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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: 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 the results of the studies performed in the Active@Home project. The first two studies have been feasibility and usability studies whereas the third study was a randomized controlled trial.

2. Feasibility Study I

2.1 Introduction

Age- and sedentary lifestyle-associated degenerative changes cause gait impairments and a higher fall risk in elderly [1]. Falling can lead to injuries, movement restrictions, loss of independence, social isolation, depression and a general decrease in well-being and quality of life [2]. Current numbers demonstrate that one out of three people aged 65 years and older fall annually and 20-30% of falls result in injury and hospitalization [2; 3; 4]. Considering the significant impact on the individual lives of the growing elderly population as well as on healthcare costs, a strong need exists to examine interventions that aim to prevent falls. To successfully prevent falls, causes and risk factors of falling must be targeted. It is well known that age-related declines in sensorimotor systems lead to muscle weakness, reduced muscle strength and increased balance problems and, therefore, to gait disturbances as well as a higher risk of falling [5; 6]. Exercise interventions, which aim to improve physical functions such as strength or balance training, have been shown to reduce fall rates and risks [7; 8; 9] .

Age-associated changes occur also on neuronal level. The aging brain exhibits structural changes in gray and white matter [10; 11; 12] and functional changes in cortical oscillatory activity patterns [13]. On a cellular level, physiological aging is characterized by a loss of synaptic contacts and an apoptosis of neurons which can lead to a decline of sensorimotor and cognitive functions [13]. Most human daily life activities, including walking, require physical and cognitive resources. Safe and stable walking, especially in a demanding environment, is based on intact continuous interactions of motor and cognitive functions [14; 15; 16; 17; 18]. With age-related changes affecting the whole system from brain to muscles, the performance of motor-cognitive activities is impaired which, in turn, is considered a main risk factor for falling in older adults [19; 20; 21]. Therefore, a combined motor-cognitive training is important for effective fall prevention [22; 23; 24] . Regular physical activity in older age effects gait stability, health status and general well-being [8; 25; 26]. However, in most existing training approaches for fall prevention, no explicit attention is paid to cognitive functions and the motor-cognitive interplay. A promising option for simultaneous training of motor and cognitive functions are interactive video game-based physical exercises or so called exergames [27].

Exergames are defined as “any types of video games that require the player to be physically active and move to play the game” [28]. Several studies demonstrated that exergames might have a high motivational potential by providing enjoyable gameplay and can be applied in diverse settings (e.g. home-based training) [29; 30]. Purpose developed exergames for public health and disease prevention are well advised to be designed according to end-users’ expectations and needs and to implement specific training principles [28]. Following a user-centered design approach, training motivation and adherence seem to increase and this, in turn, can enhance specific training effects [31; 32].

Active@Home, an international project of the Ambient Assisted Living Association (http://www.aal-europe.eu/projects/activehome/), developed an exergame prototype by incorporating theoretical background from human movement sciences, neuropsychology and arts of game design as well as considering older adults’ needs and requirements. The Active@Home exergame enables multicomponent training including strength, balance and cognitive training components. The exergame content focuses on the prevention of falls as well as on supporting and motivating older adults towards a more active lifestyle. Before conducting full-scale studies, however, the feasibility and usability of this newly developed intervention as well as its acceptance by end-users should be tested [33]. Especially for training interventions, a feasible and usable solution for the target population is mandatory for training conduction and improvements. Therefore, the primary aim of this pilot study was to determine the feasibility, usability, and user-experience of the Active@Home exergame intervention. The secondary aim was to explore whether this intervention can influence motor and/or cognitive functions as well as cortical oscillatory activity at rest.

2.2 Objectives

2.2.1 Primary Objective

The main goal was to determine the feasibility, usability, and user-experience of the newly developed Active@Home exergame prototype while using the system in a home-like laboratory setting.

2.2.2 Secondary Objective

The secondary goal was 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.

2.3 Methods

2.3.1 Study design and participants

Campbell and colleagues recommend an iterative phased approach starting with exploratory trials (phase II studies) before conducting definitive randomized controlled trials (phase III studies) [33]. This phase II pilot study used a single arm pre-post design. From March to May 2017, potential participants were recruited through public advertisements in local newspapers and from the pensioner community ETH Zurich (Switzerland). Assessments and intervention were performed at ETH Hönggerberg (Zurich, Switzerland). Measurements were conducted before (June 2017) and after (September 2017) the intervention period. In addition, a between-measurement consisting of two questionnaires was performed after the first week of training. Before the intervention period started, participants wore an activity monitoring device (StepWatch) for one week. The ETH Zurich Ethics Committee (Zurich, Switzerland) granted ethical approval (protocol number EK 2017-N-06). All participants were fully informed prior to participation and signed an informed consent form according to the Declaration of Helsinki before conducting any measurement.

The potential participants were screened using the Montreal Cognitive Assessment (MoCA) to assess cognitive status. Furthermore, the participants completed a health questionnaire including anthropometric data and questions about their health, medical history and physical activity level. Participants fulfilling all of the following inclusion criteria were eligible for the study: (1) age ≥ 65 years, (2) living independently, (3) healthy (self-reported), (4) able to walk at least 20m with or without walking aids. Participants exhibiting one of the following criteria were excluded from the study: (1) mobility impairments that prevent from training participation, (2) severe health problems (e.g. recent cardiac infarction, uncontrolled diabetes or uncontrolled hypertension), (3) orthopaedic disease that prevents from training participation, (4) neurological disease (e.g. history of stroke or epilepsy, Parkinson's disease), (5) Alzheimer disease or other forms of dementia, (6) acute severe, rapidly progressive or terminal illness, (7) cognitive impairments (MOCA < 26), (8) intake of any psychoactive substances (e.g. neuroleptics, antidepressants), (9) high alcohol, caffeine or nicotine consumption. The minimal intended study sample size of 20 participants was based on similar feasibility studies [34; 35].

