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Name:	Social Exergaming, Dancing and Tai Chi for wellbeing and fall prevention
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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)

Partner list

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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 UNIEKBO.

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 Active@Home project.

The document starts with some general background information followed by a description of the Active@Home exergame and a discussion of several important ethical aspects related to the studies. Than the document is structured in two parts: In the first part, it describes the methodology for the feasibility and usability study. In the second part, methodological details of the randomized controlled pilot-trial are described.

2. Background, rationale, and preliminary results

Age-associated degenerative changes cause gait impairments and a higher risk of falls in elderly. Falling can lead to injuries, restrictions of movement, loss of independence, social isolation, depression and a general decrease in well-being and quality of life. Current numbers demonstrate that one out of three people aged 65 and older fall annually and 20-30% of falls result in injury and hospitalization [1-3]. Considering the significant impact on individual lives but also the direct and indirect health and care costs, there is a strong need for interventions aiming to prevent the occurrence of these events.

The cause of falls and risk of repeated falling might be evoked through gait and balance disturbances as well as (lower extremity) muscle weakness [4]. It is well known that regular physical activity also in older age effects health state, gait stability and well-being in general. Exercise interventions which aim to improve physical functions such as strength or balance training have been shown to reduce fall rates and risks [5-7]. Not only age-related declines in motor and sensory functions are responsible for gait impairments and higher risks of falls but also reduced cognitive functions such as attention (selective and divided attention) and executive functions (inhibition, mental flexibility) [8-12]. Considering even routine walking as a task which requires not only physical but also cognitive abilities leads to the necessity of a combined motor-cognitive training for most effective fall prevention [13-15]. Furthermore, in daily life in general, we are normally busy with cognitive-motor multi-tasking requiring the concurrent performance and interplay of motor and cognitive functions. A promising option for simultaneous cognitive-motor training is an interactive game based training, so called exergames [16].

Exergames are defined as any types of video game interactions that require the player to be physically active and move, and therefore be active to play the game. The rapid growth in new

information and communication technologies (ICTs) 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) [17-20]. There are several studies demonstrating that exergame-based treatment is effective (e.g. in rehabilitation setting) and furthermore includes motivational benefits [21, 22]. "Having fun while training" might have a huge impact on engagement, compliance and thus also influence treatment effects [21, 23]. Exergames might therefore overcome low motivation and adherence of older adults often reported in standard fall prevention studies [24, 25] and can increase physical activity through challenging and engaging, interactive training games [26]. With the aim to provide enjoyable game experiences, the needs and constraints of the targeted population must be considered, and game design has to be adapted [18, 27, 28]. Some "off-the-shelf-games" do not apply game design guidelines for elderly people (e.g. adaption of interface with high contrasts, large font etc.) and are therefore not suitable for older adults [29].

To sum up, there is a strong need for effective fall prevention, which incorporates theoretical background from movement sciences, neuropsychology/cognitive sciences and arts of game design. In line with these requirements, the main goal of the Active@Home project is to develop a new technology-based training game considering the constraints and needs of elderly people. Not all older adults have access to public health centers and exercise facilities or they do not attend because of reduced mobility or low motivation. 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 elderly [30, 31]. Therefore, the Active@Home exergame is developed to be finally used by autonomous living elderly people at their homes. To summarize, the Active@Home multicomponent exergame is based mostly on the prevention of adverse falls and their consequences but also on supporting and motivating elderly towards healthier and more active lifestyles which will allow them to fully experience their advanced ageing and retirement years, maintaining their independence and full control of their lives. And moreover, Active@Home 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 (see also Deliverable 2.2, survey study results will be published in a scientific journal soon). Results from the investigation phase have been integrated in the second phase – the development phase – when the Active@Home exergame was developed as a first prototype. In the third phase – the trial phase – the feasibility and usability and the effects of the developed program should be evaluated. This deliverable is concerned with the third phase and outlies the trial deployment by describing the methodology, procedures and outcomes/metrics.

Table 1. Overview of the three phases of the Active@Home project.

Project phase	Goal	Methods
Investigation phase	To get insights in the end-users' needs, attitudes and expectations	Questionnaires with end-users and focus groups with other stakeholders
Development phase	To develop the Active@Home exergame	Interviews/focus groups to get feedback from end-users
Trial phase	To test the feasibility and effects of the developed program	Feasibility and usability studies (phase II trials) Randomized controlled pilot-trial (phase III trial)

In the area of public health and disease prevention, there is a strong need for implementing effective evidence-based interventions. But 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. [32], an iterative phased approach is recommended starting with exploratory trials (phase II studies) before conducting definitive randomized controlled trials (phase III studies). Beside of 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 [32-34].

Following the iterative phased approach [32], in summer 2017, a first feasibility and usability study was conducted in Switzerland with the newly developed exergame prototype in laboratory setting (feasibility study results will be published in a scientific journal soon). Results showed a general high feasibility and usability of the newly developed training system in a laboratory setting but some optimization potential got evident. The findings allowed to improve the Active@Home exergame prototype during the past months. Now as next steps, the feasibility and usability of the improved exergame has to be tested in laboratory but also in a home-based setting (see chapter 5. Feasibility and Usability Study). The final step is to conduct a large multinational, randomized controlled pilot-trial comparing the newly developed Active@Home exergame with usual care aiming to assess the proposed health benefits (see chapter 6. Randomized controlled pilot-trial). Table 2 shows an overview of planned research in the Active@Home project in 2018.

Table 2. Overview of planned research in the Active@Home project in 2018.

Jan	Feb	Mar	Apr	May	Jun	July	Aug	Sep	Oct	Nov	Dec
		Feasibility and Usability Study									
					Randomized Controlled Pilot-Trial						

3. Description of the Active@Home exergame

The Active@Home exergame is a multicomponent, motor-cognitive training for fall prevention in elderly adults (see an overview of the Active@Home exergame in figure 1). It mainly consists of three components; strength training, balance training and cognitive training. For strength training, Tai Chi-based movements are included as Tai Chi is mainly performed in a semi-squat posture that places a large load on the muscles of the lower extremities. For balance training, dancing is included in the Active@Home exergame as the execution of rapid and well-directed steps has been shown to be effective in preventing falls [35-37]. Both, Tai Chi and dancing, are 'holistic' physical activities requiring motor functions, cognition and mental involvement [38]. Moreover, Tai Chi and dancing could be more motivating and joyful than standard exercise. Some cognitive training is already included in strength and balance training with Tai Chi and dancing as both of them 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 [8-12]. Therefore, the Active@Home exergame explicitly targets on these neuropsychological functions (selective attention, divided attention, inhibition/interference control, mental flexibility, working memory). To maximize benefits for participants, the Active@Home exergame implements some basic general training principles; providing feedback, optimal load of task demands, progression of difficulty and high variability [39].

