-week study periods.

Finally, with respect to user opinion, patients felt that they had a positive experience using COGNIVITRA (91.7%, n = 11), with most of them stating that it had added value to their lives (66.7%, n = 8). A significant percentage of the patients perceived subjective cognitive improvement (41.7%), indicating that training the mind in different functions (41.7%, n = 5) and learning new exercises (25.0%, n = 3) were the most valuable advantages. In contrast, the inability to stop the game and incorrect movement detection were the most common disadvantages noted by the patients (16.7%, n = 2 for both), with improvements pointed toward making COGNIVITRA easier to interact with (33.3%, n = 4). In the case of the professionals, most felt that the interface and the avatar should be made more friendly (64.7%, n = 11), that there is a benefit in performing rehabilitation at home (41.2%, n = 7), and that they were positive about its possible application in other fields, such as mental health or in hospital rooms (29.4%, n = 5). Finally, among the patients and caregivers, 75.0% (n = 9) were willing to pay, with most of them opting for a monthly fee between EUR 20 and 100 (66.7%, n = 6). The options paying between EUR 6.5 and 30 per session and purchasing the device if priced at EUR 50–200 were both chosen by 33.3% of the participants (n = 3; Table 8).

Table 7. Unified Theory of Acceptance and Use of Technology (UTAUT) scores according to the healthcare professionals.

	n	Mean (SD)
Performance expectancy		
I would find the COGNIVITRA system useful for my job	24	5.3 (1.4)
Using the COGNIVITRA system would enable me to accomplish tasks more quickly	24	4.4 (1.8)
Using the COGNIVITRA system would increase my productivity	24	4.5 (1.9)
If I use the COGNIVITRA system, I will have a better chance of progressing in my career	24	4.1 (1.8)
Effort expectancy		
I believe that my interaction with the COGNIVITRA system would be clear and understandable	24	5.6 (1.3)
It would be easy for me to develop the skills necessary to use the COGNIVITRA system	23	6.0 (1.5)
I believe that the COGNIVITRA system would be easy to use	24	5.5 (1.6)
It would be easy to learn how to use the COGNIVITRA system	24	5.8 (1.6)
Social influence		
The people who influence my work feel that I should use the COGNIVITRA system	23	4.0 (2.0)
The people important to me think that I should use the COGNIVITRA system	23	3.8 (1.9)
The management of my organization would support the use of the COGNIVITRA system	23	5.6 (1.3)
In general, I believe that my organization would support the use of the COGNIVITRA system	23	5.7 (1.3)
Facilitating conditions		
I would have the necessary resources to use the COGNIVITRA system (e.g., Wi-Fi; computer)	24	6.5 (0.9)
I would have the necessary knowledge to use the COGNIVITRA system	24	6.3 (1.3)
The COGNIVITRA system would be compatible with my usual work dynamics	24	4.8 (2.1)
A person (or group) would be available to support me in using the COGNIVITRA system in case of difficulties	24	5.3 (1.3)
Attitude toward using technology		
Using the COGNIVITRA system would be a good idea	24	6.4 (1.0)
The COGNIVITRA system would make my work more interesting	24	5.6 (1.4)
Working with the COGNIVITRA system would be enjoyable	24	6.0 (1.0)
I would like to use the COGNIVITRA system	24	6.0 (1.3)
Self-efficacy		
I would be able to complete a task using the COGNIVITRA system even if no one told me what to do	24	4.8 (1.5)
I would be able to complete a task using the COGNIVITRA system if I could call someone to help me if I was blocked	24	5.8 (1.5)
I would be able to complete a task using the COGNIVITRA system if I had a lot of time to complete it	24	5.7 (1.6)
I would be able to complete a task using the COGNIVITRA system if someone showed me how to use it first	24	6.1 (1.4)
Anxiety/behavioral intentions to use the system		
I feel apprehensive about using the COGNIVITRA system	24	2.8 (1.9)
It scares me to think that I could lose a lot of information using the COGNIVITRA system if I performed a wrong action	24	2.8 (1.7)
I would hesitate to use the COGNIVITRA system for fear of making mistakes that I could not correct	24	2.7 (1.9)
The COGNIVITRA system is somewhat intimidating to me	24	1.9 (1.4)
Security		
I would hesitate to use the COGNIVITRA system when I know that all the data I enter would be visible to my peers/managers	24	2.5 (1.8)
It scares me to think that using the COGNIVITRA system would make my workflow more consultable by my peers	24	2.0 (1.6)
Information sharing		
I believe that the COGNIVITRA system is a secure system	24	6.2 (1.0)

Values for each item range from 1 to 7.

