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Exergame and cognitive-motor dual-task training in the healthy elderly (INCOME): a study protocol

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ABSTRACT

Background: Ageing is associated with a decrease in cognitive, motor, and dual-task capacities, leading to a possible loss of autonomy. Cognitive-motor dual-task training is known to be effective on these functions but suffers from low adherence. On this point, exergames seem to be a promising solution. We aim to evaluate the effects of a new customized exergame on 1) postural stability under dual-task conditions 2) cognitive, motor and biopsychosocial factors in the elderly. **Methods:** Thirty-nine elderly persons (65 years old or above) will carry out 30 minutes of cognitive-motor dual-task training through our exergame, 2 to 3 times a week for 12 weeks. We will assess postural control under single and dual-task conditions (stabilometric platform), mental inhibition (Stroop test), mental flexibility (Trail Making Test), working memory (N-Back), mobility (Timed Up-and-Go), balance (Berg Balance Scale), fear of falling (Falls Efficacy Scale), quality of life (EuroQol), city exploration, and tracked (Armband®) or self-reported (QAPPA) physical activity level. Lastly, we will assess the safety (adverse events) and adherence (compliance, drop-out, motivation) of this intervention. These evaluations will take place after the training protocol and after a 3-month follow-up. **Discussion:** This pilot study is expected to bring positive gains for the participants, as well as exploration of current knowledge gaps in the literature.

Trial registration: NCT04179708 ([ClinicalTrials.gov](https://clinicaltrials.gov))

KEYWORDS: cognitive-motor dual-task; exergame; study protocol; training; elderly

Background

Ageing is associated with a high risk of developing physical or cognitive impairments, contributing to invalidity and loss of autonomy in older adults [1]. Among physical capacities that decrease with age, we can mention decreases in muscle strength, balance as well as mobility [2, 3], which are fall risk factors. Regarding cognitive capacities, decrease in executive functions, reaction time and processing speed likewise represent fall risk factors [4]. Aging is associated with a

decreased ability to perform two tasks simultaneously (i.e., dual-task), one cognitive and one motor [5, 6]. The performance decrease in one or both tasks highlights cognitive-motor interference that can be explained by an overload of the attentional capacities. Most daily activities require the simultaneous performance of two tasks [7], and loss of this capacity can lead to loss of autonomy. Postural control under dual-task condition is impaired and is a predictor of falling in older adults [8, 9, 10, 11]. That is the reason why new strategies such as cognitive-motor dual-task (CMDT) intervention seem relevant to improve this function.

Abundant literature illustrates the positive effects of CMDT on cognitive, motor, and dual-task capacities in elderly persons with [12] or without [13] cognitive impairments. There are many types of interventions that induce cognitive-motor interference, such as exergames. Exergames are active video games that require physical activity in order to be played [14]. Systematic reviews studying the effectiveness of exergames

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have presented mixed results, considering them to be effective on cognitive capacities [15], but not necessarily on motor capacities [16, 17]. A recent overview has highlighted the need to assess the impact of exergames on motor and dual task functions in elderly persons [13].

In general, one of the major obstacles is the possibly insufficient participation and motivation of elderly persons in training programs [18]. On the contrary, their adhesion to exergames seems good [19], and in any event superior to conventional interventions [20, 21]. Their success may be due to the continuous and instant feedback offered by exergames [22], as well as the fun aspect [23] which enhances participant adherence and compliance by increasing their pleasure and enjoyment [22, 23]. Most of the exergames used in rehabilitation are commercial videogames such as Nintendo® Wii or Xbox® Kinect [24]. However, many recommendations for the conception, design and use of games in health indicate that in order to be effective, they must be specific to patients' needs [25, 26]. Except for a few initiatives (i.g., SylverFit, MediMoov and Mira Rehab), there are presently few exergames specific to the elderly population. Recently, we have developed a new tool, the "Virtual Carpet", to assess visuospatial working memory [27, 28, 29]. This tool uses an interactive floor which can be adapted for a training program (Figure 1) [30]. The flexibility provided by this device makes it possible to design a game that meets the needs of seniors based on their city's heritage (buildings, gardens and living spaces). Based on the reminiscence theory of knowledge [31], reference to local cultural heritage should not only increase adherence and immersion in the game, but also encourage participants to leave their homes and rediscover these places. Finally, while retention of benefits is an important criterion for interventional studies, this information is rarely reported for CMDT and exergames [32, 33, 34, 35, 36, 37], with mixed results ranging from zero to five years of retention of benefits. A recent overview highlighted the need to measure the adherence, safety and retention of benefits of CMDT and exergames among the elderly [13].

