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Feasibility, Acceptability, and Preliminary Impact of Full-Body Interaction on Computerized Cognitive Training Based on Instrumental Activities of Daily Living: A Pilot Randomized Controlled Trial with Chronic Psychiatric Inpatients

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Abstract

Objective: To conduct a pilot randomized control trial to assess the feasibility and acceptability of full-body interaction cognitive training (FBI-CT) inspired by instrumental activities of daily living in chronic psychiatric inpatients and to explore its preliminary impact on cognitive and noncognitive outcomes.
Materials and Methods: Twenty psychiatric inpatients met the inclusion criteria and were randomly allocated to the FBI-CT group ($n = 10$) or the tablet-based CT group (T-CT) ($n = 10$). Neuropsychological assessments were performed at baseline, postintervention, and 3-month follow-up.
Results: Both groups presented high completion rates at postintervention and follow-up. Participants reported high satisfaction following the interventions, with the FBI-CT group exhibiting slightly higher satisfaction. A within-group analysis showed significant improvements in the FBI-CT group for processing speed and sustained attention for short periods ($P = 0.012$), verbal memory ($P = 0.008$), semantic fluency ($P = 0.027$), depressive symptoms ($P = 0.008$), and quality of life ($P = 0.008$) at postintervention. At 3-month follow-up, this group maintained verbal memory improvements ($P = 0.047$) and depressive symptoms amelioration ($P = 0.026$). The T-CT group revealed significant improvements in sustained attention for long periods ($P = 0.020$), verbal memory ($P = 0.014$), and executive functions ($P = 0.047$) postintervention. A between-group analysis demonstrated that the FBI-CT group exhibited greater improvements in depressive symptoms ($P = 0.042$).
Conclusions: Overall, we found support for the feasibility and acceptability of both training approaches. Our findings show promise regarding the preliminary impact of the FBI-CT intervention, but due to study limitations such as the small sample size, we cannot conclude that FBI-CT is a more effective approach than T-CT for enhancing cognitive and noncognitive outcomes of chronic psychiatric inpatients. Clinical trials (number: NCT05100849).

Keywords: Computerized cognitive training, Full-body interaction, Interactive technologies, Instrumental activities of daily living, Psychiatric disorders

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Introduction

Psychiatric disorders are a major cause of disability and mortality worldwide (2.22 times higher than the general population).[1] In 2017, it was estimated that about 330 million people were living with a debilitating psychiatric condition, such as depression, bipolar disorder, and schizophrenia, accounting for around 4.3% of the global population.[2] Cognitive deficits are a well-established core feature of several psychiatric conditions, known to compromise patients' quality of life and daily functioning [e.g., ability to perform activities of daily living (ADLs)],[3] as well as hamper their adherence to therapeutic interventions.[4] For example, schizophrenia, major depressive disorder, and bipolar disorder are characterized by widely spread cognitive dysfunction affecting processing speed, attention, memory, language, and executive functions, which is typically more severe in psychotic spectrum disorders.[5,6] Cognitive deficits tend to persist after remission and can worsen with relapses,[7] posing a significant risk factor for developing neurodegenerative diseases in later life, such as dementia.[8,9]

In addition, people with severe psychiatric conditions are typically more sedentary than the general population,[10] which increases their mortality risk due to cardiovascular and metabolic health-related conditions.[11] A systematic review and meta-analysis of 69 studies involving a total of 35,682 people with severe psychiatric disorders and 2933 healthy controls demonstrated that people with psychiatric illnesses engage significantly more in sedentary behavior (around 8 waking hours) and perform less physical activity (PA) than healthy controls.[12] Currently, it is recognized that sedentary behavior negatively affects cognitive functioning.[13] In a systematic review of 45 studies, the authors found that higher PA and lower sedentary behavior are associated with greater cognitive performance in older adults.[14] Therefore, considering the current evidence, it is imperative to address psychiatric patients' cognitive deficits and sedentary behavior early to improve their prognosis by preventing future relapses and emerging neurodegenerative conditions later in life.

Combined interventions, integrating cognitive training (CT) and PA, have shown some potential in enhancing cognitive[15] and noncognitive outcomes (e.g., neuropsychiatric symptoms, quality of life)[16,17] in healthy and cognitively impaired populations. Combined simultaneous CT and PA interventions consist of CT and PA delivered concurrently, usually in a dual-task format.[18] It is hypothesized that this is a more promising approach to enhance cognitive and noncognitive outcomes for the following reasons: (a) the synergetic effects of CT and PA may increase neuroplasticity by inducing the release of brain-derived neurotrophic factors and hippocampal neurogenesis;[19] and (b) the possibility of recreating a training context that resembles daily life demands through the engagement of cognitive and motor systems and the integration of multisensory input.[18] These factors influence the interventions' ecological validity and may increase task meaningfulness and lead to higher adherence levels and, eventually, greater transfer of training gains to ADLs.[20,21] However, whether simultaneous CT and PA interventions are more efficacious than sequential ones is still a matter of debate.[22,23] A recent systematic review and network analysis of 41 randomized controlled trials (RCTs) revealed that both combined approaches led to comparable cognitive and physical benefits in healthy and cognitively impaired older adults but were preferable over single-domain training interventions.[24] In addition, the authors found insufficient evidence in the literature to support the positive impact of combined CT and PA interventions in psychosocial (i.e., neuropsychiatric symptoms and quality of life) and functional outcomes [i.e., basic and instrumental activities of daily living (BADLs and IADLs)].

