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[1] L = Legal agreement, O = Other, P = Plan, PR = Prototype, R = Report, U = User scenario

[2] PU = Public, PP = Restricted to other programme participants (including the Commission Services), RE = Restricted to a group specified by the consortium (including the Commission Services), CO = Confidential, only for members of the consortium (including the Commission Services)

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| 7 | Physio SPArtos | SPARTOS | SME | Switzerland |

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| | | **Approved by (Partner)** |

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# 1. Introduction

This document is part of *Task 4.1: Trials methodology planning and ethics, Task 4.2: User recruitment, Task 4.3: Field trials and system validation – Phase 1* and *Task 4.4: Field trials – Phase 2* within *Work package 4: Evaluation and Field Trials*. The lead partner of this work package and task is ETHZ. The general purpose of this document is to provide the results of the studies performed in the VITAAL project. The first studies have been usability studies whereas the second studies were randomized controlled trials investigating feasibility and intervention effects.

# 2. Usability Study of an Individualized Exergame Training for Older Adults Suffering from Mobility Impairment

## 2.1. Introduction

The global population aged 60 years and over is constantly rising due to increasing life expectancy. The World Health Organization forecasts that the number of older people over 60 years will double from 1 billion in 2020 to almost 2.1 billion in 2050 [1]. With the growing older population, there has been a major interest in preventing age-related problems that cause morbidity and mortality and in maintaining and improving the quality of life in older adults. Ageing is a multidimensional process of changes in the physical, mental and social domains, which often leads to functional decline. The greater proportion of older people enhances the impact on ageing and behavior-related diseases and disabilities on society. Consequently, more and more older adults suffer from one of the "geriatric giants", such as mobility impairment (MI; immobility and instability), urinary incontinence (UI), and cognitive impairment (CI, impaired intellect) described by Prof. Bernhard Isaacs [2].

Mobility Impairment (MI) is observed in about 30% of older adults, with a range of 23 to 47% in different studies [3-6], and is associated with gait changes. Gait disturbances and MI are known to be related to a decline in health followed by possible disabilities [3, 7, 8]. According to the Mild Cognitive Impairment (MCI) treatment guidelines from the American Academy of Neurology (ANN), 6% of people worldwide, aged 60 years and older, suffer from impaired cognition such as MCI, whereas the number reaches up to 37% by the age of 85 years [9]. People with MCI have a significantly increased risk of developing dementia [10], around 10 to 15% each year [11]. Almost 10 million people worldwide develop dementia every year [12]. Regarding UI, which is defined as the involuntary loss of urine [13], about 55% or more of women aged 65 years and older are suffering from incontinence problems [14] while among men aged 60-69 years and older, the percentage recorded is around 1 to 23% [15].

Changes in gait can be an indicator for physical and cognitive decline and are often found in patients with MI, CI, and UI [3, 7, 8, 16-18]. The cause of falls and risk of repeated falling might be evoked through gait and balance disturbances as well as (lower extremity) muscle weakness [19]. Furthermore, recent studies showed an association between worse balance performance and UI, which probably leads to an increased fall risk [17, 20-22]. It is well known that regular physical activity also in older age effects health state, gait speed and stability, as well as general well-being. Exercise interventions, which aim to improve physical functions such as strength or balance training, have been shown to reduce fall rates and risks [23-25]. Not only age-related declines in physical functions are responsible for gait impairments and higher risks of falls but also reduced cognitive functions (e.g. MCI), such as attention (selective, sustained and divided attention) and executive functions (inhibition, mental flexibility and working memory) [26-30]. Changes in the brain may not only be the reason for cognitive impairments but also have an influence on physical functions and might be a reason for developing UI. The prefrontal cortex is often associated with age-related changes, including bladder control [31]. Additionally, a decline of cognitive functions have shown to be associated with the incidence of the development of MI [32] as for all movements and control of physical functions (besides some reflexes), the brain and cognitive functions are involved. Furthermore, in daily life in general, we are normally busy with cognitive-motor multi-tasking requiring the concurrent performance and interplay of physical and cognitive functions. Considering even routine walking as a task, which requires not only physical but also cognitive abilities leads to the necessity of a combined cognitive-motor training for most effective prevention of MI and falls [33-35]. Therefore, a promising option for simultaneous cognitive-motor training is an interactive game based training, so called exergames [36].

Exergames are defined as any type of video game interactions that require the player to be physically active and move to play the game [37]. The rapid growth in new information and communication technologies over the last decades has supported the development of several new virtual reality-based exergames for entertainment but also for serious gaming e.g. in rehabilitation setting or disease prevention (e.g. exergames using Microsoft Kinect) [38-41]. There are several studies demonstrating that exergame-based treatment is effective in cognitive and physical healthy and impaired elderly (e.g. in rehabilitation setting) [42, 43] and furthermore includes motivational benefits [44, 45]. "Having fun while training" might have a huge impact on engagement, compliance and thus influence treatment effects [44, 46]. Exergames might therefore overcome low motivation and adherence of older adults often reported in standard intervention studies [47, 48]. Furthermore, they can increase physical activity through challenging and engaging, interactive training games [49]. With the aim to provide individually tailored and enjoyable games, the needs and constraints of the targeted population must be considered in the game [39, 50, 51]. Some "off-the-shelf-games" do not apply game design guidelines for older adults (e.g. adaption of interface with high contrasts, large font etc.) and are therefore not suitable for them [52]. Disabilities like MI, CI, or UI not only dramatically affect the lives of those with the condition, but often confer a severe burden on families, friends, caregivers, and the healthcare systems at large. Individualized exercise interventions might allow the participants to interfere in the disability progression and slow it down before it has a major impact on their quality of life.

To sum up, there is a strong need to prevent falls by down cognitive and physical decline on an individual basis, which incorporates theoretical background from movement sciences, neuropsychology/cognitive sciences. In line with these requirements, VITAAL is an international project of the Active Assisted Living Programme (AAL) including different European countries (Belgium, Portugal, Switzerland) and Canada with the main goal of developing a new technology-based training game considering the constraints and needs of elderly people. No access to public health centers and training facilities (e.g. due to a pandemic), reduced mobility or lack of motivation could be a reason why older adults do not exercise.

Thus, there is a need for training systems applicable in home-based settings. In-home interventions to prevent functional decline even seem to be preferred by older adults [53, 54]. Hence, the VITAAL exergame is developed to be finally used by autonomous living elderly people at their homes. To summarize, the VITAAL individualized multicomponent exergame training is based mostly on the prevention and slowing of physical and cognitive decline and its consequences. Moreover, it aims at supporting and motivating older adults towards healthier and more active lifestyles, which will allow them to better experience their advanced ageing and retirement years, prolonging or even maintaining their independence and full control of their lives. Additionally, the VITAAL exergame is not only physical and cognitive exercise but provides also a lot of entertainment and fun. Prior to conducting intervention studies, it is crucial to test the usability and acceptance by the target group. Therefore, the aim of this study was to investigate the usability of the VITAAL Exergame in one of the target populations, older adults with MI.

## 2.2. Material and Methods

### 2.2.1. Study Design and Participants

This study investigates the usability of an exergame prototype (VITAAL), in older adults suffering from MI. From February to September 2020, potential participants were recruited through local contact persons at Physio SPArtos (Interlaken, Bern, Switzerland) and public advertisements in local newspapers, in the surroundings of Interlaken (Bern, Switzerland). The investigation took part at a single measurement time point including screening, a 30 min exergame session, and study measurements at Physio SPArtos (Interlaken, Bern, Switzerland). The ETH Zurich Ethics Committee (Zurich, Switzerland) granted ethical approval for the study (protocol number EK 2019-N-95). All participants were fully informed prior to participation and signed an informed consent form according to the Declaration of Helsinki before conducting any measurement.

A health questionnaire was completed to screen whether the potential participants were eligible. Furthermore, two screening measurements were conducted: The Short Physical Performance Battery (SPPB) was performed to assess physical functionality and the Montreal Cognitive Assessment (MoCA) was performed to assess cognitive status. Participants fulfilling all of the following inclusion criteria were eligible for the study: (1) age ≥ 60 years, (2) living independently, in a residency dwelling, or with care, (3) standing straight for minimal 10 minutes without aids, (4) visual acuity with correction sufficient to work on a TV screen, (5) SPPB ≤ 10. Participants exhibiting one of the following criteria were excluded from the study: (1) severe mobility impairments that prevent from training participation, (2) severe cognitive impairments (below the 1st percentile according to calculations of Thomman et al. [55)], (3) severe acute or uncontrolled health problems (e.g. recent cardiac infarction, uncontrolled high blood pressure or cardiovascular disease, uncontrolled diabetes), (4) orthopaedic or neurological diseases that prevent from training participation, (5) rapidly progressive or terminal illness, (6) Chronic respiratory disease, (7) condition or therapy that weakens the immune system, (8) Cancer, (9) serious obesity (BMI > 40kg/m2). The minimal intended study sample size of 10-15 was based on the sample size rule of Hwang et al. for usability studies [56].

### 2.2.2.Exergame Intervention

The VITAAL exergame is an multicomponent exergame training based mostly on the prevention and slowing of physical and cognitive decline and its consequences. It mainly consists of three components; strength training, balance training, and cognitive training. For strength training, Tai Chi-inspired movements are included which are a combination of classical strength exercises and Tai Chi movements. Since Tai Chi is mainly performed in a semi-squat posture it places a large load on the muscles of the lower extremities. For balance training, step-based training is included in the VITAAL exergame, as the execution of rapid and well directed steps has been shown to be effective in preventing falls [55-57]. Both, Tai Chi-inspired exercises and step-based exercises, combined with challenging game tasks, provide a 'holistic' physical activity requiring motor functions, cognition and mental involvement [58]. Moreover, Tai Chi-inspired training, and step-based training could be more motivating and joyful than standard exercises. Some cognitive training is already included in these training components as they represent simultaneous cognitive-motor interaction and require motor and cognitive functions. But specific attentional and executive functions are important for walking abilities and safe gait [26-30]. Therefore, the VITAAL exergame explicitly targets on these neuropsychological functions (selective attention, divided attention, inhibition/ interference control, mental flexibility, working memory).To maximize benefits for participants, the VITAAL exergame implements some basic general training principles; providing feedback, optimal load of task demands, progression of difficulty and high variability [59]. However, this is not evaluated in the scope of this study, since the baseline levels of the games are used.

The VITAAL system set up (Figure 2.1) is very easy aiming to be used independently at home by elderly people or in clinics. As a web-based exergame, it is designed to run anywhere if there is a Bluetooth and internet enabled device with a screen (e.g. PC, laptop, tablet, etc.). The front-end is designed for large screens, and may ideally be visualized on a TV screen. The system is supported by a back-end (main server supporting the whole service and data storage), a web portal (with information about interventions, sessions, results etc.) and two wearable inertial sensors (for measuring the stepping movements and game navigation). The two inertial sensors are placed on the shoes and are capable of sensing accelerations and angular rotations caused by movement. The sensors communicate via Bluetooth with the software running on the web-enabled device.

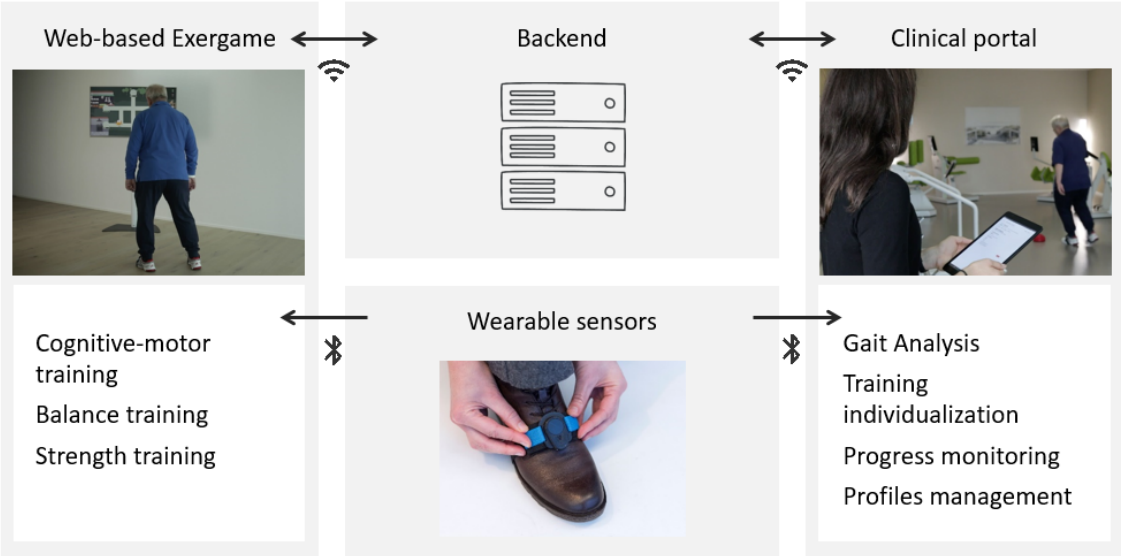


**Figure 2.1 | VITAAL system set up. The VITAAL solution consists of a web-based exergame and a clinical portal. Both communicate with the backend via a wireless connection and with the sensors via Bluetooth.**

Gait analysis functionalities will be supported by the web portal, enabling the clinician to perform spatio-temporal gait analysis to assess gait speed relying on the automatic analysis of inertial sensor data acquired on the feet. Results of gait analysis will be recorded on the server, and used to personalize training plans. For this usability study the individualization of the exergame wasn't conducted, as there was only a single measurement time point.

From March to September 2020, single measurements appointments were arranged including a gaming session with the VITAAL Exergame as described above. Participants should try to independently use the training system after a short introduction by the instructors. They should complete 10 min strength exercise, 10 min balance exercises, and 10 min cognitive-motor games. During the gaming session, an acceptance and game experience protocol was used to note observations and direct feedback to the exergame in a so called think aloud method. After the training sessions, questionnaires and interviews were used to evaluate the usability to get further feedback.

### 2.2.3.Primary Outcomes

Quantitative and qualitative assessments were combined in a mixed-methods approach to obtain more complex answers to the research question. Similar designs have been used in previous studies evaluating the usability of exergames among older adults [45]. During the exergame session, a usability protocol was completed, followed by a questionnaire and a semi-structured interview after the session. All assessments were performed by the same supervisor from Physio SPArtos (Interlaken, Bern, Switzerland), after receiving training of applied measurements and qualitative data collection. The supervisor is a trained physical therapist and has a lot of experience with training geriatric people.

#### 2.2.3.1.Qualitative Observation (Usability Protocol)

A usability protocol was filled in by the supervisor during the exergame session, noting the participants' feedback and the supervisor’s observations. During the intervention, participants were encouraged to use the 'think aloud' method by bringing up anything that came to their mind while playing the exergame [60]. The usability protocol covers the following main categories: (1) VITAAL exergame interaction, (2) game design, (3) emotions, (4) exercises, and (5) risks / limitations.

#### 2.2.3.2.System Usability Scale

An often used scale for evaluation of software products or websites but also exergames is the System Usability Scale (SUS) which was developed by Brooke [61]. It provides a global view of subjective assessments of usability. The questionnaire consists of ten items performed on a 5-point Likert scale (1 = “strongly disagree” to 5 “strongly agree”). For the calculation, the score of each odd numbered question was subtracted by one, while the score of each even numbered question was subtracted by five, giving a total score which is then multiplied by 2.5. Thus resulting in a final score ranging from 1 to 100, similar to a percentage score. The SUS is a scientifically validated and reliable with easy application [61, 62]. The scale was applied in other exergame studies and was suggested to be an appropriate measure in evaluating such systems. Based on the acceptability ranges of Bangor [63], we expect a SUS score of at least 70 to have an “acceptable” solution (adjective ratings: 52= ok, 73 = good, 85 = excellent, 100 = best imaginable).

#### 2.2.3.3.Qualitative Interview (Semi-structured interview)

A semi-structured interview was conducted by the supervisor immediately after the exergame session and the SUS. All interviews were audio recorded and lasted between 7 and 14 min (mean 10.5 min), without taking any notes to provide a natural uninterrupted conversation between the interviewer and the participant. The interviews took place in a quiet room at Physio SPArtos (Interlaken, Bern, Switzerland), ensuring that memories were still present and not distorted. Open and closed questions were asked about their experiences with the exergame in the following categories: (1) overall, (2) game, (3) VITAAL Exergame/controller, (4) body and mind, (5) motivation, (6) training, (7) comparison to conventional therapy, and (8) suggestions. Each interview was audio recorded and fully transcribed in written form. The transcripts were not returned to the participants for revision and correction, as it was thought that post-processing after the passage of time might lead to bias in this population.

### 2.2.4.Other Outcomes: Intensity Rating

Participants rated their physical and cognitive exertion after each game played during the exergame session on a scale from zero to ten, anchoring the endpoints where zero is “easy” and ten is “difficult”. Targeting moderate to vigorous exercise intensity, which is the recommended intensity for older adults [64], ratings in the range of five and a little bit higher were expected.

