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D4.1 Definition of the methodology, testing procedures and metrics

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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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1 Introduction

This document is part of *Task 4.1: Trials methodology planning and ethics, Task 4.2: User recruitment, Task 4.3: Technical validation (pre –trials), Task 4.4 Field trials and system validation – Phase 1* and *Task 4.5: 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 detailed information about the methodology, testing procedures and outcomes/metrics of the planned trials in the VITAAL project.

The document starts with some general background information followed by a description of the VITAAL exergame and a discussion of several important ethical aspects related to the studies. Then the document is structured in three parts: In the first part, it describes the methodology of the pre-trials for the technical validation of the system. In the second part, it describes the methodology for usability study. In the third part, methodological details of the randomized controlled pilot-trial are described.

2 Background, rationale, and preliminary results

As life expectancy is increasing, the number of people aged 60 years and older is rapidly growing. According to the World Health Organization, the number of older adults aged 60 years and older in 2015 was about 12% of the worldwide population and will almost double to 22% by 2050 [1]. With the growing older population, there has been a major interest in preventing 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 behaviour-related diseases and disabilities on society. Consequently, more and more older adults suffer from one of the "geriatric giants", such as Mobility Impairments (MI), Cognitive Impairment (CI), and Urinary Incontinence (UI), described by Prof. Bernhard Isaacs [2].

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 with 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 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 common 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, 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 fall prevention [33-35] and counteracting physical and cognitive decline. 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 slowing down cognitive and physical decline on an individual basis, which incorporates theoretical background from movement sciences, neuropsychology/cognitive sciences and arts of game design. 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 centres and training facilities, 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]. Therefore, 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 on 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.

The project is structured in three phases (Table 1). In the first phase – the investigation phase – the main goal was to get insights in the end-users' needs, attitudes and expectations towards the new training game. Surveys with end-users as well as focus groups with other stakeholders (e.g. therapists) were conducted (survey study results will be published soon). Results from the investigation phase have been integrated in the second phase –

the development phase – when the VITAAL exergame was developed. The development phase followed a user-centred and iterative design approach, on which users were involved to help define and validate the game user interface. Users were also involved in data collection sessions that helped us develop suitable algorithms for movement analysis to be integrated in the game. In the third phase – the trial phase – the usability of the developed program should be evaluated. In winter 2019 a usability study will be conducted in all involved countries with the newly developed exergame prototype in laboratory setting. The findings will be integrated in the VITAAL Exergame to improve the prototype before the intervention study will start. This will be a multinational, randomized controlled pilot-trial comparing the newly developed individualized VITAAL exergame with a non-individualized active control group aiming to assess the proposed health benefits in people suffering from MI, CI, and/or UI.

Table 1. Overview of the three phases of the project.

Project Phase	Goal	Methods
Investigation Phase	To get insights in the end-users' needs and expectations	Focus groups with therapists and questionnaires for end-users
Development Phase	To develop and technically validate the exergame and movement evaluation algorithms.	User-centred, iterative design process. Agile software development methods. Software testing. Pre-trials.
Trial Phase	To test the usability of the developed program	Usability study in older adults with MI (CH), CI (BEL) and UI (CH, CAN) (phase I trial)
	To test the feasibility and the effects of the developed program	Randomized controlled pilot-trial in older adults with MI (CH), CI (BEL) and UI (CH, CAN) (phase II trial)

In the area of public health and disease prevention, there is a strong need for implementing effective evidence-based interventions. Nevertheless, before conducting full-scale studies with newly developed interventions to evaluate their efficacy and effectiveness, judgements must be made about their feasibility, usability and the acceptance by end-users. Especially for training programs, it is important that they are useable for targeted users, as only in that case, they will finally use the programs, which leads to the pursued training effects. According to Campbell et al. [55], an iterative phased approach is recommended starting with observational phase (phase I studies) before continuing with the exploratory phase (phase II studies). Besides assessing usability and feasibility, the aim of phase II trials should be to test the integrity of the study protocol and data collection as well as to evaluate the selection of most appropriate (secondary) outcome measures for the main trial and to provide basis for calculating sample size of phase III trial [55-57].

To ensure that the game meets users' needs and is usable, the exergame was developed following a user-centred, iterative, design process. Until the moment of writing, three usability-lab studies involving 30 seniors and more than 45 tests have been conducted in Portugal with the newly developed exergame. These tests enabled us to make informed design decisions and iteratively improve system design to meet the needs of the target users. We also engaged in *Agile software development* methods, ensuring short cycles of iterative and incremental delivery in a feature-driven development process. Individual features were then prioritized, implemented and continuously tested by the development team, reducing the risks of failure late in the project. Technical validation and assessment of individual features ensures that no major technical issues (bugs, connectivity issues, permissions, etc.) are still to be found. All these tests are part of a pre-trials stage, allowing adequate time for debugging and fixing encountered issues. The pre-trials stage will also ensure that combined individual software modules are tested as a group, ensuring a smooth start of the trials and reducing the risk of user's bias towards a negative feeling about the system (see chapter 4 Pre-trials (technical validation)). Now as next steps, the usability of the integrated exergame has to be tested in the therapy centres (see chapter 5 Usability Study), allowing additional time for the improvement of some functionalities and the resolution of encountered issues. The final

step is to conduct a large multinational, randomized controlled pilot-trial to examine feasibility of the study design and to investigate the effects of the VITAAL exergame on cognitive and physical functions (see chapter 6 Randomized Controlled Pilot-Trial). Table 2 shows an overview of planned research in the VITAAL project in 2019/20.

Table 2. Overview of planned research in the VITAAL project in 2019/20.

2019						**2020**							
Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	June	July	Aug	Sep
Pre-trials													
					Usability Study								
										Randomized Controlled Pilot Trial			

Description of the VITAAL exergame

The VITAAL exergame is an individualized multicomponent exergame training based mostly on the prevention and slowing of physical and cognitive decline and its consequences (see an overview of the VITAAL exergame in Figure 1). It mainly consists of three (four with UI) components; strength training, balance training, cognitive training and pelvic floor muscle training (PFMT) when suffering from UI. 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 [58-60]. 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 [61]. The PFMT is divided in two categories, isolated exercises of PFM (different contraction sequences) and dual task exercises, where PFM contractions are performed with or in combination with balance exercises. Moreover, Tai Chi-inspired training, step-based training and PFMT 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 [62].