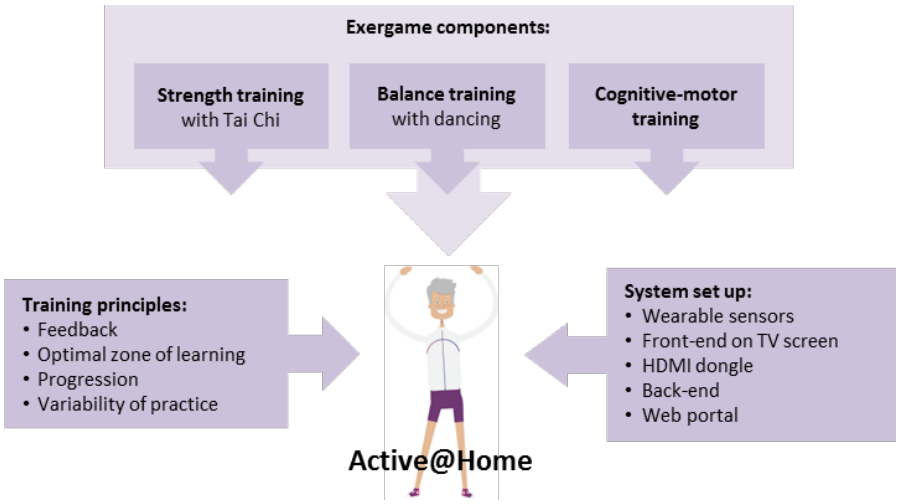

Figure 1. Overview of Active@Home exergame with relevant components

The Active@Home system set up must be very easy aiming to be used independently at home by elderly people. It consists of a HDMI dongle (for running the application) which must be plugged into the TV. There is a front-end (user interface on TV screen), a back-end (main server supporting the whole service and data storage), a web portal (with information about interventions, sessions, results etc.) and four wearable sensors (for measuring the movements). The four inertial sensors are placed in a silicon bracelet and are capable to sense accelerations

and angular rotations caused by movement. The sensors must be worn at the wrists and ankles whereby the "slap-band mechanism" of the bracelets makes them easy to attach. Figure 2 shows all the system components and figure 3 illustrates the system set up graphically.

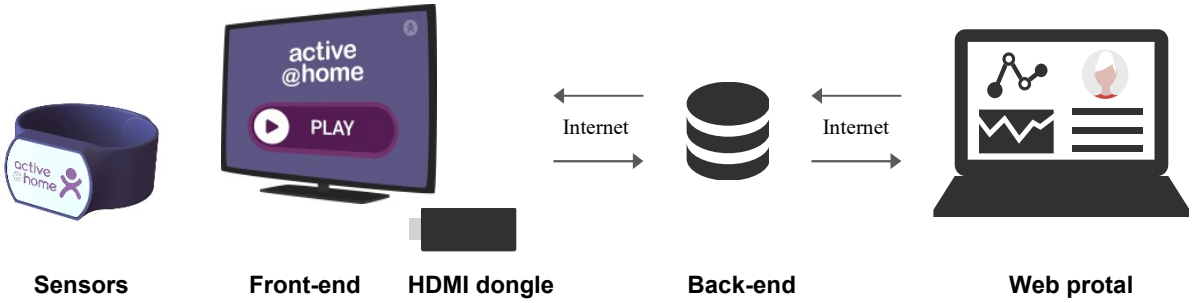

Figure 2. Overview of all system components of Active@Home exergame.

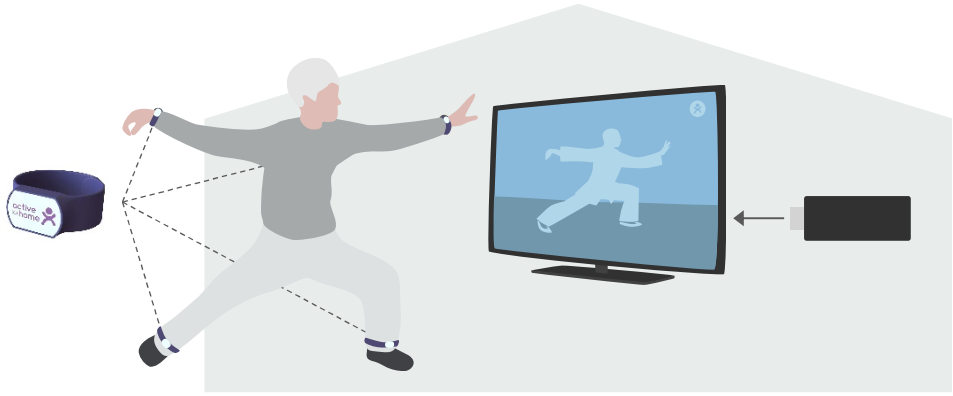

Figure 3. System setup of Active@Home exergame.

4. Ethical aspects of the trials

All ethical aspects relevant for the Active@Home trails 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.

4.1 Legislation and Ethics Authority

All the studies in the Active@Home 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) 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

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

4.2 Study information and Informed Consent

Following the national and European 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 Active@Home project.

5. Feasibility and Usability Study

5.1 Objectives

5.1.1 Primary Objective

The main goal is to determine feasibility, usability, and user-experience of the improved Active@Home exergame prototype while using the system and independently in a home-like or in-home setting. Questionnaires and qualitative evaluation are used. Adherence and attrition rates will be calculated (only in CH).

5.1.2 Secondary Objective (only in CH)

The secondary goal is to assess the efficacy of the Active@Home exergame in a smaller sample using motor and cognitive tests (pre- and post-intervention) to estimate the treatment effect and its variance to have a basis for calculations and preparations for the following randomized controlled pilot-trial.

5.2 Trial Design and Intervention

To determine the usability and user-experience of the newly developed and already improved Active@Home exergame, all involved partners (CH, NL, P) conduct one or two gaming sessions with 15 to 20 participants (healthy, independently living older adults 65+) in a home-like environment (living lab). Participants should try to independently use the training system after a short introduction by the instructors. They should complete at least two strength exercise (Tai Chi), two balance exercises (dancing) and two cognitive-motor games. After the training sessions, questionnaires and interviews are used to evaluate the usability and game experience of the users and to get further feedback.

In Switzerland, the usability study is combined with a short intervention study (phase II study according to Campbell et al. [32]) to evaluate also the feasibility and efficacy of the newly developed exergame. The intervention period includes 24 training sessions (three training sessions per week over 8-10 weeks) with the Active@Home exergame. The participants attend a first appointment at T1 performing a screening assessment and first measurements (pre-measurements). The screening includes assessments about personal information, general health and cognition state especially: gender, age, height, weight, current level of physical activity, hearing, vision, chronic disease, illnesses and injuries, cognitive screening. Before and after intervention, at T1 and T2, physical and cognitive assessments will be performed (pre- and post-measurements). Pre- and post-measurements include both: Gait analysis and tests to measure several motor and cognitive functions (see figure 4).

After screening and pre-measurements, the training intervention starts (3x per week, in total 24 sessions in 8-10 weeks). The training period and intensity is based upon studies illustrating positive training effects in older adults performing a video game on a dance plate [40, 41]. Every training session lasts around 40 minutes and includes all three training components (15 minutes

strength training with Tai Chi, 15 minutes balance training with dancing, 10 minutes cognitive-motor games). Interruptions of the training period are allowed (not more than two weeks) if not otherwise possible.