Table 8. Opinions about COGNIVITRA gathered from patients and professionals.

	n (%)
Patients	
How was your experience with the COGNIVITRA system in an individual context?	
Positive	11 (91.7)
Negative	5 (41.7)
Do you believe the system is an added value to your life?	
Yes	8 (66.7)
No	4 (33.3)
What has changed in your daily routine with the introduction of COGNIVITRA?	
Perceived cognitive improvement (memory, concentration)	5 (41.7)
No changes	4 (33.3)
Performed more cognitive training exercises	2 (16.7)
What are the advantages of the COGNIVITRA system?	
Training the mind in different functions (attention, memory)	5 (41.7)
Learning new exercises	3 (25.0)
Including head and body movements to involve coordination	1 (8.3)
Possibility to check the results after the session	1 (8.3)
What are the disadvantages of the COGNIVITRA system?	
No possibility to stop the game	2 (16.7)
Wrong movement detection	2 (16.7)
Some exercises can be stressful	1 (8.3)
Connecting the device requires technical knowledge	1 (8.3)
Repetitive exercises	1 (8.3)
Being aware of cognitive functions that the patient should improve	1 (8.3)
Visual impairment difficulties in interacting with the device	1 (8.3)
Including head and body movements to involve coordination	1 (8.3)
What aspects/functionalities do you think should be enhanced to improve COGNIVITRA?	
Make it easier to interact with	4 (33.3)
Improve detection of movements	2 (16.7)
Improve the games	2 (16.7)
Provide adaptations to the interface for colorblind people	1 (8.3)
Add examples and clearer instructions regarding how to perform the exercises	1 (8.3)
Patients and caregivers	
Would you be willing to pay for COGNIVITRA? If so, how much would you be willing to pay?	
No	3 (25.0)
Yes	9 (75.0)
Monthly (EUR 20–100)	6 (66.7)
Per session (EUR 6.5–30)	3 (33.3)
Purchase (EUR 50–200)	3 (33.3)
Professionals	
Make the interface and the avatar more friendly (graphic information, adding more colors, etc.)	11 (64.7)

Table 8. *Cont.*

	n (%)
There is a benefit to performing rehabilitation at home	7 (41.2)
Possible application in other fields such as mental health, hospital rooms, etc.	5 (29.4)
Include positive feedback	4 (23.5)
Use gamification	4 (23.5)
Would need some adaptation or training time to use COGNIVITRA	3 (17.6)
Concern regarding the implementation of COGNIVITRA in some patient populations (technology readiness, sociocultural and economic situations, etc.)	3 (17.6)
The device needs to be more portable and easier to carry around	3 (17.6)
Incorporate AI	2 (11.8)
Add the possibility to exercise in groups	1 (5.9)

3.3. Effectiveness

Regarding the effectiveness of the COGNIVITRA device in terms of quality of life, no statistically significant differences were observed in any of the modules of the EQ-5D-5L scale, with improved scores only in the case of the usual activities item in the overall sample (Figure 5A). This lack of statistical significance was also reported among patients from both home (Figure 5B) and clinical setting studies (Figure 5C). An improvement in self-health perception measured through the EQ-VAS scale was also observed, where higher values were obtained after six weeks in both the overall sample and both the home and clinical setting studies, although the difference was not statistically significant (Figure 6).