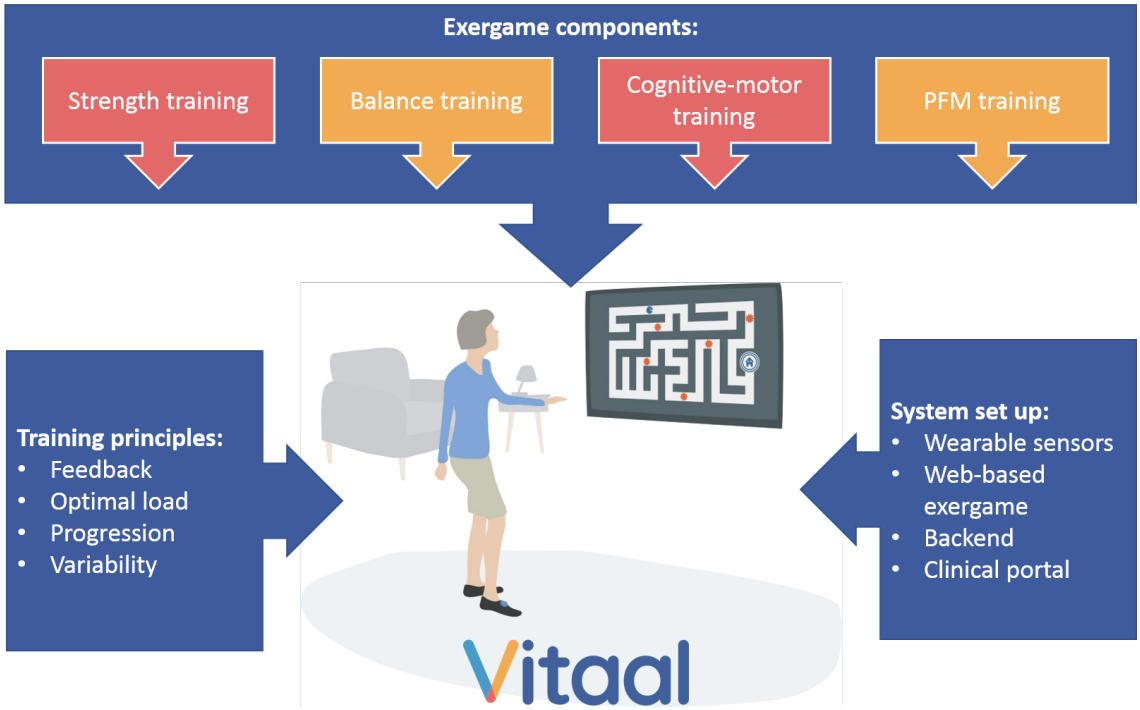

Figure 1. Overview of VITAAL exergame with relevant components

The VITAAL system set up must be 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. (see Figure 2 and Figure 3). The sensors communicate via Bluetooth with the software running on the web enabled device. Additionally, a dynamometer being developed in Canada will be integrated in the system, enabling the measurement and monitoring of PFM contractions. The dynamometer will also communicate 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 (as specified in Deliverable D3.2).

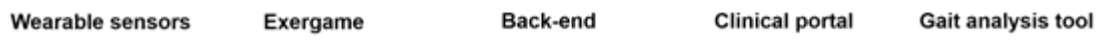

Figure 2. Overview of all system components of VITAAL exergame.

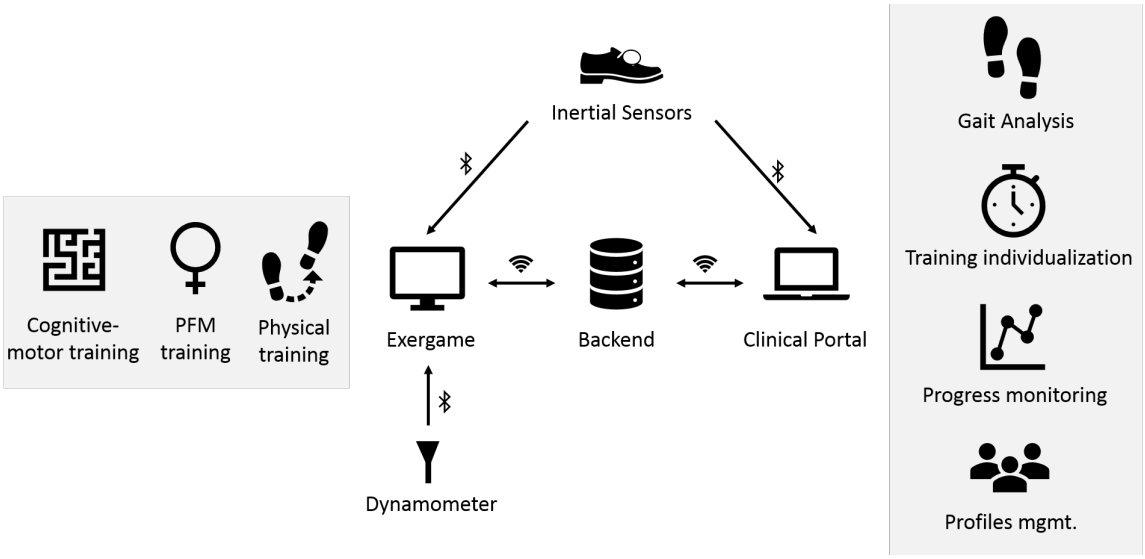

Figure 3. VITAAL system architecture.

3 Ethical aspects of the trials

All ethical aspects relevant for the VITAAL trials are discussed in detail in an earlier Deliverable (Deliverable D.2.1). Here we provide a short summary of the main aspects. For further details, we kindly ask to consult the Deliverable D2.1.

3.1 Legislation and Ethics Authority

All the studies in the VITAAL project will comply with the current legislation and regulations of the countries in which the research is carried out. Moreover, the project will comply with all relevant European Union (EU) and Canadian legislation, especially the legislation below:

- The European Charter of Fundamental Rights
- Declaration of Helsinki of the World Medical Association (WMA)
- EU-ICH-Guideline for Good Clinical Practice E6(R1)
- Directive 2001/20/EC
- International Ethical Guidelines for Biomedical Research Involving Human Subjects
- Convention of the Council of Europe on Human Rights and Biomedicine
- Directive 95/46/EC
- Québec Charter of human rights and freedoms
- Civil Code of Québec

Furthermore, in each country, there are different ethics authorities which have to approve all the research activities of the VITAAL project. Each partner is responsible to stay in contact with the respective ethics authority and get the ethical approval for the trials if needed.

3.2 Study information and Informed Consent

Following the national, European and Canadian law, all participants will get a detailed study information in the respective language and they will have to sign an informed consent before trial start.

Participants have to be informed about research goals and methods/procedures. This information will be handed out in writing (study information) and orally. Potential participants will be notified in their own language and in a comprehensible way. The researchers will make future participants aware that their participation is completely voluntary, that they have the right to refuse to participate and that if they agree to participate, they can still terminate their participation at any time and without any given reason for their decision. The researchers will inform participants on a number of important factors which could influence their decision to participate (like risks/benefits, potential inconveniences or adverse consequences, restrictions to confidentiality etc.). Participants should get ample opportunity to read through the information, to ask the researcher any question and to consider their potential participation.

Declared one of the most important principles in research ethics in many international conventions and guidelines, informed consent is meant to guarantee the voluntary participation in research and is probably the most important procedure regarding integrity and privacy issues.

Informed consent consists of three important components: adequate information, voluntariness and competence. This implies that, prior to consenting the participation, participants should be clearly informed about research goals and procedures, potential risks and the possibility to refuse participation or withdraw from research at any time and without consequences. It's important that participants are competent to understand the information and should be fully aware of the consequences of their consent. Therefore people incapable of making their own choices will not be approached for the VITAAL project.

4 Pre-trials (technical validation)

The technical validation and verification of the system is ensured through software testing. Testing starts as soon as the first code is written and increases as the game progresses towards completion.

Software testing provides an objective view on the quality of the software under test, allowing the detection of software bugs (errors or other defects) and the assessment of the risk of failure to users. The primary purpose of testing is to detect software failures so that defects may be discovered and corrected. Software tests evaluate one or more properties of interest, namely if the software:

- responds correctly to all kind of inputs;
- performs its functions within an acceptable time;
- can be installed and run in its intended environments.