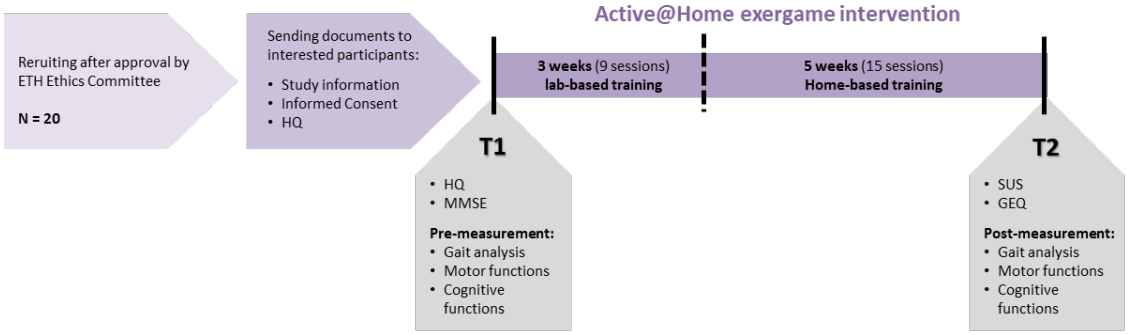

Figure 4. Flow chart of trial design with intervention and measurements. HQ = Health Questionnaire, MMSE = Mini Mental State Examination, SUS = System Usability Scale, GEQ = Game Experience Scale.

The training period is split in two parts: The training of the first three weeks will take place at a home-like setting (living lab of ETH Zurich) under supervision of instructors/students and the study leader. During these trainings, the heart rate of the participants will be measured. Any potential technical problems or difficulties with the exercises will be registered and solved if possible. The trainings of the next five weeks will take place at participants' homes. Each participant will be equipped with a complete Active@Home training system (four movement sensors, charging station for the sensors, HDMI dongle). The installation and setup of the system will be well explained and practiced with the participants the weeks before starting the training at home. During the in-home training period, participants will be called weekly to check if there are any problems and to provide support and further help and information. Attendance at the training sessions will be recorded by the instructors but also by the training system itself (data back-end).

After completing all training sessions, post-measurements are conducted at T2. Furthermore, also in Switzerland, usability and game experience will be evaluated by the participants with two questionnaires. The whole procedure is illustrated in figure 4.

In this study, each partner will be responsible for:

- Ethical approval for the trial in the respective country (if needed)
- Recruiting of 15 to 20 participants according to defined criteria (see below)
- Conducting the gaming sessions (one or two sessions)
- Conducting outcome measurements: Handing out questionnaires to acquire users' opinion and holding interviews
- Complying with internal reporting requirements (filling in data tables)
- Data transfer to CH/ETHZ where final data processing and analysis takes place

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 [22]. 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.

Outcome	Assessed by
Usability	System Usability Scale (SUS) Usability Protocol
Feasibility	Adherence and Attrition (Attendance Protocol)
Game experience/ enjoyment	Game Experience Questionnaire (GEQ)

System Usability Scale (SUS)

An often used scale for evaluation of software products or websites but also games/exergames is the SUS which was developed by Brooke [42]. 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 [42, 43]. The selected statements cover a variety of aspects of system usability such as the need for support, training and complexity but SUS focus more on pragmatic quality than hedonic aspects. Therefore, game experience and enjoyment are measured separately (see below). The scale was applied in other exergame studies and was suggested to be an appropriate measure in evaluating systems/settings with older adults. Based on the verbal categorization/adjective rating of Bangor [44], we expect a SUS score of at least 70 to have an "acceptable" solution (52= ok, 73 = good, 85 = excellent, 100 = best imaginable).

Usability Protocol

In addition to quantitative questionnaire, qualitative data will be 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 "thinking loud" method. They are asked to say everything which comes to their mind while using the game. All the feedback from participants is documented.

Adherence and Attrition

To investigate feasibility and whether elderly people adhere to the Active@Home exergame training, average adherence rates across the intervention period will be calculated in Switzerland (for the whole period but also separately for the two parts of "lab training" and "home training). Attendance at each training session will be recorded by the instructors (in the attendance protocol) but also by the training system itself (data back-end). 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 24 training sessions possible 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 [25] reveals a 50% attendance rate to falls prevention interventions 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 [45, 46].

For attrition, the number of participants lost during the trial will be recorded (drop-outs). Considering the median rate for attrition in fall prevention interventions in community settings for clinical trials [25], a 10% attrition rate can be deemed acceptable.

Game Experience Questionnaire (GEQ)

Bamidis [18] mentioned the importance of focusing also on "affective evaluation" of a new solution: "A system can be usable if it makes its users feel positive" (p. 7757). Therefore, the GEQ is included to assess subjective game experience and engagement. Ijsselsteijn and colleagues [47, 48] develop this self-report questionnaire in the FUGA EC-funded project (The fun of gaming: Measuring the human experience of media enjoyment) to assess a number of psychological feelings and emotions of a player. They understand game experience as a multidimensional construct with seven different components: competence, sensory and imaginative immersion, flow, tension/annoyance, challenge, negative affect and positive affect. 33 items are scored on a 5-point Likert scale and assess all the different components. The GEQ seems reasonable and applicable in studying player experiences with video and exergames [49]. It has been used in several other exergame studies [23, 50].

5.3.2 Secondary Outcomes (only in CH)

In table 4, the secondary outcome measures are presented including the corresponding assessments. The secondary outcome measures can be divided into two parts: outcomes concerning physical functions and outcomes concerning cognitive functions.

Table 4. Secondary outcome measures of this study and their assessments.

Outcome	Assessed by
Temporal-spatial gait parameters	Gait analysis under two conditions (single- and dual-task)
Lower extremity function	Short Physical Performance Battery (SPPB): Extended Balance Test Y-Balance Test (YBT) Senior Fitness Test (SFT): 30-Second Chair Stand Test, 2-Minute Step Test
Cognitive functions	Test of Attentional Performance (TAP): Divided attention, GoNogo, Set shifting Trail Making Test (TMT A and B) Wechsler Memory Scale-Revised (WMS-R): Digit Span Tasks Victoria Stroop Test (VST)

Gait analysis

Temporal (time) and spatial (distance) gait parameters, especially speed (cm/s), cadence (steps/min), stride length (cm), stride time (s) and toe clearance (cm), are measured with the Physilog® (Gait up Sàrl, Lausanne, Switzerland) via wearable movement sensors. The sensors are fixed with elastic straps at the forefoots of the participants for flat over ground gait analysis. A button on the sensors allows the start and stop of measurement. Physilog® provides objective and quantitative assessment of movement performance. The validity of the Physilog® has been well established [51-53]. Similar to König et al. [54], we use a 8-walk protocol with at least 50 gait cycles (five repetitions of walking a "figure 8" with a distance of about 7m between turns) which has been shown to be a reliable measure of all relevant gait parameters. Subjects perform a single-task and a dual-task condition with preferred walking speed. In the dual-task condition, a second 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 [55-57]. 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 [58].