### 2.2.5.Data analysis

SPSS 23.0 for Windows (SPSS Inc, Chicago, IL, United States) was used for statistical analysis of the quantitative data. Descriptive statistics were generated for participants' characteristics, the SUS, and the intensity ratings. The usability protocol data was, as a first step, electronically recorded by each participant and tabulated in Micorsoft Word. The transcribed version of the results was read several times by two of the authors (one movement scientist and one physiotherapist) to gain a better understanding of the data. Subsequently, the following main categories were established: (1) VITAAL exergame interaction, (2) Game design, (3) emotions, (4) exercises, and (5) risks / limitations. The data were then coded according to the categories to derive main statements. In a further step, the main statements for each category belonging to positive and negative aspects were listed. Observations and feedback were counted, avoiding multiple counting of the same statements from the same participant. For increasing the quality of the analysis procedure, coding and data analysis were performed and cross-checked by two researchers (MT and LR). For the qualitative interview analysis, the audio data were transcribed into a written format in Microsoft Word. The audio data was transcribed after listening to it repeatedly. Afterwards, the transcript was read through several times before being processed using the online software QCAmap [65-67] following a qualitative content analysis according to Mayring et al. [66, 68]. Key questions from the guideline-based interviews were assigned to the appropriate content analytic procedures (i.e., inductive category formation or deductive category assignment). The inductive category formation questions were analysed by establishing a selection criterion and level of abstraction. Deductive category assignment was chosen when the research questions allowed for the formulation of nominal or ordinal categories prior to processing the transcript. After category assignment was completed, the transcripts were analysed and coded line by line, resulting in a list of categories. These lists were then divided into major categories. Interview responses were counted, avoiding multiple counting of the same statements from the same participant's interview transcript.

## 2.3.Results

In total 13 participants gave informed consent for the study, of whom all completed the measurement appointment. A detailed overview of the participants' demographic characteristics and screening measures is presented in Table 2.1.

**Table 2.1** | **Baseline demographic characteristics of participants and screeing values.**

| **Participant characteristics** | **n = 13** |
|---|---|
| Age in years | 79.6 ± 4.9 (71-89) |
| Weight in kg | 69.1 ± 13.6 (51-98) |
| Height in cm | 164.3 ± 4.8 (158-172) |
| Education in years | 11.9 ± 2.8 (9-19) |
| MoCA Score | 26.3 ± 1.9 (23-30) |
| SPPB Score | 8.5 ± 1.3 (6-10) |
| **Sex [n, %]** | |
| Female | 9 (69.2) |
| Male | 4 (30.8) |
| **Self-evaluation of muscle strength [n, %]** | |
| Very good | 1 (7.7) |
| Good | 2 (15.4) |
| Medium | 7 (53.8) |
| Bad | 3 (23.1) |
| I don’t know | 0 (0.0) |
| **Problems with legs [n, %]** | |
| No | 6 (46.2) |
| Sometimes | 5 (38.5) |
| Always | 2 (15.4) |
| I don’t know | 0 (0.0) |
| **Fear of falling [n, %]** | |
| Never | 7 (53.8) |
| Sometimes | 4 (30.8) |
| Often | 1 (7.7) |
| Always | 1 (7.7) |
| **Number of falls during last 6 month* [n, %]** | |
| Never | 8 (61.5) |
| Once | 2 (15.4) |
| More than once | 3 (23.1) |
| **Walking aids [n, %]** | |
| No | 10 (76.9) |
| Cane/Stick/Crutch | 3 (23.1) |

| | |
|---|---|
| Rollator | 0 (0.0) |
| **Additional Physical Activity [n, %]** | |
| > 3 x/week | 8 (61.5) |
| 1-3 x/week | 5 (38.5) |
| 1 x/week | 0 (0.0) |
| No | 0 (0.0) |
| **Use of video games in everyday life [n, %]** | |
| Yes | 2 (15.4) |
| No | 11 (84.6) |
| **Experience with Exergames [n, %]** | |
| Yes | 8 (61.5) |
| No | 5 (38.5) |
| **Urinary Incontinence* [n, %]** | |
| Yes | 2 (15.4) |
| No | 10 (76.9) |
| Missing | 1 (7.7) |
| **Cognitive Impairment* [n, %]** | |
| Yes | 2 (15.4) |
| No | 10 (76.9) |
| Missing | 1 (7.7) |

*Data are mean values ± standard deviations (ranges) or number of participants per category (absolute and relative frequency). Montreal Cognitive Assessment (MoCA), Short Physical Performance Battery (SPPB). *Self-stated.*

### 2.3.1.Primary Outcome: Usability

#### 2.3.1.1.Usability Protocol

Participants' main feedback towards the VITAAL exergame and further observations from supervisors during the exergame session are summarized in Table 2.2.

**Table 2.2 | Summary of usability protocol with supervisor observations and participants' feedback.**

| | | |
|---|---|---|
| **VITAAL Exergame Interacti** | Despite the explanations built into the game, additional guidance was needed on the technical equipment, the game controls and the games. | |
| | **Positive aspects** | **Negative aspects** |

| | | |
|---|---|---|
| **on** | • The games are understood immediately (3) or after a short explanation (5)<br>• Game control by means of steps is well understood after an explanation and some practice (6)<br>• The interaction with the exergame is interesting (6) | • More detailed explanations of the start menu (5) and the game control by means of steps (5) especially their starting position in parallel stand (5) necessary<br>• Games need additional explanation (4) especially the pizza game seems difficult (4)<br>• Step recognition was not always immediate (7) especially the recognition of the backward step seems to be inconsistent (3)<br>• Tightening the sensors is difficult and needs further explanation (11)<br>• Connecting the sensors with Bluetooth causes some difficulties (5) |
| **Game Design** | The games were found to be beautifully and interestingly designed. Nevertheless, recognising specific objects was not always easy. | |
| | **Positive aspects** | **Negative aspects** |
| | • Beautiful (5), looks good (2) and is appealing in terms of design (1)<br>• Understandable (2), easy and clear to use (1)<br>• Interesting (design) (3)<br>• Good overview (main screen) (1) | • Snack icons not always very clear, so it was difficult to distinguish the healthy ones from the unhealthy ones (6)<br>• Calf raises icon unclear (3) |
| **Emotions** | The game is fun, makes you laugh and motivates you to play. However, if the game is not successful, it can also lead to disappointment, frustration and dissatisfaction. | |
| | **Positive aspects** | **Negative aspects** |
| | • The game makes you laugh (6), is fun (8) and motivating (4)<br>• The games are captivating (5) and exciting (1) | • Frustration (4), annoyance (2), irritation (1), uncertainty (1) when the steps are not detected or detected incorrectly<br>• Disappointment (1), dissatisfaction (1) and annoyance (1) when making mistakes or not understanding the game |

| | |
|---|---|
| **Exercises** | The steps and the squats can be performed properly and correctly in most cases. Most of the games are not physically demanding except for the squats. The games are mainly cognitively demanding and require concentration.<br><br>**Positive aspects**<br>• No additional breaks necessary (6)<br>• The exercises are taken seriously and performed with concentration (5)<br>• The exercises/steps are performed fast (3) and correctly (7)<br>• The training is physically demanding (3) and tiring (3)<br>• The step-based games were rated as cognitively hard (1), exhausting (4) and challenging (2), it also requires concentration (2) and a lot of thinking (2)<br>• The squats are physically demanding (4)<br><br>**Negative aspects**<br>• Additional breaks necessary (3)<br>• Some forget to go back to the starting position (2)<br>• Squats are not always performed well (3), because of fear from pain (1)<br>• The games are a bit slow (2), not very strenuous or challenging (2)<br>• The games were physically easy/not demanding (6)<br>• The games are not cognitively demanding/ difficult (3)<br>• No upper body exercises (2)<br>• The movements are a bit boring (3)<br>• Problems with balance from time to time (2) |
| **Risks/ Limitations** | The calf raises, which are needed as an exit function, are not possible for many or only possible with help. Knee pain can prevent strength training.<br><br>**Positive aspects**<br>• Calf raises work well (3)<br><br>**Negative aspects**<br>• Calf raises not possible or only with help (6)<br>• Knee pain (4), which led to the termination of strength training for a few (2) |

*(n) = number of participants or supervisors who made this statement.*

### 2.3.1.2. System Usability Scale

The usability of the VITAAL Exergame was rated with a mean SUS score of 57.7 ± 17.0 (min. = 35, max. =85, n = 13), which represents an adjective rating between an "ok" and "good" acceptance level for usability [63]. The initially intended score of 70 was not reached. Three out of 130 questions were not scored and replaced by three points, which corresponds to a neutral answer. The usability ratings of the ten SUS items are summarized diagrammatically in Figure 2.2, where the red colours indicate negative responses, the grey colours indicate neutral responses, and the green colours indicate positive responses.

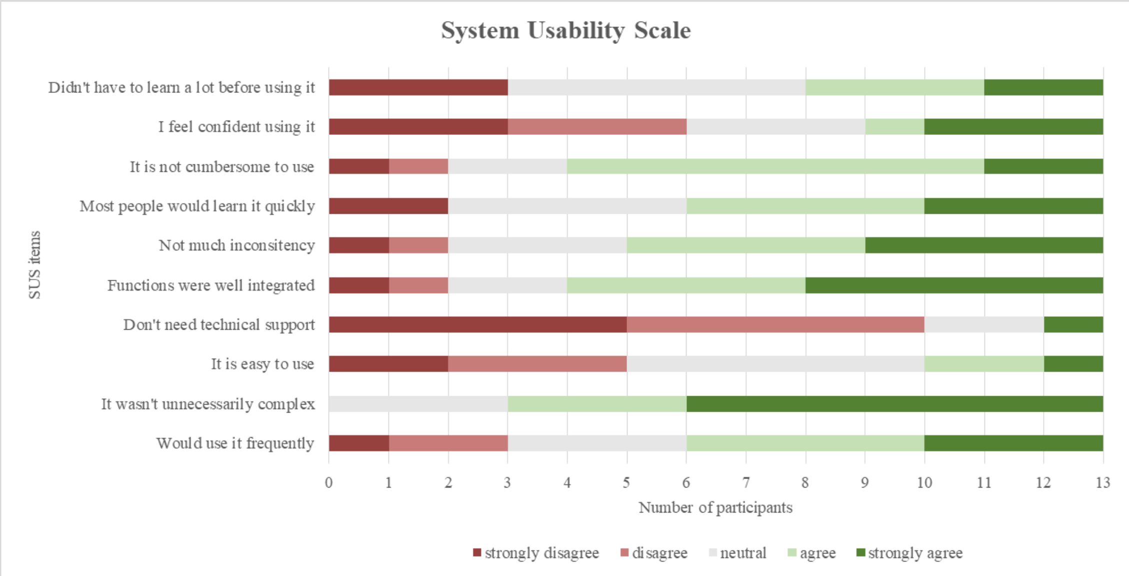


**Figure 2.2 | Summary diagram of the System Usability Scale.**

### 2.3.1.3.Qualitative Interview Analysis

The final result of the analysis of the interviews and the coding of the quotes can be summarised in seven categories: (1) game, (2) VITAAL Exergame interaction (3) body and mind, (4) motivation, (5) training, (6) comparison to conventional therapy, and (7) suggestions.

#### (1) Game

The most popular games, game design, comprehensibility and game structure were analysed under the heading of "games".

***Popular Games***. Several fun games were named. The most favourite games were Mommy Chicken (n=5), Falling Books (n=4) and Healthy Snacks (n=2). To enjoy the game play, respondents mentioned that it is important to understand the game (n=5), that they need to be challenged (n=3) or that they like to have a personal relation to the game content (n=4).

*P09: The diet, with healthy snacks. Because healthy eating is important to me.*

*P10: Mommy Chicken. Because you could go up or left/right or down. Is there enough time or not? Will the chicken catch me or not? …*

*P13: The bookcase, because it is very familiar to me from home.*

***Game Design***. In general the game design was positively described (n=4). The optical design of the games was indicated to be good (n=7), clear (n=2), beautiful (n=1), fun (n=1), and interesting (n=1).

*P06: The other games were very nice.*

*P10: … The game environment was good and interesting. You knew where you had to go. The picture is good for the game.*

Some participants have criticised the fact that the icons in the game could be a little more accurate (n=2), more realistic (n=2) and less sterile (n=2). In the Healthy Snacks game in particular, the snacks were not always recognised (n=2).

*P13: The pictures were not so clear. I didn't necessarily see a vegetable there.... Is that a vegetable or not? Maybe it shouldn't be drawn so modern, but so that you can see more of what it actually is.*

Most participants did not really notice the music (n=4), while another participant found the rhythm of the music helpful during the games (n=1).

*P08: I didn't notice any music, but I'm not that musical either.*

*P10: … Acoustics was good, the rhythm helps.*

Considering game feedback, some participants wished to see their own progress over time (n=2), while others were satisfied and did not want any further feedback (n=2).

*P04: I would like to know if I was any better or not, to know the progression.*

*P06: The feedback was perfect. I have always seen the success very well. I have not missed anything.*

***Game Structure***. Most participants considered that the game was structured in a comprehensible way (n=9, 81.8%; $n_{total}$=11).

*P06: Yes, the games were structured in an understandable way. I didn't have to think much…*

## (2) VITAAL Exergame Interaction

The interaction and experiences with the VITAAL exergame was critically discussed with the interviewees, whereby the following four subcategories emerged: comprehensibility, game control, sensors, and experiences.

***Comprehensibility***. At the beginning, the handling of the exergame was perceived as somewhat difficult and unclear (n=5) and requires an explanation (n=4). Afterwards it was understood by most users (n=6).

*P02: It took me a long time to understand what I had to do. It was difficult at the beginning, but not afterwards.*

*P06: … It needs someone to do an introduction on the screen, but then it goes very well.*

*P08: … Explanations would have been good, one could not know what was coming.*

***Game Control***. In general, the game control was understood quickly or after some time (n=6, 75.0%, $n_{total}$ =8). Controlling the game using the sensors was considered to be good (n=1), direct and not complex (n=1).

*P12: Yes. I liked that the game controls were direct and not very complex.*

Some participants noticed that the sensors do not always react equally well (n=6), which can lead to a feeling of uncertainty (n=1) or impatience (n=1) in participants.

*P03: Steps back and forth were detected less good compared to left / right. A step to the left was detected better than a step to the right.*

*P06: De The step backwards into the middle was sometimes refused. This bothered me a little and made me feel insecure. I did not know if I was causing this.*

*P10: Sometimes I was a bit too impatient until the signal from the sensor reached the screen. The screen did not follow.*

***Sensors***. Some participant had difficulties to recognize the arrow on the sensors, which indicates their orientation on the feet (n=2).

*P10: The arrow is hard to see if you have black shoes. You have to make sure that the arrow is facing forwards.*

Almost all participants found the sensors not easy to handle or could only use them with help (n=12, 92.3%; $n_{total}$=13).

*P06: Yes. The introduction on the screen was not very clear, I needed help... But otherwise it is actually very simple.*

*P08: I did not find them easy to handle. I have never put on such sensors.*

Some of the participants mentioned no or only once a technical problem with the sensors (n=3, 60.0%; $n_{total}$=5).

*P14: No, there were no technical problems. Once, the sensors did not react properly.*

***Experiences***. Overall, the exergame experience was positive and described as good (n =3), interesting (n=2), and fun (n=2).

*P12: Yes, it was fun. I haven't done anything like that in a long time.*

*P15: I really liked the handling and experience of the VITAAL Exergame, i would do it more.(3) Body & Mind*

The topics flow, awareness of game performance, focus, movement awareness, and feelings have been summarized within this category.

***Flow***. The majority of the participants were absorbed or felt immersed in the game (n=6).

*P10: Yes, I felt immersed in the game. That has to do with concentration as well. You are immediately focused.*

***Awareness of Game Performance***. About half of the participants said they were always aware of their individual game performance (n=7), while almost as many participants were not aware of the feedback provided during and after the game (n=5; not answered n=1).

*P10: Yes, I noticed how good or bad I was in the game. Especially with the cakes I was wrong for a while, there you had to concentrate a lot. I also saw the points and knew immediately whether I was good or bad.*

*P08: Did I receive points? I did not notice.*

***Focus***. Participants reported that they mostly focused on the cognitive aspect of the games (n=5), whereas few subjects were more concerned about executing the steps correctly (n=2).

> *P06: I focused more on the cognitive, 100%.*
>
> *P12: I focused on solving the task as determinedly as possible and not letting myself get distracted. I focused more on the game.*
>
> *P15: Back and forth, front / back. I focused more on the steps, more on the body than on the game.*

Another interviewee mentioned that the focus was on the coordination of both, physical and cognitive (n=1).

> *P14: I focused on both, physical and mental. You have to coordinate both.*

***Movement Awareness***. All participants experienced the movement as natural (n=7, 100%; $n_{total}$=7).

***Feelings***. Overall, the participants experienced positive feelings during playing the exergames. The subject felt good (n=6) and enthusiastic (n=1). The games were described to be fun (n=4), captivating (n=1), diverse (n=1) and interesting (n=1).