2.3.2 Intervention

From June to September 2017, the participants performed three training sessions per week for seven weeks resulting in a maximum of 21 training sessions. The training sessions were scheduled individually from Monday to Friday with a guideline of no more than one training session per day. The 21 training sessions were distributed within a period of seven to nine weeks as a maximum of two weeks holiday interruption was allowed in between. Each session consisted of 40 minutes training with the newly developed Active@Home exergame prototype including Tai Chi training (20-30 minutes) and dance exercises (10 minutes). Tai Chi-like movements were used as this ancient Chinese physical activity is often performed in a semi-squat posture placing load on the lower limbs and core muscles [36; 37; 38]. These muscles are important for functional movements as walking [39; 40] and are positively influenced by Tai Chi training in the elderly [41]. To ensure optimal training effects, muscle loading recommendations for older adults were applied to the Tai Chi exercises (e.g. time under tension of 6s per repetition, a rest of 4s between repetitions, 7-9 repetitions per set, a rest of 60s between sets, a training volume of 2-3 sets per exercise) [42]. Additionally, dance exercises were included in the Active@Home exergame. Previous interventions focusing on the execution of correct, rapid, and well-directed steps resulted in improved balance and positive effects for fall prevention [43; 44;

45; 46]. Both, Tai Chi and dancing are "holistic" and task-oriented physical activities requiring motor functions, cognition and mental involvement [47; 48]. The exercises were accentuated with background music [49].

The exergame prototype implemented some basic training principles [50] as a feedback system with a real-time colour code for performance (red colour for bad performance, orange colour for moderate performance, green colour for good performance) and performance scores after e ach exercise. To ensure optimal challenge (optimal load of task demands) and increasing difficulty (progression), several difficulty levels for Tai Chi and dance exercises were developed. Progression was reached through more complex movements in the Tai Chi exercises (e.g. additional arm movements, upper body rotations, increased range of motion, longer time in unstable position) and through additional weights (e.g. filled water bottles), while faster and more complex motion sequences were performed in dance exercises. Training intensity was individually adapted to target a moderate to vigorous training level [51]. Intervention characteristics as duration and training intensity were based on recommendations for fall prevention in elderly [42; 51; 52; 53] and on studies showing positive training effects of exergame training in older adults [54].

The game story was about travelling around the world and to train in several different European cities. To demonstrate the exercises, a virtual instructor was used. The game interface was presented on a TV screen connected to a laptop running the exergame software. For movement evaluation, the participants wore four inertial measurement units (IMUs) providing both accelerometer and gyroscope assessments. The IMU were connected via Bluetooth to the laptop and attached to participants' wrists and ankles with Velcro straps. Figure 1 shows the training set up. Participants trained alone in a home-like environment (living lab) at ETH Hönggerberg (Zurich, Switzerland) wearing comfortable sports clothes and shoes. Two postgraduate students supported the participants and systematically observed them throughout the intervention. Furthermore, they ensured that the training principles of progression and optimal load were present [50; 55].

Figure 1. Set up of the Active@Home exergame training. Participants wore four sensors at wrists and ankles for movement evaluation. On the TV screen, a virtual coach presented the training exercise which had to be imitated by the participant.

2.3.3 Primary outcome measures

The primary outcome of feasibility, usability and game experience of the newly developed exergame prototype was evaluated with the help of a combination of quantitative and qualitative data . A mixed method approach was chosen similar to other studies which evaluated the usability of exergames [34]. Questionnaires were completed by participants after three training sessions (between-measurement) and after the intervention period (post-measurement).

Feasibility

Feasibility was assessed through adherence and attrition towards the training intervention. An attendance protocol, filled in by the supervisors after each training session, was used to record the number of visited training sessions. The adherence rate was calculated using the number of visited training sessions as percentage of the maximum possible training sessions [35; 56]. Reasons for non-adherence were, when given by the participants, recorded in the attendance protocol. A 70% attendance rate (15 visited out of the 21 total training sessions) was considered "being adherent" to the training program [56; 57]. For attrition, the number of participants lost during the trial was recorded (drop-outs) and calculated as a percentage of the total sample size. Considering the median rate for attrition in fall prevention interventions for clinical trials, a 10% attrition rate (two drop-outs) was regarded acceptable [57]. Drop-outs were not considered in the calculation of the adherence rate.

Usability

For usability assessment, the System Usability Scale (SUS) and a usability protocol were used [58]. The SUS includes 10 items rated on a 5-point Likert scale (0 = "strongly disagree" to 4 = "strongly agree") and is a scientifically validated and reliable strategy for evaluating subjective usability of newly developed devices and systems [58; 59]. The sum of all item scores was multiplied with 2.5 and led to the SUS score ranging from 0 to 100 [58]. Based on the verbal categorization rate of Bangor [60], we expected a SUS score ≥ 70 for an acceptable system. An additional question was added at the end of the SUS, asking participants about their general opinion of the Active@Home exergame. This question was also rated on a 5-point Likert scale (0 = "I don't like it" to 4 = "I like it a lot") and the mean was calculated over all participants.

The usability protocol was structured in several categories (functionality and interaction with the system, sensors, design, training principles, exercises, emotions) and was filled in by the supervisors observing the participants during their training sessions. Furthermore, the protocol included support requests and feedback from participants. The participants were requested to "think aloud" and mention all thoughts that came to their mind while using the training game [61]. The collected observations and statements were separated in positive and negative aspects.