During game development, we employ feature-driven agile methodologies. In each iteration, or sprint, features are discussed and prioritized, and the development team works on design, implementation and testing. We perform software tests each time a new feature is implemented in the game, to assess its performance and functioning. All issues encountered during tests are registered on a backlog and their prioritization discussed before the next iteration. This methodology allows the development team to update the project regularly and identify errors quickly. The software Jira is used to monitor the state of individual tasks within a holistic sprint view. Combined with a user-centred design process, these methods ensure the software product meets the requirements and expectations of end-users, anticipating a high usability and the technical excellence of the system.

Once a new game is playable, the game is play-tested to identify any uncovered errors – e.g. bugs, art glitches, logic errors or level bugs. Testing at this stage requires creative gameplay to discover often subtle bugs. While some bugs are easy to document, many require detailed description so that a developer can replicate or find the bug to fix it. All encountered errors are registered on the backlog.

As more and more material are available, subtle changes to the codebase can produce unexpected changes in different portions of the game. Therefore, we need to carry out regression testing, to make sure that other previously existing features still operate correctly. Regression tests is one of the vital tasks required for effective software development.

Technical validation and assessment of features ensures that no major technical issues (bugs, connectivity issues, permissions, etc.) are still to be found in the subsequent stages of the project, ensuring a smooth transition to the trials stages.

5 Usability Study

5.1 Objectives

5.1.1 Primary Objective

The main goal is to determine usability of the improved VITAAL exergame prototype while using the system in a home like laboratory environment (living lab) in older adults with MI, CI, and/or UI. Questionnaires and qualitative evaluation are used.

5.2 Trial Design and Intervention

To determine the usability of the newly developed and already improved VITAAL exergaming, 12-15 participants of each impairment will conduct a gaming session. The participants will be recruited by the involved partners over three countries (CH, CAN, BEL). Participants should try to independently use the training system after a short introduction by the instructors. They should complete a 10 min of strength exercise (Tai Chi-inspired), 10 min balance exercises (step-based), and 10 min cognitive-motor games. Participants with UI will test the PFM exercises in addition to the other exercise components. (7.5 min per component). During the gaming session an acceptance and game experience protocol is used to note observations and direct feedback to the exergame. After the training sessions, questionnaires and interviews are used to evaluate the usability to get further feedback.

The participant will attend for one appointment that will include exergame performance as well as answering specific usability questions (see an overview in Figure 4). At the appointment, all interested participants will be screened for study eligibility (duration 30 min). During the exergame performance, different qualitative assessments will be performed to determine usability of the exergame including acceptance and game experience protocol (think aloud method) and video analysis. After the exergame performance, the participant will answer individual and guideline-based interview questions about usability including their individual experiences, which will be recorded (duration about 20 min).

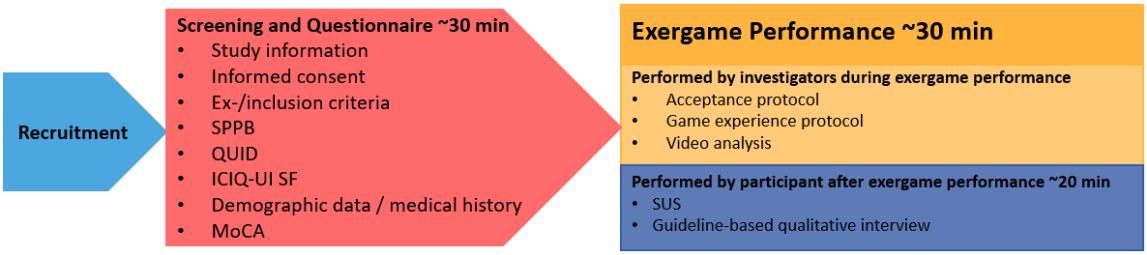

Figure 4. Study schedule. SPPB = Short Physical Performance Battery, QUID = Questionnaire for Urinary Incontinence Diagnosis, MoCA = Montreal Cognitive Assessment, SUS = System Usability Scale, ICIQ-UI SF = International Consultation on Incontinence Questionnaire – Urinary Incontinence Short Form.

In this study, each partner will be responsible for:

- ethical approval for the trial in the respective country (if needed);
- recruiting of 12 to 15 participants according to defined criteria (see below), the number of participants with UI is shared between Canada and Switzerland;
- conducting the gaming session;
- conducting outcome measurements: handing out questionnaires to acquire users' opinion and holding interviews;
- complying with internal reporting requirements (filling in data tables).

5.3 Outcomes

5.3.1 Primary Outcomes

In Table 3, the primary outcome measures are presented including the corresponding assessments. Below, these research methods are described in detail. To assess the primary outcome measures, a mixed method approach is chosen which was used by number of studies evaluating the usability of exergames [45]. We aim to use a combination of quantitative and qualitative data in order to successfully evaluate all important aspects related to our primary outcome.

Table 3. Primary outcome measures of this study and their assessments.

Assessment	Results
Acceptance protocol	Qualitative evaluation through training observation
Game Experience protocol	Qualitative evaluation through training observation
Video analysis of exergame performance	Qualitative evaluation through training observation
Questionnaire	System Usability Scale
Guideline-based qualitative interviews	Design-specific and individual evaluation through questioning

Acceptance protocol

In addition to quantitative questionnaire, qualitative data are collected. In the usability protocol, instructors report in detail their observations and evaluation of usability. They note whenever participants need support und further instructions or help and describe what the issue was about. Explanation and general instructions in the beginning of the exergame training are excluded here. Furthermore, participants are requested to use the "think aloud" method [63]. They are asked to say everything that comes to their mind while using the game.

Game Experience Protocol

In addition to quantitative questionnaire, qualitative data are collected for game experience. In the usability protocol, instructors report in detail their observations and evaluations of game experience. They note whenever participants say something about the video game content that is related to game experience. Participant are requested to use the "think aloud" method. They are asked to say everything that comes to their mind while playing the video games.

System Usability Scale

An often used scale for evaluation of software products or websites but also games/exergames is the System Usability Scale (SUS) which was developed by Brooke [64]. It provides a global view of subjective assessments of usability. The SUS consists of ten items performed on a 5-point Likert scale on which 1 corresponds to "strongly disagree" and 5 to "strongly agree". The evaluation results in an easy-to-interpret score from 1 to 100, similar to a percentage score. SUS is a scientifically validated and reliable scale with easy application [64, 65]. The scale was applied in other exergame studies and was suggested to be an appropriate measure in evaluating systems/settings. Based on the verbal categorization/adjective rating of Bangor [66], we expect a SUS score of at least 70 to have an "acceptable" solution (52= ok, 73 = good, 85 = excellent, 100 = best imaginable).

Qualitative Interviews – Design Experience

Based on the design process and decisions, a guideline for qualitative interviews is developed. The guideline-based interviews focus on the qualitative evaluation of the user's gameplay experiences related to their body, the controller and the virtual game scenario.

5.3.2 Other measures of interest

In Table 4, other (outcome) measures of interest are presented including their assessment method.

Table 4. Other (outcome) measures of interest of this study and their assessments.

Assessment	Results
Montreal Cognitive Assessment (MoCA)	Points
Short Physical Performance Battery (SPPB)	Points
Questionnaire of Urinary Incontinence Diagnosis (QUID)	Urge Score, Stress Score
International Consultation on Incontinence Questionnaire Urinary Incontinence Short Form (ICIQ-UI SF)	Score on the severity of incontinence
Exercise intensity	Borg Rating Scale
Demographic data / medical history	-

Montreal Cognitive Assessment

The Montreal Cognitive Assessment (MoCA) is a simple paper and pencil test to screen several cognitive domains including memory, language, executive functions, visuospatial skills, attention, concentration, and orientation [67, 68]. The participants can get maximal 30 points. The MoCA can be used as a quantitative estimate of the overall cognitive abilities [69]. According to Thomann et al. age, gender, and years of education are integrated to define the cognitive condition [70].