Information and Communication Technologies (ICTs), such as computerized and virtual reality (VR) applications, with natural user interfaces (e.g., speech and motion sensing devices), are an innovative solution that facilitates the provision of simultaneous CT and PA interventions. In addition, they are often more feasible and less time-consuming in inpatient settings where human resources are scarce, making them more realistic, interactive, and, possibly, more engaging.[25] There is limited but encouraging evidence on the efficacy of technology-based simultaneous CT and PA in clinical[26,27] and nonclinical populations.[28,29] Moreover, research in this field suggests that technology-based CT interventions incorporating ADL simulations appear to have more impact than conventional methods on the cognitive functions of patients with neurological[30,31] and psychiatric conditions,[32,33] potentially optimizing the degree of transfer of training or generalization of learning to the persons' everyday life. However, RCTs with a longitudinal design on the efficacy of technology-based simultaneous CT and PA in clinical populations, as is the case of psychiatric illnesses, are still scarce. In addition, most studies in this field are conducted with nonclinical samples (community-dwelling adults), mainly focus on motor outcomes, frequently neglect cognitive, mood, quality of life, and functional domains, and often lack CT interventions with an ecologically valid content [i.e., incorporate cognitive training tasks (CTTs) based on ADLs]. Thus, considering the abovementioned gaps, the purposes of this pilot RCT are twofold: (a) primarily, to establish the feasibility and acceptability of full-body interaction CT (FBI-CT), containing CTTs inspired by IADLs, in chronic psychiatric inpatients; and (b) secondarily, to explore the preliminary impact of FBI-CT on cognition, emotional status, quality of life, and functional abilities to inform subsequent large-scale studies on this domain.

Materials and Methods

Trial design

This study is a single-blind pilot RCT conducted between July 2020 and April 2021. The study was approved by the Ethics Committee of the *Casa de Saúde Câmara Pestana* (CSCP) (Madeira, Funchal) (reference number: 1/2021) and registered on clinical trials (number: NCT05100849). The CONSORT 2010 checklist for reporting a randomized trial is available in the Supplementary Data. It is important to mention two deviations to the registered trial protocol: the Rey Complex Figure Test exclusion from the neuropsychological assessment protocol and the increase of the CT sessions' frequency from two to three times per week.

Intervention

The program comprised 14 CT sessions, delivered thrice a week by a certified psychologist, with each session lasting

~30 minutes. Overall, the entire intervention process lasted 6 weeks. The program's content and CTTs were defined after semistructured interviews with neuropsychologists with expertise in rehabilitation. During these interviews, neuropsychologists were asked to propose ecologically valid CTTs inspired by IADLs. After collecting the various CTTs proposals, we organized them according to three main themes, and CT sessions were structured as follows:

(1) Functional communication and transportation use (session nr. 1, 4, 7, 10, and 13);
(2) Cooking and shopping (session nr. 2, 5, 8, 11, and 14);
(3) Financial management and health-related issues (session nr. 3, 6, 9, and 12).

A brief description of each CT session's structure is provided in Table 1. Every CT session tackled broad cognitive domains (i.e., attention, memory, language, and executive functions) and presented different difficulty levels for progression throughout the intervention process.

Computerized application and setup

The CT program was implemented using a customized version of the *Musiquence* platform. *Musiquence* consists of a computerized application, initially developed for cognitive stimulation of people with dementia, capitalizing on music and reminiscence principles. Previous studies with health care professionals who work with people with dementia[34] and those diagnosed with dementia[35] emphasize Musiquence's intuitive and user-friendly features. The *Musiquence* platform allows customization of user-centered gamified cognitive tasks in terms of training content and technological adaptation (e.g., tablet, computer, augmented reality), enabling a nonimmersive or semi-immersive training experience.[36,37] We chose *Musiquence* given the platform's numerous customization features for cognitive activities and multimodal compatibility. *Musiquence* includes a Game Editor that allows users to design and customize CTTs. The Game Editor works similarly to Microsoft PowerPoint, in which each slide is an activity that can be customized in terms of instructions, background image, and answers (correct and incorrect). After designing all CTTs, users can save them in a ''.musiquence'' file and run it afterward on both the tablet and the PC. Overall, the following activities were used and customized for the present CT program:

- Quiz 2.0 activity: This is a quiz game in which participants must select the correct answer among several wrong answers. This activity also allows adding a background image to provide a realistic context for the activities;
- Association activity: In this activity, participants need to associate an answer to the correct container;
- Search activity: Here, participants must find hidden target answers using a virtual magnifying glass.

A psychologist developed each CTT and adapted task difficulty according to its clinical judgment by manipulating the CTT's underlying parameters (e.g., number of target stimuli, number of distractors, length of the instructions). Thus, CTTs got harder between training sessions. Before starting the intervention, a psychologist conducted a brief pretraining session where participants were instructed on how to perform the different activities available on the *Musiquence* platform. During the intervention phase, participants would progress in the training session if they answered each question correctly. To answer a question, participants had to place a virtual cursor on the answer (in both Quiz 2.0 and Association activity), while a virtual magnifying glass was used in the search activity. If the answer was correct, positive feedback—''Very good!'' —was played in the background, while negative feedback—''Oh, try again''—was given when answering erroneously. Irrespective of the setup/training condition, all participants were administered the same CT program and training dosage. Each experimental setup is described below.

Setup 1. FBI-CT condition

In this training condition, the CTT's were projected on the wall using a BenQ mirror-based projector (BenQ, Taiwan) positioned very close to the wall. To complete the activities, participants had to place the virtual cursor on the correct answer by performing physical movements (e.g., walking upwards, downwards, sideways, and squatting), which were detected by the Microsoft Kinect (Microsoft Corporation). Participants would be placed ~2 m from the Kinect. In addition, physical markers were used on the floor to indicate the interaction area (Fig. 1a).

Setup 2. Tablet-based CT condition

In this condition, participants were seated on a chair using a Lenovo Tablet (Lenovo Group Ltd.). To complete the CTTs, participants had to drag the virtual cursor to the correct answer using upper limb movements (cf. Fig. 1b).

Outcome measures

Sociodemographic and clinical data were collected from participants' clinical files without compromising their anonymity. Primary outcomes were feasibility and acceptability. Secondary outcomes were cognitive and noncognitive neuropsychological instruments validated for the Portuguese population.