Game experience

The Game Experience Questionnaire (GEQ) assessed several categories of subjective game experience (competence, immersion, flow, tension, challenge, negative affect, positive affect) [30; 62], and includes in total 42 items rated on a 5-point Likert scale (0 = "not at all" to 4 =

“extremely”). Competence implies feelings of being successful, strong or skilful in the game. Immersion includes the interest and pleasure of a player in the game. Flow summarizes the feelings of being deeply concentrated and absorbed, forgetting time and losing connection to the world outside the game. Tension includes feelings of annoyance, frustration and pressure. Challenge implies feelings of being stimulated and challenged. Negative affect summarizes feelings related to a bad mood and boredom, whereas positive affect includes feeling of happiness and enjoyment. The GEQ was analyzed by calculating the average rating for each of the seven categories [63]. Two categories involved only negative coded items (tension and negative affect). These two categories were reverse evaluated [62].

2.3.4 Secondary outcome measures

As secondary outcome, physical and cognitive functions as well as cortical oscillatory activity were measured before and after the intervention period (pre-measurement and post-measurement, respectively).

Physical functions

Parameters of gait kinematic were assessed using the Physilog IMU (Gait Up Sàrl, Lausanne, Switzerland), which has been shown to reliably measure gait performance [64]. The Physilog IMUs were fixed to the right and left forefoot of participants using elastic straps. A USB port allows data transfer to the computer for further data analysis. A walking protocol involving at least 50 gait cycles was used [65]. Participants walked a straight distance of 80m under two conditions: (1) single-task condition (ST): participants were instructed to walk at preferred normal speed without talking; (2) dual-task condition (DT): participants had to walk at preferred normal speed and simultaneously count backwards (cognitive task) in steps of seven from a randomly given number between 200 and 250. In this condition, participants were asked to perform both tasks concurrently and not to prioritise one task at the cost of the other. This is a common method to measure multitasking capabilities [22; 66]. Speed [m/s], cadence [steps/min], stride length [m], and minimal toe clearance [cm] were evaluated and expressed as mean values of both legs in the two walking conditions. For each parameter, the dual-task cost (DTC) of walking was calculated as a percentage of relative loss of the DT to the ST condition according to the formula : $(ST - DT)/ST \times 100$ [67].

To assess lower extremity functioning, the Short Physical Performance Battery (SPPB) was applied [68; 69]. A maximum of 12 points can be achieved where a low score is associated with a higher risk of falls [70]. The SPPB includes a balance test, a 4m-walk test and a 5-chair rises test (maximally 4 points for each subtests). In line with Eggenberger et al. [22], we extended the balance test with two additional tasks to avoid ceiling effects. The first additional task was a 20s single-leg stance (with preferred leg) where two points were achieved for reaching 20s, one point for 10-20s and zero points for < 10s. The second additional task was a single-leg stance with eyes closed (with preferred leg) where one point was assigned for every 5s . For the extended version of the SPPB, the maximum point score is unlimited. For the analysis, the total score of the extended SPPB was calculated as well as the score for each subtest (balance score, 4m-gait score, 5-chair rises score). For pre- and post-measurement comparison, time measures of the 4m-gait test and the 5-chair rises test were also evaluated.

Cognitive functions

Higher cognitive functions such as working memory, divided and selective attention, inhibition and mental flexibility were assessed using four tests of the computerized test battery Test for Attentional Performance (D-TAP 2.3 VL, PSYTEST, Psychologische Testsysteme, Herzogenrath, Germany). The TAP is a valid assessment of different attentional and executive functions [71]. The following tests were performed on a computer using two answer buttons: Working memory (difficulty level 3), Divided attention, GoNogo (1 out of 2), Set-shifting (alternating letters and numbers). Each test was preceded by a short familiarization session. Details about this protocol can be found elsewhere [71]. For each of the four tests, reaction times [ms] and number of errors and omissions were analysed.

Cortical activity

In order to assess cortical oscillatory activity, five minutes of resting state EEG was recorded at 500Hz sampling rate, using a 20-channels dry-electrodes cap (ENOBIO 20, Neuroelectrics, Barcelona, Spain) placed according to the international 10-20 system [72] and referenced using the Driven-Right-Leg (DRL) / Common Mode Sense (CMS) technique (two external electrodes placed on either side of the left earlobe with an ear-clip). Before electrode placement on the forehead and earlobe, the skin was cleaned with paste (H+H Medizinprodukte GbR, Münster, Germany). EEG data analysis was performed using custom scripts written in MATLAB R2017b (The Mathworks, Natick, Massachusetts, USA) and using the EEGLAB 14.1.0b open source toolbox [73]. EEG data was first high-pass filtered [zero-phase Hamming windowed sinc FIR, cut-off frequency (−6dB) 0.5Hz, passband edge 1Hz, transition bandwidth 1Hz, order 1651] and subsequently low-pass filtered [zero-phase Hamming windowed sinc FIR, cut-off frequency (−6dB) 45Hz, passband edge 40Hz, transition bandwidth 10Hz, order 167]. Further analysis was performed to seven parieto-occipital EEG electrodes (Pz, P3/4, P7/8 and O1/2) only, since this cortical area is widely used to detect individual alpha frequency (IAF) reliably [74; 75]. Channel rejection was performed using the automatic procedure supplied by the clean_rawdata EEGLAB extension by taking into account if the correlation of a channel to a reconstruction of it based on other channels, in a given time window, was less than 0.4 as well as if a channel was flat for more than five seconds. On average, ~95% of the parieto-occipital channels in the pre-measurement EEG recordings remained for further analysis (σ: ~10%; range: ~71-100%) and ~92% (σ: ~9%; range: ~71-100%) in the post-measurement EEG recordings. Noisy/artifactual data points were rejected if their amplitude was higher than ±75μV within a 500ms width time window as detected by the trimOutlier EEGLAB plugin. On average, ~6% of data was rejected in the pre-measurement EEG recordings (σ: ~9%; range: ~0-30%) and ~8% (σ: ~14%; range: ~0-48%) in the post-measurement EEG recordings. Afterwards, two IAF measures were estimated: peak alpha frequency (PAF) and center of gravity (CoG), by means of the restingIAF v1.0 open source package available from https://github.com/corcorana/restingIAF. This allowed a fully automatic and reliable strategy to determine IAF estimates during resting state EEG recordings, of which a more detailed and extensive description can be found in elsewhere [75;