Short Physical Performance Battery (SPPB): Extended Balance Test

The effects of the intervention also need to be interpreted in terms of standardized clinical measures, as those are the most useful for health coaches/therapists. Therefore, the balance test of the SPPB should be included to assess static balance. Balance also known as postural control can be defined statically as the ability to maintain a base of support with minimal movement, and dynamically as the ability to perform a task while maintaining a stable position. The SPPB, described in detail by Guralnik et al. [59, 60], was developed by the National Institute of Aging to measure especially lower extremity functioning by using tasks that mimic daily activities. It's an objective, valid and reliable assessment instrument. The Balance test of the SPPB consists of the following tasks: 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. With scores ranging from 0 (not able to complete the tasks) to 4 (good function), the performance can be categorized [60]. To avoid ceiling effects, the standard SPPB balance test will be extended with two additional levels of difficulty according to previous studies [13, 61]: The first additional level includes a 20s single-leg stance. One point is added to the SPPB balance test score when 10s are reached and another point when 20s are completed. For the second additional level, a single-leg stance with eyes closed is required to maintain for as long as possible. There are three trials of this last task whereas the highest value counts. One point is added to the balance score for every 5s the position is held.

Y-Balance Test (YBT)

The YBT is a reliable and valid tool for quantitative assessment of dynamic balance [62-66]. Participants are only allowed to conduct the YBT if they were able to maintain 20s single-leg stance in the balance test of the SPPB. The participants reach with one foot in the anterior, posteromedial, and posterolateral direction during standing on the other foot on a central position (hands on the pelvis) and the reach distance will be recorded. All practices and testing are performed barefoot with both the left and right limbs. Each subject is allowed four practice trials in each direction and on each leg prior to formal testing for familiarization. Between practice and test trials, a short break is allowed. Then three trials are conducted in each direction (order: right anterior, left anterior, right posteromedial, left posteromedial, right posterolateral, left posterolateral) and the mean value of the three test trials will be determined for data analysis. A trial is classified as invalid if the participant does not return to the starting position or fails to maintain a unilateral stance or removes the hands from the hips. If an invalid trial occurs, the data is discarded, and the subject has to repeat the trial. For normalization, the participants' lower limb length while lying in the supine position will be measured bilaterally.

Senior Fitness Test (SFT): 30-Second Chair Stand Test and 2-Minute Step Test

To evaluate the functional fitness performance of older adults, researchers at California State University, Fullerton, developed and validated a new fitness test battery; the SFT [67-70]. One unique feature of the SFT is that is measures physiological parameters (as muscle strength or endurance) using functional movement tasks.

30-Second Chair Test: To assess lower body strength, a subtest of the SFT is used in this study; the 30-Second Chair Stand Test. Participants have to sit down on a chair and get up again as fast as they can during 30 seconds with their arms folded across the chest. The number of completed full stands is counted. If the participant has to use his arms, the score is 0. The risk zone is defined as "less than 8 unassisted stands for men and women". Furthermore, there are age-grouped normative scores for older adults from 60 to 94 [69].

2-Minute Step Test: To assess aerobic endurance, another subtest of the SFT is used in this study; the 2-Minute Step Test. Participants have to alternatingly raise their knees to a predefined point (midway between the patella/kneecap and iliac crest/top hip bone). The score is the number of times the right knee reaches the required height in two minutes. The risk zone is

defined as "less than 65 steps for men and women". Furthermore, there are age-grouped normative scores for older adults from 60 to 94 [69].

Test of Attentional Performance (TAP): Divided attention, GoNogo, Set shifting

The TAP was initially developed to assess deficits in attention. The valid test battery consists of 13 subtests to asses a variety of statistically independent attentional aspects [71]. The D-TAP 2.3 VL (PSYTEST, Psychologische Testsysteme, Herzogenrath) is a computerized procedure running on PC. In this study, we focus on three specific subtests:

Divided attention: This subtest consists of visual and acoustic signals. The visual task consists of crosses appearing in a random configuration. The participant has to detect whether the crosses form the corners of a square. The acoustic part consists of low and high peeps playing in a regular sequence. The participant has to detect irregularity in the sequence.

GoNogo – 1 out of 2: The participant suppresses a response in the presence of irrelevant stimuli and has to react as fast as possible to the relevant stimuli. The test includes two different stimuli, one of them is the target stimulus.

Set-shifting – Alternating letters and numbers: On the left or right side of the screen letters and numbers are presented in a randomized order. The participant must react on the target stimulus (e.g. "letter" – "number" – "letter"...) pushing a right or left button.

In all the tasks, we are interested in reaction times (mean, standard deviation) but also in number of errors. There are norm values for different age categories also for older adults.

Trail Making Test (TMT A and B)

The TMT is a widely used, reliable and valid neuropsychological test only requiring paper and pencil [72-75]. 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. 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 [74, 76].

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

The Digit Forward Task of the WMS-R measures the short-term attention span [77, 78]. Participants have to remember and repeat digits in the correct order, which were read to them loudly by the tester. The Digit Backward Task of the WMS-R is used to evaluate working memory which is another executive function [77]. 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 [76].

Victoria Stroop Test (VST)

The VST was developed as a brief version of the original Stroop tasks [79-81]. It's a widely used neuropsychological test to assess response inhibition and interference as part of executive functions. The VST involves control tasks, which require the participant to name colors of dots and no-color/neutral words. The interference task requires the participant to name the color of color words. The color words are printed in other colors (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 color-naming response. The interference effect is determined by calculating the extra time required to name colors in the interference task in comparison to the control tasks. Furthermore, we are interested in the number of errors made in the interference task.

5.3.3 Other measures of interest

In table 5, other (outcome) measures of interest are presented including their assessment method.

Table 5. Other (outcome) measures of interest of this study and their assessments.

Outcome	Assessed by
Cognitive state screening	Mini Mental State Examination (MMSE)
Health state screening	Health Questionnaire of ETHZ

Mini Mental State Examination (MMSE)

The MMSE is a simple and quick paper and pencil test to systematically assess mental status. It's an 11-question measure that tests several cognitive domains including orientation to time and place, learning and recall of three words, attention and calculation, language and visuoconstruction [82, 83]. Since its creation in 1975, the MMSE has been validated and extensively used in both clinical practice and research. The investigator performs the test together with the participant. The maximal score is 30 point. A score of 23 or lower indicate a cognitive impairment.

Health Questionnaire of ETHZ (HQ)

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

5.4 Participants

5.4.1 Exact number of participants

For the usability study, it is planned to include 15-20 subjects in each country. The main goal of this trial is to evaluate the feasibility and usability of the newly developed exergame for fall prevention in older adults. It represents a phase II study in preparation for a following large randomized controlled pilot-trial (phase III study). Therefore, the aim of this study is also to acquire information on the estimate of the treatment effect (efficacy) and the estimate of the variance of the treatment effect and provide basis for calculating sample size of phase III trial.