Primary outcomes

Feasibility was examined by considering two specific indicators, namely the retention rates (i.e., the ratios between the number of participants that completed the postintervention and the follow-up assessments and the number of allocated participants for each experimental condition) and the CT sessions attendance.

Acceptability was assessed in both training conditions at postintervention through an ad hoc satisfaction questionnaire containing 14 questions concerning the interventions' structure and content (e.g., number of sessions, task diversity, interaction with the CT content). Participants were required to indicate their level of satisfaction using a five-point Likert scale (ranging from 1 = not satisfied at all to 5 = very much satisfied). The scale's maximum score was 70 points.

Table 1. Cognitive Training Program

Themes	*Sessions*	*CTT description*
Functional communication and transportation use	1,4,7,10,13	Reality orientation: selecting the correct answer to 5 reality orientation questions (e.g., What is the day of the month? What is the month?) among a set of distractors (quiz 2.0); Find the items: finding specific items according to the instructions (e.g., Search for all the public transportations that go to Santa Cruz) (Search); Spot the difference: comparing two images and identifying in which details they are different (quiz 2.0); Read the journal article: reading a brief journal article and answering specific questions related to the article (quiz 2.0); Remind me later: reading and memorizing a piece of specific information and having to recall the psychologist about it after a certain period of time (e.g., Do not forget to give me that red pen in around 10 minutes) (quiz 2.0); Answer a text message: reading a text message and selecting the correct answer having the context in mind (e.g., What should you answer a person that tells you that her mother is ill?) (quiz 2.0); Organize the telephone's contact list: organizing the telephone's contact list in alphabetical order (quiz 2.0); Complete the adage: determining the missing sentence to complete a well-known Portuguese adage (quiz 2.0); Find the adage meaning: identifying the correct interpretation of a well-known Portuguese adage (quiz 2.0); Check the schedule: analyzing a bus schedule and answering several questions (e.g., At what time should you take the bus in Funchal to be in Santa Cruz at 19h45?) (quiz 2.0); Estimate the time: calculation of the amount of time needed to get from one location to another while analyzing a bus schedule (e.g., How long will you take from *Avenida do Mar* to *Hospital Dr. Nélio Mendonça*?) (quiz 2.0); Action sequencing (text or image): organizing a set of images or sentences related to day-to-day situations (e.g., How should you proceed when missing the bus) in the correct order (quiz 2.0).
Cooking and shopping	2,5,8,11,14	Reality orientation: selecting the correct answer to 5 reality orientation questions (e.g., What is the day of the month? What is the month?) among a set of distractors (quiz 2.0); Find the items: finding specific items according to the instructions (e.g., Search for all foods starting with the letters A and C) (search); Spot the difference: comparing two images and identifying if they are the same or different (quiz 2.0); Find the missing ingredients: analyzing the ingredients' list for a traditional Portuguese recipe, and then identifying which ingredients are missing in the pantry (e.g., Which ingredients needed to make the *Cozido à Portuguesa* recipe are missing in your pantry?) (quiz 2.0); Find the ingredients that are not in the recipe: analyzing the ingredients' list for a traditional Portuguese recipe, and then identifying which ingredients from the pantry are not needed to make the recipe (e.g., Which ingredients from your pantry are not needed to make the *Cozido à Portuguesa* recipe) (quiz 2.0); What was the recipe: answering a series of questions related to the previous recipe (e.g., What was the name of the recipe? What ingredients were listed in the recipe?). Participants were required to select the correct response among a set of distractor responses. To do so, they must have retained information concerning the recipe and recalled it during the task (quiz 2.0); Categorization: classifying a series of items into several categories (e.g., How many categories can you identify? Please say what are the different categories) (quiz 2.0); Similarities: identifying in what way are the images alike. This task was presented as a quiz-like activity, where participants needed to select the correct answer among incorrect answers (quiz 2.0); Action sequencing (images and text): organizing a set of images or sentences related to a traditional Portuguese recipe in the correct order (quiz 2.0); Organize the products: organizing the products according to specific instructions (e.g., Organize the products from the least expensive to the most expensive and vice-versa) (quiz 2.0); Estimate the total groceries cost: calculating the total cost of the groceries (e.g., How much will you pay for your groceries? You have 297€ in your wallet, how much money will you have after paying for your groceries?) (quiz 2.0); Choose the correct invoice: based on the prices of the grocery items from the previous task, participants were required to select the correct invoice among incorrect invoices. To do so, they needed to retain the information regarding the prices, the number of items, and then perform some calculations to estimate the total cost of their purchase (quiz 2.0).

(*continued*)

Table 1. (Continued)

Themes	*Sessions*	*CTT description*
Financial management and health-related issues	3,6,9,12	Reality orientation: selecting the correct answer to 5 reality orientation questions (e.g., What is the day of the month? What is the month?) among a set of distractors (quiz 2.0); Find the items: finding specific items according to the instructions (e.g., Search for all coins that are not 1€, 20 cents, and 5 cents) (search); Prioritize the bills: organizing bills chronologically according to their due date (e.g., What bill do you need to pay first and next?) (quiz 2.0); Analyze the bill: analyzing a specific bill (e.g., internet, electricity, gas) and answering several questions regarding that bill (e.g., What is the bill that you need to pay? What is the total cost of the bill?) (quiz 2.0); Choose the lunch menu: analyzing several lunch menus and selecting the correct menu/s according to specific instructions (e.g., Which lunch menu/s can you buy with 73.55€?) (quiz 2.0); Pay the lunch: selecting the correct amount of money needed to pay the previously selected lunch menu/s (quiz 2.0); Store showcase estimation price: estimating which is the least expensive store showcase and the most expensive store showcase (association); Estimate the store showcase's total cost: calculation of the total cost of the items in the store showcase (e.g., How much will you pay for all the items in the showcase? You have 1400.50€ in your bank account, how much money will you receive after paying for all the items (quiz 2.0)); Myth or fact: reading several health-related sentences and classifying them as a myth or a fact (quiz 2.0); Medical appointment: reading a letter from the doctor and answering various questions related to the letter (e.g., When will your doctor's appointment be? What is the purpose of your doctors' appointment?). There was a retention phase, in which participants were required to retain the letter's information, and a recognition phase, in which participants needed to select the correct answer to specific questions among a pool of incorrect answers (quiz 2.0); Action sequencing (text): organizing a set of images or sentences related to health issues (e.g., Organize correctly the steps needed to schedule a doctors' appointment in the hospital) (quiz 2.0); Medication schedule: analyzing a medical prescription and identifying when specific medicines should be taken (e.g., When do you need to take your diabetes and sleep medicine?) (quiz 2.0).