76]. Briefly, one-sided channel-wise power spectral density (PSD) was first calculated in the 1-40Hz frequency range by the Welch's modified periodogram method, using a 2048 sample (~4s) Hamming window (50% overlap) across segments (frequency resolution = 0.244Hz) and normalized by dividing each PSD channel estimate (within the passband) by the mean spectral power. Then, each PSD estimate was smoothed using a Savitzky-Golay filter with frame length equals to 11 frequency bins and polynomial degree of five. From the smoothed PSD estimates, the first derivative was used to detect evident frequency peaks within the a priori defined alpha frequency band (7-13Hz), yielding to spectral peaks' boundaries from which IAF estimates can be computed. Using the first derivative to detect spectral peaks seemingly yields truly estimates compared to simply searching from maximal values within a predefined alpha frequency band [74]. Finally, IAF estimates were computed by averaging the obtained spectral peaks estimates across channels. The minimum number of valid channels necessary to estimate IAF was set to 1, given the relatively low-density parieto-occipital EEG channels used for this analysis. Additionally, spectral power within the alpha frequency band was calculated by averaging in each participant the PSD estimates of all the included channels, and then summing the obtained channels mean power across the alpha frequency band. Alpha spectral bandwidth was defined as the individual PAF ±2Hz.

2.3.5 Other outcome measures

The participants wore a StepWatch (Orthocare Innovations LLC, Edmonds, Washington, USA) for one week before the intervention period started to assess their daily physical activity behaviour. The StepWatch recorded every step and calculated the number of steps for each day. The mean of seven days was used as baseline characteristic. Before every training session, the participants rated their current training motivation on a Visual Analog Scale (1 = unmotivated lethargic smiley to 5 = motivated happy smiley). After each training session, the participants estimated their exertion on the Borg scale from 6-20 (6 = "less than very light", 20 = "more than very hard") for Tai Chi and dance exercises, respectively.

2.4 Results

A total of 21 participants signed informed consent and were included in the study. Nineteen participants completed the seven-week training intervention. Two participants prematurely terminated study participation because of family reasons and due to lack of motivation, respectively. The two male, 71 years old and highly educated drop-outs were comparable to the rest of the sample regarding their characteristics. Table 1 summarizes the demographic characteristics and screening measures of the remaining participants. The study flow chart is presented in Figure 2 .

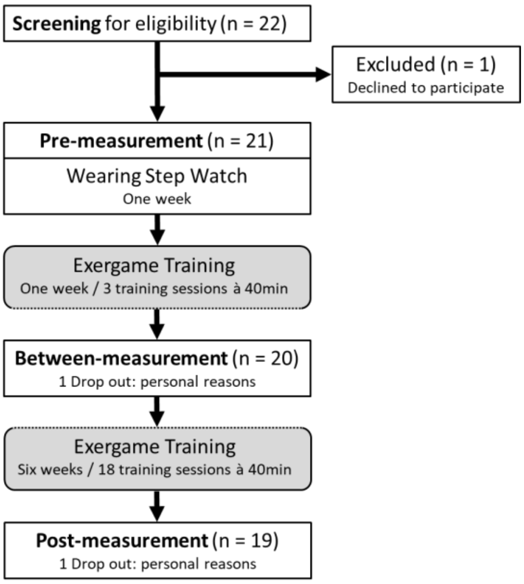

Figure 2. Study flow chart. Screening of participants for eligibility included an assessment of cognitive and health state. Physical and cognitive functions as well as brain activity were measured at pre- and post-measurement. Questionnaires assessing usability and game experience were filled in at between- and post-measurement.

Table 1. Demographic characteristics of participants and screeing values.

Participant characteristics	n = 19
Age in years	71.4 ± 6.1 (65 – 91)
Weight [kg]	69.7 ± 19.5 (42 – 122)
Height [cm]	169.9 ± 8.8 (150 – 181)
Daily physical activity+	7410 ± 2079 (4605 – 12247)
MOCA Score	28.1 ± 1.4 (26 – 30)
Female [n, %]	10 (52.6)
Education [n, %]	
Primary school	1 (5.3)
Upper school	0 (0.0)
Apprenticeship	9 (47.4)
Gymnasium	2 (10.5)
University	7 (36.8)
Fear of falling [n, %]	
Never	14 (73.7)
Sometimes	5 (26.3)
Often	0 (0.0)
Always	0 (0.0)
Number of falls during last month++ [n, %]	
Never	17 (89.5)
Once	2 (10.5)
More than once	0 (0.0)
Self-evaluation of health state [n, %]	
Very good	4 (21.1)
Good	14 (73.7)
Medium	1 (5.3)
Bad	0 (0.0)
Self-evaluation of balance [n, %]	
Very good	5 (26.3)
Good	8 (42.1)
Medium	6 (31.6)
Bad	0 (0.0)
Self-evaluation of muscle strength [n, %]	
Very good	0 (0.0)
Good	18 (94.7)
Medium	0 (0.0)
Bad	1 (5.3)

Data are mean values ± standard deviation (range) or number of participants per category (absolute and relative frequency) as indicated. MoCA = Montreal Cognitive Assessment. +Average steps per day measured with the StepWatch. ++Self-stated.

2.4.1 Primary outcome results: Feasibility, usability, and game experience

Participants completed on average 18 out of the 21 total training sessions, resulting in an adherence rate of 90.0%. Six participants reached the recommended training dose of three training sessions per week. Reasons for non-adherence were: holidays, being busy, family affairs. With two participants lost during the trial, the attrition rate amounted to 9.5%.