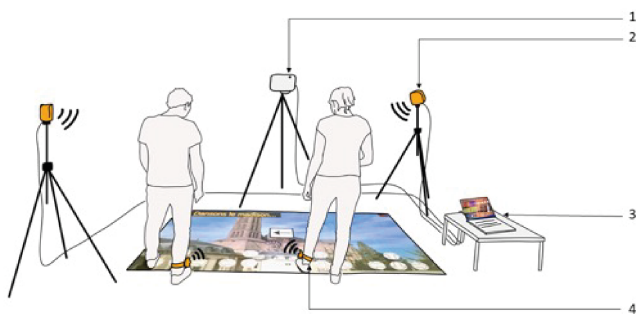


Figure 1 The exergame. 1) Video projector, 2) Projected scene 3) Computer. In this illustration, only two participants are present, the objective being to maximize visibility

Primary aim of the trial

The primary aim of this study is to compare postural control under dual-task conditions with a stabilometric platform before (T1) and after (T2) CMDT using a custom-made exergame as support in an elderly population.

Secondary aims of the trial

The secondary aims of this study are to assess the effects of this exergame after training (T2) and a follow-up (T3) period on the cognitive and motor capacities, physical activity level, city exploration, and quality

of life of elderly participants. We also aim at assessing the safety and adherence levels of this exergame.

Methods

Study design and settings

The INCOME project (INterference COgnitivo-Motrice Exercise) is a 24-week prospective multicentric pilot study. The HAVAE laboratory from the Limoges University will conduct this study in Nouvelle-Aquitaine, France, and the Limoges University Hospital will be the promoter. The study protocol is in accordance with the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) guidelines. Participants will perform CMDT through an exergame for 12 weeks, followed by 12 weeks without training (see detailed study flowchart in Figure 2).

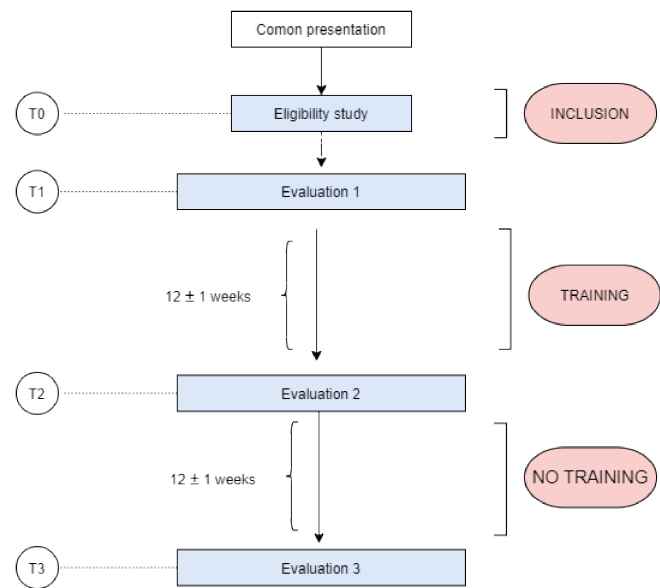


Figure 2 Study flowchart

Participants

Recruitment The principal investigator will recruit participants among elderly persons living in autonomous municipal residences (RAMs) or participating in senior clubs in the city of Limoges. The principal investigator will introduce the study to potential participants. Volunteers will be received individually for an eligibility study. If they meet the inclusion criteria and give their written consent (see supplemental material), they will be included and will then receive an information notice (see supplemental material). Participants will be excluded from the study if: a) they withdraw their consent to participate in this study during or after data collection, b) a serious adverse event occurs (deterioration of the participant's state of health, fall, injury, onset of disabling pain).