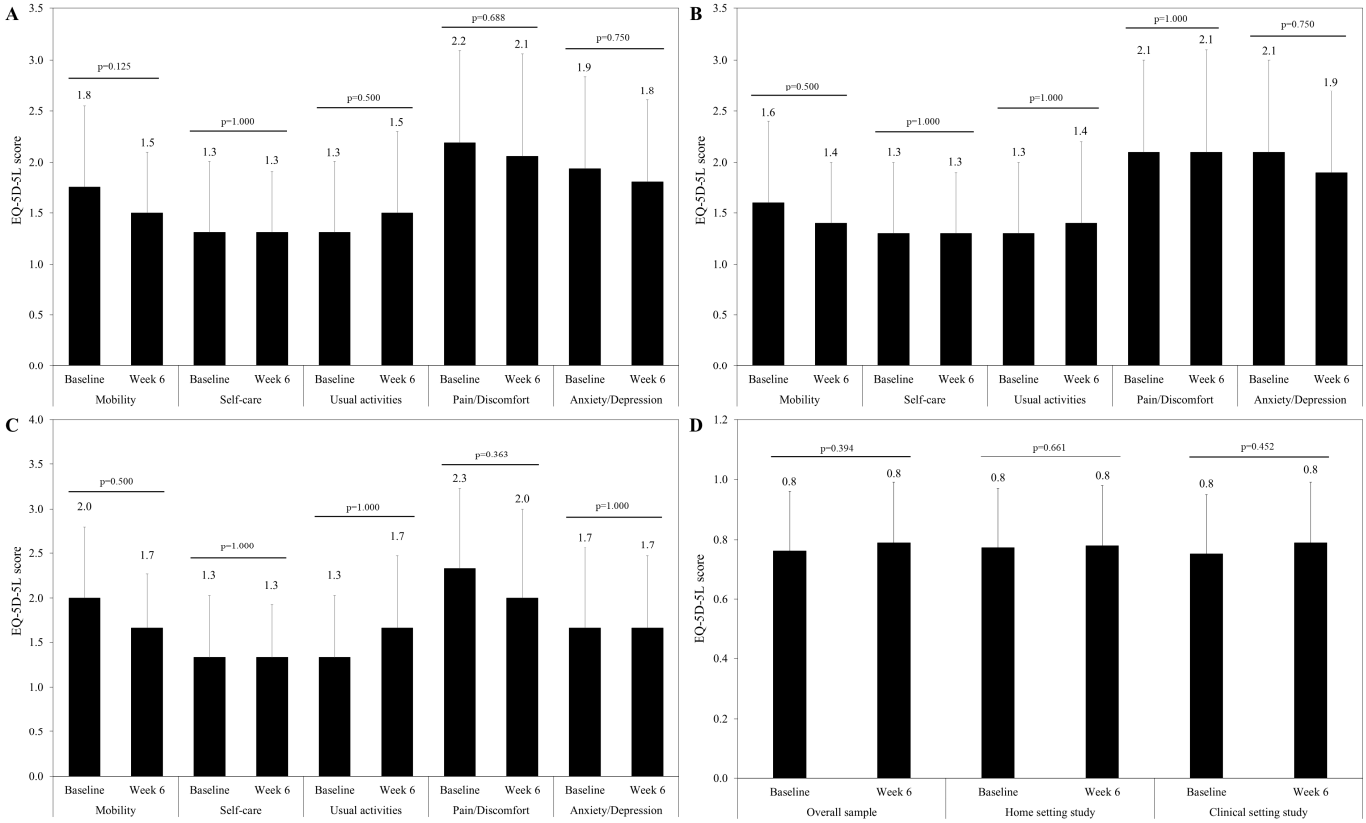

Figure 5. Patient quality of life measured through the EQ-5D-5L questionnaire among the overall sample (**A**), patients from the home study (**B**), and patients from the clinical setting study (**C**), as well as the overall index values (**D**) at both baseline and after the 6-week study period.