CTT, cognitive training task.

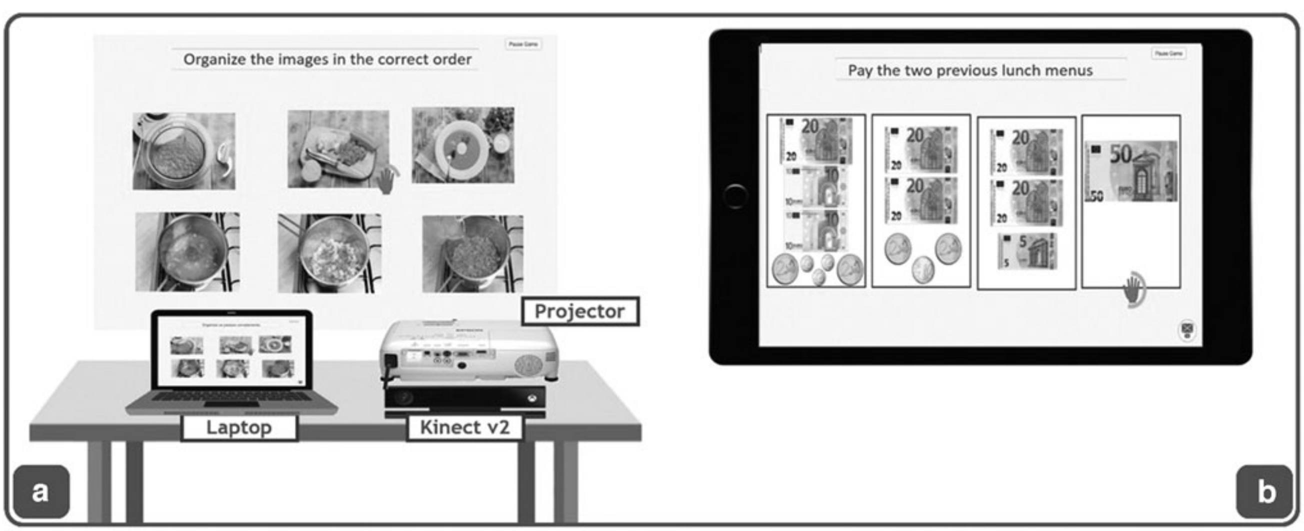

FIG. 1. **(a)** Action-sequencing task consisting of the correct organization of a series of images portraying a carrot soup preparation in the full-body interaction CT (FBI-CT) condition (on the left), and **(b)** calculation task involving the selection of the correct amount of money to pay two lunch menus in the tablet-based CT (T-CT) condition (on the right).

Secondary cognitive outcomes

Screening assessments of general cognitive functioning and executive functioning were conducted using the Montreal Cognitive Assessment (MoCA)[38] and the Frontal Assessment Battery (FAB),[39] respectively. In addition, we selected a set of domain-specific cognitive tests to evaluate several cognitive functions, namely: processing speed and sustained attention for short periods (Symbol Search and Digit Symbol tests from the Wechsler Adult Intelligence Scale III–WAIS-III),[40] sustained attention for long periods (Toulouse-Piéron),[41] verbal memory (Free and Cued Selective Reminding Test–FCSRT),[42] and verbal fluency (Semantic and Phonemic verbal fluency tests).[43]

Secondary noncognitive outcomes

Depressive symptoms were assessed using the Beck Depression Inventory (BDI-II),[44] quality of life using the World Health Organization Quality of Life–Bref (WHOQOL-Bref),[45] and finally, functional abilities were assessed using the Adults and Older Adults Functional Assessment Inventory (IAFAI).[46]

Statistical analysis

Data were analyzed using the SPSS software (version 26). The normality of the data was assessed using the Shapiro–Wilk test. Normally distributed continuous variables were presented as mean and standard deviation, non-normally distributed variables as median and interquartile ranges (IQR), and categorical variables as frequency and percentage. Between-group differences in demographic and clinical variables were analyzed with the Mann–Whitney test, the independent samples *t*-test, and the Fisher's exact test. Since most neuropsychological assessment data were not normally distributed, nonparametric tests were used to evaluate within (i.e., Wilcoxon signed-rank test) and between-group (i.e., Mann–Whitney U test) differences across the three assessment moments (baseline, postintervention, and follow-up). No corrections for multiple comparisons were performed. Effect size (r) estimates were calculated ($r = Z/\sqrt{N}$) and interpreted as: 0.2 = small, 0.5 = medium, and 0.8 = large.[47] In all analyses, a significance level of $\alpha = 0.05$ was applied.