Eligibility To participate in this study, volunteers must: a) be over 65 years old, b) be a resident of a RAM or a member of a senior club in the city of Limoges, c) have normal or corrected vision and hearing, d) be able to walk and stand without assistance (a single cane as the maximum technical aid allowed). We will not include people who present diagnosed psychiatric disorders or neurological pathologies (cardiovascular accidents, Parkinson's or Alzheimer's disease, dementia), drug intake affecting walking or balance, a need for technical assistance (double cane, walker), inability to carry out the training program, as well as people under curatorship, guardianship or legal protection, not affiliated to social security, or unable to understand the protocol.

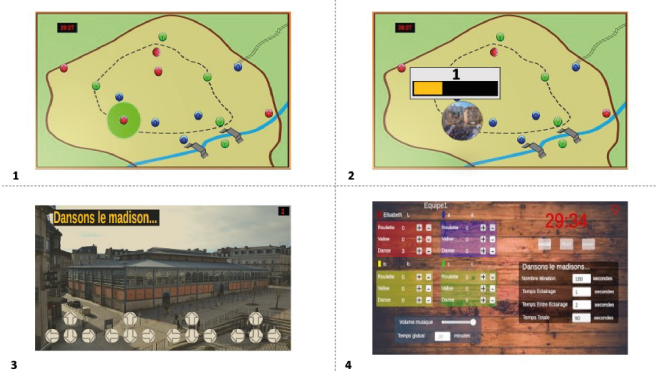


Figure 3 The different exergame interfaces displayed on the ground for players (3.1-3.3) or on the screen for the animator (3.4). The city of Limoges and its 15 points of interest (3.1), Loading of a mini game (3.2), Mini-game interface (e.g., stepper) (3.3), Animator interface (3.4).

Sample size calculation The calculation is based on a previous study by Fraser et al., assessing postural control during a concurrent cognitive task [38]. We hypothesized that the program would improve center of pressure oscillation speed ($mm.s^{-1}$) when performing a Stroop test by 30%. We performed an estimation with .80 power and .05 α risk. The resulting required sample size was 32 subjects. We added 20% to ensure the statistical power of the study, taking into account drop-out. As a result, the total sample will consist in 39 participants.

Ethical approval and considerations

All procedures will follow the principles of the Good Clinical Practice Guidelines of the Declaration of Helsinki. This project received authorization from the ethics and individual protection committee (IPC) sud-est 2 (specific reference number: 2020-A02805-34). Any significant amendment to the protocol will have to be approved by the Committee prior to its implementation. This project is registered at [ClinicalTrials.gov](https://www.clinicaltrials.gov) (NCT04803799). The consent form and the information notice will be drawn up in triplicate, one copy of which will be given to each participant. Results will be published in relevant scientific journals and be disseminated in international conferences.

Intervention

Exergame conceptualization We conceptualized our exergame based on recommendations from senior training [13]. The game consists in a projection of the city of Limoges onto the ground as a game board. The space needed for the game setting is 5 meters x 5 meters. This allows projection of the board game on the ground (3 meters x 4 meters) while keeping space for participant displacement and chair placement for any needed pause. The aim of the game is for players to explore the main places in the city, which hosts mini-games involving CMDT lasting an average of 3 minutes. The 30-minute sessions will take place in groups of 4 participants who will collectively try to obtain the highest possible score. The scores are assigned by the animator for each mini-game as follows: a player's presence counts as 1, his participation as 2, and his satisfactory achievement as 3 (see Figure 3.4). The sessions will take place 2 to 3 times a week for 12 weeks (2 sessions in even weeks, 3 in odd weeks); this training rate is based on published guidelines [39]. Since the groups are set in advance, the players will be able to see the progression curve of individual and collective scores over the course of the 12 weeks. To facilitate understanding of the game, we use slow animations, large fonts, and simple menus and rules [40].