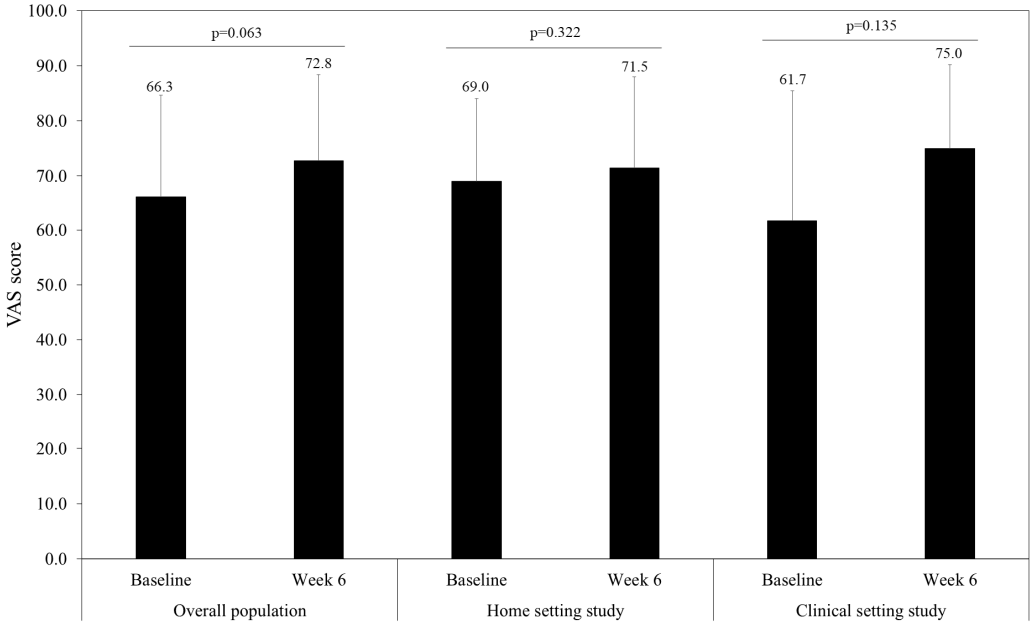

Figure 6. Patient quality of life as measured through the VAS scale among the overall sample and patients from both the home study and the clinical setting study.

For the T25-FW scale, a nonsignificant decrease in scores was observed after 6 weeks in both the one-task (from 6.0 ± 2.0 to 5.5 ± 1.1, $p = 0.600$) and two-task (from 6.9 ± 2.3 to 6.4 ± 1.6, $p = 0.434$) options. No significant differences were observed in the home study (from 6.8 ± 2.5 to 5.5 ± 0.9 in the one task option [$p = 0.375$] and from 6.8 ± 1.9 to 6.1 ± 1.0 [$p = 0.405$] in the two-tasks option) or clinical setting study (from 5.2 ± 0.7 to 5.4 ± 1.3 [$p = 0.559$] in the one task option and from 6.9 ± 2.8 to 6.7 ± 2.0 [$p = 0.827$] in the two-tasks option) (Figure 7).

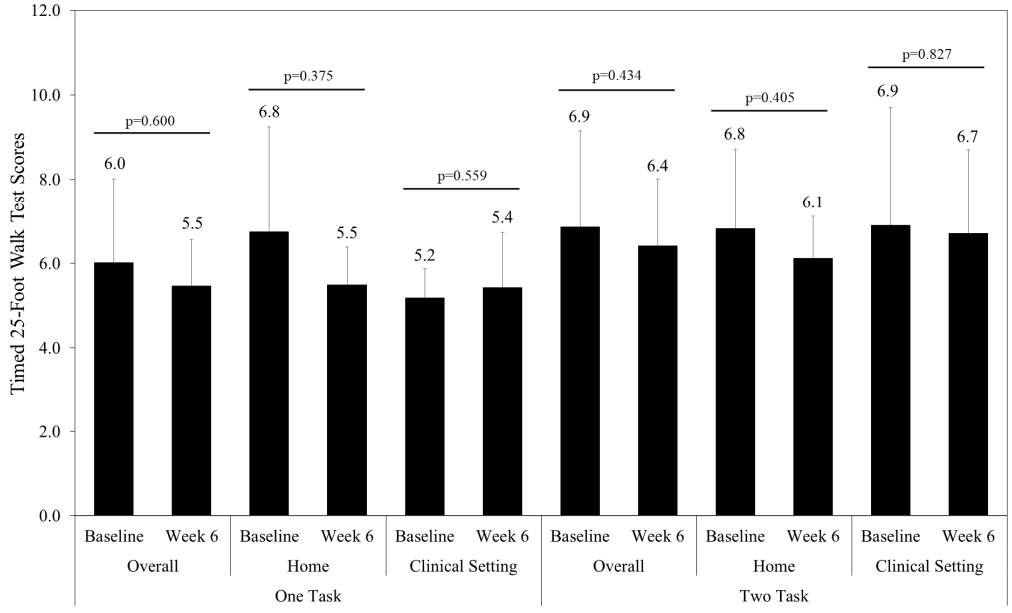

Figure 7. Timed 25-Foot Walk scores for the patients at both baseline and after the 6-week study period.

No statistically significant differences were reported in the MoCA scores, which ranged from 0 to 30, with slight improvements in both the overall study (from 24.6 ± 3.2 to 25.0 ± 3.8 after 6 weeks, $p = 0.574$) and clinical setting study (from 23.2 ± 3.8 to 24.3 ± 4.8

after 6 weeks, $p = 0.287$). In the case of the home study, a small decrease in the MoCA score was observed (from 25.9 ± 2.1 to 25.6 ± 2.9 after 6 weeks, $p = 0.760$; Figure 8).