5.4.2 Inclusion and exclusion criteria

Criteria for inclusion

The study is designed for independently living elderly people aged 65 or older. They must be healthy (self-reported) apart from the normal age-related troubles and without cognitive impairment. Participants have to be able to stand unsupported on their feet for at least 10-15 minutes.

In summary, participants fulfilling all of the following inclusion criteria are eligible for the study:

- Age >65 years
- Live independently or in a residency dwelling
- Healthy (self-reported)
- Able to stand unsupported on feet for at least 10-15 minutes (self-reported)

Criteria for exclusion

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

- Mobility impairments (that avoid to stand unsupported on feet for at least 10-15 minutes)
- Cognitive impairments (MMSE ≤ 23)
- Severe health problems (e.g. recent cardiac infarction, uncontrolled diabetes or uncontrolled hypertension)
- Orthopaedic or neurological diseases that inhibit training participation
- Alzheimer disease or another dementia
- Acute severe illness
- 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 [89]. 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 [89]. 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

Participants will be recruited in the cities of Zurich, Utrecht and Porto and city surroundings 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. Randomized Controlled Pilot-Trial

6.1 Objectives

6.1.1 Primary Objective

The main goal is to assess the effects of the Active@Home exergame on physical and cognitive functions compared to usual care in elderly. Motor and cognitive tests will be used pre- and post-intervention to estimate the efficacy of the newly developed exergame.

6.1.2 Secondary Objective (only in CH)

To understand underlying mechanisms, the secondary goal is to assess the effects of the Active@Home exergame on neuronal level. To evaluate changes in brain structure (cortical thickness or volume of especially frontal areas and the hippocampus), a structural MRI scan will be conducted pre- and postintervention.

6.2 Trial Design and Intervention

The planned trial is a phase III study according to Campbell et al. [32] to evaluate the efficacy of a newly developed multicomponent exergame for fall prevention including a total of 48 training sessions (three training sessions per week over 16 - 18 weeks) with the Active@Home exergame. In each involved county (CH, NL, P), a total of 40 participants (healthy, independently living older adults 65+) will be recruited and randomly assigned into training and control group.

All participants attend a first appointment at T1 performing a screening assessment and first measurements (pre-measurements). The screening includes assessments about personal information, general health and cognition state especially: gender, age, height, weight, current level of physical activity, hearing, vision, chronic disease, illnesses and injuries, cognitive screening. Before and after intervention, at T1 and T2, physical and cognitive assessments will be performed (pre- and post-measurements). Pre- and post-measurements include both: Gait analysis, motor and cognitive functions tests (see figure 5).

For the training group, after screening and pre-measurements, the training intervention starts (3x per week, in total 48 sessions in 16 - 18 weeks). Every training session lasts around 40 minutes and includes all three training components (15 minutes strength training with Tai Chi, 15 minutes balance training with dancing, 10 minutes cognitive-motor games). Interruptions of the training period are allowed (not more than two weeks) if not otherwise possible. The trainings will take place at participants' homes. Each participant will be equipped with a complete Active@Home training system (four movement sensors, charging station for the sensors, HDMI dongle). The installation and setup of the system will be well explained and practiced with the participants in an introduction session (combined with pre-measurements or separately). During the in-home training period, participants will be called weekly to check if there are any problems and to provide support and further help and information.

For the control group, there is the instruction to go on with usual daily business and activities (usual care, no specially instructed activities). All participants (in the intervention and in the control group) have to fill in an activity protocol during the whole study period.

After completing all training sessions (in the intervention group), post-measurements are conducted at T2 with all participants. Measurements take place in a room/lab of the research partner. Furthermore, in Switzerland, before and after the intervention, MRI scans are conducted. It has to be stated that after the study period, the participants of the control group get the Active@Home exergame for their personal use at home. They can train with the system as often as they want. There will be no more measurements in this period. The whole procedure is illustrated in figure 5.

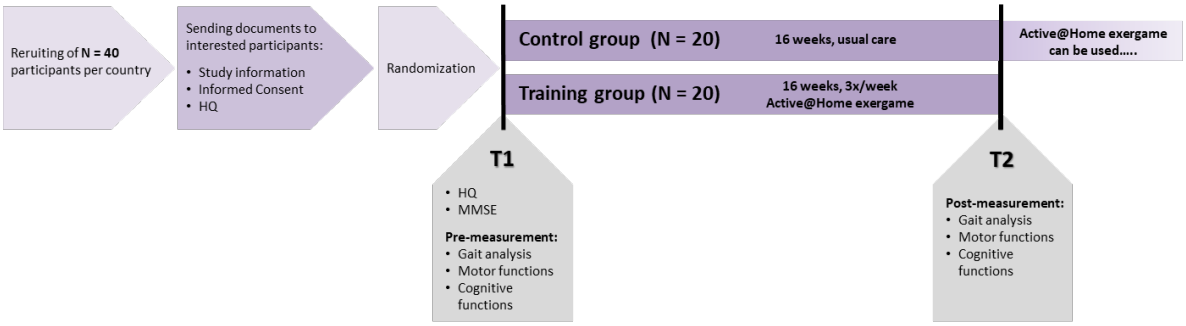

Figure 5. Flow chart of trial design with intervention and measurements. HQ = Health Questionnaire, MMSE = Mini Mental State Examination.

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)
- Data transfer to CH/ETHZ where final data processing and analysis takes place

6.3 Outcomes

6.3.1 Primary Outcomes

In table 6, 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 6. Primary outcome measures of this study and their assessments.

Outcome	Assessed by
Temporal-spatial gait parameters	Gait analysis under two conditions (single- and dual-task)
Lower extremity function	Short Physical Performance Battery (SPPB): Extended Balance Test Senior Fitness Test (SFT): 30-Second Chair Stand Test, 2-Minute Step Test
Cognitive functions	Trail Making Test (TMT A and B) Wechsler Memory Scale-Revised (WMS-R): Digit Span Tasks Victoria Stroop Test (VST)

Gait analysis

Temporal (time) and spatial (distance) gait parameters, especially speed (cm/s), cadence (steps/min), stride length (cm), stride time (s) and toe clearance (cm), are measured with the Physilog® (Gait up Sàrl, Lausanne, Switzerland) via wearable movement sensors. The sensors are fixed with elastic straps at the forefoots of the participants for flat over ground gait analysis. A button on the sensors allows the start and stop of measurement. Physilog® provides objective and quantitative assessment of movement performance. The validity of the Physilog® has been well established [51-53]. Similar to König et al. [54], we use a 8-walk protocol with at least 50 gait cycles (five repetitions of walking a "figure 8" with a distance of about 7m between turns) which has been shown to be a reliable measure of all relevant gait parameters. Subjects perform a single-task and a dual-task condition with preferred walking speed. In the dual-task condition, a second 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 [55-57]. 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 [58].