The scores of the SUS and GEQ measured after the three initial training sessions (between-measurement) and after the training period (post-measurement) are presented in Table 2. In the additional question which was added at the end of the SUS, asking participants about their general opinion of the Active@Home exergame, the mean score was 3.1 ± 0.7 (n = 20) at between-measurement and 3.0 ± 0.8 (n = 19) at post-measurement (on a scale from 0 = "I don't like it" to 4 = "I like it a lot"). Table 3 summarizes the main feedback of the participants and observations of the supervisors during the training.

Table 2. Primary outcome results of usability and game experience (quantitative measurements).

Primary outcomes	T2 (n = 20)	T3 (n = 19)	z	p	r
System Usability Scale (SUS)	75.0 (67.5; 87.5)	75.0 (70.0; 85.0)	0.240	.823	0.04
Game Experience Quesionnaire (GEQ)					
Competence	2.5 (2.2; 2.7)	2.3 (2.2; 3.0)	0.081	.945	0.01
Immersion	1.9 (1.5; 2.5)	2.3 (1.5; 2.7)	0.881	.395	0.14
Flow	1.3 (0.7; 1.8)	1.0 (0.7; 1.5)	1.281	.210	0.21
Tension	0.2 (0.0; 0.5)	0.2 (0.0; 0.3)	1.279	.229	0.21
Challenge	1.2 (1.0; 1.5)	1.2 (0.7; 1.5)	1.455	.157	0.24
Negative Affect	0.2 (0.0; 0.6)	0.5 (0.2; 0.8)	3.134	.001*	0.51
Positive Affect	2.8 (2.4; 3.2)	2.8 (2.0; 3.3)	0.569	.590	0.09

Data are median values (interquartile range). T2 = after three training sessions (between-measuement), T3 = after trainnig intervention (post-measurement). *p < .05, p-values are exact sig. two-tailed. T2-T3 differences were evaluated using Wilcoxon signed-rank test (n = 19). For effect size r, r = 0.10-0.24 indicates a small effect, r = 0.25-0.39 a medium effect and r = ≥ 0.40 indicates a large effect (Cohen, 1988). SUS scale ranges from 0 to 100. GEQ scale ranges from 0 = "not at all" to 4 = "extremly". Two categories of the GEQ (tension, negative affect) have to be evaluated reversely which means a low score is favorable.

2.4.2 Secondary outcome results: Effectiveness of the intervention

On group level, the gait speed under the dual-task walking condition increased significantly (z = -2.012, p = .045, r = 0.33) after the training intervention. In the 5-chair rises test of the SPPB, the time needed to perform five chair rises significantly decreased (z = -2.853, p = .003, r = 0.46) after exergame training. In the divided attention task of the TAP, participants reacted significantly faster (z = -2.495, p = .011, r = 0.40) to auditory stimuli after the training intervention. No significant changes in resting state EEG were found for the pre- and post-measurement comparison. The results are presented in Table 4.

2.4.3 Other outcome results

The participants' average daily physical activity resulted in 7410 steps per day (Table 1). Training motivation was on average rated with 4.5 ± 0.5 by participants (on a visual scale from 1 = unmotivated lethargic smiley to 5 = motivated happy smiley). The average rating of participants' exer tion for Tai Chi exercises was 10.7 ± 2.3 and for dance exercises 9.7 ± 2.0 on the 20-point Borg scale (6 = "less than very light" to 20 = "more than very hard").

Table 3. Primary outcome results of usability (qualitative measurement): Summary of usability protocol with observations and participants' feedback.

Criteria	Positive aspects	Negative aspects
Functionality and interaction with the system	– Good and stable connection of laptop (with system software) to TV – Simple set up – Easy usable game composition	– Technical issues (as system crashes or frozen pictures on the screen) – Unstable (Bluetooth) connection of sensors to the system – Navigation via laptop keyboard instead by sensors (as cursors) – Inaccurate evaluation of movements by sensors (evaluation algorithms)
Sensors	– Comfortable to wear (participants did not notice them)	– Suboptimal material of sensor cover (sensor cover expanded after heating up while charging) – Suboptimal material of sensor strap (difficult to clean the Velcro fixation, material sticks on some clothes) – Difficulties to attach the sensors with the Velcro fixation (especially at wrists)
Design	– Exciting game story of travelling around the world to different cities – Pleasant music – Helpful cues (arrows) to prepare the next movement – Virtual instructor guiding through exercises – Helpful indication of number of exercise repetitions	– No variation in music – No explanation about feedback system (colour code, performance points)
Training principles	– Visual feedback with colour code (green, orange, red) during exercising – Performance points as feedback after exercising	– No specific feedback regarding exercise execution and single body part movements – Training load and progression determined by supervisors (no automatic progression) – Low variability in exercises – Training load even in high levels not exhausting
Exercises	– Clear structure of exercise levels – Complex exercises with additional arm movements provide more fun than simple (boring) movements	– No proper introduction of exercises (just start copying the movements of the virtual coach) – Only frontal view of exercises (side view missing) – No further information about exercise (e.g. muscles involved)
Emotions	– General enjoyment and fun – Increased motivation through virtual coach (better than train alone) – Happy when seeing a progress or achieving more performance points	– Frustrated and displeased by technical issues and inaccurate evaluation of movements – Missing challenge in case of too easy exercises – Bored of low training variability

Table 4. Secondary outcome results.