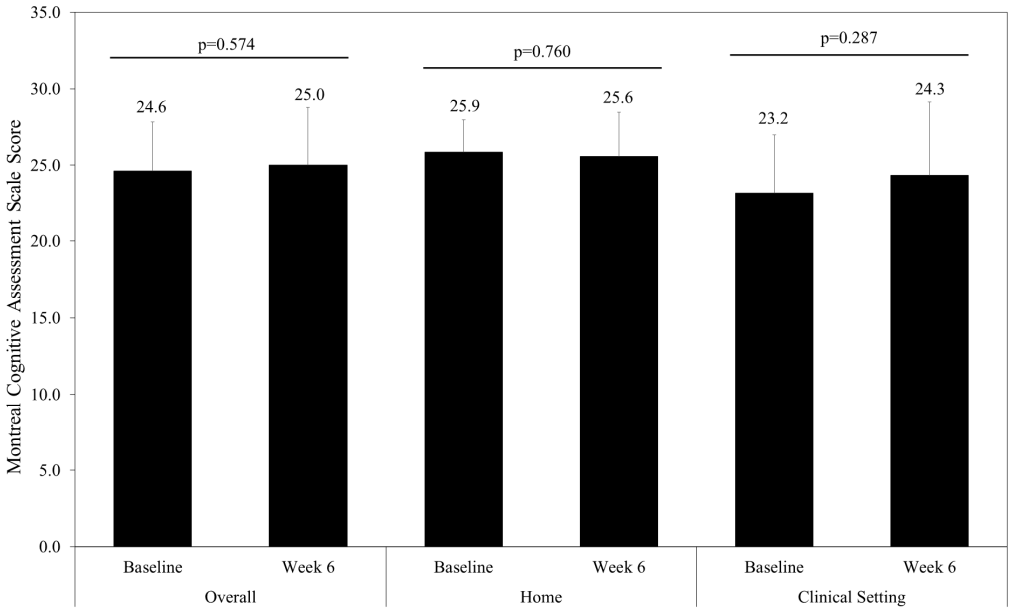

Figure 8. Montreal Cognitive Assessment Scale (MoCA) scores for the patients at both baseline and after the 6-week study period.

Finally, the average time the professionals spent on patient training was 23.3 min/week and 86.3 min/week in the home and clinical setting studies, respectively, whereas the professional/patient ratio was also higher in the clinical setting study (1.02 vs. 0.22) (Figure 9).