> *P03: I felt good while playing. It was fun, varied and enjoyable.*
>
> *P06: ... I am enthusiastic about Exergame, I think it is very good. ... after 6-7 minutes you are part of the game.*

Few participants (n=3) felt some uncertainty in the beginning of the exergame session.

> *P12: … There were fluctuations at the beginning, a bit of uncertainty about what it's all about, what I have to do. After that, it became a bit more relaxed.*

## (4) Motivation

In the interview motivating and non-motivating factors were identified, and it was discussed whether a future use of the exergame is conceivable.

***Game variability***. Presenting a variety of games (n=2) is motivating. Consequently, the exergame itself was perceived by most participants as encouraging movement (n=6, 66.7%; $n_{total}$=9).

> *P10: Was interesting, especially what was good that it has different games.*
>
> *P15: Yes, it motivated me very much. I had to move a lot.*

***Improvement***. Other motivators can be, if the subject is shown that their performance can still be improved (n=2).

> *P09: The game is fun when you can learn something and improve your reaction.*

***Challenge***. For motivation to be maintained, the difficulty level should be adjusted (n=1) so that the game remains challenging (n=1) and one become ambitious (n=1).

> *P10: Yes, I could imagine that the games are still fun after playing several times and that you become ambitious over time.*

***Understanding/Education***: Few participants (n=2) mentioned an understanding and awareness for what they are exercising as a motivator.

*P14: It's certainly good for the body when you do something like this.*

***Exercise Selection***. The subjects did not find it motivating when the exergame gave them too few opportunities to get moving. (n=4).

***Game Design***. If the game design does not correspond to the individual wishes, it can have a demotivating effect on the subjects (n=1).

*P13: I can't do anything with this subject matter and these drawings. It could be that it becomes boring. For it not to be boring, the subjects and drawings would have to be more realistic, like photographs, not sketches.*

***Future Use***. Most participants think that the VITAAL exergame would still be fun after playing it several times (n=8, 80.0%; $n_{total}$=10) and could imagine using such games as part of therapy in addition to the exercise therapists traditionally offer (n=6; 66.7%, $n_{total}$=9). The majority of interviewees can also picture using the training at home or in a center for the elderly (n=8, 66.7%; $n_{total}$=12).

*P10: Yes, I could imagine it, if you could download it. For the brain, coordination, agility… it has a little bit of everything in it.*

### (5) Training

In the interview, participants shared their training experiences and provided insights into training challenges, effort, concentration, training duration, and safety

***Challenge***. The majority of participants experienced the exergame as challenging in terms of cognition (n=5), balance (2), physical effort (n=1), coordination (n=1), and correct movement of steps (n=2).

*P03: Yes, it was challenging. Especially mentally.*

*P12: To really step on the ground with the tip of your foot was challenging.*

The squats were mentioned to be strenuous (n=1) and the exhaustion was felt in the back (n=1).

*P14: In the back was the effort, there was fatigue.*

*P15: ... especially the squats at the end. That's when I needed a rest.*

In contrast, some subjects wished for a more physically demanding training program (n=5).

*P09: ... More physically demanding would also be good.*

***Training effort***. Most of the participants indicated that they did not feel optimally or only partially challenged (n=4, 80%; $n_{total}$=5), which was also reflected in their opinion about physical effort. Several participants stated that they did not or rather not have to make any physical effort (n=7; 70.0%; $n_{total}$=10. The cognitive training was perceived to be demanding (n=4, 57.2%; $n_{total}$=7) as well as not demanding to almost the same degree.

The majority of the interviewees believed that the desired functions, cognitive and physical, were being trained (n=8, 88.9%; $n_{total}$=9).

***Concentration***. Several subjects mentioned that they had to really concentrate during the training (n=3).

*P15: You had to really concentrate, and make sure you took the right steps.*

***Training Duration***. Most of the participants felt comfortable with a training time of 30 minutes (n=5).

*P12: It shouldn't be much more at a time, that half hour was good.*

*P14: That was good. Not much longer at the moment or at the beginning*

***Safety***. In general the participants felt safe and were not afraid of falling during the training (n=5, 100%; $n_{total}$=5).

*P09: No, I have never been afraid to fall.*

## (6) Comparison to conventional therapy / exercises

When comparing the VITAAL Exergame to conventional exercise therapy different opinions were mentioned. On one hand, the VITAAL Exergame is found to be more challenging (n=2), cognitively more strenuous (n=2) and physical more exhausting (n=1).

*P15: In my head, I had to do more compared to the other therapies.*

On the other hand, participants experienced the VITAAL Exergame to be not exhausting (n=2) or easier (n=1), cognitively less challenging (n=1), and physical less strenuous (n=1).

*P04: It is easier than what we do that in therapy.*

A minority found the VITAAL Exergame to be equally strenuous compared to conventional therapy or other activities (n=1).

*P02: About the same effort compared to therapy/ everyday life.*

## (7) Suggestions

Some ideas were mentioned to adapt and improve the exergame. There was a wish for more intensive physical exercises (n=3), more challenge (n=1), more games (n=1), and games with other animals (n=2).

*P01: It just doesn't have enough body intensity in it. The body is not used enough in this game.*

*P15: Yes, I would have more ideas, games with chamois or ibex.*

### 2.3.2. Other Outcome Results

The ratings of the physical and cognitive effort of the different games using a scale from 0 to 10 are presented in Table 2.3.

**Table 2.3 | Physical and cognitive intensity of the VITAAL exergames.**

| | **Physical (0 - 10 Scale)** | **Cognitive (0 - 10 Scale)** |
|---|---|---|
| ***Balance*** | | |
| **Falling Books [n]** | **n = 12** | **n = 9** |
| | 5.7 ± 1.4 (4-8) | 4.9 ± 2.8 (1-9) |
| **Mommy Chicken [n]** | **n = 8** | **n = 5** |
| | 5.6 ± 1.7 (3-8) | 5.6 ± 3.0 (2-9) |
| ***Cognitive-motor*** | | |
| **Healthy Snacks [n]** | **n = 10** | **n = 8** |
| | 2.5 ± 1.7 (0-6) | 4.0 ± 2.2 (2-8) |
| **Pizza [n]** | **n = 10** | **n = 9** |
| | 5.2 ± 2.5 (2-9) | 5.9 ± 1.9 (3-8) |
| **Shopping List [n]** | **n = 3** | **n = 3** |
| | 3.3 ± 4.2 (0-8) | 5.7 ± 3.5 (2-9) |
| ***Strength*** | | |
| **Narrow Squats [n]** | **n = 7** | **n = 7** |
| | 6.6 ± 1.0 (5-8) | 2.4 ± 2.2 (0-7) |
| **Wide Squats [n]** | **n = 3** | **n = 3** |
| | 6.3 ± 2.1 (4-8) | 2.0 ± 2.0 (0-4) |

*Data are mean values ± standard deviations (ranges) or number of participants per category.*

## 2.4. Discussion

The aim of this study was to explore the usability of the VITAAL exergame prototype in older adults with MI. To the best of our knowledge, this is the first study investigating the usability of an exergame in older adults with MI, incorporating older aged target users (mean age 79.6) at the beginning of active prototype testing in a user centred design approach.

In terms of quantitative analysis using the SUS for assessing usability of the VITAAL exergame prototype, the score (57.7 ± 17.0) revealed a user-friendliness between "ok" and "good". However, this was below the initially intended score of 70, which would have been needed to present a passable exergame [63]. According to Bangor et al., a SUS score below 50 can be interpreted as having a non-acceptable system whereas a score between 50 and 70 is in a marginal range [63]. The worst rated items influencing this score were; *"I think that I would need the support of a technical person to be able to use this system."* (77% agreed), *"I felt very* *confident using the system"* (46% disagreed), and *"I thought the system was easy to use."* (38% disagreed). Those answers are in line with statements of the usability protocol and the interview, indicating that for example tightening and connecting the sensors would not have been possible without help in most participants. Furthermore, many participants wished for more instructions and explanations of the start menu, the game control, and the games themselves. Interestingly, about the same amount of participants mentioned that the usage of the exergame was clear after some time, indicating that a short familiarization and learning period is required but within one training session. This is further supported by positive rated items: "*I found the system unnecessarily complex*." (77% disagreed), "*I would imagine that most people would learn to use this system very quickly*."(54% agreed), "*I found the system very cumbersome to use.*" (69% disagreed). Older adults often have limited knowledge of technology, thus ensuring a technology-based training system that can provide technical confidence (for example by a simple set-up, stable connections, and intuitive game environment) is very important [69]. Thereby, a better playing experience and a more successful training can be achieved. Previous literature has highlighted the importance of age-appropriate design and impeccable technical functionality for the usability of exergames as well [70-72]. In other exergame studies, the SUS score was usually around 70 points or higher, and included participants with a mean age in the early seventies [73-75]. Compared to the mean age of the subjects in this study (79.6 ± 4.9 years), an age difference of almost one decade is evident. A study by Bangor et al. has shown that a significant correlation between age and SUS score exists, revealing that the age of the user might have some negative influence on the usability rating [76]. This was also supported by a study of Vaziri et al. investigating user experience and technology acceptance for a fall prevention system by analysing the SUS considering the participants' age [71]. The study showed an overall SUS score of 62, however, participants with an age younger than 72 years scored the system with 72 points compared to the participants aged older than 72 years, which scored the system with 53 points. Not only can there be a large difference in SUS ratings due to age differences, but in this study many items were rated neutral, which could be interpreted as having no opinion about these items. One reason for this could be that the SUS was filled in after just one appointment compared to many usability studies using the SUS only after several appointments [74, 75], allowing participants to make more experiences and build a clearer opinion on the game.

Despite the marginal rating of the SUS score and the before mentioned difficulties at the beginning of the exergame usage, qualitative analysis gave a good insight in the overall user experience and resulted in a generally positive feedback. The games were considered to be structured in a comprehensible way and beautifully as well as interestingly designed. Especially games that were designed with a theme to which one has a personal relation, like animals or books, were well received. Apart from that, one game (Healthy Snacks) has been criticised to use sterile and unrealistic design. When it comes to game design for older adults, it is important that the graphical user interface will be adjusted in terms of visual game element size, font size, contrast etc. [69]. However, the different games were mostly described as fun and made the participants laugh. Furthermore, participants were encouraged to move by the exergame. A high motivation seems to be crucial for the success of an exergame and training interventions in general. Since people are motivated, higher training compliance can be expected and thereby might increase training success [77]. The most motivating factors seem to be a high game variability, ongoing challenge and awareness of the (health) goal of an exercise. In contrast, it can be demotivating when the sensors do not react properly, which led to uncertainty, frustration, and impatience in some participants. Neither is it motivating if the desired functions can not be trained. In general, the training with the exergame was perceived to be cognitively more challenging than physically. However, most of the participants didn't feel optimally trained and described the games as not physically demanding. This may be due to the decision in applying the baseline difficulty level for the exergame session for all participants in this study to gain a better understanding regarding the entry level of the target population. When exercising more than once with the VITAAL exergame, the difficulty level of the games will be automatically adjusted, using a progression algorithm based on the performance of the subjects. In addition, some participants mentioned that they really had to concentrate during the game and others needed an extra break between the exercise. Comparing this with the results of the 0 to 10 scale rating of the perceived physical and cognitive exertion gives another impression. The cognitive exertion was rated the highest in balance and cognitive-motor training with a rating above five assuming "moderate" to "vigorous" intensity in most games, whereas the physical exertion was rated the highest in strength and balance training  assuming "moderate" to "vigorous" intensity. This can lead to the assumption that moderate to vigorous training intensities, recommended for older adults [64], were achieved. However, this is only an average result and must be interpreted with caution. The discrepancy to the usability protocol and the interview might be explained by the high variability in the individual ratings. Even though the training content might not have been perceived challenging enough, most felt comfortable with a training duration of 30 minutes. Moreover, about half of the participants seem to have reached a flow state, indicated by feeling absorbed and immersed in the game. This experience is also underlined by the fact that the feedback given during the games was not perceived, which might be a result of total concentration when conducting a task. Flow describes a state that occurs when individuals are attentive and engaged in certain activities [78], and when the individuals' skills are well balanced with the challenges. Furthermore, the flow experience has been shown to encourage exergame play and thus further promote their health [79].

In summary, the feedback on the exergame was generally positive. This may also be supported by the fact that most participants could imagine still having fun with the VITAAL Exergame even after playing it several times. Moreover, most could envision using such games, in addition to their usual therapy, at home or in a center for the elderly.

### 2.4.1. Limitations

Some limitations need to be discussed. First, usability of the VITAAL exergame was assessed within only one exercise session, which might not allow enough time to reflect properly and familiarize with the exergame. Initial insecurities that would disappear within the first training sessions could have negatively influence the results. Secondly, a basic level of difficulty of the exercises was tested, which may mean that not everyone feels optimally challenged. Thirdly, to maintain objectivity, the analysis was not conducted by the same person who conducted the exergame session and the interview. However, this could also lead to misinterpretation of the qualitative data, as non-verbal impressions might be lost and should therefore be interpreted with caution.

### 2.4.2. Implications for the VITAAL Exergame

Based on the results of this usability study, minor implications for improving the current VITAAL exergame prototype for older adults with MI can be presented:

- Another movement for the "exit-function" should be considered, as calf rises seem to be difficult for older adults with MI.
- Design aspects such as contrast and size are important when it comes to the usability of exergames for older adults. Therefore, the size or contrast of the arrow on the sensors should be adjusted to ensure easier handling. Furthermore, the design of the snacks in the Healthy Snack game should be revised and presented in a more realistic design.
- Especially for older adults explanations on how the game is installed (sensor connection), how the game control works and what the game tasks includes, needs good explanation and instructions.
- Connecting the sensors with the web-based exergame should be easy and well instructed.
- Even though the step detection algorithm works quite well, minor changes should be made to react faster to participant movements.

## 2.5. Conclusion

**The VITAAL exergame prototype received general positive feedback and can be considered usable for older adults with MI, taking into account minor improvements to the system in terms of design, instructions and technical aspects. After this first evaluation of the newly developed exergame prototype, the results warrant the implementation of the algorithm that allows individualised training and the testing of its feasibility and impact on the physical and cognitive functions of the adapted multicomponent VITAAL exergame.**

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# 3. Stepping balance exergaming for people with major neurocognitive disorder: a usability study

## 3.1. Introduction

The number of people with major neurocognitive disorder (MNCD) is increasing, primarily driven by population aging [1]. MNCD is a clinical syndrome marked by cognitive decline, motor deficits and psychological and behavioural problems [2]. People with MNCD often require added assistance with their activities of daily living [3] and this can ultimately lead to a displacement to a long-term care facility [6]. This is imposing a compelling burden on health care systems and has resulted in MNCD being considered a global public health priority [4]. The burden of MNCD on health care systems is further compounded by a high risk of falling and associated injuries and disability [5].

In order to reduce the risk of falling in people with MNCD residing in long-term care facilities, physical activity should be an important component of the multidisciplinary approach [6, 7]. There is compelling evidence that physical activity improves strength, endurance, balance, gait stability, gait speed, and overall wellbeing in people with MNCD [6, 8, 9]. Currently, clinical practice guidelines do not refer to combined cognitive and physical training programs [10, 11]. This is surprising as not only a decline in physical functions is responsible for gait impairments and higher risks of falls, but also impaired cognitive performance including impairments in executive functioning [12-16]. More recently, the coexistence of physical limitations and cognitive decline, dubbed motoric cognitive risk syndrome, has been linked to a 10% prevalence in aging adults [17].

To slow down the cognitive and physical decline, and to prevent falls, combined motor-cognitive interventions which are adapted to the participants' individual needs might be useful [18-20]. A promising option for such a simultaneous cognitive-motor training are exergames [21]. Exergames are videogames that require movement in order to play the games [22, 23]. Previous studies have found that exergaming improves gait speed, mobility, balance, and cognitive functions, and reduces fear of falling in people with MNCD [24, 25]. Another advantage is that exergames are engaging and might overcome low adherence rates that are often reported in physical interventions for this population [6].

Stepping exergame training is feasible and engaging in people with MNCD in long-term care facilities [26]. Stepping exergames require participants to stand upright and perform steps, which directly address gait and balance [27]. Exergaming in an upright standing body position also enhances processing speed and attentional selectivity [28] and influences visual working memory performance [29]. However, compared to seated cognitive games, exergames impose a higher risk of falling than seated exergames.

Currently, stepping exergame programs designed for older adults that are portable and affordable are still lacking. Therefore, the international research group VITAAL is developing an individualised multicomponent exergame training device [30].

VITAAL is a project that is funded by the European Commission as part of the Active and Assisted Living program [31]. The developed exercise device consists of wearable sensors and a web-based interface and aims to provide evidence-based motor-cognitive training with high usability and quick application.

To develop a user-friendly and acceptable training device, end user involvement is required. When new exergames are being developed, it is important to assess the usability aspects within the target population. People with MNCD can often still communicate their opinions about what is important to them [32]. Researchers have previously recommended an end user participatory design with direct involvement of people with MNCD throughout the whole development process [33]. It has been highlighted that people with MNCD can still contribute to finding technological solutions that support them in the self-management of their symptoms and challenges in daily living, as well as contribute to the development by providing useful feedback, also in long-term care facilities [34, 35].