Interfaces The mini-games sequences proceed as follows: each player is associated with a color (red, yellow, green, or blue) represented by his

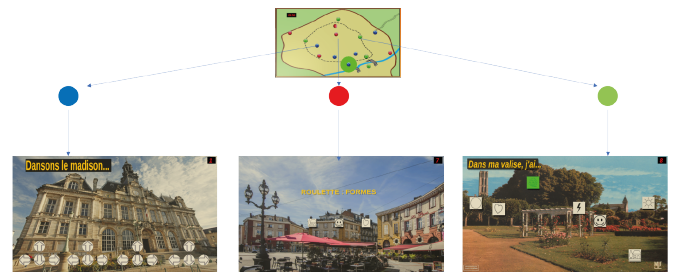


Figure 4 Three points of interest and exercises types. The schematic view of the city contains 15 points of interest, grouped into three categories: five buildings in blue, five events in red and five parks in green. These points of interest also represent exercises types: *The buildings* represent a stepping activity. Arrows are displayed successively on the projected image, and participants must reproduce them on a pad with one foot, two feet, a squat, a lunge, etc. The additional cognitive tasks are to not reproduce an arrow (i.e. go/no go), to invert them (mental flexibility), or to perform them with a delay (working memory). *The events* represent muscle strength and coordination. Participants must perform muscle strengthening exercises (e.g. squats and lunges). At the same time, they must solve mental arithmetic exercises appearing on the projected image, alternate the exercises performed according to the images appearing, perform a “categories” game or build a word giving a letter at each turn. *The parks* represent visuospatial memory and balance. Eight elements displayed within the projected area turn on and off at a fixed frequency, constituting a growing span. Participants must memorize this sequence and then recall it while moving around. At the same time, they perform motor exercises (knee raising, buttocks-heels, squats, lunges, jumping jacks). The additional cognitive tasks are to not consider one of the icons, or to recall all from the end.

HTC® Vive tracker. The projected city of Limoges includes 15 points of interest (parks, buildings, or events). At each step, a single point of interest is randomly selected, and circled with one of the four colors (Figure 3.1). It is then up to the player with the corresponding color to step on the circled point of interest for 3 seconds (materialized by a visible countdown). The scene then changes to the corresponding mini-game interface (Figures 3.2 and 3.3). Once the 3-minute mini-game has been completed, the game board goes back to the projected city of Limoges (Figure 3.1), where a new point of interest is selected (with a color corresponding to a different player). It bears mentioning that successively, each player will have an active role in launching the mini-games, using a random selection from an updated list of previously unsolicited players (at each step, the selected player is removed from the list). When the list is empty, it is simply refilled with each participant, thereby maintaining awareness, even between mini-games.

The scene changes are triggered using the collision between the estimated position of the players (given by the HTC® Vive trackers in the real world) and their collision with the known position of the points of interest (in the application). To detect such collisions and given that both positions are expressed in different coordinate systems, a projection of the player's position in the game frame must be performed (in real time). In other words, given a point $\mathbf{p} = (x_w, y_w)$ expressed in the world coordinate system, it is required to estimate its position $\mathbf{q} = (x_g, y_g)$ in the game scene. This is given by $\mathbf{q} = \mathbf{H}\mathbf{p}$, where H is the homography matrix between the world scene and the game scene, obtained by calibration when the game is installed - a specific tool was designed for this purpose. Given that the position of each player is estimated by the HTC® Vive trackers with accuracy [41] but with some noises, a low pass filter is applied to improve player experience.

Finally, a second view projected on an independent screen is specifically

dedicated to the animator (Figure 3.4). It acts as a control panel, and enables the functioning of essential supervision tools, such as mini-game pause or reset, difficulty settings (i.e. how often or how quickly items are displayed), and point management.