Short Physical Performance Battery

The SPPB is composed of three subtests:

- *Balance test*: Starting with their feet in the side-by-side position and followed by adopting the semi-tandem and, finally, tandem stance position, the participants will be required to stand unsupported for 10 seconds.
- *4-meter gait test*: For testing walking speed, participants have to walk twice a 4 m distance with their usual walking speed with a standing start.
- *5-chair rises test*: For the timed chair stands, participants will be instructed to rise from a chair for five times as quickly as possible and with arms crossed on the trunk. We will measure the time using to complete the five chair rises; from the beginning sitting position to the final standing position of the fifth attempt.

With scores ranging from 0 (not able to complete the task) to 4 (good function), each test can be categorized according to timed quartiles previously established in a large population [71, 72]. A maximal total score of 12 can be achieved and a higher score indicates better performance. A score below 10 is predictive for a higher risk of all-cause mortality [73] and will be used as an inclusion criteria for participants with MI and to assess the physical condition in the participants with UI and CI who attend in the usability study.

Questionnaire for Urinary Incontinence Diagnosis (only in UI and MI)

The validated Questionnaire for Urinary Incontinence Diagnosis (QUID) consists of a 6-item urinary incontinence (UI) symptom questionnaire to distinguish stress and urge UI. The QUID has acceptable psychometric characteristics [74, 75].

International Consultation on Incontinence Questionnaire - Urinary Incontinence Short Form (only in UI)

The International Consultation on Incontinence Questionnaire - Urinary Incontinence Short Form (ICIQ-UI SF) is a brief and psychometrically robust patient-completed questionnaire for evaluating the frequency, severity and impact on quality of life of urinary incontinence in men and women. It is scored on a scale from 0-21. With a higher score indicating greater severity of symptoms [76].

Exercise intensity

Participants rate their exertion after each training session (resp. after each training component in one session). The Borg CR10 scale is an often used subjective, quantitative measure to assess the intensity of training on a nonlinear scale with which the perceived exertion is rated [77]. It's a linear scale from from 0 = "nothing at all" to 10 = "extremely strong" with 0.5 = "extremely weak", 1 = "very weak", 2 = "weak", 3 = "moderate", 5 = "strong", 7 = "very strong", 10 = "extremely strong".

Demographic data and medical history

The Health Questionnaire was developed by ETH Zurich to assess general personal information about participants covering also general health, medical history and physical activity.

5.4 Participants

5.4.1 Exact number of participants

In the framework of this project, the study focuses on the investigation of older adults with MI, CI, and /or UI. It is planned to include 10-15 subjects with each impairment across Switzerland, Belgium and Canada. In Switzerland, it will be focused on elderly with MI and/or UI. The aim of this trial is to evaluate usability of the VITAAL exergame in older adults suffering from MI, UI, and CI.

5.4.2 Inclusion and exclusion criteria

Inclusion criteria

Participants fulfilling all of the following inclusion criteria are eligible for the study:

- Aged 60+ years (for UI group: only female)
- Live independently, in a residency dwelling, or with care
- Standing straight for minimal 10 minutes without aids
- SPPB < 10 (only for the study group with MI)
- diagnosed with mixed urinary incontinence (MUI) or urge urinary incontinence (UUI) according to the Questionnaire for Urinary Incontinence Diagnosis (QUID) (only study group with UI)
- correct contraction of PFM must be possible (only study group with UI)
- Visual acuity with correction sufficient to work on a TV screen
- MMSE ≤ 23 (only for CI)

Criteria for exclusion

Participants are excluded from the study, if they exhibit one of the following exclusion criteria:

- Mobility impairments that don't allow to play the exergame
- Heavy noticeable cognitive impairments according to Thomman et al. [70] (only in UI and MI group)
- Severe acute or uncontrolled health problems (e.g. recent cardiac infarction, uncontrolled diabetes or hypertension)
- Orthopaedic or neurological diseases that inhibit Exergame training
- Rapidly progressive or terminal illness
- Important pelvic organ prolapse (only UI)

In the elderly population, targeted and individualized physical activity programs can provide a myriad of health benefits. In almost all older people, (additional) physical exercise can generate positive health effects and it is important to emphasize that only few contraindications to exercise exist [78]. In the context of "physical exercise", no high-risk group can be classified (except people suffering from rapidly progressive or terminal illnesses or health problems listed above). Consequently, low testing scores (in physical functioning tests) demonstrate no general reasons for exclusion from this study. It is rather important that the training program is geared toward an individual's health status, capabilities and limitations [78]. Therefore, the study provides a suitably adapted training program tailored to the demands of each participant according to the training principles of optimal load and progression.

5.4.3 Recruitment of participants

Eligible participants will be preselected in Interlaken, (Switzerland), in Montréal (Canada), and Leuven (Belgium) through contact persons e.g. of the "Physio SPArtos Centre" in Interlaken but also through public advertisement. All interested people will be fully informed prior to the first measurement day by the use of a Participant Information Sheet and it will be made clear that withdrawal is permitted at any time during the study without giving any reason. Furthermore, the investigators will explain the procedure, benefits and risks of the study in detail.

5.5 Study adaptions according to the participants group

5.5.1 Mobility Impairment

No adaptions

5.5.2 Urinary Incontinence

The participants must be able to undergo a gynaecological (digital and dynamometric) examination so the quality of the PFM contraction can be assessed.

All scales and questionnaires will be translated to French and German if not already translated.

5.5.3 Cognitive Impairment

Suffering from cognitive impairment will not be an exclusion criterion in this population group.

The demographical and medical data will be completed by the researcher, based on an interview with the participant. This will be supplemented with information from the resident files in the care facility centre, in order to fill it in complete and correct.

In participants where the verbal communication is more difficult, due to the consequences of dementia, the "Key Questions Interview Exergames" document will be adapted. For example, some questions will be left out or simplified. This will be adapted during the conversation.

In addition, all scales and questionnaires will be translated to Dutch.

6 Randomized Controlled Pilot-Trial

6.1 Objectives

6.1.1 Primary Objective

The primary objective of this study is to evaluate the feasibility of the intervention and the study design in a home like laboratory environment (living lab).

6.1.2 Secondary Objective

The primary objective of this study is to evaluate the effects of an individualized exergame training on physical and cognitive functions in older adults with MI, CI and/or UI compared to a non-individualized training control group using physical function assessments and cognitive tests.