Recruitment and eligibility criteria

Sample recruitment was conducted at CSCP, which is a female mental health institution located in Madeira Island, Funchal. We recruited a convenience sample and aimed to include the greatest number of participants possible considering our inclusion criteria. No sample size calculation was performed. A total of 32 participants from three long-term care units were assessed for eligibility. Participants were enrolled in this study if they met the following eligibility

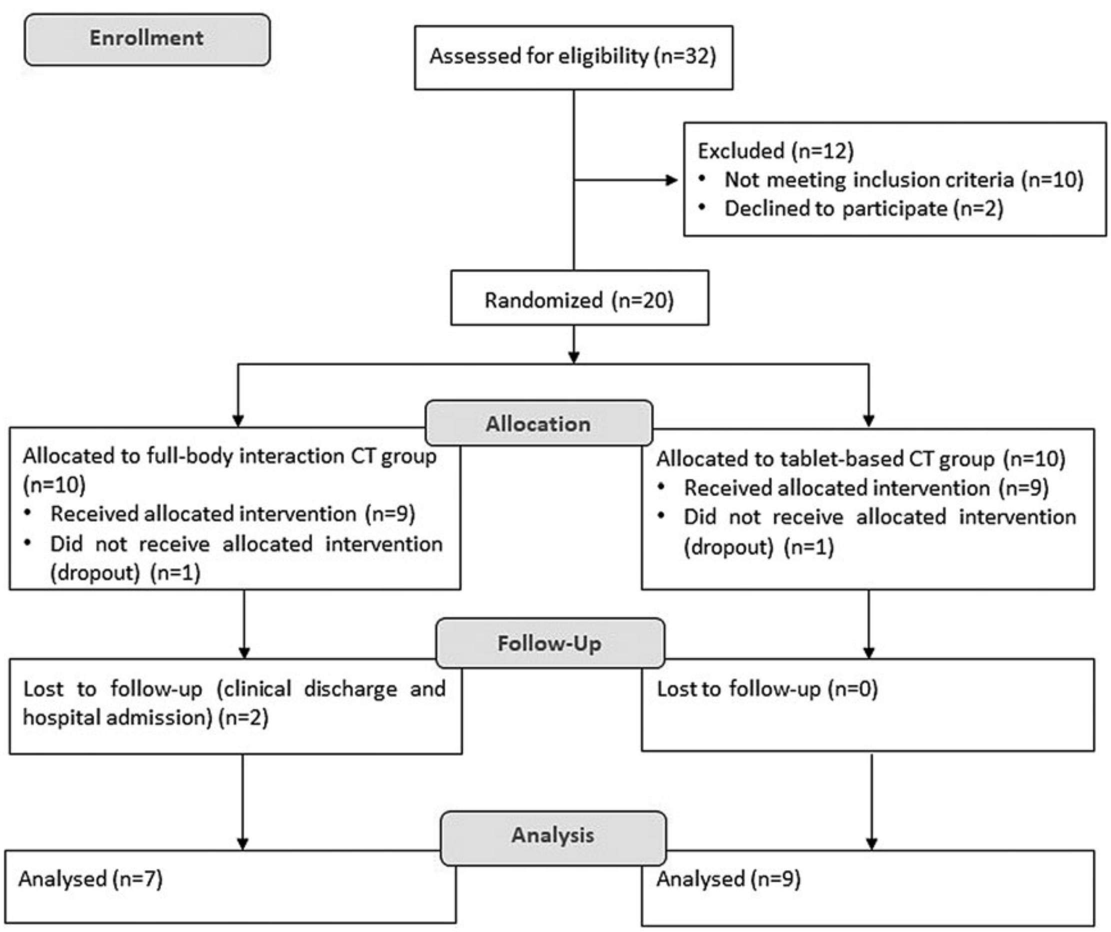

FIG. 2. Study design, according to the CONSORT flow diagram.

criteria: age ≤70 years old, ability to read and write, preserved visual and auditory acuity, maintained language abilities (expressive and receptive), evidence of cognitive decline on the MoCA (≥1.5 standard deviations below the mean in MoCA), and motivation to participate. As for exclusion criteria, we had: being in an acute stage of the disorder, physical limitations that could interfere with the training sessions, and personal history of neurological disorders (e.g., stroke, traumatic brain injury, and epilepsy). Among those, 12 were excluded (10 did not meet the inclusion criteria, and two declined to participate due to chronic pain and lack of motivation). Thus, a total of 20 participants were eligible. After recruitment, a certified psychologist randomly assigned participants to the FBI-CT group ($n=10$) or the T-CT group ($n=10$), using the Research Randomizer (cf. https://www.randomizer.org/), a free web-based resource that offers random sampling and assignment (Fig. 2).

Procedure

Participants enrolled in this study underwent a comprehensive neuropsychological assessment at baseline, postintervention, and follow-up (3 months). Neuropsychological assessments were performed by a certified psychologist, with each session lasting 1 hour and 30 minutes. Concerning the CT sessions, participants in each arm underwent a time-matched intervention, encompassing 30-minute sessions administered thrice a week by the same certified psychologist. The entire intervention process lasted approximately 6 weeks. The psychologist was aware of participants allocation, whereas the latter were blinded to the interventions.

Results

Table 2 summarizes participants' baseline sociodemographic background and clinical characteristics. No differences between groups were found in terms of sociodemographic data (age, education), previous experience with the use of technological devices, and clinical data (years of hospitalization, quarantine period, and diagnosis) ($P>0.05$). In addition, there were no between-group differences in neuropsychological assessment scores at baseline ($P>0.05$), except for semantic verbal fluency ($P=0.014$), meaning that participants' cognitive functioning, emotional state, functional abilities, and quality of life could be perceived as equivalent.

Primary outcomes

In terms of the interventions' feasibility, we verified that postintervention completion rates were very high for both the FBI-CT group ($n=9$) and the T-CT group ($n=9$) (90%). One participant from each group did not complete the intervention due to a lack of motivation to attend the sessions and behavioral changes significantly interfering with their compliance with the intervention. The remaining participants attended all scheduled 14 CT sessions (Attendance rate: 100%), revealing a high level of engagement during sessions. At 3-month follow-up, the completion rate in the FBI-CT group was 77.78% ($N=7$) and in the T-CT group was 100% ($n=9$). Two participants in the FBI-CT group were lost to follow-up due to unpredictable reasons, which were not related to their engagement and motivation for the intervention: clinical discharge and hospital admission (surgical procedure). Regarding the acceptability results, participants in the FBI-CT group obtained 62 points out of 70 in the satisfaction questionnaire, whereas the T-CT group obtained 59 points out of 70. These results indicate that both groups demonstrated high satisfaction following the interventions, with the FBI-CT group exhibiting slightly higher satisfaction.