Short Physical Performance Battery (SPPB): Extended Balance Test

The effects of the intervention also need to be interpreted in terms of standardized clinical measures, as those are the most useful for health coaches/therapists. Therefore, the balance test of the SPPB should be included to assess static balance. Balance also known as postural control

can be defined statically as the ability to maintain a base of support with minimal movement, and dynamically as the ability to perform a task while maintaining a stable position. The SPPB, described in detail by Guralnik et al. [59, 60], was developed by the National Institute of Aging to measure especially lower extremity functioning by using tasks that mimic daily activities. It's an objective, valid and reliable assessment instrument. The Balance test of the SPPB consists of the following tasks: 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. With scores ranging from 0 (not able to complete the tasks) to 4 (good function), the performance can be categorized [60]. To avoid ceiling effects, the standard SPPB balance test will be extended with two additional levels of difficulty according to previous studies [13, 61]: The first additional level includes a 20s single-leg stance. One point is added to the SPPB balance test score when 10s are reached and another point when 20s are completed. For the second additional level, a single-leg stance with eyes closed is required to maintain for as long as possible. There are three trials of this last task whereas the highest value counts. One point is added to the balance score for every 5s the position is held.

Senior Fitness Test (SFT): 30-Second Chair Stand Test and 2-Minute Step Test

To evaluate the functional fitness performance of older adults, researchers at California State University, Fullerton, developed and validated a new fitness test battery; the SFT [67-70]. One unique feature of the SFT is that is measures physiological parameters (as muscle strength or endurance) using functional movement tasks.

30-Second Chair Test: To assess lower body strength, a subtest of the SFT is used in this study; the 30-Second Chair Stand Test. Participants have to sit down on a chair and get up again as fast as they can during 30 seconds with their arms folded across the chest. The number of completed full stands is counted. If the participant has to use his arms, the score is 0. The risk zone is defined as "less than 8 unassisted stands for men and women". Furthermore, there are age-grouped normative scores for older adults from 60 to 94 [69].

2-Minute Step Test: To assess aerobic endurance, another subtest of the SFT is used in this study; the 2-Minute Step Test. Participants have to alternatingly raise their knees to a predefined point (midway between the patella/kneecap and iliac crest/top hip bone). The score is the number of times the right knee reaches the required height in two minutes. The risk zone is defined as "less than 65 steps for men and women". Furthermore, there are age-grouped normative scores for older adults from 60 to 94 [69].

Trail Making Test (TMT A and B)

The TMT is a widely used, reliable and valid neuropsychological test only requiring paper and pencil [72-75]. 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. 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 [74, 76].

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

The Digit Forward Task of the WMS-R measures the short-term attention span [77, 78]. Participants have to remember and repeat digits in the correct order, which were read to them loudly by the tester. The Digit Backward Task of the WMS-R is used to evaluate working memory which is another executive function [77]. 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 [76].

Victoria Stroop Test (VST)

The VST was developed as a brief version of the original Stroop tasks [79-81]. It's a widely used neuropsychological test to assess response inhibition and interference as part of executive functions. The VST involves control tasks, which require the participant to name colors of dots and no-color/neutral words. The interference task requires the participant to name the color of color words. The color words are printed in other colors (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 color-naming response. The interference effect is determined by calculating the extra time required to name colors in the interference task in comparison to the control tasks. Furthermore, we are interested in the number of errors made in the interference task.

6.3.2 Secondary Outcomes (only in CH)

In Switzerland, as secondary outcome, structural brain scans (MRI) will be conducted before and after training intervention to evaluate the efficacy of the newly developed exergame on a neuronal level. These neuronal changes are supposed to be the underlying mechanisms for the changes on a behavioral level (changes in motor and cognitive functions as primary outcomes). Analyses will focus on frontal brain structures and the hippocampus (cortical thickness, volume).

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	Assessed by
Cognitive state screening	Mini Mental State Examination (MMSE)
Health state screening	Health Questionnaire of ETHZ

Mini Mental State Examination (MMSE)

The MMSE is a simple and quick paper and pencil test to systematically assess mental status. It's an 11-question measure that tests several cognitive domains including orientation to time and place, learning and recall of three words, attention and calculation, language and visuoconstruction [82, 83]. Since its creation in 1975, the MMSE has been validated and extensively used in both clinical practice and research. The investigator performs the test together with the participant. The maximal score is 30 point. A score of 23 or lower indicate a cognitive impairment.

Health Questionnaire of ETHZ (HQ)

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

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. [32].

6.4.2 Inclusion and exclusion criteria

Criteria for inclusion

The study is designed for independently living elderly people aged 65 or older. They must be healthy (self-reported) apart from the normal age-related troubles and without cognitive impairment. Participants have to be able to stand unsupported on their feet for at least 10-15 minutes.

In summary, participants fulfilling all of the following inclusion criteria are eligible for the study:

- Age >65 years
- Live independently or in a residency dwelling
- Healthy (self-reported)
- Able to stand unsupported on feet for at least 10-15 minutes (self-reported)

Criteria for exclusion

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

- Mobility impairments (that avoid to stand unsupported on feet for at least 10-15 minutes)
- Cognitive impairments (MMSE ≤ 23)
- Severe health problems (e.g. recent cardiac infarction, uncontrolled diabetes or uncontrolled hypertension)
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- Alzheimer disease or another dementia
- Acute severe illness
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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 [89]. 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 [89]. 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

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References

1. Berg, W.P., et al., *Circumstances and consequences of falls in independent community-dwelling older adults.* Age and ageing, 1997. **26**(4): p. 261-268.
2. Hausdorff, J.M., et al., *Increased gait unsteadiness in community-dwelling elderly fallers.* Archives of Physical Medicine and Rehabilitation, 1997. **78**(3): p. 278-283.
3. Gill, T., A.W. Taylor, and A. Pengelly, *A population-based survey of factors relating to the prevalence of falls in older people.* Gerontology, 2005. **51**(5): p. 340-5.
4. Rubenstein, L.Z., *Falls in older people: epidemiology, risk factors and strategies for prevention.* Age and ageing, 2006. **35**(suppl 2): p. ii37-ii41.
5. Schoene, D., et al., *The effect of interactive cognitive-motor training in reducing fall risk in older people: a systematic review.* BMC geriatrics, 2014. **14**(1): p. 1.
6. Sherrington, C., et al., *Effective Exercise for the Prevention of Falls: A Systematic Review and Meta-Analysis.* Journal of the American Geriatrics Society, 2008. **56**(12): p. 2234-2243.
7. Skelton, D.A. and S.M. Dinan, *Exercise for falls management: Rationale for an exercise programme aimed at reducing postural instability.* Physiotherapy theory and practice, 1999. **15**(2): p. 105-120.
8. de Bruin, E. and A. Schmidt, *Walking behaviour of healthy elderly: attention should be paid.* Behavioral and Brain Functions, 2010. **6**.
9. Segev-Jacubovski, O., et al., *The interplay between gait, falls and cognition: can cognitive therapy reduce fall risk?* Expert Review of Neurotherapeutics, 2011. **11**(7): p. 1057-1075.
10. Yogev-Seligmann, G., J.M. Hausdorff, and N. Giladi, *The role of executive function and attention in gait.* Movement Disorders, 2008. **23**(3): p. 329-342.
11. Holtzer, R., et al., *Cognitive processes related to gait velocity: results from the Einstein Aging Study.* Neuropsychology, 2006. **20**(2): p. 215.
12. Mirelman, A., et al., *Executive function and falls in older adults: new findings from a five-year prospective study link fall risk to cognition.* PloS one, 2012. **7**(6): p. e40297.
13. Eggenberger, P., et al., *Multicomponent physical exercise with simultaneous cognitive training to enhance dual-task walking of older adults: a secondary analysis of a 6-month randomized controlled trial with 1-year follow-up.* Clinical Interventions in Aging, 2015. **10**: p. 1711-1732.
14. Pichierri, G., et al., *Cognitive and cognitive-motor interventions affecting physical functioning: A systematic review.* Bmc Geriatrics, 2011. **11**.
15. Bamidis, P., et al., *A review of physical and cognitive interventions in aging.* Neuroscience & Biobehavioral Reviews, 2014. **44**: p. 206-220.
16. de Bruin, E., et al., *Use of virtual reality technique for the training of motor control in the elderly Some theoretical considerations.* Zeitschrift Fur Gerontologie Und Geriatrie, 2010. **43**(4): p. 229-234.
17. Rizzo, A. and G.J. Kim, *A SWOT analysis of the field of virtual reality rehabilitation and therapy.* Presence-Teleoperators and Virtual Environments, 2005. **14**(2): p. 119-146.
18. Bamidis, P.D. *Building neuroscientific evidence and creating best practices for Active and Healthy Aging through ubiquitous exergaming and Living Labs*. in *2015 37th Annual International Conference of the IEEE Engineering in Medicine and Biology Society (EMBC)*. 2015. IEEE.
19. Konstantinidis, E.I., et al., *Design, implementation, and wide pilot deployment of fitForAll: an easy to use exergaming platform improving physical fitness and life quality of senior citizens.* IEEE journal of biomedical and health informatics, 2016. **20**(1): p. 189-200.