Therefore, the aim of this study is to investigate the usability of the VITAAL exergame through a mixed methods study that combines observations, the think aloud approach, semi-structured interviews, and a usability scale in institutionalised people with MNCD. This combination of both quantitative and qualitative data provides a full picture of the users' perspectives.

## 3.2. Methods

A mixed methods design was used. The Consolidated criteria for reporting qualitative research (COREQ) framework for reporting qualitative research was implemented [36]. The trial was registered in ClinicalTrials.gov (Identifier: NCT04664920).

### 3.2.1. Participants and procedure

Over a period of one month, residents of long-term care facility de Wingerd in Leuven, Belgium, with a MNCD were screened for inclusion. Possible causes of major neurocognitive disorder eligible for inclusion were vascular dementia, Alzheimer's disease, mixed dementia, Parkinson's disease or Lewy body disease, as well as unspecified, as stated by the criteria of the fifth edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM 5) (American Psychiatric Association, 2013). Diagnoses were made by the treating psychiatrist. Additional inclusion criteria were age ≥ 60 years; visual acuity with correction sufficient to work with a TV screen; a minimum stay of two weeks in the long-term care facility at the time of inclusion and being physically capable of doing stepping exercises without extra support. Subjects manifesting one or more of the following criteria were excluded from the study: any unstable health condition which according to the American College of Sports Medicine Standards might lead to unsafe participation [37]; and mobility impairments that don't allow to play the exergame. All eligible participants performed an exergame for 30 minutes on one try-out session. During the exergame performance, the think aloud method [38] was used, and field notes were taken by the observer. After the exergame performance, participants completed the System Usability Scale [39] and a structured in-depth interview about the usability of the device including their personal experiences. In order to be able to describe the population in more detail, prior to the exergame participants completed the Montréal Cognitive Assessment (MoCA) [40] and the Short Physical Performance Battery (SPPB) [41, 42]. Their comorbidities, indoor mobility, fear of falling, and level of physical activity prior to participation were investigated. The protocol was approved by the Medical Ethics committee of UZ Leuven (registration: S63304/B322201941828). Written informed consent was obtained from the participants according to the Declaration of Helsinki. No compensation for participation was given.

## 3.2.2. Exergame session

Participants individually performed one single exergame session using the VITAAL prototype, which is an innovative, comprehensive system for geriatric rehabilitation. The exergame mainly consists of three components: strength training, balance training, and cognitive training [30]. For strength training, a combination of classical strength exercises and Tai Chi-inspired movements are included. Since Tai Chi is mainly performed in a semi-squat posture, a large load is placed on the muscles of the lower extremities. For balance training, step-based training is included, as the execution of rapid and well directed steps has been shown to be effective in preventing falls [43-45]. Both Tai Chi-inspired exercises and step-based exercises, combined with challenging game tasks, provide a holistic physical activity requiring motor functions, cognition and mental involvement [46, 47]. Some cognitive training is already included in these training components as they represent simultaneous cognitive-motor interaction and require motor and cognitive functions. Specific attentional and executive functions are important for walking abilities and safe gait [12-16]. Therefore, the VITAAL exergame explicitly targets these neuropsychological functions (selective attention, divided attention, inhibition/interference control, mental flexibility, working memory). See Figure 3.1 for an overview of the different games and the focus of training per game.

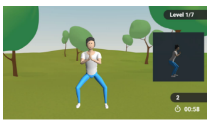
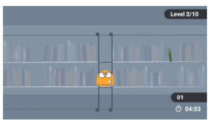
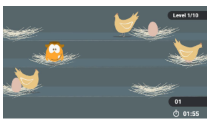
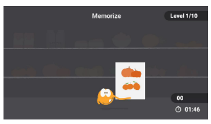
|  |  |  |  |  |
|---|---|---|---|---|
| **Outdoor game** | **Library game** | **Mommy chicken** | **Healthy food** | **Shopping list** |
| Tai-Chi inspired strength training | Balance training | Inhibition control | Inhibition control | Short-term memory |
| Player imitates movements of an avatar instructor | Player avoids books from falling through multidirectional stepping | Player collects eggs while avoiding mommy chicken | Player points out healthy food and avoids unhealthy food | Player indicates whether the shown items correspond to the previously memorised shopping list |

**Figure 3.1 | Game description.**

To maximise benefits for participants, the exergame implements some basic general training principles; providing feedback, optimal load of task demands, progression of difficulty and high variability [48]. The system set-up was developed to be easily applied with limited technical equipment and knowledge in long-term care facilities or in clinics. As a web-based exergame, it is designed to run anywhere if there is a Bluetooth and internet-enabled device connected with a screen (e.g. PC, laptop, tablet, etc.). The front-end is designed for large screens and is ideally visualised on a TV screen. The system is supported by a backend (main server supporting the whole service and data storage), a web portal (with information about interventions, sessions, results etc.) and two wearable inertial sensors for measuring the stepping movements, game navigation and gait analysis. The two inertial sensors are placed on the shoes and are capable of sensing accelerations and angular rotations caused by movement. They communicate via Bluetooth with the software running on the web-enabled device. Participants played all the games that were available in this prototype, namely the outdoor game, the library game, the mommy chicken game, the healthy food game, and the shopping list game. An example of the system set-up is included in Figure 3.2.

**Figure 3.2 | System set-up.**

### 3.2.3.Think aloud method [38, 49]

Participants were encouraged to explain their views and experiences during exergaming through a think aloud approach [38]. The think aloud approach is a common observational technique for eliciting insight into the users' thinking process while actively using the developed exercise solution. The participant was encouraged to say everything that came to mind out loud while performing the exergame tasks. Field notes were made during and after exergaming performance to complement the information gained from the think aloud approach. The observer wrote down the user actions for each of the tasks, as well as noting any problems. It has been demonstrated previously that the think aloud method is an appropriate method to engage people with a MNCD as co-creators of solutions to accommodate to their life [34].

### 3.2.4.System Usability Scale (SUS) [39]

After the exergame session, the System Usability Scale (SUS) was completed [39]. It is a commonly used scale for exergame evaluation and provides a global view of subjective usability of a product or a system. The SUS consists of ten items which are scored on a 5-point Likert scale, ranging from 1 (strongly disagree) to 5 (strongly agree). The SUS consists of 5 questions with a rather negative connotation and 5 with a positive connotation. The evaluation results in a total score, provided in a scale from 0 to 100. The score is calculated by subtracting one from the user responses for items with a positive connotation (items 1, 3, 5, 7 and 9) and by subtracting the user responses from five for items with a negative connotation (2, 4, 6, 8 and 10). This scales all values from 0 to 4, with 0 being the most negative and 4 the most positive response. The converted responses were multiplied by 2.5 to convert the scale from 0 to 100 instead of from 0 to 40. SUS scores below 25 correspond to a worst imaginable system; scores from 25 to 39 correspond to worst imaginable to poor; scores from 39 to 52 correspond to ok; from 52 to 73 correspond to ok to good; scores from 73 to 85 correspond to good to excellent and from 85 to 100 corresponds to excellent to best imaginable [50]. The SUS is reliable and valid in non-clinical adults [39, 51]. Previous studies have reported internal reliability with Cronbach’s alpha values between 0.79 and 0.97 [52, 53]. The convergent validity with other measures of perceived usability were acceptable. Regarding exergames, SUS provides information on whether older adults are confident playing the games, whether they will want to use the exergames frequently, and whether the exergames are easy to use for balance training and physical activity.

### 3.2.5.Semi-structured interview regarding the participants’ exergame experiences

A semi-structured interview was taken after the exergame to acquire the participants’ experiences on the exergame device. The interviews focused on the qualitative evaluation of the user’s gameplay experiences related to the body movements and the virtual game scenario. During the interview, no notes were made in order to fully focus on the participants’ verbal and non-verbal communication. The recorded interviews lasted between 3 and 11 minutes (mean 6 minutes). The interviewer was also the person that observed the exergame sessions. Therefore, the interviewer and participants were familiar with each other. Every interview was recorded and fully transcribed to a written form. Transcripts were not returned to participants for comment or correction. Guidelines for ethical and methodological issues in qualitative research in people with major neurocognitive disorder [54, 55] were applied. The interviewer had a respectful attitude, made eye contact when appropriate, used a calm voice, and avoided contradicting participants’ statements or asking about details. The interviewer bared in mind the communication challenges such as word-finding difficulties, abstract reasoning, memory deficits, fluctuating awareness, attention, and concentration by allowing sufficient response time, and gently redirecting the dialogue when needed.

### 3.2.6.Montréal Cognitive Assessment (MoCA) [40]

Participants completed the MoCA before the exergame try-out. The MoCA is a paper and pencil test that assesses memory, language, executive functions, visuospatial skills, attention, concentration, abstraction, calculation, and orientation. The scores range from 0 to 30, with higher scores indicating better cognitive functioning. The MoCA has good construct validity (r-values range from .46 to .75) [56], inter-rater reliability (r=0.97), test-retest reliability (r=0.88) and internal consistency (Cronbach's alpha= 0.89) [40].

### 3.2.7.Short Physical Performance Battery (SPPB) [41, 57]

Prior to the exergame, the SPPB was executed. The SPPB assesses gait speed, balance, and lower limb strength [41, 57]. It is composed of three subtests; a standing balance test, a short 4-meter walk at usual pace [58] and 5 chair rises. The maximal total score is 12 and higher total scores indicate a better lower extremity functioning. The reliability of the SPPB is high in older adults with dementia, with intraclass correlation coefficient values ranging between 0.82 and 0.92 [42, 59, 60].

### 3.2.8.Data analysis

Descriptive statistics were used to provide general information on the study outcomes (means and standard deviations). To aid management and analysis of the think aloud method, the field notes and the interviews, NVivo 12 Microsoft software (© QSR International Pty Ltd., Victoria, Australia) was used [61, 62]. Individual interviews, field notes and think-aloud data were transcribed in Microsoft Word format and afterwards inserted into one project in NVivo 12. A thematic analysis of this project was performed through six consecutive steps [63, 64]. The first step in the analysis comprised of two master students repeatedly reading the transcripts and listening to the interview recordings to obtain further information from tone of voices and pauses. Next, initial codes were created by open coding, the process of indexing or categorizing the text to establish a framework of ideas which are related. Subsequently, the residual data were examined through axial coding, which is relating codes to possible sub-codes to form a more precise and complete explanation. Codes with similar content were merged. The categories that remained were further interpreted and abstracted into the remaining themes. Although the observations and interview transcripts in NVivo 12 formed the primary data set, the SUS scores were investigated separately. After these steps, a composite description of the patients' perspectives of using the exergames was written, while using quotes to underpin the interpretation.

## 3.3. Results

### 3.3.1. Participants

Twenty-two participants were enrolled in the study. 81.8 % were female, with a mean age of 84.3 ± 5.5 (70-95) years, a SPPB score of 7.5 ± 3.2 (1-12), and a MoCA score of 11.9 ± 4.4 (2-19). Table 3.1 gives an overview of the characteristics of the included participants. A more detailed description of the participants' individual characteristics is provided in Table 3.2. None of the participants suffered adverse events during or after the exergame session.

**Table 3.1 | Characteristics of the included participants (n=22)**

| | |
|---|---|
| Age, median | 85 (70-95) |
| Women, n (%) | 18 (81.8%) |
| Montréal Cognitive Assessment, (0-30), mean ± standard deviation | 11.9 ± 4.4 (2-19) |
| **Diagnosis** | |
| - Alzheimer's Disease, n (%) | 10 (45.5) |
| - Vascular Dementia, n (%) | 5 (22.7) |
| - Neurocognitive Disorder not otherwise specified, n (%) | 6 (27.3) |
| - Lewy Body Disease | 1 (0.05) |
| **Comorbidities** | |
| - Diabetes, n (%) | 9 (40.9) |
| - Heart failure, n (%) | 5 (22.7) |
| - Dizziness, n (%) | 9 (40.9) |
| - Urinary incontinence, n (%) | 9 (40.9) |
| - Mild back pain, n (%) | 4 (18.2) |
| **Indoor mobility** | |
| - 4-wheeled walker, n (%) | 4 (18.2) |
| - Single-point walking cane, n (%) | 3 (13.6) |
| - No walking aid, n (%) | 15 (68.2) |
| **Fear of falling** | |
| Never, n (%) | 12 (54.5) |
| Sometimes, n (%) | 3 (13.6) |
| Regularly, n (%) | 5 (22.7) |
| Always, n (%) | 2 (9.1) |
| **Physical activity level before participation** | |
| No physical activities | 8 |
| One walking session per week | 7 |
| One to three walking sessions per week | 5 |
| More than three walking sessions per week | 2 |
| One gymnastics session per week | 1 |

**Table 3.2 | Individual Characteristics of the Participants.**

| Subject ID | Age | Gender | MoCA | Diagnosis | Mobility |
|---|---|---|---|---|---|
| 1 | 88 | F | 19 | AD | No aid |
| 2 | 87 | F | 4 | AD | No aid |
| 3 | 86 | F | 13 | AD | No aid |
| 4 | 87 | F | 2 | AD | No aid |
| 5 | 70 | F | 15 | AD | No aid |
| 6 | 80 | F | 7 | NCD NOS | No aid |
| 7 | 88 | F | 8 | AD | Walker |
| 8 | 83 | F | 14 | VD | Cane |
| 9 | 82 | F | 15 | NCD NOS | Cane |
| 10 | 80 | M | 11 | LBD | No aid |
| 11 | 85 | F | 8 | AD | No aid |
| 12 | 82 | F | 15 | VD | No aid |
| 13 | 95 | M | 17 | NCD NOS | Walker |
| 14 | 77 | F | 17 | NCD NOS | No aid |
| 15 | 89 | F | 7 | VD | No aid |
| 16 | 90 | F | 13 | AD | Walker |
| 17 | 84 | F | 12 | AD | No aid |
| 18 | 78 | M | 16 | NCD NOS | No aid |
| 19 | 85 | F | 14 | VD | Walker |
| 20 | 81 | F | 13 | AD | No aid |
| 21 | 92 | M | 12 | VD | Cane |
| 22 | 85 | F | 9 | NCD NOS | No aid |

*AD = Alzheimer's Disease; F = Female; LBD= Lewy body disease; M = Male, MoCA= Montréal Cognitive Assessment, NCD NOS = Neurocognitive Disorder Not Otherwise Specified; VD = Vascular Dementia; AD/VD = mixed Alzheimer's Disease and Vascular Dementia*

## 3.3.2.System Usability Scale (SUS)

The mean rating given to the VITAAL exergame by participants was 57.8 (SD= 12.3) with total scores ranging from 37.5 to 90.0. The mean SUS score of 57.8 corresponds to a system that is considered ok to good [50]. The SUS scores per participant are provided in Table 3.3.

**Table 3.3 | System Usability Scale scores.**

| Participant ID | Q1 | Q2 | Q3 | Q4 | Q5 | Q6 | Q7 | Q8 | Q9 | Q10 | Sum | Score |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | 4 | 3 | 4 | 4 | 4 | 2 | 4 | 2 | 2 | 4 | 23 | 57.5 |
| 2 | 4 | 4 | 3 | 5 | 5 | 3 | 4 | 2 | 4 | 1 | 25 | 62.5 |
| 3 | 1 | 2 | 5 | 5 | 3 | 3 | 4 | 3 | 4 | 3 | 21 | 52.5 |
| 4 | 4 | 4 | 2 | 5 | 4 | 4 | 4 | 3 | 2 | 5 | 15 | 37.5 |
| 5 | 1 | 1 | 4 | 5 | 3 | 2 | 5 | 1 | 5 | 2 | 27 | 67.5 |
| 6 | 4 | 2 | 4 | 5 | 4 | 4 | 4 | 2 | 4 | 3 | 24 | 60 |
| 7 | 1 | 2 | 4 | 5 | 3 | 3 | 2 | 2 | 2 | 4 | 16 | 40 |
| 8 | 4 | 2 | 4 | 5 | 4 | 4 | 5 | 2 | 5 | 3 | 26 | 65 |
| 9 | 5 | 2 | 4 | 5 | 4 | 2 | 2 | 4 | 4 | 5 | 21 | 52.5 |
| 10 | 4 | 4 | 4 | 1 | 4 | 2 | 4 | 4 | 2 | 1 | 26 | 65 |
| 11 | 4 | 2 | 4 | 4 | 5 | 4 | 2 | 2 | 5 | 2 | 26 | 65 |
| 12 | 4 | 1 | 4 | 2 | 4 | 3 | 3 | 1 | 4 | 2 | 30 | 75 |
| 13 | 4 | 3 | 4 | 4 | 4 | 3 | 4 | 2 | 4 | 2 | 26 | 45 |
| 14 | 5 | 2 | 5 | 2 | 5 | 2 | 4 | 1 | 5 | 1 | 36 | 90 |
| 15 | 2 | 2 | 4 | 2 | 3 | 3 | 4 | 2 | 3 | 2 | 25 | 62.5 |
| 16 | 4 | 4 | 3 | 5 | 3 | 2 | 2 | 2 | 5 | 2 | 22 | 55 |
| 17 | 3 | 4 | 4 | 4 | 4 | 3 | 4 | 4 | 5 | 1 | 24 | 60 |
| 18 | 2 | 2 | 2 | 5 | 4 | 3 | 2 | 2 | 4 | 2 | 20 | 50 |
| 19 | 4 | 2 | 3 | 4 | 4 | 4 | 5 | 2 | 2 | 1 | 25 | 62.5 |
| 20 | 2 | 3 | 2 | 5 | 4 | 2 | 2 | 3 | 2 | 2 | 17 | 42.5 |
| 21 | 4 | 4 | 4 | 2 | 4 | 2 | 4 | 4 | 5 | 4 | 25 | 62.5 |
| 22 | 1 | 2 | 2 | 5 | 4 | 2 | 3 | 2 | 2 | 4 | 17 | 42.5 |

*1: strongly disagree, 2: disagree, 3: neutral, 4: agree, 5: strongly agree*

*Q: SUS question*

*Questions:*
1. *I think that I would like to use this system frequently.*
2. *I found the system unnecessarily complex.*
3. *I thought the system was easy to use.*
4. *I think that I would need the support of a technical person to be able to use this system.*
5. *I found the various functions in this system were well integrated.*
6. *I thought there was too much inconsistency in this system.*
7. *I would imagine that most people would learn to use this system very quickly.*
8. *I found the system very cumbersome to use.*
9. *I felt very confident using the system.*
10. *I needed to learn a lot of things before I could get going with this system.*

### 3.3.3.Thematic analysis results

The analysis of the interviews revealed 5 main themes which describe the experiences of the participants: (1) perceived user friendliness and acceptability of the exergames; (2) interactional experience; (3) motivational factors; (4) training; and (5) risks.