Secondary cognitive outcomes

Table 3 illustrates the secondary cognitive outcome measure scores for both groups at baseline, postintervention, and follow-up. A within-group analysis demonstrated that the FBI-CT group showed a significant increase at postintervention in the Digit Symbol (Coding) subtest [Pre:

Table 2. Sociodemographic and Clinical Characteristics of the Sample

	FBI-CT (n = 9)	*T-CT* (n = 9)	*Statistical test and* P-*value*
Age	50.78 ± 10.80	55.22 ± 10.93	$t=-0.868$; $P=0.398$
Education (years)	8.56 ± 3.94	6.00 ± 2.60	$t=1.624$; $P=0.095$
Institutionalization (years)	5.67 ± 5.24	8.44 ± 5.92	$t=-1.054$; $P=0.651$
Quarantine (days)	14 (7)	14 (14)	$U=32.500$; $P=0.427$
Experience with technology use (computer, smartphone, tablet)			
Have used technological devices (computer, smartphone, tablet) before this study	2 (22.22%)	2 (22.22%)	FET = 1.00; $P=0.712$
Never used technological devices (computer, smartphone, tablet) before this study	7 (77.78%)	7 (77.78%)	
Diagnosis			
Schizophrenia	4 (44.44%)	7 (77.78%)	FET = 6.43; $P=0.475$
Unspecified nonorganic psychosis	1 (11.11%)	0	
Recurrent depressive disorder	1 (11.11%)	0	
Adjustment disorders	1 (11.11%)	0	
Personality disorders	0	1 (11.11%)	
Bipolar affective disorder	1 (11.11%)	1 (11.11%)	
Mental and behavioral disorders due to the use of alcohol	1 (11.11%)	0	

t, independent sample *t*-test; U, Mann–Whitney Test; FET, fisher exact test; FBI-CT, full-body interaction cognitive training; T-CT, tablet-based cognitive training.

Table 3. Secondary Cognitive Outcome Measures Scores (Presented as Medians and IQR) in the Three Assessment Moments

	FBI-CT			T-CT		
	Baseline (n=9)	*Post* (n=9)	*FU* (n=7)	*Baseline* (n=9)	*Post* (n=9)	*FU* (n=9)
MoCA Total	22 (8.5)	23 (4.5)	19 (8)	16 (11)	17 (7)	20 (10)
FAB total	12 (3)	14 (4)	14 (4)	9 (4.5)	**11 (5)**	10 (6)
Digit Symbol (Coding)	35 (13.5)	**43 (14)**	38 (4)	20 (34)	13 (36.5)	22 (30)
Symbol Search	12 (11)	14 (12.5)	10 (9)	7 (12.5)	17 (26)	6 (18.5)
Dispersion index (TP) (%)	23.4 (57.85)	17.7 (66.02)	14.96 (64.98)	34.61 (129.56)	25 (45.22)	44.79 (55.26)
Work efficiency (TP)	88 (87.5)	86 (128.5)	104 (88)	17 (92.5)	**86 (82)**	53 (109)
Total free recall (FCSRT)	44 (8)	**47 (5.5)**	**46 (4)**	33 (16.5)	**37 (14.5)**	41 (17)
Total delayed recall (FCSRT)	16 (4)	16 (1.5)	16 (2)	13 (8)	14 (5)	15 (6.5)
Semantic verbal fluency (animals)	14 (5)	**17 (7.5)**	13 (7)	8 (6)	8 (6.5)	8 (6.75)
Phonemic fluency	19 (13.5)	22 (10)	31 (9)	13 (9)	11 (15.5)	15 (13.5)

Within-group significant differences are represented in bold.

Mdn = 35, IQR = 13.5; Post: Mdn = 43, IQR = 14 ($W_{(9)}$ = 36.000, Z = –2.527, P = 0.012, r = 0.84)], in the FCSRT's total free recall trials [Pre: Mdn = 44, IQR = 8; Post: Mdn = 47, IQR = 5.5 ($W_{(9)}$ = 36.000, Z = –2.524, P = 0.008, r = 0.84)], and in the Semantic verbal fluency test [Pre: Mdn = 14, IQR = 5; Post: Mdn = 17, IQR = 7.5 ($W_{(9)}$ = 41.000, Z = –2.203, P = 0.027, r = 0.73)]. As to the T-CT group, there was a significant improvement at postintervention in FAB's total score [Pre: Mdn = 9, IQR = 4.5; Post: Mdn = 11, IQR = 5 ($W_{(9)}$ = 26.500, Z = –2.132, P = 0.047, r = 0.71)], in the Work Efficiency Index [Pre: Mdn = 17, IQR = 92.5; Post: Mdn = 86, IQR = 82 ($W_{(9)}$ = 42.000, Z = –2.312, P = 0.020, r = 0.77)], and in the FCSRT's total free recall trials [Pre: Mdn = 33, IQR = 16.5; Post: Mdn = 37, IQR = 14.5 ($W_{(9)}$ = 41.000, Z = –2.201, P = 0.014, r = 0.73)]. At 3-months follow-up, only the FBI-CT group revealed a significant increase in FCSRT's total free recall trials [Pre: Mdn = 44, IQR = 8; FU: Mdn = 46, IQR = 4 ($W_{(7)}$ = 26.5000, Z = –2.117, P = 0.047, r = 0.80)]. We did not find any differences between-group in all secondary cognitive outcomes across the three assessment moments.