6.2 Trial Design and Intervention

The study is a randomized controlled pilot trial designed to examine the feasibility of the intervention and the study design as well as the effect of a newly developed individualized multicomponent exergame training on physical and cognitive functions. The whole study will last around 20 weeks with four weeks screening and pre-measurement period, max. 12 weeks of training intervention and four weeks post-measurement period. During these periods, each participant gets one appointment for pre-measurements (T1) and one appointment for post-measurement (T2), each measurement session lasting around 1-1.5 hours. The study is designed monocentric but measurements will be done one a multinational basis (in three different countries CH, BEL, CAN). However, each country is conducting the study on their own within the AAL project VITAAL and will apply for approval at the local ethic committees. Considering a recent paper from Whitehead et al. a sample size of 16-26 participants per group for medium effect size and an upper confidence limit of 80-95% is recommended [79]. Therefore, the study will include a total of 96-156 older adults 60 years and older, living either independently, in a residency dwelling, or with care. All interested participants will be screened if they are eligible for the study. Then the eligible participants are randomly allocated to either the intervention group or the active control group. At the first appointment (T1), pre-measurements are conducted (physical and cognitive functions) with all participants. The participants will arrange the first appointment for the training with the exergame or the active control program at the therapy centre, followed by 35 further exercise sessions in the next 12 weeks. At the first appointment of the intervention group, 8-12 repetition maximum is defined for squats, (which is adapted every four weeks with additional weight cuffs) and they will get instructions about the exergame. The active control group will also get instructions about their program at the first appointment. Not later than one week after the pre-measurement session, participant should start exercising at the training centre. The intervention period lasts for 12 weeks (no longer than two weeks of break/holiday allowed) with three training sessions per week each lasting about 30 minutes. For the intervention group, one training session includes an individually calculated amount of strength, cognitive-motor, balance, and pelvic floor muscle training, which remains the same over the 12 week intervention period. Additionally, a training progression is achieved by adapting the game difficulty by including more challenging movements, tasks or by increasing the speed of the game. The three training sessions should be conducted at three different days (it's recommended to have a day of break in between the sessions but it is not mandatory). The training of the active control group includes 15 minutes walking exercise (in nature or on treadmill) and additional 15 minutes of strength, balance, cognitive-motor, and PFM exercises when suffering from UI. The training components will not be individually adapted for

this group. Participants in both groups will report their trainings in an attendance protocol. All participants have to fill in an activity protocol during the whole intervention period (activities besides the training itself).

All participants have to fill in an activity protocol during the whole intervention period (activities besides the training itself). The participants of the control group will get three different training videos including the same exercise components as the exergame. The first training session, will take place in the physio centre to give proper instructions for the training over the next 12 weeks. The participants of the control group have the same number of training sessions as the intervention group. After 4 weeks of exercising they change to the second video and after eight weeks to the third.

Once all training sessions have been completed, post-measurements are conducted at T2 with all participants (not later than one week after the last training session). In Switzerland measurements will take place at the Physio SPArtos at Interlaken, Bern, in Canada at the Centre de recherche de l'Institut universitaire de Gériatrie de Montréal in Montréal, and in Belgium in long term care facility 'De Wingerd' in Leuven. The whole procedure is illustrated in Figure 5.

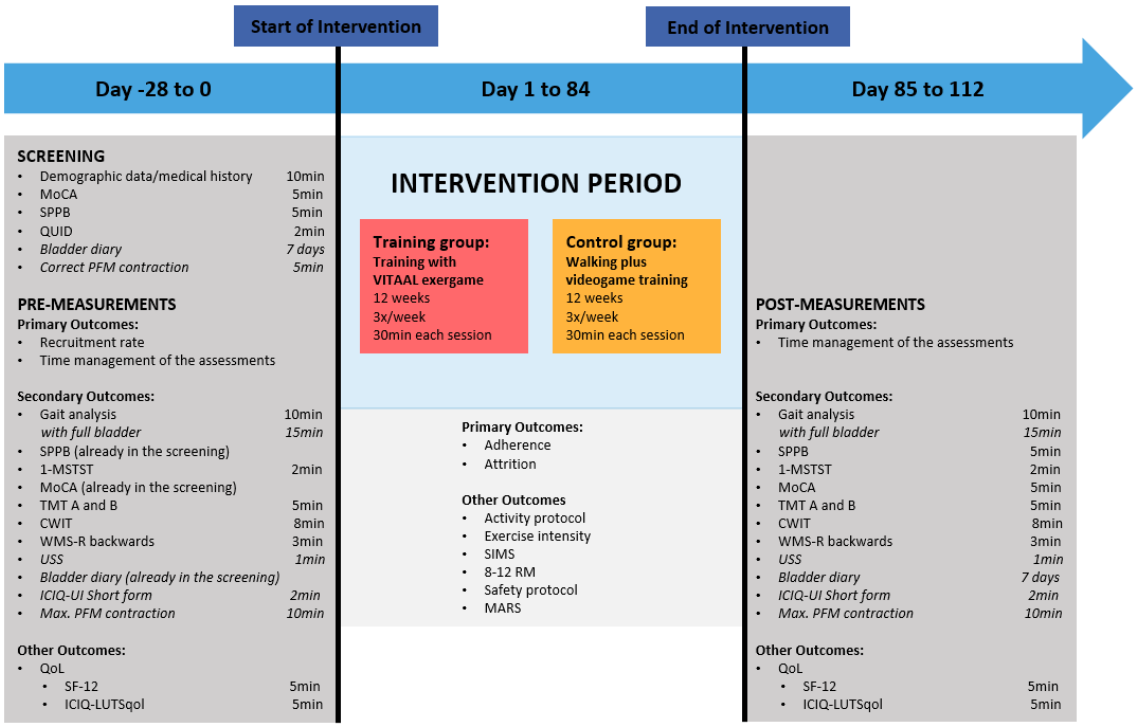

Figure 5. Flow chart of trial design with intervention and measurements. MoCA = Montreal Cognitive Assessment, SPPB = Short Physical Performance Battery, QUID = Questionnaire of Urinary Incontinence Diagnosis, 1-MSTST = 1 Minute Sit to Stand Test, TMT = Trail Making Test, CWIT = Color Word Interference Test, WMS-R = Wechsler Memory Scale – Revised, USS = Urinary Sensation Scale, ICIQ-UI = International Consultation on Incontinence Questionnaire - Urinary Incontinence, PFM = Pelvic Floor Muscle, QoL = Quality of Life, SF-12 = Short Form – 12, ICIQ-LUTSqol = International Consultation on Incontinence Questionnaire - Lower Urinary Tract Symptoms Quality of Life, DQoL = Dementia Quality of Life, RM = Repetition Maximum, MARS = Mobile Application Rating Scale.

In this study, each partner will be responsible for:

- Ethical approval for the trial in the respective country (if needed)
- Recruiting and randomizing participants according to defined criteria (see below)
- Training the participants on the usage of the system (introduction session)
- Monitoring the trial for the entire trial period
- Conducting outcome measurements/Testing participants before and after intervention
- Complying with internal reporting requirements (filling in data tables)

6.3 Outcomes

6.3.1 Primary Outcomes

In Table 5, the primary outcome measures are presented including the corresponding assessments. They can be divided into two parts: outcomes concerning physical functions and outcomes concerning cognitive functions.

Table 5. Primary outcome measures of this study and their assessments.

Outcome	Assessed by
Feasibility	
Recruitment rate	Recruitment protocol *Final number of study participants compared to number of initial interested people:* - *Number of interested people* - *Number of participants with informed consent* - *Number of eligible participants*
Adherence	Adherence protocol *Number of attended training sessions (intervention & control)*
Attrition	*Number of dropouts*
Time management of the assessments during pre-/post-measurements and the intervention	*Question*

Recruitment rate

People with MI get recruited through advertisement in the local newspaper and flyers in the region. Therefore, the number of people who are addressed is not clear which can be described as an "open recruitment pool". To define the recruitment rate for people with MI, the number of interested people is noted and compared with the number of participants which sign the informed consent and this in turn is compared with the number of participants eligible for the study. To define the recruitment rate for people with MI. In contrast to this, people suffering from CI or UI are directly approached by the therapists to determine whether they would like to participate in the study. This can be determined "as closed recruitment pool". To define the recruitment rate of people with CI and UI, the number of people asked is compared to the number of interested people, people who signed the informed consent, and eligible participants.