#### Perceived user friendliness and acceptability of the exergames

***Attitude towards using the exergame device***. All participants liked the exergames and experienced enjoyment while playing the games (n= 22, 100%). Ten participants stated that they would be interested in using the exergames in the future, next to traditional activities in the long-term care facility (n= 45.5%).

> *I would like that because I feel that it's good for my lower vertebrae (P9)*

Five participants were not sure about using the exergame device in the future (n= 22.7%).

> *I would have to think about that… it's something peculiar, isn't it? (P17)*

Six participants would not be interested in exergaming in the future (n= 27.3%).

> *I prefer to go walking instead of exergaming (P3)*

***Ease of use and understandability of the instructions.*** Participants were all assisted by the guiding therapist with the setup of the device and the application of the sensors. They were not expected to do this independently. Participants experienced difficulties in navigating between different games. The games were depicted at the home screen and could be accessed by performing steps in the right direction. Participants needed verbal guidance to assist them to perform steps in different directions to access the various games from the home screen. In addition, they did not understand the game instructions and needed extra explanation from the therapist to understand how to play the games. In addition, verbal guidance was needed in all participants during game performance (n= 22, 100%). Three participants kept looking at their feet and had to be reminded to look up to the screen to see the game interface (n= 13.6%). Four participants initially moved their hands to the screen (instead of using whole-body movements to interact with the game) because they did not understand that they needed to perform steps to play the game (n= 4, 18.2%). Nine participants were not able to play the game without constant verbal guidance (n= 40.9%).

***Sensor application***. Eight participants said that the sensors were user-friendly (n= 36.4%). Some participants said that they forgot that they were even wearing sensors (n=3, 13.6%).

*The sensors didn't bother me, I wasn't even aware that they were attached to my feet (P5)*

Two participants stated that they expected that they would not be able to apply the sensors to their feet themselves (n= 9.1%).

*I wouldn't be able to apply the sensors myself (P4)*

***Sensor reactivity***. One participant accidentally exited the game ten times, because the sensors often falsely perceived her steps as a toe raise, the movement required to go to the menu. In five participants, the exergame did not respond correctly to a good execution of the toe stand (n= 22.7%). Two participants accidentally exited the game because the sensors did not communicate well to the device (n= 9.1%).

One participant performed her steps very slowly, so when she placed her foot back in the centre, this was perceived as an opposite direction sidestep by the device. Often, the steps were not detected at all, or with a delay. In most participants, the sensors did not correctly process steps, so the guiding therapist had to assist by clicking the arrows on the keyboard to play the games and navigate through the games.

***Technical problems***. Apart from the problems with the sensors, participants did not experience any technical problems with the exergame device during exergaming.

***Physical limitations***. Five participants were not able to perform the toe raise on both feet to exit the game or to go back to the menu without assistance of the guiding therapist (n= 22.7%). Seven participants needed extra support from the guiding therapist, a walker, or a walking cane to play the games (n= 13.6%).

The step backward was regarded as the most difficult step direction, because this action requires a good equilibrium.

It was also hard for participants with hearing difficulties to understand the game instructions that the guiding therapist gave.

*I feel it in my back (P22)*

***Mental effort***. The games are more cognitively challenging than physically challenging for most participants. They had to stay focused and some had difficulties staying concentrated on the games.

Twelve participants said that exergaming was mentally exhausting (54.5%) and nine said that it was not (40.9%).

> *It was a bit mentally challenging because it was all new to me (P20)*
>
> *It was necessary to keep your attention (P6)*

## Interactional Experience

***Feedback***. Participants enjoyed receiving feedback from the device (n= 17, 77.3%) and some even laughed out loud when positive feedback was given (n= 6, 27.3%).

> *Oh, it feeds your ego of course! (P12)*
>
> *It is encouraging (P19)*
>
> *I realised that I was good at it due to the score (P14)*

Sometimes participants were performing well but received negative feedback because the sensors were not receiving correct information from the steps (n= 22, 100%).

***Multidirectional steps***. Some participants were not able to link the steps to the directions in the games (n= 5, 22.7%). For example, it was hard to link the backward step with downstairs in the library game. For several participants, it was difficult to navigate between the games, so the guiding therapist had to assist by pressing the arrows on the keyboard. Some participants had a hard time learning to just tap their feet and they took a whole sidestep with both feet instead, causing the games to react falsely (n= 9, 40.9%).

***Avatar interaction***. Participants were able to associate themselves to their avatar. They enjoyed seeing their avatar and found it easy to imitate the avatar's movements. The squatting avatar in the outdoor game especially was perceived as enjoyable and helpful. A picture of this avatar can be found in Figure 1. One participant even scratched her hair when her avatar did (n= 4.5%). However, the home screen avatar "Vita" was recognised as a dog by one participant (n= 4.5%).

## Motivational factors

***Exergame Motivation***. Most of the participants found exergaming to be motivating (n=19, 86.4%).

> *It motivated me because the exercises were easy to perform (P9).*
>
> *It is very healthy, and you must know that I am very patient, but lately (due to COVID-19 restrictions) we are not allowed to do gymnastics anymore (P11)*
>
> *I don't exercise enough, and you should exercise, exercise, exercise! (P14)*

However, four participants said that they were already active enough and did not need exergames to motivate them to be physically active (n= 18.2).

> *The exergame did not motivate me because everything hurts. I never really enjoy physical activity. I have done enough in my life already (P7)*

***Enjoyment and positive emotions***. All participants experienced having fun and smiled during the exergames (n= 100%). Some stated that they just liked being invited to go outside their living unit and enjoyed the distraction. Participants were enthusiastic about the exergame. Exergaming evoked memories and three participants spontaneously started talking about past experiences with physical activity (n= 13.6%). Eight participants felt that they were really good at it (36.4%).

***Engagement***. Participants spontaneously started talking about healthy food while playing the healthy food or not game (n=4, 18.2%). Seventeen participants experienced feeling "in" the game regularly (n= 77.3%).

> *In the beginning, I had to listen carefully to understand the instructions, but afterwards I experienced it (P11)*

***Long-term acceptability***. Fourteen participants said that they expected that the exergames would still be nice, even after they would have played them several times (n= 63.3%). Two of them argued that this would be the case, provided that the games would become more difficult.

> *I think it would be even more nice, because then you really know how it works and it's easier (P16)*

> *I will become better at it and these are movements that you usually don't do; you never step backwards and it's actually very beneficial for your balance (P8)*

***Game design: sounds and images***. Participants liked how the games looked. They enjoyed the music that was played during the exergames and while navigating between the games. Two participants (9.1%) spontaneously started dancing to the exergame music.

## Training modalities

***Exergame intensity***. Most of the participants stated that the exergames were low intense

(n= 13, 59.1%). However, three participants said that performing the squats was particularly difficult and needed to rest in between (n= 13.6%). Two participants said that the walk to the exergame room was already exhausting for them (n= 9.1%).

> *I would prefer to do more high intense exercises (P14)*

> *I was already fatigued and to perform this on top of that… It's particularly exhausting for my eyes (P7)*

***Training duration***. All participants said that the duration of the exergame session was good (n= 22, 100%).

***Feeling safe***. Although all participants felt safe during exergaming (n= 22, 100%), four stated that they were extra careful not to fall (n= 18.2%).

*I am not afraid of falling, but I try to be careful not to fall (P22)*

### Risks

Fall risk. The supervisor always individually guided the participant and there were no fall incidents. Two participants indicated that the floor on which they were standing was slippery (n= 9.1%). This feeling was augmented because the sensors were attached to the feet with fabric straps that slid on the floor very easily.

Negative emotions. Four participants felt confused because they didn't understand the instructions of the games (n= 18.2%). One participant said that the games were childish. Another participant said that at first sight, the games might seem childish, but in fact, they are not.

*It might seem childish at first, but it's not (P10)*

## 3.4. Discussion

The primary aim of this study was to evaluate the usability of a stepping exergame prototype in residential people with MNCD. Specific adaptations were made by the developers in order to create a rehabilitation tool for older adults with cognitive and physical limitations, as was advised in a previous exergame-based balance training usability study [65]. Overall, the mean SUS score given to the VITAAL exergame was 57.8, which corresponds to a system usability that is ok. The SUS scores also correspond to supervisors' observations and the content of the interviews. Participants had a positive attitude towards the VITAAL exergame. However, during and after exergame performance, participants also reported some issues regarding the use and the difficulty of the games, which should be considered when finalising the device. The thematic analysis resulted in 6 main themes: (1) perceived user friendliness and acceptability of the exergames; (2) interactional experiences; (3) motivational factors; (4) training modalities; and (5) risks.

First, the VITAAL exergame was accepted well by participants. They liked playing the games and experienced enjoyment. Participants were always assisted by the supervisor with the setup of the device and the correct application of the sensors to the feet (n= 100%). However, some difficulties regarding user friendliness and acceptability were reported. For example, participants experienced difficulties in understanding some game instructions. Additional verbal guidance from the supervisor was needed in all participants (n= 22, 100%). Some participants were not able to play the game without constant verbal guidance (n= 9, 40.9%). Participants also experienced difficulties in navigating between different games. However, difficulties regarding understanding of the game instructions and game navigation might also be because participants only had one try-out session.

In people with MNCD, one session might not be sufficient to get familiarised with the instructions and execution of the exergames. Therefore, the acceptability should also be investigated in longitudinal qualitative or mixed methods study. Five participants were not able to perform the toe raise on both feet to exit the game or to go back to the menu without assistance of the guiding therapist (n= 22.7%). The final design should consider a possible alternative movement that is required to exit the games, instead of the toe raise, in particular for old-aged populations at risk for falling. The game was accidentally exited by two participants (n= 9.1%) and one participant accidentally exited the game up to ten times, because the sensors falsely perceived her steps as toe raises (n= 4.5%). Also, when performing the steps slowly, the steps back to the centre were perceived as opposite direction sidesteps by the device in one participant (n= 4.5%). In most participants, the sensors did not correctly perceive steps. For example, the steps were not detected at all, or with a delay. In addition, participants were not able to navigate between games because the sensors were not responding correctly (n= 100%). To solve this, the supervisor assisted by clicking the arrows on the keyboard in order to play the games and navigate through the games. In some participants, the exergame did not respond correctly to a correct execution of the toe stand (n= 5, 22.7%). When the sensors were not working well and the system falsely provided negative feedback, the supervisor tried to solve this by giving appropriate positive verbal feedback. In addition, the supervisor assisted the gameplay by clicking the arrows on the keyboard, that corresponded to the tapping movements of the feet in the four directions. A possible explanation is that Bluetooth devices, such as a smartphone or a tablet from nearby staff in the long-term care facility, might have caused interference in the connection between the sensors and the software. Therefore, it is recommended to examine the difficulties with sensor reactivity and solve them before using the prototype in a future trial. Despite these issues, the sensors were perceived as user-friendly (n= 36.4%) and participants did not experience any technical problems with the exergame device during exergaming (n= 100%). A possible explanation for this is that the supervisor took over the gameplay by clicking the arrows on the keyboard and, hence playing the game. Moreover, some participants needed extra physical support and were assisted by the supervisor, their walker, or their walking cane during exergame performance (n= 7, 13.6%). This was not standardised because it depended on the individual's balance and fall risk at that moment. Therefore, the use of extra support was recorded in the field notes. Also, the exergames were cognitively challenging for most participants. Twelve participants reported that exergaming was mentally exhausting (54.5%) and nine said that it was not (40.9%). It would be interesting to examine the level of experienced cognitive challenge in the updated prototype that will individually adapt to the performance level and needs of the individual. Despite experiencing some difficulties, nearly half of the participants expressed a wish to continue exergaming in the future, supplementary to their traditional activities in the long-term care facility (n= 10, 45.5%).

Second, the interactional experience was overall positive. Participants particularly liked the squatting avatar in the outdoor game. Participants found it helpful to imitate the avatars' movements because they were able to associate themselves to their avatar. A reason for this might be that in the outdoor game, the avatar was displayed as a full human body. This contrasts with the avatar of the home screen and the other games, which was more abstract and did not resemble a human being. For application in our population, it might be helpful to consider adapting Vita to resemble a more human-like avatar, like the squatting avatar in the outdoor game. Concerning the audio-visual feedback, the VITAAL exergame focused on positive feedback and this was greatly accepted by the participants. They enjoyed receiving feedback (n= 17, 77.3%) and laughed out loud when positive feedback was given (n= 6, 27.3%). Besides this, some interactional issues were detected. For example, participants had difficulties learning to just tap their feet and took a whole sidestep with both feet instead, causing the games to react falsely (n= 9, 40.9%). Moreover, some participants initially pointed their fingers to the screen or tried to grab items displayed on the screen, instead of performing steps to control the games (n= 4, 18.2%). This was easily solved by extra verbal guidance of the supervisor.

Third, most of the participants found exergaming to be motivating (n=19, 86.4%). Some participants felt that they were "really good" at exergaming (n= 8, 36.4%). All participants experienced enjoyment and fun while playing the exergames (n= 100%). Experiencing enjoyment is a strong predictor for training adherence in exergame programs for old-age populations [66]. Most participants experienced feeling "in" the game regularly (n= 17, 77.3%). This feeling possibly reflects the experience of participants being in their "flow zone", a feeling of complete and energised focus in order to improve the enjoyment and learning experience, which is in line with previous recommendations on the use of active videogames in older adults with Alzheimer's disease [67]. Also, the long-term acceptability is expected to be positive. Most participants expect the exergames to be engaging after playing them several times (n= 14, 63.3%). It was also argued by some that exergaming will still be nice, provided that the games will increase in difficulty level (n= 2, 9.1%). This will be addressed in a next prototype, where the complexity of the games will be individually adapted to the player's performance. Participants in our study stated that they really liked the game design. In addition, they enjoyed the music while playing the exergames and when they were navigating between the games. Two participants spontaneously started dancing to the exergame music (n= 9.1%). The healthy food game was preferred by all participants and some of them spontaneously started talking about healthy food while playing (n= 4, 18.2%). We believe that this reflects a right choice of game theme and a possible relation of their game experience to daily life situations. In addition, because the participants verbally interacted with the supervisors, exergaming was considered as a social activity.

Fourth, the training modalities were well accepted by the participants. Most of the interviewees stated that they experienced the intensity of the exergames as low (n= 13, 59.1%). However, executing the squats in the outdoor game was perceived as more intense, and some participants sat down on a chair to rest in between (n= 3, 13.6%). Since people with MNCD are less able to assess their perceived exertion validly due to impaired judgment, awareness, and insights as well as increased communication difficulties, it might be hypothesized that an automatic adaptation of the exergames to the individual needs and performance of the player will increase the usability of the exergame even further. The duration of the exergame session was thirty minutes and this was unanimously perceived as good (n= 22, 100%). It should be considered, however, that once the device can be adapted to the individual's needs and performance, it might be more physically intense and consequently thirty minutes from the beginning of the training might be too long for our sedentary population. In such a case gradual progression of exergame play time should be warranted and the thirty minutes should be a target that should only be reached following a skilling-up phase [68].