Secondary Outcomes	Assessed by	Pre (T1)	Post (T3)	z	p	r
Physical functions	**Gait analysis with Physilog®**					
	Speed [m/s]					
	ST walking	1.42 (1.36; 1.61)	1.52 (1.36; 1.62)	0.684	.515	0.11
	DT walking	1.26 (1.17; 1.46)	1.31 (1.22; 1.51)	2.012	.045*	0.33
	DT costs in %	6.4 (5.1; 17.6)	8.4 (3.0; 18.2)	1.449	.156	0.24
	Cadence [steps/min]					
	ST walking	117.2 (114.6; 125.7)	120.7 (115.1; 126.1)	1.529	.134	0.25
	DT walking	111.7 (105.4; 116.9)	113.2 (109.5; 120.4)	1.690	.096	0.27
	DT costs in %	4.0 (1.8; 8.7)	3.5 (1.0; 9.0)	1.046	.312	0.17
	Stride length [m]					
	ST walking	1.48 (1.41; 1.56)	1.47 (1.41; 1.56)	0.402	.709	0.07
	DT walking	1.36 (1.28; 1.50)	1.36 (1.33; 1.49)	1.610	.113	0.26
	DT costs in %	3.8 (2.1; 10.3)	4.2 (0.0; 9.2)	1.006	.332	0.16
	Toe clearance min [cm]					
	ST walking	2.3 (2.1; 3.1)	2.9 (2.0; 3.4)	1.891	.060	0.31
	DT walking	2.2 (1.7; 2.7)	2.7 (1.6; 3.2)	1.248	.225	0.20
	DT costs in %	3.9 (-4.9; 16.6)	6.7 (-7.1; 19.3)	0.241	.829	0.04
	Extended Short Physical Performance Battery					
	Total score	14 (13; 15)	14 (13; 15)	0.266	.797	0.04
	Balance score	6 (6; 8)	7 (5; 7)	0.134	.947	0.02
	4m-gait score	4 (4; 4)	4 (4; 4)	0.000	1.000	<0.01
	4m-gait time [s]	3.3 (2.9; 3.7)	3.2 (2.8; 3.6)	1.449	.153	0.24
	5-chair rises score	4 (3; 4)	4 (3; 4)	0.816	.750	0.13
	5-chair rises time [s]	10.5 (8.3; 12.8)	8.8 (7.3; 12.3)	2.853	.003*	0.46
Cognitive functions	**Test of Attentional Performance**					
	Working memory					
	RT [ms]	741 (597; 843)	677 (603; 840)	0.348	.742	0.06
	Errors	3 (0; 6)	3 (1; 5)	0.416	.696	0.07
	Omissions	3 (2;4)	3 (1; 4)	1.719	.088	0.28
	Divided attention					
	RT auditory [ms]	652 (584; 769)	594 (580; 714)	2.495	.011*	0.40
	RT visual [ms]	893 (822; 948)	881 (834; 945)	0.080	.945	0.01
	Errors	1 (0; 3)	1 (0; 2)	0.641	.541	0.10
	Omissions	1 (0; 3)	1 (1; 2)	1.388	.190	0.23
	Selective attention (GoNogo)					
	RT [ms]	454 (397; 487)	468 (396; 504)	0.543	.602	0.09
	Errors	1 (0; 2)	0 (0; 2)	0.265	.848	0.04
	Omissions	0 (0; 0)	0 (0; 0)	1.890	.125	0.31
	Mental flexibility					
	RT [ms]	932 (798; 1124)	848 (786; 1018)	1.610	.113	0.26
	Errors	3 (1; 9)	3 (1; 4)	1.163	.258	0.19
Cortical activity	**Resting state EEG**					
	Peak alpha frequency [Hz]	9.3 (8.4; 9.9)	9.3 (8.7; 10.0)	1.274	.232	0.26
	Center of gravity [Hz]	9.2 (8.5; 9.7)	9.3 (8.4; 9.6)	1.013	.340	0.20
	Alpha spectral power [μV^2]	20.5 (16.1; 35.7)	27.0 (16.8; 46.9)	0.078	.970	0.02

Data are median values (interquartile range). n = 19. *p < .05, p-values are exact sig. two-tailed. Pre-post differences were evaluated using Wilcoxon signed-rank test. For effect size r, r = 0.10-0.24 indicates a small effect, r = 0.25-0.39 a medium effect and r = ≥ 0.40 indicates a large effect (Cohen, 1988). ST = single-task. DT = dual-task. RT = reaction time. DT costs are calculated as (ST – DT)/ST × 100.

2.5 Discussion

The primary goal of this study was to test the feasibility of the newly developed Active@Home exergame prototype in older end-users and to gain information about its usability for further development. Furthermore, potential training-related changes in physical and cognitive functioning were assessed. In summary, study results showed a generally feasible and usable exergame that resulted in measurable training improvements in some physical and cognitive functions.

2.5.1 Feasibility, usability, and game experience

The adherence rate of 90.0% found in this study indicates a good acceptance of the training system. An attrition rate of less than 10% (in this study 9.5%) can be considered acceptable. The reasons for non-adherence were not related to the training system itself. Only one participant prematurely terminated the training due to a lack of motivation. However, the general training motivation was rated high. High motivation is an important key factor for long-term exercising leading to and sustaining training benefits [79; 80]. Thus, we can conclude that the Active@Home exergame prototype was feasible and resulted in a high adherence and an expectable attrition. This result is in line with previous studies showing that exergames are feasible for older adults [56; 81]. Furthermore, adherence has been shown to be often higher in interventions using exergames compared to standard fall prevention exercises [35; 56; 82]. An explanation might be the entertaining and captivating character of exergames resulting in positive emotions [59; 62; 83]. Bamidis mentioned the importance of positive emotional experiences when using a system, as they might lead to higher motivation and therefore increased long-term compliance [84]. Our study results, referred to GEQ, showed medium to high ratings of positive emotions as feeling captivated and pleased as well as low ratings of negative emotions as feeling tensed and annoyed. The significant increase in negative affect from between- to post-measurement might be due to an accumulation of negative emotions related to technical issues. In sum, we can conclude that the Active@Home exergame provided mainly a positive emotional experience leading to high training motivation and high adherence.