Time management of the assessments

To investigate whether the time used for the assessments was appropriate to the study population one question will be asked about the time management of the assessments during the pre- and post-measurement and another about the time management of the assessments during the intervention. This makes it easier to assess whether the number of assessments during the study is feasible for a future study.

Adherence and Attrition

To investigate feasibility and whether elderly people adhere to the VITAAL exergame training or the control video-based training, average adherence rates across the study period will be calculated. Attendance at each training session will be recorded in an attendance protocol by the participants themselves (in the attendance protocol) but also by the training system itself (data back-end, only in the intervention group). Adherence will be calculated as the number of completed training sessions as a percentage of the maximal possible training sessions. There is a total of 36 possible training sessions for each participant over the whole training period. Any reasons for non-adherence will be recorded in the attendance protocol if available. A review by Nyman and Victor [48] reveals a 50% attendance rate to preventive interventions for elderly in clinical trials. Nevertheless, in this study, a 70% adherence rate for the training sessions is set as the definition for being adherent to the training program [80, 81]. For attrition, the number of participants lost during the trial will be recorded (drop-outs). Considering the median rate for attrition in preventive interventions for elderly in community settings for clinical trials [48], a 10% attrition rate can be deemed acceptable.

6.3.2 Secondary Outcomes

In Table 6, the secondary outcome measures are presented including the corresponding assessments. They can be divided into three parts: outcomes concerning physical functions, outcomes concerning cognitive functions and outcome concerning PFM functions. The PFM functions are only measured in participants suffering from UI.

Table 6. Secondary outcome measures of this study and their assessments.

Assessment methods (test)	Outcome
Motor functions	
Gait analysis with Physilog®& VITAAL sensor: *Walking at comfortable self-selected speed over at least 15 m (min. 10 strides of steady state walking)* - *under single-task* - *under dual-task* - *with full and empty bladder (only for UI)* *Walking at maximal speed over at least 4 m*	Gait speed (m/s), cadence (step/min), min. toe clearance (m), stride time (s), intercyclic variability, Swing width (only UI), Dual-task cost Gait speed (m/s)
Short Physical Performance Battery (SPPB): *Gait speed, chair stands, balance tests (extended)*	Lower extremity functioning and mobility
1 – Minute Sit to Stand Test (1MSTST): *Number of chair stands in 1 minute*	Exercise capacity
PFM functions	
Urinary Sensation Scale (USS)	Urinary urgency during walking with full bladder

Score on a 5-point likert scale	
Bladder diary – 7 days *Number of leakages per week*	Severity of incontinence
International Consultation on Incontinence Questionnaire Urinary Incontinence Short Form (ICIQ-UI Short form) *Score*	Severity of incontinence
Maximal PFM contraction: 1) with dynamometer *Number (pressure)* *2)* with digital palpation (oxford scale by Laycock) *Score*	Maximum voluntary contraction of PFM
Cognitive functions	
Montreal Cognitive Assessment (MoCA) *Score*	Several cognitive domains including memory, language, executive functions, visuospatial skills, attention, concentration, and orientation
Trail Making Test (TMT): *Speed (s), Number of errors*	TMT A: Information processing speed TMT B: Mental Flexibility, Divided Attention
Color-word interference test (CWIT): *Speed (s), Number of errors*	Information processing speed, Inhibition/Interference control, Selective Attention
Wechsler Memory Scale-Revised (WMS-R) backwards: *Score of span length*	Working memory

<u>Motor functions</u>

Gait analysis

Temporal (time) and spatial (distance) gait parameters, especially speed (m/s), cadence (steps/min), stride length (m), stride time (s), swing width (m) and minimal toe clearance (m), are measured with the VITAAL gait analysis solution and with Physilog® (Gait up Sàrl, Lausanne, Switzerland) via wearable movement sensors. The sensors are fixed at the forefoots (VITAAL) or at the foot exterior (Physilog®) of the participants for flat over ground gait analysis. VITAAL sensors will be connected via Bluetooth to a clinical web-portal, that will allow the clinician to start and stop the measurements. Collected data will be analysed and results recorded on the backend, associated to the participant being tested. A button on the Physilog® sensors allows the start and stop of the measurement. Physilog® provides objective and quantitative assessment of movement performance. The validity of the Physilog® has been well established [82-84]. We use a 15m straight line walking course resulting in at least 10 strides. Subjects perform a single-task and a dual-task condition with preferred walking speed. In the dual-task condition, a second (cognitive) task is added; participants have to count backwards in steps of seven from a random given number between 200 and 250 while they are walking. The participants have to count loud, otherwise, the trial is recorded as failure. The dual task-condition quantifies participants' ability to executing two tasks concurrently. It's a common method used to quantify the automaticity of movements and multi-tasking capabilities [85-87]. For each subject and for each gait parameter, we calculate the relative dual task costs (DTC) of walking as percentage of loss relative to the single-task walking performance, according to the formula DTC

[%] = 100 * (single-task score - dual-task score)/single-task score [88]. Furthermore, the coefficient of variation (CV) is calculated for cadence, stride time, and minimal toe clearance, according to the formula CV [%] = standard deviation (SD) / mean * 100 [89]. Besides the above mentioned spatiotemporal gait parameters maximal gait speed over at least 4 meters is measured [90].

Additional gait analysis for participants with UI:
For those suffering from UI, the same procedure will take place but will be repeated twice under two different conditions: 1) walking with a full bladder (urge to urinate) and 2) walking with an empty bladder. The same measurements describe above will be recorded in both conditions (except maximal gait speed measurements). Swing width is only analysed in participants with UI.

Short Physical Performance Battery (SPPB)
The SPPB is composed of three subtests:

- Balance test: Starting with their feet in the side-by-side position and followed by adopting the semi-tandem and, finally, tandem stance position, the participants will be required to stand unsupported for 10 seconds.
- 4-meter gait test: For testing walking speed, participants have to walk twice a 4 m distance with their usual walking speed with a standing start.
- 5-chair rises test: For the timed chair stands, participants will be instructed to rise from a chair for five times as quickly as possible and with arms crossed on the trunk. We will measure the time using to complete the five chair rises; from the beginning sitting position to the final standing position of the fifth attempt.

With scores ranging from 0 (not able to complete the task) to 4 (good function), each test can be categorized according to timed quartiles previously established in a large population [71, 72]. A maximal total score of 12 can be achieved and a higher score indicates better performance. A score below 10 is predictive for a higher risk of all-cause mortality [73] and will be used as an inclusion criteria for participants with MI and to assess the physical condition in the participants with UI and CI who attend in the usability study.

1- Minute Sit To Stand Test (1-MSTST)
The 1-MSTST first described by Koufaki et al. in 2002 [91], is an easy applicable test which requires only a chair and a stop watch to measure exercise capacity. Furthermore, some studies showed that this test might be a good alternative for the 6 minute walking test (6MWT) [92-94]. The participants are required to rise from a chair with their arms across their chest as often as possible in one minute, using the procedure of a recently published systematic review from Bohannon and Crouch (2019) for standardization [95].

PFM functions

Amount of urinary urgency

To assess the amount of urinary urgency during ST and DT walking with full bladder, the participants will complete the urinary sensation scale (USS). The USS is a 5-point Likert scale developed to assess feelings of urinary urgency (i.e., intense and/or sudden need to urinate) associated with each urination [96].