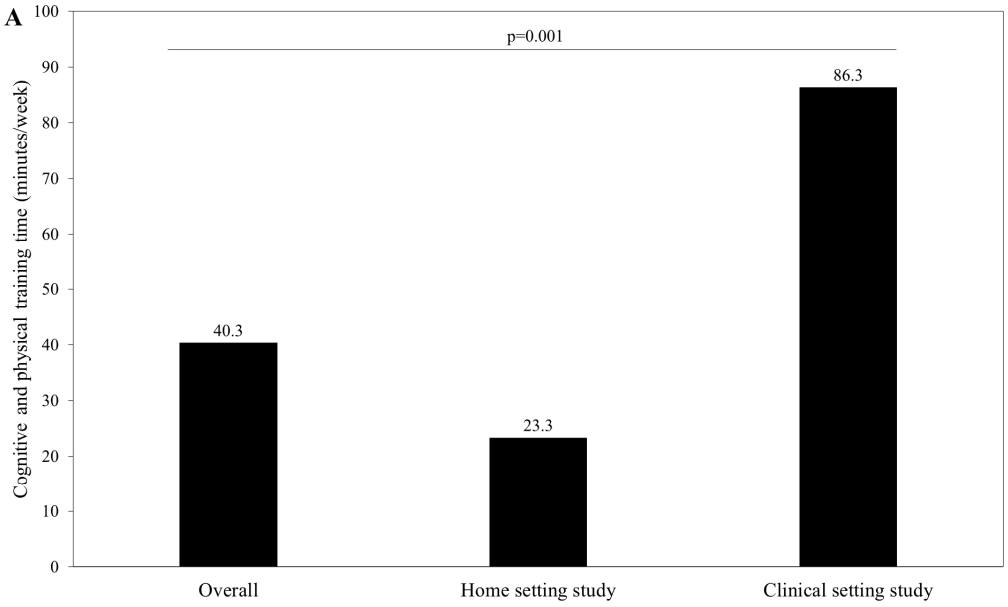

Figure 9. *Cont.*

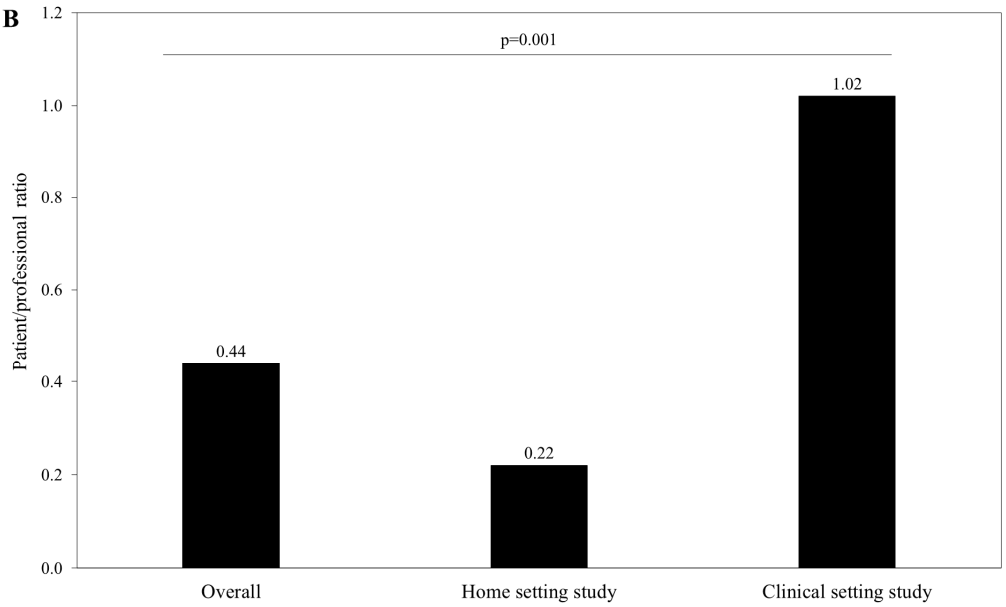

Figure 9. Time spent performing the cognitive and physical exercises (**A**) and patient/professional ratios (**B**) among the total sample and patients from both the home study and the clinical setting study.

4. Discussion

According to the results presented in this study, the evaluation of usability revealed notable results among patients, particularly in the home study. Patient responses indicated favorable outcomes in terms of user satisfaction and learning simplicity. With respect to usability, while higher values were observed, no statistically significant differences were found in the overall SUS scores between 6 weeks and baseline. However, in the home setting, these differences were statistically significant, indicating a better SUS score at 6 weeks than at baseline. Additionally, professionals reported high SUS scores. High adherence was observed overall, with participants exceeding the mandatory number of weeks, especially among those in the home setting compared with those in the clinical setting. In addition, some participants, all from the home study group, surpassed the prescribed frequency of sessions. However, it is noteworthy that the percentage of completed weeks was lower in the home setting than in the clinical setting. One potential explanation could be the lack of immediate professional assistance when issues arose or differences in motivation levels. Nonetheless, the total number of training hours was greater among the participants in the home study. Observational grid assessments demonstrated a high success rate for tasks, although an increase in errors was noted during the home study. In the case of the professionals, they provided positive feedback on the use of the device, while patients also reported heightened satisfaction levels and a positive inclination toward adopting COGNIVITRA. With respect to effectiveness, a noninferiority significant change toward improving patient quality of life, ambulation, and cognitive improvement was reported. In fact, the values obtained at the 6-week time point indicate that patients perceived themselves to be in general good health (according to EQ-5D-5L values) [20], to have good mobility with some difficulties but still relatively functional (according to the T25-FW scores) [21], and as having mild cognitive impairment (according to the MoCA scores) [22]. The slight improvement in most values or the maintenance of the patient's situation for some scores remains a strength of the obtained results. Although there was a nonsignificant increase in satisfaction after 6 and 12 weeks of training, satisfaction seemed to be more pronounced in the home setting than in the clinical setting. Importantly, most participants reported a positive experience with COGNIVTIRA, with many noting an overall improvement in their subjective perception of general health, as evidenced by the EQ-VAS scores. This satisfaction with the device was translated as 75.0% of patients and caregivers being willing to pay either a monthly/per use fee or purchase the product.