Fifth, some risks regarding the use of the VITAAL exergame were identified. Although all participants felt safe during exergaming (n= 22, 100%), some explained that they were extra attentive not to fall (n= 4, 18.2%). The supervisor considered five participants as having a risk of falling, although this was not objectively represented [69]. Therefore, in future trials, supervisors should always be aware of the potential risk of falling in similar exergame trials. The sensors were attached to the feet with fabric straps that slid on the floor very easily. Depending on the floor, this might increase the risk of falling during exergame performance. The VITAAL exergame evoked negative emotions such as confusion when the participants did not understand the instructions of the games (n= 4, 18.2%). Therefore, the supervisor assisted by explaining the game instructions in a friendly way. This also underscores the advantage of the one on one guidance during exergaming.

Some limitations of this study should be considered. First, the current study was limited to only one long-term care facility in Belgium, so the findings may have limited generalisability to other settings and countries. Second, only residents who were willing to participate, in other words, people who were more interested in technology than the average person with MNCD, were included. This limits the generalisability to all people with MNCD. A third limitation of the study was that more female (81.8%) than male (18.2%) participants were included. A reason for this might however be that women are at greater risk for developing Alzheimer's disease [70] and more women than men are living in long-term care facilities in Belgium [71]. This emphasises the importance of especially assessing exergame usability in women. Fourth, the SUS has not been validated in people with MNCD yet [72]. Therefore, our results were interpreted in combination with the data from the observations and interviews. Fifth, although the think aloud method has been applied in research in people with MNCD before [38], it also has a limitation. For most participants, talking out loud while exergaming was complex. This is in line with a previous usability study in people with MNCD stating that participants experienced difficulties in verbalising and narrating their experiences, even when prompted and reminded to do so during completion of the tasks [72]. Finally, the results may have been influenced by social desirability bias, which is a common problem in research. This was considered during the interviews by for example actively asking about negative opinions. Despite these limitations, some strengths should be acknowledged. The number of participants allowed for a rich data collection of experiences and usability opinions. Although the exergame prototype did not adapt to the individual needs of the participant, which might be considered as a limitation from a clinical perspective, it allowed us to investigate a standardised exergame training session. Moreover, interviews were performed directly following the exergame try-out and in the same room, which facilitated participants' recall of the events and experiences during the exergame session. Also, the interviewer was the same person who had supervised the participants' exergame session, and so they were familiar with each other. They could reflect on observations and statements and this might have facilitated the interview conditions as well. Furthermore, the supervisor always attempted to use a neutral body language, in order not to influence the participants' responses. The authors' different education, age, knowledge, and disciplines were also a strength of this study. The end user participatory design was adopted to enhance the development of a user-friendly exergame device that would be well accepted by the target group. The findings (and abundance of feedback) of this study underscore the value of end users' involvement in the development of exergames.

## 3.5. Conclusion

Based on the current findings, it can be concluded that the VITAAL exergame is not only considered useful by residential people with MNCD, but it's also experienced as entertaining. Technical issues with the sensor reactivity and the difficulty of the game navigation and instructions should be addressed before the prototype can be implemented in a longitudinal trial. Following that, the assessment of whether this exercise solution is able break up sedentary behaviour [73] in this population seems warranted.

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# 4. Acceptability, game experience and usability of a newly designed exergame and connected sensors for the treatment of women's geriatric incontinence

## 4.1. Hypothesis/aims of the study

Geriatric urinary incontinence (UI) is often related to impaired mobility, balance and cognition. The present study aimed to assess the acceptability, game experience and usability of a newly designed exergame and wearable sensors for the treatment of geriatric UI.

## 4.2. Study design, materials, and methods

An international research consortium from Belgium, Canada, Portugal and Switzerland developed a geriatric rehabilitation exergame that uses wearable sensors and a web-based interface to provide evidence-based training for geriatric UI. The present cohort study is the first evaluation loop of an iterative design approach comprising design prototyping and evaluation.

Participants were community-dwelling women age 60 and over with mixed or urgency UI, as defined by the questionnaire for UI diagnosis (QUID). To be included in the study, participants were required to experience at least three urine leakage per week on the seven-day bladder diary and contract their pelvic floor muscles (PFMs) (as demonstrated during vaginal digital assessment). Additionally, participants were also required to maintain a standing position for at least 30 minutes without assistance and have sufficient visual acuity (with or without correction) to view the games on a television screen.

After signing the informed consent form, participants completed a demographic questionnaire, as well as the Montreal Cognitive Assessment (MoCA) to document overall cognitive ability, the Short Physical Performance Battery (SPPB) to document overall physical condition and the QUID to document UI severity. Then, a PFM force sensor (dynamometer) was inserted into the participant's vagina and two inertial sensors for movement analysis were attached to the participant's feet.

Women took part in an exergame session of 30 minutes, which included cognitive and physical activities. The participants performed specific exercises such as maximal PFM contractions and stepping exercises in different directions to control the video game scenario presented on a frontal screen.

During the exergame performance, acceptability and game experience were qualitatively assessed using the think out loud method. After the exergame, participants completed the System Usability Scale (SUS), a validated scale for game and exergame evaluation. Finally, women took part in an individual interview to document the usability of the game.

## 4.3. Results

10 women participated in the study (five from Switzerland and five from Canada). Participants' mean age was 72.4 + 9.08 years, mean weight was 66.28 + 12.59 kilograms, mean height was 1.62 + 0.39 meters, and mean years of education was 12.1 + 2.4 years. Mean values for the MoCA was 26.6/30 + 2.4, SPPB 10.4/12 + 1.26 and the total QUID score was 11.5/30 + 6.2.

The SUS score was 67.00/100 + 18.77. Table 1 presents the Think out loud data. Table 2 presents the post-game interview data.

**Table 4.1 | *Think out loud* data**

| | Positive | Negative |
|---|---|---|
| **Game Interaction** | Fun and entertaining (n = 1)<br>Interesting (n = 1)<br>Motivating/challenging (n =1)<br>Sensors interact well (n=1) | More explanation needed to understand game (n = 4)<br>Need assistance for placing/connecting sensors (n=4)<br>Participant's displacement in space is wide at beginning (n=4) |
| **Game Design** | Adequate (n = 3)<br>somewhat similar to Pac-Man (n = 1) | Too simple, childish, dull (n = 3)<br>Not clear that the game has to be controlled by feet (n=4)<br>How to get to the menu was not clear (n=3)<br>Aim of some games not clear mother chicken (n=2) music game (n=2) pizza game: (n=1)<br>Music (n = 2) |
| **Emotions** | Joy (n = 3)<br>Positive emotions (n = 3)<br>Fun (n = 4)<br>Laughing (n=3)<br>Happyness (n=1) | Frustrating (n = 1)<br>Not challenging enough (n=2)<br>Confusing (n=4)<br>Boring (n=1)<br>Stressful (n=1)<br>Brings anger at oneself (n=1) |
| **Training** (Exercises, Intensity, Training priciples) | The game requires feasible multitasking (n = 2)<br>The intensity/rhythm is adequate (n = 3)<br>The pelvic floor exercises are adequate (n = 1)<br>Leg displacements (steps) work well with the PFM sensor (n=1)<br>Cognitive load is good (n=1) | Hard to understand the exercises (n = 2)<br>Intensity is too slow at the beginning (n = 1)<br>There is displacement of the dynamometer during movement (n=4)<br>Foot sensor fell off the shoe (n=1)<br>Game is cognitively intensive (n=1)<br>PFM exercises are not clear (n=1)<br>Steps are too big and too slow to accommodate game (n=1)<br>Game duration could be longer (n=1)<br>Physical load is not challenging enough (n=1)<br>Verbal instructions to contract PFM necessary (n=1)<br>PFM sensor's processing unit interfering with game (n=1) |
| **Risk/Limitations** | No fear of falling (n = 1)<br>Not dangerous (n = 1)<br>No risk (n = 4) | The space required to do the exercises is large (n = 1)<br>Participant didn't want to wear PFM sensor (n=1) |
| **Further Comments** | Monitoring the progress with sensor is important (n = 1)<br>It is nice to have feedback from the game for every PFM contraction (n = 1) | The pelvic floor sensor is uncomfortable (n = 3) |

**Table 4.2 | Interview**

| | Positive | Negative |
|---|---|---|
| **Emotions** | Fun (n = 2) | Was frustrating because the goal of the game was not obvious (n =1) |
| **Usability** | Had a great experience (n = 3)<br>Quickly understood how to control the game with the sensors (n = 2)<br>The sensors were easy to use/comfortable to wear (n = 2) | Did not really understand how to control the game with the sensors (n = 3)<br>Mild discomfort associated with the pelvic floor sensor (n = 3)<br>Experienced technical problem regarding the stepping movement (n =2) |
| **Training** | Game was motivating (n = 1)<br>Contracting/staying active is good (n = 1)<br>Did not require too much concentration (n = 2) | Training is too easy (n = 1)<br>Training requires lots of concentration (n = 2)<br>Stepping movement was hard to understand, it was not natural and required more explanation (n = 2) |
| **Games** | Enjoyed the urinary incontinence game the most (n = 3)<br>Particularly enjoyed the library game as it helped to understand how to contract correctly (n = 1)<br>Liked the fact that there was a lot of different games (n = 1) | The game menu was hard to understand (n = 1)<br>The games were difficult at the beginning because it was hard to contract PFM correctly (n = 1) |
| **Design & Game Environment** | The themes of the game were adequate (n = 3)<br>The sound/look of the game were both adequate (n = 1)<br>The game was well structured, versatile, simple and easy to follow (n = 1) | |

## 4.4. Interpretation of results

During the *think out loud* assessment, study participants experienced mixed positive and negative impressions of the exergame. Most importantly, they requested more comprehensive explanations regarding the goal of the game and its different activities, the placement/ connection of sensors and how to browse the game using the menu to select the different activities. This misunderstanding of the game led to wider leg movements, which in turn led to more displacement in the room, influencing responsiveness of the foot sensors. Additionally, PFM sensors were displaced leading to discomfort and eventually frustration with the game in participants who did not understood the game.

In the post-intervention interview, participants were more positive with the exergame, which was supported by a SUS score corresponding to a marginally high acceptability range.

## 4.5. Concluding message

This study highlights the mixed feelings of older women with geriatric UI regarding our newly designed exergame and wearable sensors. Of interest, most issues identified by the study participants regarding the game and sensors were resolved using simple modifications. A more intuitive introduction to the game and goals of the activities was developed. Clearer instruction was provided regarding the sensor placement/connection. Additionally, two PFM dynamometer sizes were made to accommodate different vaginal hiatus sizes, which helped prevent discomfort during the game. All these modifications will be studied in the next evaluation loop of our iterative design.

# 5. Feasibility of a newly designed exergame and connected sensors for the treatment of mobility impaired older adults

## 5.1. Overview VITAAL Feasibility Motor Impaired Older adults

As per 29.10.2021 the Motor Impairment-trial is still ongoing in Switzerland. In total 66 older adults expressed to be interested in partaking. From these 33 had to be excluded. Reasons for exclusion were:

Too fit: balance, strength (16)

Cancellation before first appointment (2)

Included in Urinary Incontinence study (1)

Due to the situation of COVID-19 (3)

Heart-problem (1)

Mentally and physical not ready, personal reason (1)

Not willing to share data (1)

Parkinson disease (1)

Bad health condition (3)

Balance not good enough (1)

Not able to see a TV-screen (1)

Cancellation without reason (1)

Cancellation because of overstrain (1)

Included were 33 individuals. Allocated to the intervention group were 16 individuals and the Control group contained 17 persons.

Dropouts so far are 16 because of the following reasons:

Too fit: balance, strength (4)

Health problem, stop on recommendation of a treating doctor (1)

Increased physical problems (3)

Incidents, not related to the study and training (2)

Lack of motivation (2)

Home-training too difficult (1)

Difficulties playing the game due to eye-problems (1)

Several reasons: physical and problems with the bright screen (1)

No reason given (1)

For the Post-measurements 16 were performed (of planned 17). The final post-measurement is planned at 01.11.2021.

Status as of 30.11.2021 are sizes for the Intervention group = 8; Control group = 9 study participants.

The trial could not be granted an extension with further financial support by the Swiss Confederation represented by the State Secretariat for Education, Research and Innovation (SERI; agreement number 1315001415). The researchers strive to find support enabling finalising the study results with other means.

As per 30.11.2021 the Motor Impairment-trial results for Single Task (ST) and Dual Task (DT) gait velocity are available from Switzerland (Table below).

| ***Control group ST gait velocity-pre*** | | ***Intervention group ST gait velocity-pre*** | |
|---|---|---|---|
| Mean | 0.977556 | Mean | 0.9495 |
| Standard Error | 0.059574 | Standard Error | 0.10385584 |
| Median | 1.044 | Median | 0.8935 |
| Mode | #N/A | Mode | #N/A |
| Standard Deviation | 0.178723 | Standard Deviation | 0.29374868 |
| Sample Variance | 0.031942 | Sample Variance | 0.08628829 |
| Kurtosis | -1.02772 | Kurtosis | -1.7699051 |
| Skewness | -0.51944 | Skewness | 0.22060108 |
| Range | 0.513 | Range | 0.721 |
| Minimum | 0.672 | Minimum | 0.602 |
| Maximum | 1.185 | Maximum | 1.323 |
| Sum | 8.798 | Sum | 7.596 |
| Count | 9 | Count | 8 |
| | 0 | | 0 |

| ***Control group ST gait velocity-post*** | | ***Intervention group ST gait velocity-post*** | |
|---|---|---|---|
| Mean | 1.090778 | Mean | 0.9785 |
| Standard Error | 0.059024 | Standard Error | 0.07020633 |
| Median | 1.156 | Median | 0.907 |
| Mode | #N/A | Mode | #N/A |
| Standard Deviation | 0.177072 | Standard Deviation | 0.19857348 |

| | | | |
|---|---|---|---|
| Sample Variance | 0.031354 | Sample Variance | 0.03943143 |
| Kurtosis | 1.946948 | Kurtosis | -1.0250723 |
| Skewness | -1.48117 | Skewness | 0.4614425 |
| Range | 0.558 | Range | 0.564 |
| Minimum | 0.709 | Minimum | 0.712 |
| Maximum | 1.267 | Maximum | 1.276 |
| Sum | 9.817 | Sum | 7.828 |
| Count | 9 | Count | 8 |
| | 0 | | 0 |

| *Control group DT gait velocity-pre* | | *Intervention group DT gait velocity-pre* | |
|---|---|---|---|
| Mean | 0.84522 2 | Mean | 0.77125 |
| Standard Error | 0.05976 3 | Standard Error | 0.107428 |
| Median | 0.832 | Median | 0.7215 |
| Mode | #N/A | Mode | #N/A |
| Standard Deviation | 0.17929 | Standard Deviation | 0.303853 |
| Sample Variance | 0.03214 5 | Sample Variance | 0.092327 |
| Kurtosis | -0.42881 | Kurtosis | -1.39256 |
| Skewness | -0.77062 | Skewness | 0.29076 |
| Range | 0.514 | Range | 0.825 |
| Minimum | 0.537 | Minimum | 0.372 |
| Maximum | 1.051 | Maximum | 1.197 |
| Sum | 7.607 | Sum | 6.17 |
| Count | 9 | Count | 8 |
| | 0 | | 0 |

| *Control group DT gait velocity-post* | | *Intervention group DT gait velocity-post* | |
|---|---|---|---|
| Mean | 0.83188 9 | Mean | 0.804875 |

| | | | | |
|---|---|---|---|---|
| Standard Error | 0.07294<br>4 | | Standard Error | 0.085875 |
| Median | 0.912 | | Median | 0.7385 |
| Mode | #N/A | | Mode | #N/A |
| Standard Deviation | 0.21883<br>1 | | Standard Deviation | 0.242892 |
| Sample Variance | 0.04788<br>7 | | Sample Variance | 0.058997 |
| Kurtosis | -1.96155 | | Kurtosis | 0.395144 |
| Skewness | -0.28154 | | Skewness | 0.810439 |
| Range | 0.566 | | Range | 0.763 |
| Minimum | 0.52 | | Minimum | 0.493 |
| Maximum | 1.086 | | Maximum | 1.256 |
| Sum | 7.487 | | Sum | 6.439 |
| Count | 9 | | Count | 8 |
| | 0 | | | 0 |

The results of training with the VITAAL system so far indicate no differences between the groups for the gait velocity outcomes, however, this is probably due to the related power.