Secondary noncognitive outcome measures

The secondary noncognitive outcome measure scores for both groups in the three assessment moments are described in Table 4. A within-group analysis revealed that the FBI-CT group presented significant improvements in the BDI-II inventory at postintervention [Pre: Mdn = 4, IQR = 6.5; Post: Mdn = 0, IQR = 1.5, $W_{(9)}$ = 0.000, Z = –2.539, P = 0.008, r = 0.85)] and follow-up [Pre: Mdn = 4, IQR = 6.5; FU: Mdn = 0, IQR = 0, $W_{(7)}$ = 0.000, Z = –2.226, P = 0.026, r = 0.84)]. A between-group analysis also revealed greater improvements in BDI-II in this group, compared to the T-CT group, at follow-up (U = 12.000, Z = –2.064; P = 0.042; r = 0.78). Considering the WHOQOL-Bref total score, the FBI-CT group was the only one that exhibited a significant increase in quality of life at postintervention [Pre: Mdn = 72.9, IQR = 20.35; Post: Mdn = 84.2, IQR = 17.65 ($W_{(9)}$ = 44.000, Z = –2.547, P = 0.008, r = 0.85)]. A between-group analysis demonstrated that the T-CT group showed significantly greater improvements in quality of life compared to the FBI-CT group at follow-up (U = 11.000, Z = –2.196; P = 0.028; r = 0.73).

Discussion

This pilot RCT sought to examine FBI-CT's feasibility, acceptability, and preliminary impact on cognitive and noncognitive outcomes in a sample of psychiatric inpatients. The FBI-CT intervention was compared to a homologous condition in terms of structure (frequency, number of sessions) and content—the T-CT—but different in terms of the experimental setup used.

The high rates of treatment completion at postintervention and 3-month follow-up, as well as participants' CT session attendance, demonstrate the feasibility of both FBI-CT and T-CT for psychiatric inpatients. Although both training conditions were associated with high satisfaction following the intervention process, participants assigned to the FBI-CT group reported a slightly higher satisfaction (62/70 points) than those assigned to the T-CT group (59/70 points). These results suggest that FBI-CT may be associated with higher acceptability among inpatients, possibly due to the dynamic nature of the interaction that the intervention requires (i.e., performing the CTTs by producing specific

Table 4. Secondary Noncognitive Outcome Measures Scores (Presented as Medians and Interquartile Ranges) in the Three Assessment Moments

	FBI-CT			T-CT		
	Baseline (n=9)	*Post* (n=9)	*FU* (n=7)	*Baseline* (n=9)	*Post* (n=9)	*FU* (n=9)
BDI-II	4 (6.5)	**0 (1.5)**	**0 (0)***	4 (6.5)	2 (5.5)	4 (7.5)
WHOQOL-Bref total (%)	72.9 (20.35)	**84.2 (17.65)**	73.4 (20.9)	70.2 (17.65)	74.4 (19.85)	73.3 (21.55)*
Global disability index (IAFAI) (%)	1.89 (2.59)	1.89 (7.69)	2.77 (6.82)	2.63 (13.27)	2.94 (8.32)	5.41 (14.54)

Within-group significant differences are represented in bold, and between-group differences are indicated with an asterisk.

movements), since the intervention's structure and content are the same for both conditions.

Now, considering specifically the secondary cognitive outcomes, our preliminary results appear to suggest that both training conditions are associated with different cognitive gains in the short term (postintervention), possibly related to variations in the training setups (full-body interaction vs. tablet) that might have influenced patients' interaction with the CTTs. More specifically, the FBI-CT group demonstrated significant improvements in cognitive domains such as processing speed and sustained attention for shorter periods, verbal memory (spontaneous recall processes), and semantic verbal fluency. In contrast, the T-CT group revealed significant improvements in sustained attention for long periods, verbal memory (spontaneous recall processes), and executive functions. Moreover, only the FBI-CT group maintained its verbal memory improvements 3 months after the intervention.

Interestingly, our results are not entirely in accordance with previous studies on the efficacy of technology-based simultaneous CT and PA in nonclinical[28,29] and clinical populations,[27] namely, concerning the impact of the FBI-CT condition on sustained attention for long periods and executive functions. Nonetheless, these previous studies were not conducted with psychiatric patients and varied greatly in terms of technologies used, intervention content, session frequency, assessment moments, and outcome measures, making it challenging to compare them with the present pilot RCT. For instance, a pilot study[27] conducted with 6 acquired brain injury patients assessed the feasibility and efficacy of the Active Brain Trainer—a motion-based VR CT program targeting executive functions—and found nonsignificant improvements in divided attention and executive functions (strategic planning). A study[28] with 18 community-dwelling older adults compared semi-immersive VR-based CT combined with locomotor activity ($n=9$) with conventional CT ($n=9$) and verified that the latter resulted in greater gains in sustained attention for short periods, working memory, and gait speed. Another study[29] with 41 community-dwelling adults revealed that a 12-week dual-task Tai Chi intervention using Kinect improved the elderly's executive functions. In all these studies, there appears to be a tendency toward improving executive functions following the technology-based simultaneous combined CT and PA intervention. This is a finding we could not verify in our study, except for the FBI-CT group improvements in retrieval processes associated with verbal episodic memory at postintervention and follow-up, which can be a result of executive gains, since executive control mechanisms underlie retrieval processes.[48] We suspect that this could be explained by the fact that not all CT sessions in the FBI-CT group involved dual-tasking training. After all, only the *Musiquence* search activities required participants to walk continuously to find the targets while avoiding the distractor items and keeping the instructions in mind (e.g., ''Find all items starting with the letter B and C, and not with the letter A and D''). Hence, we should have increased the cognitive-motor interference during the CTTs' performance to improve the executive training.