With a SUS score of 75, a good and acceptable usability of the Active@Home exergame prototype was showed. One might conclude that the newly developed training system might be usable. However, some limitations were evident in the observations of supervisors and the feedback of participants during training sessions. Several technical issues occurred during training with the exergame prototype (e.g. system crashes or unstable connection to sensors). Considering that older adults' technical knowledge and experiences with new technologies are often restricted, a newly developed technology-based system has to work without any technical failures. An easy set-up, stable connections, flawless functionality and an intuitive interaction with the system are mandatory aspects especially when the system is expected to be deployed at older end-users' home. Otherwise, technological problems can lead to unintentional avoidance and disuse of a training system.

In order to maximize the benefits of a training, exercise interventions should implement some basic training principles including optimal feedback, progression and variability [50]. The observations and participants' statements showed that the feedback system integrated in the Active@Home exergame is, currently, not yet optimal. To facilitate learning and the acquisition of new skills and knowledge, optimal feedback is mandatory [85]. Negative feedback helps to correct errors while positive feedback satisfies and often increases motivation [85]. One reason for the dissatisfaction with the feedback system might be that the movement evaluation was slightly inaccurate and, thus, the evaluation algorithms of the sensors have to be improved. Another reason might be that the used feedback system was too superficial (e.g. evaluation of whole-body movements), while more specific and precise feedback was missing (e.g. feedback of upper/lower limbs movements separately). Nevertheless, participants could benefit from the real-time feedback while training and were proud and motivated when reaching high performance scores. Considering the training principles of optimal load and progression, the task demands have to be adapted to each participant's skill level achieving a challenging situation and avoiding an under- or overload. For the Active@Home exergame, however, some participants stated that the training was not challenging enough. A reason might be that the exergame had to comply with a wide range of ability levels of older adults. Therefore, more difficult and complex exercises should be added to the exergame to satisfy also fitter older adults. Despite these limitations, participants reported high usability of the system set-up and a pleasant-to-wear sensation of the IMUs. Moreover, the participants generally enjoyed the game story of travelling around Europe, the music during the exercises and the guidance of the virtual instructor. Comparing to existing literature, exergames in general have been shown to be well accepted and usable for healthy older adults [28; 34; 59]. The importance of an age-appropriate design and flawless technical functionality were emphasized to be crucial for the usability of exergames [59; 86; 87].

To summarize, this study showed an acceptable usability of the Active@Home exergame prototype with several points to improve: technical aspects, movement evaluation and implementation of training principles. After this first evaluation of the newly developed exergame prototype in a monitored and supervised environment, the findings warrant an extended trial testing the feasibility and usability of the adjusted Active@Home exergame in an in-home setting.

2.5.2 Effectiveness of the intervention

Our study showed significant improvement of dual-task walking speed after exergame training, which is in line with several other studies [66; 81; 88]. In the Active@Home exergame, dual-task abilities are trained, which are important in daily life activities and for fall prevention in older adults [89]. Furthermore, our study resulted in a significant increase of lower limbs muscle power. This improvement might be due to the Tai Chi-based exercises. These exercises were mainly performed in squat position placing load on the lower limb and core muscles [36; 37; 38]. Despite of this positive result, the training guidelines considered for strength training turned out to be unsuitable [42]: The required intensity of 70-79% of 1RM (one repetition maximum) could not be reached using mainly body weight-based exercises. Furthermore, the breaks in between Tai Chi exercises, composed for very large exercise efforts, were too long. Consequently, the participants' subjective rating of perceived exertion for Tai Chi training was on average on a low rate (10.7 ± 2.3). The optimal zone for strength training corresponds to Borg scale ratings of 15-17 on the 20-point scale. The suboptimal training load and the rather short training period of seven weeks might have restricted the training impact on additional physical outcomes. We, therefore, recommend to increase exercise complexity and intensity and extend the training period.

In the computer-based cognitive tests, results showed a significant improved reaction time for auditory stimuli in a divided attention task. Surprisingly, the reaction time to visual stimuli did not improve. This might be due to the fact that especially for dance exercises listening to auditory information (music, rhythms) was important. These findings are similar to the results of a recent exergame study in older adults [66]. Furthermore, several studies including a simultaneous motor-cognitive training provided indications that this training approach boosts particular executive functions as mental flexibility, inhibition, or working memory [81; 90; 91; 92]. Executive functions are higher order cognitive functions playing an important role in planning of actions and guiding through everyday life. The absence of improvements in executive functions might be due to the fact that the cognitive training itself was not specific enough or too short. For exercise to have effects on cognitive functions, a dose of at least 52 hours of training is required for a measurable response [93].

For older adults, a variety of studies reported age-related changes in cortical oscillatory activity [94]. Most of these studies showed a general "slowing" of the resting state EEG with a power increase in the slow frequency ranges (< 7Hz) and a power decrease in higher frequencies (e.g. alpha power frequency band: ~7-13Hz) especially in posterior brain regions [13; 95]. Accordingly, the individual alpha frequency peak is known to decrease in the later part of lifespan [94]. Furthermore, alpha power is considered to be positively correlated to global cognitive status in healthy and impaired older adults [94; 96; 97; 98]. The pathological processes on neuronal level during aging leading to altered EEG power are presumed to be counteracted with physical and cognitive training [95]. However, we found no significant changes in resting state EEG after exergame training in our study which might be also due to the short intervention period.

2.5.3 Implications

Based on the encouraging feasibility and usability results of this study, several suggestions can be provided to support the development and improvement of fall preventive exergame training approaches for independently living older adults:

- A mature concept should be composed including game design, technology and training aspects.
- The system set-up should be simple and age-appropriate (e.g. regarding technological devices, screen size, game design, in-program navigation).
- Technical issues (e.g. systems crashes or unstable connections) must be fixed.
- If technological devices as IMUs are attached to players' bodies, material and fixation must be optimized, user-friendly, comfortable and size-adjustable.
- Easy applicable charging solutions should be used for technological devices as the IMUs.
- Players should be sufficiently informed about the game story, goals, evaluation and feedback system.
- Exercises have to be well explained and instructed before and during their execution (e.g. exercise tutorial with frontal and side view, further information about exercise goals, cues during execution, and time indications).