20. Smith, S.T. and D. Schoene, *The use of exercise-based videogames for training and rehabilitation of physical function in older adults: current practice and guidelines for future research.* Aging Health, 2012. **8**(3): p. 243-252.
21. Pirovano, M., et al., *Exergaming and rehabilitation: A methodology for the design of effective and safe therapeutic exergames.* Entertainment Computing, 2016. **14**: p. 55-65.
22. Nawaz, A., et al., *Usability and acceptability of balance exergames in older adults: A scoping review.* Health Informatics J, 2016. **22**(4): p. 911-931.
23. Hoffmann, K., et al., *Personalized Adaptive Control of Training Load in Cardio-Exergames--A Feasibility Study.* Games Health J, 2015. **4**(6): p. 470-9.
24. Uzor, S. and L. Baillie. *Investigating the long-term use of exergames in the home with elderly fallers*. in *Proceedings of the SIGCHI Conference on Human Factors in Computing Systems*. 2014. ACM.
25. Nyman, S.R. and C.R. Victor, *Older people's participation in and engagement with falls prevention interventions in community settings: an augment to the Cochrane systematic review.* Age Ageing, 2012. **41**(1): p. 16-23.
26. Thornton, M., et al., *Benefits of activity and virtual reality based balance exercise programmes for adults with traumatic brain injury: perceptions of participants and their caregivers.* Brain Inj, 2005. **19**(12): p. 989-1000.
27. Ijsselsteijn, W., et al. *Digital game design for elderly users*. in *Proceedings of the 2007 conference on Future Play*. 2007. ACM.
28. Gerling, K.M., J. Schild, and M. Masuch. *Exergame design for elderly users: the case study of SilverBalance*. in *Proceedings of the 7th International Conference on Advances in Computer Entertainment Technology*. 2010. ACM.
29. Laver, K., et al., *Is the Nintendo Wii Fit really acceptable to older people?: a discrete choice experiment.* BMC geriatrics, 2011. **11**(1): p. 1.
30. Eckert, J.K., L.A. Morgan, and N. Swamy, *Preferences for receipt of care among community-dwelling adults.* J Aging Soc Policy, 2004. **16**(2): p. 49-65.
31. Silveira, P., et al., *Motivating and assisting physical exercise in independently living older adults: A pilot study.* International Journal of Medical Informatics, 2013. **82**(5): p. 325-334.
32. Campbell, M., et al., *Framework for design and evaluation of complex interventions to improve health.* British Medical Journal, 2000. **321**(7262): p. 694-696.
33. Lancaster, G.A., S. Dodd, and P.R. Williamson, *Design and analysis of pilot studies: recommendations for good practice.* J Eval Clin Pract, 2004. **10**(2): p. 307-12.
34. Thabane, L., et al., *A tutorial on pilot studies: the what, why and how.* Bmc Medical Research Methodology, 2010. **10**.
35. Okubo, Y., D. Schoene, and S.R. Lord, *Step training improves reaction time, gait and balance and reduces falls in older people: a systematic review and meta-analysis.* British journal of sports medicine, 2016: p. bjsports-2015-095452.
36. Kattenstroth, J.-C., et al., *Six months of dance intervention enhances postural, sensorimotor, and cognitive performance in elderly without affecting cardio-respiratory functions.* Frontiers in aging neuroscience, 2013. **5**: p. 5.
37. Merom, D., et al., *Can social dancing prevent falls in older adults? a protocol of the Dance, Aging, Cognition, Economics (DAnCE) fall prevention randomised controlled trial.* BMC public health, 2013. **13**(1): p. 1.
38. Gajewski, P.D. and M. Falkenstein, *Physical activity and neurocognitive functioning in aging - a condensed updated review.* European Review of Aging and Physical Activity, 2016. **13**.
39. Healy, A.F., J.A. Kole, and L.E. Bourne Jr, *Training principles to advance expertise.* Psychological perspectives on expertise, 2007: p. 166.