Anova: **Single Task gait velocity**

SUMMARY

| *Groups* | *Count* | *Sum* | *Average* | *Variance* |
|---|---|---|---|---|
| Column 1 | 9 | -1.01<br>9 | -0.11322 | 0.01160<br>2 |
| Column 2 | 8 | -0.23<br>2 | -0.029 | 0.01988<br>9 |

ANOVA

| *Source of Variation* | *SS* | *df* | *MS* | *F* | *P-value* | *F crit* |
|---|---|---|---|---|---|---|
| Between Groups | 0.03004<br>3 | 1 | 0.03004<br>3 | 1.94205<br>9 | 0.18375<br>1 | 4.54307<br>7 |
| Within Groups | 0.23204<br>2 | 15 | 0.01546<br>9 | | | |

| | | | | | | |
|---|---|---|---|---|---|---|
| Total | 0.262084 | 16 | | | | |

Anova: **Dual Task gait velocity**

SUMMARY

| *Groups* | *Count* | *Sum* | *Average* | *Variance* |
|---|---|---|---|---|
| Column 1 | 9 | -0.787 | -0.08744 | 0.044807 |
| Column 2 | 8 | 0.557 | 0.069625 | 0.128498 |

ANOVA

| *Source of Variation* | *SS* | *df* | *MS* | *F* | *P-value* | *F crit* |
|---|---|---|---|---|---|---|
| Between Groups | 0.104488 | 1 | 0.104488 | 1.245943 | 0.281891 | 4.543077 |
| Within Groups | 1.25794 | 15 | 0.083863 | | | |
| | | | | | | |
| Total | 1.362428 | 16 | | | | |

# 6. Usability of a newly designed exergame and connected sensors for the treatment of women's geriatric incontinence

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## 6.1. Abstract

HYPOTHESIS / AIMS OF STUDY

Geriatric urinary incontinence (UI) is often related to impaired mobility, balance and cognition (1). This study aimed to assess the usability of a newly designed exergame and wearable sensors for the treatment of geriatric UI.

## 6.2. STUDY DESIGN, MATERIALS AND METHODS

An international research consortium from Belgium, Canada, Portugal and Switzerland developed a geriatric rehabilitation exergame that uses wearable sensors and a web-based interface to provide evidence-based training for geriatric UI. The present mixed method study is the first evaluation loop of an iterative design approach comprising design, prototyping and user evaluation.

Participants were older community-dwelling women with mixed or urgency UI, as defined by the questionnaire for UI diagnosis (QUID) (2). To be included in the study, participants had to be: ≥ 65 years, experiencing at least three incontinences per week on the seven-day bladder diary, able to contract their pelvic floor muscles (PFMs) (as confirmed by vaginal assessment), able to maintain a standing position for at least 30 minutes without assistance and have sufficient visual acuity to view the games on a television screen.

After signing the informed consent form, participants completed a demographic questionnaire, the Montreal Cognitive Assessment (MoCA), the Short Physical Performance Battery (SPPB) and the Questionnaire on UI Diagnosis (QUID). Then, a trained PFM physiotherapist placed an intravaginal PFM force sensor into the participant's vaginal cavity to monitor PFM force during the game. Two inertial sensors assessing movement were attached to the participant's feet to monitor steps.

Women played the exergame, which included 30-minutes of cognitive and physical activities during one try-out session. They performed maximal PFM contractions and/or steps in different directions to control the video game scenario presented on a frontal screen. During the exergame, acceptability and game experience were qualitatively assessed using the think out loud method and field notes were taken by the observer. Following the exergame, participants completed the System Usability Scale (SUS), a reliable and valid 10-item scale (3). This commonly used scale provides a global view of subjective usability of a product/system. Total scores ranged from 0 to 100, with scores between 25 to 39 corresponding to poor game usability; 39 to 52 corresponding to ok; 52 to 73 corresponding to ok to good; 73 to 85 corresponding to good to excellent, and 85 to 100 corresponding to excellent game usability. Finally, women took part in a semi-structured in-depth interview to document usability based on their personal experience. Think out loud data, field notes and interviews were coded and analysed.

## 6.3. RESULTS

From February to October 2020, 10 women participated in the study (five from Switzerland and five from Canada). Participants' mean age was 72.4 ± 9.08 years, mean weight was 66.28 ± 12.59 kilograms, mean height was 1.62 ± 0.39 meters, and mean years of education was 12.1 ± 2.4 years. Mean values for the MoCA was 26.6/30 ± 2.4, SPPB 10.4/12 ± 1.26 and the total QUID score was 11.5/30 ± 6.2. All participants completed the try-out session. All but one participant accepted using the vaginal sensor. No adverse events were reported during or after the exergame session.

The SUS score was 67.00/100 ± 18.77, corresponding to a 'marginally high' acceptability range. The analysis of the qualitative data revealed six main themes describing the experiences of the participants: 1- overall experience, 2- game environment 3- game interaction; 4- sensors usability, 5- training intensity, 6- risk and limitations.

## 6.4. INTERPRETATION OF RESULTS

Overall experience: All participants liked the exergame and experienced 'joy', 'fun' or 'happiness' while playing the game (n= 10; 100%).

Game environment: 70% of participants appreciated the overall platform design, the game versatility and enjoyed the music played, using words such as 'motivating' and 'entertaining'. A few, however, found the game environment 'somewhat childish' (n=2; 20%).

Game interaction: 40 % of participants had difficulty understanding game instructions and needed explanation from the physiotherapist to understand game goals/rules and navigation. Verbal guidance was needed for most participants, particularly at the beginning, regarding the goal of each game and how to navigate through the games using steps. This misunderstanding of the game led to wider leg movements and more displacement of the participant in the room, leading to frustration (n =4; 40%).

Sensor usability: Foot sensors were accepted by all. Participants used words like 'easy to use' and 'comfortable' to qualify them. Although many (n = 7; 78%) appreciated the feedback given by the vaginal sensor during the game, some reported technical issues with the vaginal sensor, such as 'discomfort' (n = 4; 44%) and 'displacement' (n = 2; 22%), respectively, while playing the game.

Training intensity: Most participants stated that the game was of 'adequate' intensity (n = 8; 80%). Most reported that the games required 'concentration', particularly in games where both foot and vaginal sensors were used. All participants said that the duration of the exergame session was good.

Risk and limitation: Only one participant reported a fear of falling when stepping backward.

The overall qualitative findings were supported by the SUS score corresponding to a 'marginally high acceptability' range. Most issues identified by the study participants regarding the game and sensors were resolved. Difficulty with instruction and navigation in the game were addressed. Additionally, two PFM sensor sizes were made to accommodate different vaginal hiatus sizes and help prevent discomfort during the game.

## 6.5. CONCLUDING MESSAGE

Based on this study findings, it can be concluded that VITAAL exergame was not only acceptable by study participants, but it was also experienced as a fun, entertaining and motivating. Game and sensor improvements will be studied in the next evaluation loop of our iterative design, which will be an RCT assessing of this exercise solution for geriatric UI.

Overall, the findings of this study underscore the value of end users' involvement in the development of exergames.

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## 6.6. DISCLOSURES

**Current Trial Status** (as per 29.10.2021) The UI-trial is still ongoing in Canada. Due to the COVID situation the trial was granted an extension with further financial support by the Canadian Institute of Health Research (88200-Y3F8Q3).

- till now 34 participants are/ were interested
- till now 8 participants did not match the inclusion criteria
- till now 16 participants are included
- 2 drop-outs
- For the current statusof the trial we can report that 8 participants finished the study (4 control and 4 intervention group)
- We will present preliminary results on the Pelvisuisse symposium November 20th 2021.

**Funding** This study was supported by the AAL VITAAL project (www.aal-europe.eu/projects/vitaal/) and partially funded by the Canadian Institute of Health Research (88200-Y3F8Q3) and by the Swiss Confederation represented by the State Secretariat for Education, Research and Innovation (SERI; agreement number 1315001415). The funders had no role in the writing or approval of this manuscript. Clinical Trial No Subjects Human Ethics Committee the Research Ethics Committee of Institut universitaire de gériatrie de Montréal (CER IUGM CER VN19-20-50) and the ETH Zürich Ethics Committee (EK 2019-N-95) Helsinki Yes Informed Consent Yes

**Vitaal project Summary of clinical trial in Montreal as November 28th, 2021.**

Recruited participants: 21 participants

- Excluded in the recruitment: 7 participants were recruited but not evaluated for lack of leakages or personal reasons. (Vitaal 2-3-5-9-15-17-20)

Total of participants evaluated: 14 participants

- Drop out: 1 participant, just did the evaluation and no treatment because of husband's health condition (Vitaal 6)
- Excluded after the evaluation: 1 because of a rectocele that was found during pelvic floor exam (Vitaal 16)
- Finished the project after the 30th of November: 5 participants (Vitaal 1-4-7-8-10)

- In process with the project: 7 participants (Vitaal 11-12-13-14-18-19-21)

12 new participants, waiting to be assessed after the Xmas.

Participants in control group: 6

Participants in intervention group: 6

Patient 16 was not randomised because was excluded before treatment and patient Vitaal 19 is yet to be randomised because evaluation is coming on November 30th (n = 2).

Data for micturition, leakage, ICIQ LutSqol and 1-MSTS

| **Participant** | ICIQ UT Pre | ICIQ UT Post | ICIQ Lut Pre | ICIQ Lut Post | Moy. Mictions pre | Moy. Mictions post | Fuites Pre | Fuite post | 1-MSTS pre | 1-MSTS Post |
|---|---|---|---|---|---|---|---|---|---|---|
| Vitaal _01 | 15 | 11 | 29 | 23 | 777 | 777 | 29 | 5 | 12 | 13 |
| Vitaal _04 | 16 | 0 | 51 | 38 | 20,71 | 14,14 | 38 | 0 | 19 | 26 |
| Vitaal _07 | 17 | 18 | 48 | 55 | 14,29 | 15,57 | 26 | 22 | 22 | 19 |
| Vitaal _08 | 13 | 0 | 46 | 28 | 4,71 | 6,43 | 12 | 0 | 21 | 20 |
| Vitaal _10 | 13 | 8 | 32 | 22 | 5,57 | 6,29 | 9 | 1 | 22 | 33 |

Groupe contrôle

Data for the graphs of (fast) walking speed and oscillation width

| | Mesures pré | | | | Mesure post | | | |
|---|---|---|---|---|---|---|---|---|
| **Participant** | Vitesse / v. pleine (m/sec) | Vitesse / v. vide (m/sec) | Largeur / v. pleine (cm) | Largeur/ v. vide (cm) | Vitesse / v. pleine (m/sec) | Vitesse / v. vide (m/sec) | Largeur / v. pleine (cm) | Largeur/ v. vide (cm) |
| Vitaal _01 | 0,701 | 0,784 | 2,771 | 3,207 | 0,956 | 0,967 | 3,854 | 3,462 |
| Vitaal _04 | 1,01 | 1,047 | 2,821 | 2,51 | 1,371 | 1,25 | 3,097 | 3,339 |
| Vitaal _07 | 1,064 | 1,097 | 2,959 | 4,118 | 1,202 | 1,194 | 4,006 | 3,382 |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Vitaal _08 | 0,958 | 1,078 | 4,749 | 4,244 | 1,269 | 1,302 | 6,812 | 3,779 |
| Vitaal _10 | 1,225 | 1,365 | 6,05 | 6,919 | 1,386 | 1,454 | 5,775 | 6,546 |

Groupe contrôle

# 7. Individualized exergame training for residential older adults with major neurocognitive disorder: a mixed methods study

## 7.1. Abstract

**Purpose (background)**
The primary objective of this study was to evaluate the efficacy of an individualized stepping exergame program on motor and cognitive functions and mental wellbeing in older adults with major neurocognitive disorder (MNCD) residing in a long-term care facility.
The secondary objective was to explore participants' experiences regarding the stepping exergame program.

**Materials and methods:**
A mixed methods study was conducted. Participants were randomly assigned to 12 weeks, three times weekly, 30 minutes of stepping exergame training (exergame intervention group), 12 weeks, three times weekly, 30 minutes of non-individualized training (active non-individualized training group), or 12 weeks care as usual (passive control group). The exergames were depicted on a TV screen and two sensors were attached to the feet in order to assess participants' movements.
The Short Physical Performance Battery (SPPB), Montréal Cognitive Assessment (MoCA), Mini-Mental State Examination (MMSE), Neuropsychiatric Inventory (NPI), Cornell Scale for Depression in Dementia (CSDD), Dementia Quality of Life (DQoL), and the VITAAL gait analysis were assessed at baseline and post intervention. A Quade's non-parametric ANCOVA controlling for baseline values with post-hoc Bonferroni correction ($p<0.00x$) was used to analyze pre- and post-differences between the groups. Partial eta-squared ($\eta^2p$) effect sizes were calculated.
Semi-structured interviews were conducted in all participants of the intervention group after six and twelve weeks of exergame training. Interview recordings were transcribed, and facilitators' field notes (observations) were added. Qualitative data were thematically analyzed using NVivo 12. Adherence and attrition rates were calculated.

**Results**
Thirty-six older adults with mild to moderate MNCD (Mini-Mental State Examination score=x ± x; aged x-x; x women) completed the study. The exergame intervention group (n=12) demonstrated…
The mean attendance rate was x% in the exergame intervention group, x% in the active non-individualized training group and x% in the passive control group. One participant in the active non-individualized training group fell and dropped out due to a transfer to the hospital. There

were no other study-related adverse events reported by the participants, nor observed by the research team.

**Conclusions**

The findings of this mixed methods study suggest that in inpatients with MNCD residing in a long-term care facility.

**Trial registration**

The trial was registered in ClinicalTrials.gov (Identifier: NCT04436315)

**Keywords**: cognition, dementia, exercise, physical activity, qualitative research, serious game

## 7.2. Introduction

Global population aging is associated with an increased number of older adults with major neurocognitive disorder (MNCD) [1]. MNCD is a clinical syndrome resulting in cognitive function impairments, motor decline, psychological difficulties, and behavioral problems [2]. MNCD is associated with slow gait speed [3], increased risk of falling [4], and related disability [5]. The progressive functional decline in people with MNCD contributes to reduced quality of life and increased caregiver effort [6]. Often, transfers to long-term care facilities are inevitable [6]. The interest in preventing problems that cause morbidity and mortality and in maintaining or even improving the quality of life is increasing. At present, the primary goals for institutionalized people with MNCD are maintaining or improving their physical condition and quality of life. Non-pharmacological therapies including environment adaptation [7] and physical activity [8] are recommended and aspire to improve health and well-being [9]. It is well known that physical activity improves strength, endurance, balance, gait stability, gait speed, and overall wellbeing in older adults with MNCD [8, 10, 11]. Combined motor-cognitive training might slow down physical and cognitive decline and even prevent falls [12-14]. Exergames, which are videogames directed with physical movements, present an easy tool for combining cognitive and motor tasks in an enjoyable and motivating setting [15, 16]. Stepping exergaming improves mobility, balance, gait speed, cognitive functioning, and reduces apathy and fear of falling in older adults with MNCD [17-19]. Physical interventions in this population are characterized with low adherence rates and exergames might overcome this problem [8, 20]. Previous research has indicated that stepping exergame training is feasible and engaging in older adults with MNCD in long-term care facilities [21]. It requires participants to perform steps from a standing position, which directly addresses gait and balance [22]. However, stepping exergames might cause a higher risk of falling when compared to seated exergames. Currently, portable and affordable stepping exergames, designed for older adults with MNCD, are still lacking. In order to address this, an international research group developed a solution for geriatric rehabilitation [23]. This project, entitled VITAAL, was launched in May 2018 and is funded by the European Commission as a part of the Active Assisted Living Program [24]. The individualized multicomponent stepping exergame training prototype consists of a web-based interface that allows a direct follow-up and data processing by healthcare professionals. The system aims to provide evidence-based motor-cognitive training with high usability and easy setup in the clinic and at home. The system consists of a TV screen and two wearable sensors that are attached to the feet of the player. Therefore, the primary aim of the current study was to explore the physical, mental, and cognitive effects of the VITAAL exergame program added to care as usual as compared to an active, non-individualized physical training and a passive control condition (care as usual) in older adults with MNCD residing in long-term care facilities.

It has been stated that institutionalized older adults with MNCD can contribute to the development of solutions by providing useful feedback [25, 26].

Therefore, the secondary aim of this study was to investigate the experience and perception of the VITAAL exergame prototype. This study used a mixed methods design that combined observations and semi-structured interviews with physical, mental, and cognitive effects in institutionalized older adults with MNCD.

The combination of qualitative and quantitative data provides a full picture of the VITAAL solution.

## 7.3. Methods

A mixed methods design was used and the Consolidated Standards of Reporting Trials guidelines (CONSORT, Boutron et al., 2008; Cuschieri, 2019) were followed. The CONSORT extensions for pilot abstract and pilot trials were added in Additional file 1 [27]. The Consolidated criteria for reporting qualitative research (COREQ) framework was implemented [28]. The trial was registered in ClinicalTrials.gov (Identifier: NCT04436315).