Training program The training program is made up of dual-task exercises, which are proposed during 3 mini-games (Figure 4). These mini-games are represented by 3 different point of interest categories: parks, buildings, or events. “Parks” bring together visuospatial memory and gait, “buildings” the stepping exercise, and “events” muscular strength and coordination training. The requested motor tasks are stepping, postural control and resistance training which are conventional in fall prevention programs for seniors [42, 43, 44]. The postural control exercises consist of working on ground supports, uni or bipodal balance, displacement of the center of pressure, with or without intrinsic and extrinsic destabilization. The strengthening exercises target the lower limbs and the trunk, in endurance and functional, with or without equipment (weights, rubber bands). Cognitive tasks include verbal fluency, mental inhibition, flexibility, visuospatial memory and processing speed training [4, 39, 45]. To illustrate, one of the exercises consisted in performing lunges while walking on the projected scene, the objective being to recreate the presented path in the city while counting backward or giving the name of a city on each point of interest. These cognitive and motor dual-task exercises are based on the recommendations found in the literature: increasing difficulty in speed, number of repetitions, or use of gymnastic equipment (weights, rubber bands, etc.) [33], complex tasks [14, 33] carried out simultaneously [46], with variable priority instruction [32, 33], and feedback at the end of each training session [33, 39]. Frequency ranges from 15 to 30 movements per minute. The speed and the number of repetitions depend directly on frequency, because each exercise time is set in advance (3 minutes on average). We preliminarily designed an incremental program. The milestone underlying the decision to increase the overall difficulty is the success of each participant at a certain level during one week. Our exergame and the different exercises it offers have already been presented in a pre-study in young and healthy subjects [47].

Outcomes and Evaluations

The approximate duration of the assessment is 2 hours. Assessment of the participants' physical activity level takes place over 1 week. See Table 1 for the details of evaluations performed at T1, T2 and T3.

Primary outcome The primary outcome of the study will be an analysis between T1 and T2 of the center of pressure speed oscillation ($mm.s^{-1}$) on a stabilometric platform (Win-Posturo, Médicaptureurs®) during the performance of a concurrent Stroop test. Postural control in dual-task condition is widely used in studies involving elderly persons [38, 48, 49, 47, 50, 51, 52, 53, 54, 55]. During the evaluation, the participant is standing still on the platform, arms along the body. The participant is instructed to actively control his posture, standing as still as possible, and to perform a Stroop test during the 30-second evaluation. The Stroop test is presented on a poster (2m x 1m) pinned on the wall, 1.5 meters away from the platform.

Secondary outcome Measured at different times (T1, T2 or T3, see Table 1), the secondary outcomes are as follows:

1. Cognitive capacities: we will assess the dominant executive functions
 - (a) **Mental inhibition:** During the Stroop test [56], the participant must distinguish the name of the written color from the color of the ink used. Scoring includes the time to complete the test (s), and the number of corrected and uncorrected errors
 - (b) **Mental flexibility:** During the Trail Making Test (TMT) [57], the participant must link a consecutive sequence of 25 targets

in ascending order; initially numbers (1,2,3, etc.), then letters (A, B, C, etc.), and finally the alternation between the two (1, A, 2, B, 3, C, etc.). Scoring includes the time to complete the test(s) as well as the number of errors.