The improvement or maintenance of patients' cognitive status and user engagement with these types of devices among patients with MCI has already been described in similar studies. A pilot study comprising 49 participants, 20 with MCI and 29 healthy participants, investigated SmartWalk [23], a novel tool that combines aerobic exercise and cognitive protocols to stimulate cognitive function through the use of foot inertial sensing and a test for the auditory sustained attention domain to detect the user's gait and performance on cognitive tasks that are synchronized with the user's walking pace. The results showed that the tool was effective in improving cognitive function in both groups, particularly in the areas of sustained attention and vigilance. In our study, longer training periods were needed to assess the effectiveness of COGNIVITRA thoroughly. With respect to usability, the participants using the SmartWalk tool indicated a mean SUS score of 86.84 ± 9.97 [23], which is higher than those obtained in our study from both the patients (72.3 ± 17.2) and healthcare professionals (68.9 ± 12.2). Thus, future improvements in the robustness of the technology to improve usability must be made to enhance the patient's experience.

In a 6-month single-blind randomized controlled trial among 150 community-dwelling older adults with subjective and/or objective cognitive impairment who used the StandingTall program, a digital exercise program designed to improve mobility delivered via a tablet, a nonsignificant difference in gait speed of 0.04 m/s (p = 0.09) was observed. Thus, this finding reinforces the fact that even longer periods of training still have limitations in terms of effectiveness (in this case, mobility). Finally, the average SUS score was slightly higher than that of our healthcare professionals sample (76.7 ± 15.3 vs. 68.9 ± 12.2), although it was similar to that of the patients in our study (72.3 ± 17.2). In addition, 89.1% of patients reported a subjective benefit from the StandingTall program [24]. In comparison, in our study, 91.7% of the participants stated that they had an overall positive experience with COGNIVITRA, which was higher than that reported in the StandingTall study.

Tele-FootX™ is a motion sensor module equipped with a custom application that is designed to improve balance and cognition during distractive conditioning through gamified balance tasks and explicit augmented visual feedback, while a telemedicine interface remotely supervises the exercise [25]. A clinical trial involving 14 patients with mild cognitive impairment reported good acceptability, perceived benefits, and positive attitudes toward the use of the system. The Technology Acceptance Model (TAM) scores were significantly lower for exergaming adherence and increased for the participants' level of interest while performing in-home exergaming exercises. In our study, it is noteworthy that overall adherence was high, with participants completing more weeks than needed, which was particularly evident among those in the home setting compared with those in the clinical setting. In fact, as mentioned above, some participants exceeded the prescribed number of sessions, exclusively among those in the home study. On the other hand, values significantly increased for the questions that indicated that participants benefitted from performing in-home exergaming exercises to improve their physical and mental functions and quality of work. In terms of cognition and anxiety, an improvement in the average MoCA score of 9.7% and a decrease in the average Beck Anxiety Inventory (BAI) score of 27.6% were observed [25]. In our study, a nonsignificant improvement in the MoCA score was also observed, although only in the overall study (from 24.6 ± 3.2 to 25.0 ± 3.8) and clinical setting study samples (from 23.2 ± 3.8 to 24.3 ± 4.8), with a slight decline observed in the home study sample (from 25.9 ± 2.1 to 25.6 ± 2.9). These results might be explained by the different patient populations, study lengths, and numbers of sessions per week.

With respect to the willingness to pay for the device, user satisfaction often correlates with the perceived value of a medical device, as well as its quality, performance, and user-friendly interfaces. This satisfaction can positively influence users' willingness to pay for the device, as they see it as worth the investment. In our study, most of the participants (75.0%) were willing to pay to use COGNIVITRA, which was positively correlated with the overall high satisfaction scores reported among the users. Interestingly, this scenario is not always observed; as in other devices, user satisfaction and willingness to pay do not always correlate [26].

COGNIVITRA is an innovative advancement in cognitive care that integrates dual-task training, combining cognitive and physical exercises with advanced information and communications technology (ICT). Unlike traditional cognitive training programs, which are typically confined to clinical settings, COGNIVITRA extends these interventions to the home environment. This extension is made possible through a user-friendly interface, virtual coaching, and real-time feedback mechanisms that adapt to the user's performance. These features provide a holistic approach to cognitive rehabilitation that is accessible and customizable to individual patient needs. The platform also facilitates seamless communication between patients and care providers, enhancing the continuity of care and potentially leading to more sustained cognitive and physical improvements.