### 7.3.1. Participants and procedure

Over a period of ten months (April 2021 – February 2022), all residents of long-term care facility de Wingerd in Leuven, Belgium, with MNCD were screened for inclusion. Diagnoses were made by the treating psychiatrist and possible diagnoses eligible for inclusion were vascular dementia, Alzheimer's disease, mixed dementia, Parkinson's disease, or Lewy body disease, as well as unspecified MNCD, as stated by the criteria of the fifth edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM 5) (American Psychiatric Association, 2013). Additional inclusion criteria were age ≥ 60 years; visual acuity with correction sufficient to see images on a TV screen; having been residing at least two weeks in the care facility at the time of inclusion and with a perspective of at least 10 more weeks of stay; and the physical capability of executing stepping exercises. Subjects manifesting one or more of the following criteria were excluded from the study: any unstable health condition which, according to the American College of Sports Medicine Standards, might lead to unsafe participation [29], and mobility impairments that prevented exergaming or exercising in an upright standing position. Participants were randomly assigned by an independent statistician using a random number generator (https://www.random.org/) to twelve weeks, three times per week 30 minutes of stepping exergaming added to care as usual (experimental group), non-individualized physical exercise, at a same volume, added to care as usual (active control group), or care as usual (passive control group). Care as usual consisted of pharmacotherapy, group activities and physiotherapy focusing on comfort care. Participants were assessed at baseline (pretest) and after twelve weeks (posttest) by a physiotherapist using the Short Physical Performance Battery (SPPB) in order to assess gait speed, balance and lower limb strength [30, 31], the VITAAL gait analysis test, the Montreal Cognitive Assessment (MoCA) [32-34], the neuropsychiatric inventory (NPI) [35], the Cornell Scale for Depression in Dementia [36], the Dementia Quality of Life (DQoL) questionnaire [37, 38] and Activities of Daily Living [39, 40].

### 7.3.2. Ethics

The study protocol was approved by the Medical Ethics committee of UZ Leuven (reference number S64592). All participants were fully informed prior to participation and signed an informed consent form according to the Declaration of Helsinki before inclusion. In addition, participants gave their verbal consent before each test and interview. No compensation was granted to the participants.

## 7.3.3.VITAAL exergame prototype

The VITAAL prototype was applied, which is an innovative, comprehensive system for geriatric rehabilitation and treatment in geriatric healthcare. The VITAAL solution implements the VITAAL gait analysis to create individually adapted training programs. The exergame program is based on three components: strength training, balance training, and cognitive training [23]. Based on the VITAAL gait analysis and the performance of the player, the difficulty levels adapt during exergame play. The strength training consists of a combination of classical strength exercises and Tai Chi-inspired movements. Here, a large load is placed on the muscles of the lower extremities since Tai Chi is mainly performed in a semi-squat posture. Balance training consists of stepping movements of both feet, as the execution of rapid and correctly directed steps is effective in preventing falls [41-43]. When combined with challenging game tasks, these exercises provide a holistic training requiring simultaneous cognitive-motor interaction and mental engagement [44, 45]. The VITAAL exergame explicitly targets specific attentional and executive functions that are important for safe gait [46-50]. An overview of the different minigames and the focus of training per game are shown in Figure 1. The system can be be applied effortlessly with limited technical equipment and knowledge in long-term care facilities or in hospitals. The games are web-based and designed to run everywhere if there is a device connected with a screen (e.g. laptop connected with a TV screen) and a Bluetooth and internet connection. The minigames are ideally visualized on a TV screen. The system is backed by a main server supporting the whole service and data storage, a web portal (with information about interventions, sessions, results per session or over a specific period, etc.), and two wearable inertial sensors to measure the stepping movements and handle the game navigation. The web portal provides relevant follow-up data for researchers or healthcare providers. The two inertial sensors are attached to the shoes with Velcro tape. The sensors perceive accelerations and angular rotations caused by stepping movements and communicate these via Bluetooth with the software running on the web-enabled device. Participants played every minigame that was available in this prototype. There was a minigame focusing on strength training, inspired by Tai Chi (outdoor), two minigames focusing on balance training (library and mommy chicken), two minigames focusing on inhibition control (healthy snacks and pizza), and a minigame focusing on short-term memory training (shopping list). The design and development of these VITAAL minigames considered inputs from older adults in the investigation phase of the project [24], from the feedback obtained in a previous study [51], and from a multidisciplinary team including movement scientists, clinicians and game designers. It was agreed that an exergame based on the execution of multidirectional steps would fit the needs of the target population the best. The participants played the exergames autonomously and the facilitator (the guiding physiotherapist) only intervened when help was required. An example of the system set-up is included in Figure 2.

| Outdoor | Library | Mommy chicken | Healthy food | Shopping list |
|---|---|---|---|---|
| Tai-Chi inspired strength training | Balance training | Inhibition control | Inhibition control | Short-term memory |
| Player imitates movements of an avatar instructor | Player avoids books from falling through multidirectional stepping | Player collects eggs while avoiding mommy chicken | Player points out healthy food and avoids unhealthy food | Player indicates whether the shown items correspond to the previously memorized shopping list |

Figure 1. Game description

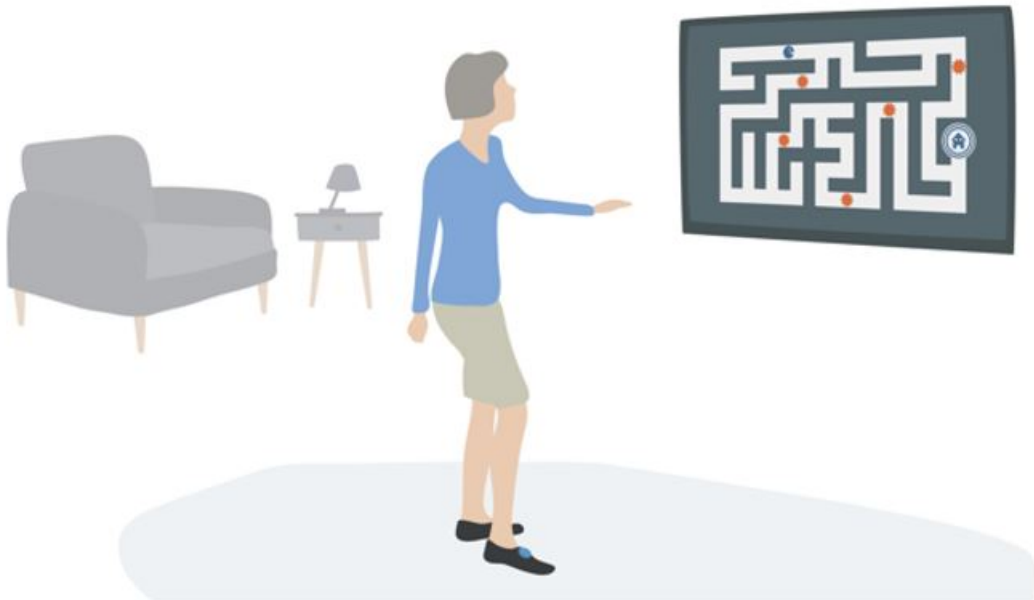

Figure 2. System set-up

## 7.3.4.Experimental condition

Participants performed three individual sessions per week for a period of twelve weeks, resulting in a total of maximum 36 sessions. Each session consisted of a walk to the exercise room (approximately 10 minutes), 30 minutes of exergaming and a walk back to the ward. The duration of exergaming in previous research varied from 10 minutes [52, 53] up to 60 minutes [54]. In our previous study, which examined the usability of the VITAAL exergame prototype, participants stated that 30 minutes of exergaming was physically not too demanding (add ref, unpublished but accepted VITAAL usability study). Therefore, a duration of 30 minutes was expected to be feasible for this specific population. The VITAAL exergame prototype device was administered. The starting position was an upright stance and participants interacted with the game interface by performing a stepping movement of one foot in one of the four directions: up, down, left, and right. When the game required the player to perform a step to the left or right, the associated lower limb was used. For a step in the two other directions, the player chose the lower limb of preference. The minigames provided real-time visual and auditory cues and feedback to enrich the game experience. The sessions consisted of multiple games and the duration of each video game varied between x and x seconds. All participants were individually supervised by a facilitator to ensure safety and comfort. A Template for Intervention Description and Replication (TIDieR) checklist [55] was added in Additional file 2.

### 7.3.5.Active control condition

Participants were invited to perform three individual non-individualized exercise sessions per week for a period of twelve weeks, resulting in a total of maximum 36 sessions. Each session consisted of a 15-minute walk and the performance of squatting and stepping exercises, similar to those performed in the VITAAL minigames. These were added to care as usual.

### 7.3.6.Passive control condition

Participants performed the pretest and posttest battery, and received care as usual for 12 weeks.

### 7.3.7.Outcome measures

#### 7.3.7.1.Short Physical Performance Battery (SPPB)

Balance, agreeable gait speed and lower limb strength were assessed with the SPPB [30, 31]. It comprises three subtests; a hierarchical standing balance test, a short 4-meter walk at usual pace [56] and five chair rises. The maximal total score is 12 and score ranges indicate mobility levels. Total scores between 10 and 12 indicate good functioning and no risk of mobility disability, total scores between 4 and 9 indicate an elevated risk of mobility disability, and scores between 0 and 3 indicate an already present mobility disability. Although concerns have been expressed regarding the feasibility and validity of quantitative functional assessments in older adults with MNCD [57, 58], the reliability of the SPPB is high in older adults with and without MNCD, with intraclass correlation coefficient (ICC) values ranging from 0.82 to 0.92 [59-61]. SPPB test instructions were concise and repeated when needed, and tasks were presented by the facilitator [57]. Participants were allowed to use their assistive devices such as a walker or a walking cane during the 4-meter walk.

#### 7.3.7.2.VITAAL gait analysis

#### 7.3.7.3.Montreal Cognitive Assessment (MoCA)

The MoCA is a paper and pencil test designed for mild MNCD. It aims to assess memory, language, executive functions, visuospatial skills, attention, concentration, abstraction, calculation and orientation. The scores range from 0 to 30, with higher scores indicating better cognitive functioning. The MoCA has good construct validity (r-values range from .46 to .75) [62], inter-rater reliability (r=0.97), test-retest reliability (r=0.88) and internal consistency (Cronbach's alpha= 0.89) in older adults with MNCD [63].

#### 7.3.7.4.Neuropsychiatric Inventory (NPI)

Psychopathological issues were assessed with the NPI [35]. An interview was taken with a close caregiver. The included behavior domains are delusions, apathy, hallucinations, disinhibition, agitation/aggression, irritability, depression/dysphoria, aberrant motor behavior, anxiety, nighttime behavior disturbances, euphoria, and appetite and eating abnormalities. Behavior frequency is scored on a 4-point scale, ranging from 1 to 4. Symptom severity is scored on a 3-point scale ranging from 1 to 3. The NPI total score results from multiplying the frequency and severity rates per domain and adding them up. The NPI total score ranges from 0 to 144. The test–retest reliability is 0.79 for behavior frequency (P=0.0001) and 0.86 for symptom severity (P=0.0001) [64]. The Cronbach's alpha coefficient for the overall score is 0.88 [65].

#### 7.3.7.5.Cornell Scale for Depression in Dementia (CSDD)

Symptoms of depression were assessed with the observation based CSDD. An interview was taken with a close caregiver who reported on observations of the residents' behavior during the week prior to the interview. The CSDD consists of 19 items and each item is scored on a 3-point scale ranging from 0 to 2 [36]. A score 0 indicates absence of the behavior, a score 1 indicates mild or intermittent behavior expression, and 2 indicates that behavior is severely present. The items are classified in five categories: mood, behavioral disturbance, physical signs, cyclic functions, and ideational disturbance. The CSDD has adequate internal consistency and reliability in an older, frail nursing home population with MNCD. Cronbach's alpha is 0.81 and the kappa values of two studies included are 0.57 and 0.91 [66].

#### 7.3.7.6.Dementia Quality of Life (DQoL) questionnaire

Quality of life was assessed with the DQoL questionnaire [38], which was administered in the form of an interview with the participant. It consists of 29 items, measuring five domains: self-esteem (4 items), positive affect (6 items), negative affect (11 items), feelings of belonging (3 items) and sense of aesthetics (5 items). A higher score per domain reflects better QoL, with the exception of the negative affect dimension. Cronbach's alpha coefficient for internal consistency ranges from 0.71 to 0.84. The ICC for test-retest reliability ranges from 0.69 to 0.80 [37].

#### 7.3.7.7.Secondary outcomes

Secondary outcomes were the experiences and perception of the participants regarding the VITAAL exergame program. Interviews and field notes were taken.

A semi-structured interview was carried out individually after 6 (mid-intervention) and after 12 weeks (post-intervention) of VITAAL exergame training. In this way, experiences were explored on two different moments in the program such that more thorough information could be assembled. Participants were interviewed face-to-face in the intervention room to stimulate recall of the exergame training. Open and closed-ended questions were asked regarding the experiences, advantages and disadvantages of participation in the VITAAL exergame program. The interviewer actively asked about positive and negative experiences. The interviews were recorded and no written notes were taken during the interview in order to focus attention on the participant. Prompts were provided in the interview protocol to ensure that sufficient information was obtained on specific topics [67]. The recorded interviews lasted between x and x minutes (mean x minutes). The interview guide is included in Additional file 3. The facilitator of the sessions was also the interviewer. Every interview was transcribed and transcripts were not returned to participants for comment or correction.

Guidelines for best practice qualitative research in older adults with MNCD were applied [68, 69]. The interviewer had a respectful attitude, made eye contact, used a calm voice, and avoided contradicting statements or asking details. The interviewer was always aware of the communication challenges such as word-finding difficulties, abstract reasoning, memory deficits, fluctuating awareness, attention and concentration. Effective communication strategies were applied, such as simplifying the structure of questions, allowing more response time, and redirecting the dialogue when necessary.

In addition, activity logs with participants' attendance, behavior and feedback per session were were recorded in a personal log file.

Attendance and adherence rates were secondary outcome measures as well. Attendance sheets were completed each session to record the number of training sessions. Attendance rates were calculated by dividing the number of attended training sessions by the maximum possible number of training sessions (36 sessions). An attendance rate of 70% or higher (minimum 25 attended out of 36 planned sessions) was considered as being adherent to the exergame or exercise program [70]. The adherence rate was determined by calculating the dropouts (attrition) as a percentage of the entire sample size. Participants signed an informed consent stating that they were not obliged to give a reason for non-attendance or drop-out. Therefore, it was not possible to examine reasons for non-attendance.

### 7.3.8.Statistical analysis

Data were screened for normality using the Shapiro-Wilks test.

Statistical analysis was performed using the statistical package SPSS version 28.0 (SPSS Inc., Chicago, IL).

### 7.3.9.Qualitative data analysis

Multiple readings of the interviews were done during data analysis, combined with the observations. NVivo 12 Microsoft software (© QSR International Pty Ltd., Victoria, Australia) was used for management and analysis of the qualitative data [71, 72]. The audio files were transcribed in Microsoft Word format and entered into NVivo 12.

A thematic analysis was performed through six steps [73, 74]. The first step involved repeatedly reading the interviews. Next, initial codes were created by open coding, the process of indexing or categorizing the text in order to assemble a framework of related thematic ideas. Subsequently, the remaining data were re-examined with axial coding, and codes were related to possible sub-codes. The codes were compared for similarities and differences, and codes with similar contents were merged. The remaining categories were further interpreted and abstracted into x remaining themes. Although the interview transcripts formed the primary data set, the field notes/observations complemented the overarching themes from the interviews. Analysis of the field notes did not result in new categories or themes.

## 7.4. Results

### 7.4.1.Participants

X of the 147 residents in the long-term care facility were eligible. Main reasons for exclusion were limited comprehension due to a more advanced stage of MNCD, wheelchair use, or being bedridden. X residents refused as they were not interested in participating. Therefore, in total 36 participants were enrolled in the study. They had a mean age of ± (x-x) years, a SPPB score of x ± x (x-x), and a MoCA score of x ± x (x-x). The majority/ x% of the participants were female. Table 1 gives an overview of the characteristics of the included participants. A more detailed description of the participants' individual characteristics is provided in Table 2. None of the participants suffered adverse events during or after the exergame session. One participant from the non-individualized training group fell during the walk around the facility and dropped out from the trial.

| **Variables** | **Sub-category** | **Exergame intervention group (*n*=x)** | **Active control group (*n*=x)** | **Passive control group (*n*=x)** | ***p*[a]** |
|---|---|---|---|---|---|
| Age in years, mean (SD) | | | | | |
| Gender, *n* (%) | Male | | | | |
| | Female | | | | |
| MMSE, mean (SD)[b] | | | | | |
| Diagnosis, *n* (%) | Alzheimer's Disease | | | | |
| | Vascular Dementia | | | | |
| | Mixed Alzheimer's and Vascular Dementia | | | | |
| | Frontotemporal Degeneration | | | | |
| | Lewy body disease | | | | |
| | Neurocognitive Disorder not otherwise specified | | | | |
| Somatic comorbidities, *n* (%) | Diabetes type II | | | | |
| | Heart disease | | | | |
| | Hypertension | | | | |
| | Gait disorders | | | | |
| | Visual deficiencies (cataract, glaucoma) | | | | |
| Indoor mobility, *n* (%) | Wheelchair | | | | |
| | 4-wheeled walker | | | | |

| | | | | | |
|---|---|---|---|---|---|
| | Single-point walking cane | | | | |
| | No walking aid | | | | |
| Attendance rates (%) | | | | | |

**Table 1.** Participant characteristics (final data not yet available at 30.11.2021 because study analysis is still ongoing)

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