Concerning the T-CT improvements in sustained attention for long periods, we believe that the training setup—that is, the tablet—was more suitable to train this cognitive domain, as participants are solely focused on solving the CTTs. In opposition, participants in the FBI-CT condition were required to interact with the CTTs by performing specific movements, which means they needed to divide their attentional resources, which is an ability that was not covered by our neuropsychological assessment protocol. In this sense, it would have been helpful to measure divided attention and cognitive flexibility with a neuropsychological instrument such as the Trail Making Test-part B to identify if patients in the FBI-CT condition revealed improvements in these domains. Regarding the semantic verbal fluency improvements in the FBI-CT group, we need to interpret them with caution as both groups differed in this domain at baseline (i.e., the FBI-CT group was superior in terms of semantic fluency abilities before the intervention phase).

As to the secondary noncognitive outcome measures, we verified that the FBI-CT group reported fewer depressive symptoms and greater quality of life following the intervention, maintaining mood-related gains 3 months later. These preliminary findings are encouraging and align with previous results that show that combined CT and PA results in greater improvements in noncognitive domains.[16,17] Improvements in these noncognitive domains can result from the fact that this type of training was perceived as more meaningful than CT alone. After all, FBI-CT implemented through ICTs can help to simulate a training context that is closer to reality by allowing the integration of ADL-based CTTs, motor activity, and multisensory input.[18,21] In contrast, the T-CT group reported a higher quality of life at 3-month follow-up compared to the FBI-CT group, which was not an expected result.

Furthermore, it is important to note that the cognitive and noncognitive gains observed in both training conditions did not transfer to functional abilities, even though our CT program included ecologically oriented CTTs. We found nonsignificant raises in the IAFAI global disability index for both groups at follow-up, which were more pronounced for the T-CT group. In our view, there are at least three possible reasons for this result:

(1) At the end of the intervention, an increase in participants' awareness of their cognitive and functional limitations may have occurred, translating into a more negative self-report toward functional disability;
(2) Participants involved in this study were institutionalized in a long-term care psychiatric facility and, therefore, could not perform several IADLs (e.g., cooking, managing their finances, and using public transportation) listed in the IAFAI. In fact, the IAFAI was not developed to be administered in an institutional setting, as most items do not apply to these patients.[42] It would have been helpful to assess functional capacity through a performance-based instrument designed to be applied in an inpatient setting and that considered BADLs and IADL-related items that patients usually performed within this context;
(3) Due to the COVID-19 pandemic, many adjustments to the institution's policies entailed several restrictions on participants' involvement in functional and occupational activities. These restrictions further narrowed their opportunities of carrying out daily

activities that are fundamental for promoting their sense of autonomy and independence, possibly increasing their perception of functional disability.

Limitations

Several limitations to this study must be mentioned. The small sample size, the fact that all participants were female, and the high heterogeneity in participants' psychiatric diagnoses hinder the generalization of our findings to the broader community of adults with psychiatric illnesses. Focusing specifically on the fact that our sample was composed of only female inpatients, it is essential to note that, since sex differences in cognition may be considered a ''patchwork,'' where women perform better on some measures and men on others,[49] the results could be different in a male sample. Consequently, the interpretation and generalization of our findings should be cautious. Concerning the variability in psychiatric diagnosis, and despite no significant differences between both groups being found in clinical diagnosis, it is worth mentioning that the T-CT group was primarily composed of patients with schizophrenia (around 70%) compared to the FBI-CT group (around 40%). Schizophrenia is known to be a debilitating psychiatric condition that affects more profusely cognitive functioning. As participants with more pronounced cognitive impairments tend to benefit more from cognitive interventions,[50] within-group changes in cognitive outcome measures in the T-CT group might have resulted from the cognitive gains exhibited by participants with schizophrenia, given that they may potentially have more room for improvement.

Furthermore, an intention to treat analysis was not carried out, we only analyzed data from participants who completed baseline, post, and follow-up neuropsychological assessments. In this study, as this is a single-blind pilot RCT, only participants were blind to the experimental conditions. The psychologist responsible for performing the neuropsychological assessments and the training sessions was aware of patients' allocation, which could likely have introduced bias in the current findings. Moreover, this study occurred during the COVID-19 pandemic, which posed additional challenges during data collection. Thus, some participants were required to comply with quarantine to control the COVID-19 outbreak in the institution. We believe that the burden of quarantine associated with the psychosocial impact of the pandemic, in general, may have worsened participants' clinical condition, therefore interfering with our preliminary results. Notwithstanding, by conducting this study in such a critical period, it was possible to guarantee that patients were given the possibility to participate in interventions intended to stimulate their cognitive functions, as many inpatients' services, including the institutions' psychology service, were suspended. Finally, we did not consider physical indicators, such as gait analysis, risk of fall, and PA levels; nonetheless, this was not the goal of this study once the FBI-CT intervention was not conceived to be an exergame intervention.

Conclusions

In summary, we found support for the feasibility and acceptability of the two training approaches. In addition, both FBI-CT and T-CT appeared to be associated with different cognitive and noncognitive positive effects. Unfortunately, the training gains did not transfer to ADLs. Nonetheless, it is not yet possible to conclude which type of approach leads to greater gains due to the pilot nature of this study and the limitations mentioned above. Our results, despite preliminary, are encouraging and will, hopefully, inform future effectiveness research in this field. Future large-scale studies should be carried out to clarify whether FBI-CT is a more effective approach than T-CT for enhancing cognitive and noncognitive outcomes of chronic psychiatric inpatients in the short and long term.

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Ethical Approval

The study was approved by the CSCP's Ethics Committee (Reference number: 1/2021) (Funchal, Madeira Island), who confirmed that it complied with the national and international guidelines for scientific research with humans. All participants gave their written informed consent before participating.

Authors' Contribution

J.C., L.F., A.L., M.V., and S.B.i.B. contributed to the design of the study. J.C. performed the data collection and the data analysis. J.C., L.F., A.L., and S.B.i.B. wrote the article for publication. The authors reviewed and approved the final version of the article. This article has been submitted solely to this journal and is not published or submitted elsewhere.

Author Disclosure Statement

No competing financial interests exist.

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Supplementary Material

Supplementary Data

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