7 days bladder diary

The bladder diary is a common method used to evaluate the frequency and characteristics of incontinence episodes in both research and clinical practice. The bladder diary has also been used routinely as a primary outcome measure in incontinence research [97]. It is a prospective method that reduces recall error and results in higher levels of reporting for most conditions. The bladder diary has the advantage of assessing incontinence "in the individual's own environment and under actual daily life conditions." Is has been demonstrated that a one-week diary was sufficient to obtain reliable reports of frequency of incontinence.

International Consultation on Incontinence Questionnaire Urinary Incontinence Short Form (ICIQ-UI Short form)

The ICIQ-UI short form is a brief and psychometrically robust patient-completed questionnaire for evaluating the frequency, severity and impact on quality of life of urinary incontinence in men and women. It is scored on a scale from 0-21. With a higher score indicating greater severity of symptoms [76].

Maximal PFM contraction (strength):

- Manual muscle testing:
  Laycock developed the modified Oxford Grading System to measure PFM strength using vaginal palpation of the PFM [98]. This is a 6-point scale: 0=no contraction, 1=flicker, 2=weak, 3=moderate, 4=good (with lift), and 5=strong. It is an easy method to use and does not require expensive equipment. Interrater reliability for vaginal palpation was high. With this method, the evaluator insert one finger inside the vaginal cavity of the patient who is asked to perform to attempt to perform a maximum voluntary contraction of the PFM.
- Dynamometer:
  The dynamometer is a vaginal pressure device connected via Bluetooth to a computer showing the pressure as a measure of PFM strength. To perform the measurement, the dynamometer is inserted inside the vaginal cavity of the patient who is asked to attempt to perform a maximum voluntary contraction of the PFM. Dynamometry has been showed to be a reliable measure of assessment.

Cognitive functions

Montreal Cognitive Assessment

The Montreal Cognitive Assessment (MoCA) is a simple paper and pencil test to screen several cognitive domains including memory, language, executive functions, visuospatial skills, attention, concentration, and orientation [67, 68]. The participants can get maximal 30 points. The MoCA can be used as a quantitative estimate of the overall cognitive abilities [69]. According to Thomann et al. age, gender, and years of education are integrated to define the cognitive condition [70].

Trail Making Test (TMT A and B)

The TMT is a widely used, reliable and valid neuropsychological test only requiring paper and pencil [99-102]. The main goal of the TMT Part A (TMT-A) is to assess general information processing speed. The task is to connect circled numbers (1-25) allocated randomly on the paper as fast as possible. TMT Part B (TMT-B) is used to test executive functions especially mental flexibility but also divided attention. The task is to connect circled numbers and letters alternatingly (number-letter-number-letter…). Time is measured how long it takes

participants to complete TMT-A and TMT-B. Furthermore, errors are counted. There are age-grouped norm values for older adults up to 90 years old [101, 103].

D-KEFS Color Word Interference Test (CWIT)

The CWIT is part of the D-KEFS neuropsychological test battery which was developed to investigate executive functions [104]. This subtest investigates response inhibition, interference and selective attention as part of executive functions. The CWIT involves control tasks, which require the participant to name colours of squares and no-colour/colour words. The interference task requires the participant to name the colour of colour words. The colour words are printed in other colours (e.g. red is written in blue ink). Therefore, this latter task requires the participant to inhibit the automatic response of reading and to produce a more effortful colour-naming response. The inhibition/switching task requires the participants to name the colour of the colour words, but if the words are in boxes, the participant is required to name the colour words. The interference effect is determined by calculating the extra time required to name colours in the interference task in comparison to the control tasks. Furthermore, we are interested in the number of errors made in the interference tasks.

Wechsler Memory Scale-Revised (WMS-R): Digit Backward Tasks

The Digit Backward Task of the WMS-R is used to evaluate working memory which is another executive function [105]. Participants have to repeat digits, which were read to them loudly by the tester in reversed order. The digit spans get longer in progress of the task. There are age-grouped norm values for older adults up to 90 years old [103].

6.3.3 Other measures of interest

In Table 7, other (outcome) measures of interest are presented including their assessment method.

Table 7. Other (outcome) measures of interest of this study and their assessments.

Outcome	Assessment methods
Screening measurements	
Urinary Incontinence Screening	Questionnaire for Urinary Incontinence Diagnosis (QUID)
Demographic data and medical history	Health Questionnaire
Correct PFM contraction	Digital palpation and intra-vaginal dynamometer
Training related interests	
Activity monitoring	Activity protocol
Exercise intensity (physical and cognitive)	Borg CR10 scale
Motivation	Situational Motivation Scale (SIMS)
Individual 8-12 Repetition Maximum	8-12 RM with individual amount of additional weight
Safety	Safety protocol
Quality of Life	Different questionnaire for each group: • MI: SF-12 • UI: ICIQ-LUTSqol • CI: DQoL
Quality of the Exergame	MARS
Technical interests	

Comparison of gait measurement systems	VITAAL gait analysis solution vs. Physilog® Gait Up

Screening measurements

Questionnaire for Urinary Incontinence Diagnosis (only in UI and MI)

The validated Questionnaire for Urinary Incontinence Diagnosis (QUID) consists of a 6-item urinary incontinence (UI) symptom questionnaire to distinguish stress and urge UI. The QUID has acceptable psychometric characteristics [74, 75].

Demographic data and medical history

The Health Questionnaire was developed by ETH Zurich to assess general personal information about participants covering also general health, medical history and physical activity.

Correct PFM contraction (only UI)

To assess a correct PFM contraction, the evaluator teach the participant how to contract the PFM by use of models, anatomical drawings and imagery. After the participant has undressed, he is asked to lie down on the bench with hips and knees bent and shoulder width apart (crook lying), pelvic area is covered with a towel. The participant is then asked to breathe normally and lift the perineum inwards and squeeze around the openings without any movement of the pelvis or visible co-contraction of the gluteal or hip-adductor muscles. A small drawing in of the lower abdomen with the PFM contraction is accepted. The evaluator observe the patient's attempt to contract and register how the contraction was performed (correct, no contraction, inconclusive, straining). If the contraction is incorrect, some more specific cues can be giving such as "do as if you want to stop urinating or hold back a gas". Kegel described a correct PFM contraction as a squeeze around the urethral, vaginal and anal openings, and an inward lift that could be observed at the perineum. Following perineal observation, with the patient in the crook lying position, with gloves on and gel, the evaluator place one finger in the distal one-third of the vagina and ask the woman to lift inwards and squeeze around the finger and record whether PFM contraction is: correct; only possible with visible co-contraction of other muscles; not present; in the opposite direction (straining or Valsalva).

Training related interests

Activity monitoring

Participants need to fill in an activity protocol during the whole intervention period, where they note physical activities besides the training itself.

Exercise intensity (physical and cognitive)

Participants rate their physical and cognitive exertion after each training session (resp. after each training component in one session). The Borg CR10 scale is an often used subjective, quantitative measure to assess the intensity of training on a nonlinear scale with which the perceived exertion is rated [77]. It's a linear scale from from 0 = "nothing at all" to 10 = "extremely strong" with 0.5 = "extremely weak", 1 = "very weak", 2 = "weak", 3 = "moderate", 5 = "strong", 7 = "very strong", 10 = "extremely strong".

Situational Motivation Scale

To assess the motivation during the intervention period, participants will fill in the SIMS, a 16 item validated questionnaire developed by Guay et al. [106]. The questionnaire assesses intrinsic motivation, identified regulation, external regulation, and amotivation. Participants will fill in the questionnaire in the first and the last training week, whereby the items get rated on a 7-point Likert scale from 1 = "corresponds not at all" to 7 = "corresponds exactly".