- (c) **Working memory:** During the visual N-Back test [58], a continuous sequence of letters is presented to the participant. The task is to continuously indicate the letter previously displayed. The score corresponds to the number of errors.
2. Motor capacities: We will assess motor functions with a major component concerning the risk of falling.
 - (a) **Mobility:** During the Timed Up-and-Go test (TUG) [59], the subject will have to rise from his chair, walk 10 feet, turn around a mark, return to the chair, and sit down. The rating corresponds to the time taken to complete the test (s).
 - (b) **Balance:** During the Berg Balance Scale (BBS) test [60], the subject is required to complete 14 simple balance tasks, ranging from getting up from a chair to standing on one leg. Scoring is done on a scale of 0 to 56 corresponding to the 14 items. Association between TUG sensitivity and BBS specificity is recommended in evaluation of the elderly [61].
 - (c) **Fear of falling:** The Falls Efficacy Scale International (FES-I) [62] explores the participant's concern about the possibility of falling while performing activities. Scoring is done on a scale of 16 to 64 corresponding to the 16 items.
 - (d) **Postural control in a single task condition:** Evaluation is made by studying the center of pressure oscillation speed ($mm.s^{-1}$) on a stabilometric platform (WIN-POSTURO, Médicaptureurs®). During the evaluation, the participant is standing still on the platform, arms along the body. The participant is instructed to actively control his posture to stand as still as possible during the 30-second evaluation.
 3. Physical activity level, assessed with:
 - (a) A French questionnaire, the « Questionnaire d'activité physique pour les personnes âgées » (QAPPA) [63], assessing average weekly physical activity level (MET/min/week).
 - (b) Wearing an Armband® (Sensewear Bodymedia) : mobile sensor worn on the arm during 7 days, assessing active energy expenditure (MET) and the number of steps [64].
 4. City exploration: We will carry out an analysis of the city exploration made by the participants during the 12 weeks of training and the 12-week follow-up by means of a quantitative and qualitative survey concerning participants' departures from their residence or domicile. Participants must complete a weekly diary, indicating the number of times they leave their residence as well as the frequency of visits to the points of interest highlighted in the game (buildings, gardens, etc.).
 5. Quality of life: We will carry out an analysis of the participants' quality of life by using the EuroQol 5 dimensions 5 levels (EQ-5D-5L) [65].
 6. Safety: We will carry out a qualitative and quantitative analysis of the adverse events having occurred during the intervention (number, nature, severity and causes).
 7. Adherence, including:
 - (a) **compliance**, i.e. the number of sessions actually performed compared to the total number of sessions,

Table 1 Summary of participants' monitoring.

	INCLUSION	EVALUATION 1 ^a	TRAINING	EVALUATION 2 ^a	FOLLOW-UP	EVALUATION 3 ^a
	T0	T1 T0 + 1 week	T1 + 12 weeks (+ / - 1 week)	T2	T2 + 12 weeks (+ / - 1 week)	T3
Information and consent	X					
Eligibility	X	X				
Sociodemographic		X				
PC DT		X		X		X
Stroop		X		X		X
TMT		X		X		X
N-Back		X		X		X
TUG		X		X		X
BBS		X		X		X
FES-I		X		X		X
PC ST		X		X		X
Security			X			
Compliance			X			
Drop-out			X			
EMAPS		X		X		X
Armband ^{®1}		X		X		X
QAPPA		X		X		X
City exploration			X			
EQ-5D-5L		X		X		X

¹ Armband[®] worn for 7 days ; ^a : evaluations carried out over 2 weeks. BBS : Berg balance scale ; DT dual task ; EMAPS: échelle de motivation pour l'activité physique à des fins de santé; EQ-5D-5L : EuroQol 5 dimensions 5 levels ; FES-I: falls efficiency scale international; PC : postural control ; QAPPA: questionnaire d'activité physique des personnes âgées ; ST: single task; TMT : trail making test ; TUG : timed up and go.

(b) **drop-outs**, i.e. the number of participants not going on until the end of the program,

(c) **motivation**, assessed through a French scale, the « Echelle de Motivation pour l'Activité Physique à des fins de Santé » (EMAPS) [66].

Data, constraints, and monitoring

Data collection and management A case report form will be used to collect personal and clinical data, and any missing data will have to be justified. The investigator will then have to transcribe this anonymized data on the secure servers of the Limoges CHU. Construction and securing of these databases is the CHU's responsibility, has been validated by the CNIL, and may be audited by the promoter or the ANSM. Storage will be maintained for 15 years after the end of the study.