40. Pichierri, G., et al., *The effect of a cognitive-motor intervention on voluntary step execution under single and dual task conditions in older adults: a randomized controlled pilot study*. Clinical Interventions in Aging, 2012. **7**: p. 175-184.
41. Pichierri, G., K. Murer, and E.D. de Bruin, *A cognitive-motor intervention using a dance video game to enhance foot placement accuracy and gait under dual task conditions in older adults: a randomized controlled trial*. Bmc Geriatrics, 2012. **12**.
42. Brooke, J., *SUS-A quick and dirty usability scale*. Usability evaluation in industry, 1996. **189**(194): p. 4-7.
43. Tullis, T., et al., *Measuring the User Experience: Collecting Analyzing, and Presenting Usability*. 2008.
44. Bangor, A., P. Kortum, and J. Miller, *Determining what individual SUS scores mean: Adding an adjective rating scale*. Journal of usability studies, 2009. **4**(3): p. 114-123.
45. de Bruin, E., et al., *Feasibility of strength-balance training extended with computer game dancing in older people; does it affect dual task costs of walking?* Journal of Novel Physiotherapies, 2012. **2011**.
46. Van Tulder, M., et al., *Updated method guidelines for systematic reviews in the Cochrane Collaboration Back Review Group*. Spine, 2003. **28**(12): p. 1290-1299.
47. IJsselsteijn, W., Y. De Kort, and K. Poels, *The game experience questionnaire: Development of a self-report measure to assess the psychological impact of digital games. manuscript in preparation*. 2013.
48. Poels, K., Y. De Kort, and W. Ijsselsteijn. *It is always a lot of fun!: exploring dimensions of digital game experience using focus group methodology*. in *Proceedings of the 2007 conference on Future Play*. 2007. ACM.
49. Nacke, L., *Affective ludology: Scientific measurement of user experience in interactive entertainment*. 2009, Blekinge Institute of Technology.
50. Proffitt, R. and B. Lange, *Feasibility of a Customized, In-Home, Game-Based Stroke Exercise Program Using the Microsoft Kinect(R) Sensor*. Int J Telerehabil, 2015. **7**(2): p. 23-34.
51. Aminian, K., et al., *Physical activity monitoring based on accelerometry: validation and comparison with video observation*. Medical & biological engineering & computing, 1999. **37**(3): p. 304-308.
52. Dubost, V., et al., *Relationships between dual-task related changes in stride velocity and stride time variability in healthy older adults*. Human movement science, 2006. **25**(3): p. 372-382.
53. de Bruin, E.D., et al., *Quantification of everyday motor function in a geriatric population*. J Rehabil Res Dev, 2007. **44**(3): p. 417-28.
54. König, N., et al., *Is gait variability reliable? An assessment of spatio-temporal parameters of gait variability during continuous overground walking*. Gait & posture, 2014. **39**(1): p. 615-617.
55. Abernethy, B., *Dual-task methodology and motor skills research: some applications and methodological constraints*. Journal of Human Movement Studies, 1988. **14**(3): p. 101-132.
56. Wright, D.L. and T.L. Kemp, *The dual-task methodology and assessing the attentional demands of ambulation with walking devices*. Physical Therapy, 1992. **72**(4): p. 306-312.
57. Wulf, G., N. McNevin, and C.H. Shea, *The automaticity of complex motor skill learning as a function of attentional focus*. The Quarterly Journal of Experimental Psychology: Section A, 2001. **54**(4): p. 1143-1154.
58. McDowd, J.M., *The effects of age and extended practice on divided attention performance*. Journal of Gerontology, 1986. **41**(6): p. 764-769.

59. Guralnik, J.M., et al., *Lower extremity function and subsequent disability: consistency across studies, predictive models, and value of gait speed alone compared with the short physical performance battery.* J Gerontol A Biol Sci Med Sci, 2000. **55**(4): p. M221-31.
60. Guralnik, J.M., et al., *A short physical performance battery assessing lower extremity function: association with self-reported disability and prediction of mortality and nursing home admission.* J Gerontol, 1994. **49**(2): p. M85-94.
61. Eggenberger, P., et al., *Exergame and Balance Training Modulate Prefrontal Brain Activity during Walking and Enhance Executive Function in Older Adults.* Frontiers in Aging Neuroscience, 2016. **8**.
62. Lee, D.-K., et al., *Relationships among the Y balance test, Berg Balance Scale, and lower limb strength in middle-aged and older females.* Brazilian Journal of Physical Therapy, 2015. **19**: p. 227-234.
63. Robinson, R.H. and P.A. Gribble, *Support for a Reduction in the Number of Trials Needed for the Star Excursion Balance Test.* Archives of Physical Medicine and Rehabilitation, 2008. **89**(2): p. 364-370.
64. Chimera, N.J., C.A. Smith, and M. Warren, *Injury history, sex, and performance on the functional movement screen and Y balance test.* Journal of athletic training, 2015. **50**(5): p. 475-485.
65. Shaffer, S., et al., *Y-Balance test: A reliability study involving novice raters.* journal of Orthopaedic & Sports Physical, 2011. **41**(1): p. A91-A92.
66. Plisky, P.J., et al., *The reliability of an instrumented device for measuring components of the star excursion balance test.* North American journal of sports physical therapy: NAJSPT, 2009. **4**(2): p. 92.
67. Jones, C.J. and R.E. Rikli, *Measuring functional.* The Journal on active aging, 2002. **1**: p. 24-30.
68. Rikli, R.E. and C.J. Jones, *Development and validation of a functional fitness test for community-residing older adults.* Journal of aging and physical activity, 1999. **7**(2): p. 129-161.
69. Rikli, R.E. and C.J. Jones, *Functional fitness normative scores for community-residing older adults, ages 60-94.* Journal of Aging and Physical Activity, 1999. **7**(2): p. 162-181.
70. Rikli, R.E. and C.J. Jones, *Development and validation of criterion-referenced clinically relevant fitness standards for maintaining physical independence in later years.* The Gerontologist, 2013. **53**(2): p. 255-267.
71. Zimmermann, P. and B. Fimm, *A test battery for attentional performance.* Applied neuropsychology of attention. Theory, diagnosis and rehabilitation, 2002: p. 110-151.
72. Lezak, M., D. Howieson, and D. Loring, *Neuropsychological assessment. 5th edn Oxford University Press.* Oxford, New York, ISBN, 2012. **10**: p. 9780195395525.
73. Bowie, C.R. and P.D. Harvey, *Administration and interpretation of the Trail Making Test.* Nature protocols, 2006. **1**(5): p. 2277-2281.
74. Tombaugh, T.N., *Trail Making Test A and B: normative data stratified by age and education.* Archives of clinical neuropsychology, 2004. **19**(2): p. 203-214.
75. Reitan, R.M., *Validity of the Trail Making Test as an indicator of organic brain damage.* Perceptual and motor skills, 1958. **8**(3): p. 271-276.
76. Peña-Casanova, J., et al., *Spanish Multicenter Normative Studies (NEURONORMA Project): norms for verbal span, visuospatial span, letter and number sequencing, trail making test, and symbol digit modalities test.* Archives of Clinical Neuropsychology, 2009. **24**(4): p. 321-341.
77. Wechsler, D., *Wechsler memory scale-revised (WMS-R)*. 1987: Psychological Corporation.
78. Hester, R.L., G.J. Kinsella, and B. Ong, *Effect of age on forward and backward span tasks.* Journal of the International Neuropsychological Society, 2004. **10**(4): p. 475-481.

79. Strauss, E., E. Sherman, and O. Spreen, *A Compendium of Neuropsychological Tests 3 edition New York*. 1991, NY: Oxford University Press.
80. Strauss, E., E.M. Sherman, and O. Spreen, *A compendium of neuropsychological tests: Administration, norms, and commentary*. 2006: American Chemical Society.
81. Troyer, A.K., L. Leach, and E. Strauss, *Aging and response inhibition: Normative data for the Victoria Stroop Test*. Aging, Neuropsychology, and Cognition, 2006. **13**(1): p. 20-35.
82. Folstein, M.F., S.E. Folstein, and P.R. McHugh, "*Mini-mental state*". *A practical method for grading the cognitive state of patients for the clinician*. J Psychiatr Res, 1975. **12**(3): p. 189-98.
83. Tombaugh, T.N. and N.J. McIntyre, *The mini-mental state examination: a comprehensive review*. J Am Geriatr Soc, 1992. **40**(9): p. 922-35.