Individual 8-12 Repetition maximum (RM)

Participants 8-12 RM of squats hip wide is defined previous to the exergame session, in order to do the strength exercise at an individual optimal load. The participant is asked to perform as many squats as possible, in his individual range of motion (ROM). When reaching 15 repetitions the participant is instructed to make a break of at least 1 minute and then repeat the exercise with additional 2-4 kg added on a waist belt or on a weight vest. The procedure is repeated until the optimal load of 8-12 RM is found.

Safety

A protocol will be kept of all SAEs related to the intervention and the study participants will receive a questionnaire at the end of the intervention regarding safety during the exercises.

Quality of Life

Short Form – 12 (SF-12) – only with MI

The Short Form health survey, SF-12 [107], is a commonly used instrument to measure health-related quality of life at various ages. The instrument is a shorter version of the SF-36, developed by Ware and Sherbourne [108]. The SF-12 is a shorter version of the SF-36 and uses only 12 questions to measure functional health and wellbeing from the patient's perspective. The original objective was to develop a short, generic health-status measure that reproduces the 2 summary scores of the SF-36, i.e., the physical component summary (PCS) score and the mental component summary (MCS) score. The SF-12 is validated for older people and was found suitable to be used in populations with cognitive impairment [109, 110].

International Consultation on Incontinence Questionnaire - Lower Urinary Tract Symptoms Quality of Life (ICIQ-LUTSqol) – only with UI

The ICIQ-LUTSqol consists of 19 items concerning different aspects of everyday life that might be affected by leakage or other bladder conditions. Each item provided four choices, which were rated 1 "not at all"/"never," 2 "slightly"/"sometimes," 3 "moderately"/ "often," or 4 "a lot"/"very much"/"all the time." The points are summed to an overall score ranging from 19 to 76 points. A higher score indicates a larger impact on quality of life. Three of the items concern personal relationships, and have an additional response: "not applicable.' The ICIQ-LUTSqol was derived from the validated KHQ and added to the ICIQ module, with the alteration of one question and a simplification of the scoring system. It has been proven reliable in both paper and electronic formats [111].

Dementia Quality of Life Scale (DQOL) – only with CI

Assessing quality of life in people with dementia is complex and often done by proxy measures. In this study, we will use the DQOL which is a 30-item instrument designed to assess QOL by direct interview with the person with dementia. It consists of five domains: self-esteem, positive affect, negative affect, feelings of belonging, and sense of aesthetics [112].

Quality of the Exergame

The Mobile Application Rating Scale (MARS) (Section A, B, C, and E) a simple, reliable and objective questionnaire for classifying and assessing the quality of mobile health applications will be used to assess the quality of the exergame [113]. Section D is excluded because it refers to marketing characteristics (e. g. App description, visual information) of commercial products.

Technical interests

Comparison of gait measurement systems (only in CH and BEL)

The aim of this study is to determine the concurrent validity and levels of agreement of the well-established Physilog® with the newly developed VITAAL gait analysis solution for spatio-temporal gait parameters at maximal and self-selected walking speed in participants suffering from mobility problems (CH) and cognitive impairment (BEL).

6.4 Participants

6.4.1 Exact number of participants

For the randomized controlled pilot-trial, it is planned to include 40 subjects in each country (20 participants in the training group and 20 participants in the control group). The main goal of this trial is to evaluate the efficacy of the newly developed exergame for fall prevention in older adults. It represents a phase III study according to Campbell et al. [55].

6.4.2 Inclusion and exclusion criteria

Criteria for inclusion

Participants fulfilling all of the following inclusion criteria are eligible for the study:

- Aged 60+ years, only female when suffering from UI
- Live independently, in a residency dwelling, or with care
- Standing straight for minimal 10 minutes without aids
- SPPB < 10 (only for the study group with MI)
- diagnosed with mixed urinary incontinence (MUI) (only study group with UI)) or urge urinary incontinence (UUI) according to the Questionnaire for Urinary Incontinence Diagnosis (QUID)
- correct contraction of PFM must be possible (only study group with UI)
- Visual acuity with correction sufficient to work on a TV screen
- MMSE ≤ 23 (only for CI)

Criteria for exclusion

Participants are excluded from the study, if they exhibit one of the following exclusion criteria:

- Mobility impairments that don't allow to play the exergame
- heavy noticeable cognitive impairments according to Thomman et al. [70] (only for UI and MI)
- Severe acute or uncontrolled health problems (e.g. recent cardiac infarction, uncontrolled diabetes or hypertension)
- Orthopaedic or neurological diseases that inhibit exergame training
- Rapidly progressive or terminal illness

In the elderly population, targeted and individualized physical activity programs can provide a myriad of health benefits. In almost all older people, (additional) physical exercise can generate positive health effects and it is important to emphasize that only few contraindications to exercise exist [78]. In the context of "physical exercise", no high-risk group can be classified (except people suffering from rapidly progressive or terminal illnesses or health problems listed above). Consequently, low testing scores (in physical functioning tests) demonstrate no general reasons for exclusion from this study. It is rather important that the training program is geared toward an individual's health status, capabilities and limitations [78]. Therefore, the study provides a suitably adapted training program tailored to the demands of each participant according to the training principles of optimal load and progression.

6.4.3 Recruitment of participants

Participants will be recruited in Switzerland, Canada, and Belgium through contact persons and associations but also through public advertisement. All interested people will be fully informed prior to trial start by the use of a study information and it will be made clear that withdrawal is permitted at any time during the study without

giving any reason. Furthermore, the investigators will explain the procedure, benefits and risks of the study in detail. All participants have to sign an informed consent before trial start.

6.5 Study adaptions according to the participants group

Adaptions which are not already described in the chapters before will be mentioned in this chapter.

6.5.1 Mobility Impairment

No further adaptions

6.5.2 Urinary Incontinence

Concerning the recruitment, the eligible participants for the study are women (in Canada and CH) diagnosed with urge or mixed urinary incontinence confirmed by using the validated Questionnaire for Incontinence Diagnosis (QUID). Furthermore, they must undergo a gynaecological (digital vaginal and dynamometry) examination and have reported at least three episodes of involuntary urine loss per week (on 7 days bladder diary) and during the preceding three months. They also must be able to perform a correct contraction of the PFM.

Other than the ones mentioned above, exclusion criteria included are:

- untreated chronic constipation;
- important pelvic organ prolapse;
- physiotherapy treatment or surgery for UI or pelvic organ prolapse in the past year;
- use of medications for UI or affecting skeletal muscles;
- change in hormonal replacement therapy in the last six months;
- having an active urinary or vaginal infection in the past three months;
- any co-morbidities/risk factors interfering with the study.

6.5.3 Cognitive Impairment

Suffering from cognitive impairment will not be an exclusion criterion in this population group.

The demographical and medical data will be completed by the researcher, based on an interview with the participant. This will be supplemented with information from the resident files in the care facility centre, in order to fill it in complete and correct.

In participants where the verbal communication is more difficult, due to the consequences of dementia, the documents will be adapted. For example, some questions will be left out or simplified. This will be adapted during the test session.

In the gait analysis during the dual-task condition with preferred walking speed, participants will count backwards in steps of seven. Depending on the cognitive resources of the participant, the task can be simplified (subtraction of 3, 2 or 1, listing animals).

The MARS won't be conducted in this population.

To assess the quality of life, the DQOL will be used in this population group.

In addition, all scales and questionnaires will be translated to Dutch.

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