Statistical analysis We will describe quantitative variables as mean ± standard deviation, or median and interquartile, and qualitative variables as numbers, percentages and 95% confidence intervals. We will compare dual-task postural control before and after training (between T1 and T2) using either the paired Student's t test or the non-parametric Mann-Whitney test, depending on whether the data follow a normal distribution. The effect of time on the training program will be evaluated using a

repeated measures ANOVA or Friedman test, depending on whether the data follow a normal distribution. All participants will be included in the analysis (intention-to-treat analysis). A per-protocol analysis based on available (non-missing) data will also be carried out. The analysis will be performed using SPSS V.23.0.0.3 (IBM® SPSS Statistics).

Data monitoring and auditing The INCOME intervention protocol does not present a major risk for participants. As a result, we will not establish an independent data monitoring committee (IDMC). A clinical research technician will conduct data monitoring and auditing. The auditing will ensure research quality, result validity and compliance with French laws and regulations.

Constraints and compensation The main constraint in this study is the requirement of continuous training; participants will be allowed to enter another research project only once their participation in this study has ended, that is to say, after evaluation 3 has been completed. Participation in this study does not involve any compensation. Members of senior clubs who wish to participate will be compensated for their travel on a flat-rate basis of €100 or in proportion to the sessions carried out in the event of the participant leaving the study prematurely.

Discussion

The aim of this study is to evaluate the effects of a CMDT training program carried out through a custom-made exergame on dual-task, cognitive and physical capacities, physical activity level, city exploration, and quality of life of elderly participants, as well as safety and adherence to the exergame. This study is expected to bring positive gains for the participants as well as exploration of current knowledge gaps in the literature.

Based on the results of previous studies, which have shown an effect of exergames on cognitive [15, 42, 67] and motor [16, 20, 42, 68], functions in elderly persons, we expect to observe in participants an improvement in executive functions, as well as mobility and postural control. There are few studies evaluating the impact of exergames on dual-task abilities, and they have been without conclusive results [69, 70]. We can expect positive results among the elderly participants, exergames being a certain type of CMDT, which have been shown to be effective [13]. We can also expect satisfactory overall adherence [20, 21] and safety [12, 13]. Another positive impact of this trial is to increase the participants' levels of physical activity, either directly by training, or indirectly by highlighting their cultural heritage and encouraging them to explore their city. Improvement in participants' cognitive and motor functions and an increase in their level of physical activity should result in a reduction in risk factors for falls, maintenance of autonomy, and improved quality of life [7, 8, 9, 10, 11]. A fourth and final possible result of this study is inherent to the sustainability of the developed solution. The exergame will be left available to RAMs at the end of the study, and development of new mini-games will be possible in the future. The long-term availability of home training support is a crucial point in the context of the current global COVID-19 pandemic, which has rendered access to material and human rehabilitation resources particularly complex.

The main limitation of this study is the low level of evidence inherent to uncontrolled trials. However, this pilot study will serve as a basis for calculation of the sample size for a future randomized controlled clinical trial, comparing the level of effectiveness of the exergame on cognitive and motor capacities with a "traditional" CMDT training scheme known to be effective [12, 13].

Trial status The trial is currently in the recruitment phase. We have enrolled 27 out of the targeted 39 participants in the study and collected their initial data (T1).

Disclosure of interest

The authors declare they have no conflicting interests with the content of the article.

Ethics

This project received authorization from the ethics and individual protection committee (IPC) sud-est 2 (reference number: 2020-A02805-34).

Data availability

This project is registered and available at [ClinicalTrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT04803799) (NCT04803799)

Authors' contribution

Manuscript: M. Gallou-Guyot: Conceptualization, Methodology, Writing - original, Illustrations; S. Mandigout: Conceptualization, Methodology, Writing - corrections, Project management; P.S. Almeida Prado: Writing - corrections; R. Marie: Writing - corrections; A. Perrochon:

Conceptualization, Methodology, Writing - original, Illustrations, Supervision

Protocol: M. Gallou-Guyot: Animation, Assessment, Evaluation, Coordination; S. Mandigout: Coordination; P.S. Almeida Prado: Animation, Evaluation; R. Marie: Software development; J.-C. Daviet: Coordination; A. Perrochon: Coordination

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