Despite its promising features, the deployment of COGNIVITRA presents challenges. One primary concern is ensuring digital literacy among elderly individuals, as effective use of the platform depends on the user's comfort with technology. Although the system is designed to be intuitive, varying levels of technology adoption among older adults could impact its overall usability and acceptance. Another challenge is the integration of COGNIVITRA with existing healthcare systems, which requires ensuring compatibility with different electronic health record (EHR) platforms and securing patient data. Additionally, there may be resistance from healthcare providers who are accustomed to traditional methods of cognitive care, highlighting the need for comprehensive training and demonstration of the platform's efficacy to gain full support.

The anticipated impact of COGNIVITRA on cognitive care is substantial. By enabling continuous cognitive and physical training outside of clinical settings, COGNIVITRA has the potential to significantly enhance patient outcomes, particularly in slowing the progression of MCI. Its accessibility could lead to broader population-level benefits by reaching individuals who are unable or unwilling to visit clinical facilities frequently. Moreover, the platform could have a considerable economic impact at the institutional level by reducing the need for in-person visits and hospital-based interventions, thereby lowering healthcare costs. In the long term, the success of COGNIVITRA could stimulate further technological developments in cognitive care, fostering innovations that integrate AI-driven personalized training programs and expanding the scope of remote healthcare solutions.

COGNIVITRA stands out from other cognitive training solutions through its dual-task training and home-based accessibility. Traditional programs often require in-person attendance, limiting their accessibility and scalability. In contrast, COGNIVITRA is designed for use both in clinical settings and at home, featuring a virtual coach to guide users and advanced motion sensors and real-time feedback systems to enhance the user experience. These design elements ensure that exercises are performed correctly, maximizing the training's effectiveness. Additionally, COGNIVITRA's ability to facilitate communication between patients and healthcare providers is a significant advantage over other programs that may operate in isolation from the broader healthcare ecosystem. This integration of communication tools allows for the continuous monitoring and adjustment of the training programs, ensuring that they remain aligned with the patient's evolving needs. The intended purpose of COGNIVITRA extends beyond providing cognitive exercises; it aims to maintain and enhance cognitive vitality through a multifaceted approach that includes physical activity. While many alternative solutions focus exclusively on cognitive enhancement, COGNIVITRA's dual-task framework is designed to delay cognitive decline by simultaneously improving physical health. The platform is also intended to be a long-term solution that patients can integrate into their daily lives, offering a more sustainable approach than alternatives that may be episodic or limited in duration. Moreover, by enabling home-based training, COGNIVITRA seeks to reach a broader population, including those with limited access to clinical facilities.

One of COGNIVITRA's core features is its ability to enhance communication between patients and care providers through integrated real-time data monitoring and reporting systems. This allows healthcare providers to monitor patient progress remotely, making adjustments as necessary to optimize outcomes. By maintaining continuous interaction,

particularly for elderly patients, COGNIVITRA helps reduce the sense of isolation that can accompany home-based care, contributing to better mental health and overall patient satisfaction. Finally, COGNIVITRA has significant economic implications for healthcare institutions. By enabling home-based training, it reduces the frequency of in-person visits, leading to cost savings for both providers and patients. The platform's ability to monitor patient progress remotely also allows for early intervention, potentially preventing more serious cognitive decline and reducing long-term healthcare costs. In this way, COGNIVITRA contributes to a more efficient and cost-effective approach to cognitive rehabilitation. Finally, gathering data from a real-world setting, with the tasks being performed in both home and clinical settings, can be included among the strengths of the study. In contrast, the low number of patients in the analysis can be included among the weaknesses of the study. Therefore, it is essential to conduct prospective studies with larger groups of participants and longer follow-up periods to validate and build upon our results.

5. Conclusions

COGNIVITRA generally demonstrated positive usability, especially in the home setting study. Patients indicated an overall increase in satisfaction over time and a favorable perception of its usefulness and ease of both use and learning, highlighting a high success rate in tasks for patients and healthcare professionals. Although no statistically significant differences were reported, positive values regarding patient quality of life, ambulation and improvement in cognitive domains were observed. In addition, the use of COGNIVITRA resulted in a professional time expenditure that was approximately 4.5 times less than that required in the clinic setting. Although the technology on which COGNIVITRA is built is still immature and in development, as indicated by the presence of technological bugs, the results provided in this study show that it can still generate engagement and adapt to the needs of patients, with participants performing the exercises properly, as seen in the number of successful sessions.

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Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

Data Availability Statement: The raw data supporting the conclusions of this article will be made available by the authors on request.

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Conflicts of Interest: The authors declare no conflicts of interest.

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