- Including music in exergames might be important and motivating provided that the music is appropriate and fits the game story, training content and movements.
- Performance feedback has to be accurate, easy to understand and as detailed as possible, since feedback is one of the most important motivational factors and necessary for training benefits.
- Games and exercises should be challenging for a wide range of player prerequisites.
- Automatic configuration of optimal training load and progression is desirable.
- A high variability in games and exercise options is needed.
- For fall prevention, stimulation of specific cognitive functions (attentional and executive functions) has to be considered besides strength and balance training.

2.5.4 Conclusion

To summarize, aging is one of the major global demographic trends which will be intensified during the next decades. Aging is strongly associated with motor and cognitive impairments and thus a higher risk of falling. Therefore, in the area of public health and disease prevention, a strong need exists for implementing effective evidence-based interventions for healthy aging including fall prevention. For this purpose, a video game-based physical exercise training was developed. Our study results showed a generally high feasibility and usability of the newly developed Active@Home exergame providing a positive emotional game experience. The results of this study led us to a solid basis for important suggestions for continued exergame development and other technology-based training systems for older adults. Implications include elimination of technical issues as well as ensuring a simple system set-up, accurate feedback and challenging and diverse exercises for a wide range of skill levels. Although the Active@Home exergame used in this study was limited in several aspects due to being a prototype version, we found significant improvements in muscle strength, in dual-task gait speed and in reaction time in a divided attention task. Therefore, this study indicates that this video game-based multicomponent training might enhance physical and cognitive functions. The study results warrant the further development of the Active@Home exergame and may help other researchers in the design process of exergame interventions for older adults.

3. Feasibility Study II

3.1 Introduction

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 above was about 9% of the worldwide population in 2015 and will more than double to 22% by 2050 [1]. Considering the rapid growth in the elderly population, the maintenance and improvement of health and independence of older adults is important for social, economic and political reasons. A major focus is to prevent problems that cause health restrictions and morbidity, e.g. fall events [2; 3]. 30 to 40% of the 65 years and above older adults fall once per year with a higher incidence with increasing age [2; 4; 5; 6; 7; 8; 9] . Falling can lead to serious adverse consequences as injuries, movement restrictions, and part to full loss of independence [10; 11]. In addition to the physical consequences, falls can also lead to fear of falling resulting in further activity restriction, social isolation, feelings of helplessness, depression, and a general decrease in well-being [3; 10; 12]. Considering the significant impact on individual lives and on healthcare costs, a strong need exists to develop and examine interventions that aim to prevent falls in older adults.

In order to successfully prevent falls, risk factors of falling have to be identified. Age- and behaviour-associated degenerative changes in motor and sensory systems are linked to gait impairments and a higher fall risk in elderly [13]. The often described decline in muscle strength and loss of balance are discussed as potential risk factors for gait disturbances and falling [4; 14]. Exercise interventions aiming to improve physical functions, such as strength or balance, have been shown to reduce fall rates and risks in older adults [15; 16; 17; 18; 19]. However, walking, as most daily life activities, requires physical and cognitive resources [20; 21; 22; 23; 24]. A continuous interaction of motor and cognitive functions is mandatory for safe gait and intact daily life functioning in general [25; 26; 27]. Therefore, more recently increased attention is paid to cognition as a further aspect of fall prevention programs. The aging brain undergoes several structural and functional changes which can lead to a decline in cognitive functions [28; 29; 30; 31]. The reduced cognitive resources might contribute to fall events due to an impaired motor-cognitive interplay. Thus, a combined motor-cognitive training is important for effective and holistic fall prevention [32; 33; 34]. Promising options for simultaneous training of motor and cognitive functions are video game-based physical exercises, or so-called exergames [35].

The term exergaming is a portmanteau composed of "exercise" and "gaming" and is defined as "any type of video game play requiring players' whole body movements" [36]. More recently, exergames have gained increasing popularity in fall prevention [37; 38]. This might be related to the technological development but also to the multifaceted potential of exergames. Poor adherence is described for numerous existing conventional exercise interventions for fall prevention [39]. Such barriers, that hinder physical activity and exercise intervention attendance, can be related to personal (behavioural) factors such as motivation, personal beliefs, lack of time or feeling uncomfortable in social settings (e.g. in training classes) [40; 41; 42; 43]. Furthermore, environmental factors including distance to an exercise facility, poor access to transportation options and costs may as well lead to low(er) exercise compliance [40; 41; 42; 43]. Many of these barriers may be counteracted by exergames as they provide enjoyable and, therefore, motivating gameplay [44; 45]. Furthermore, exergames can be applied in diverse settings. For example, the application in an in-home setting facilitates access without obstructions. Moreover, exergames can be adapted to specific purposes and target populations which might be important when using interventions for public health and disease prevention. To summarize, advantages of exergames compared to conventional exercises are: (1) Exergames can imply simultaneous training of motor and cognitive functions [37]. (2) Users get motivated through an engaging and interactive training [39]. (3) Training principles (e.g. feedback, progression, task variability) can be implemented in the exergame structure [46; 47]. (4) Exergame training can be conducted in diverse settings, e.g. at home. Recent studies have shown high acceptability of home-based exergame training for older adults after a mild injury and for elderly living in a nursing home [48; 49] Thus, developing an exergame for an in-home fall prevention solution might be a promising strategy to overcome some of the barriers for training attendance in older adults.

Considering the theoretical background from human movement science and neuropsychology together with the art of game design, we developed the Active@Home exergame for fall prevention. Following a user-centred design approach, the needs and requirements of older adults as end-users have been incorporated [50]. The Active@Home exergame includes strength, balance, and cognitive training components focussing on the prevention of falls as well as on motivating older adults towards a more active lifestyle. A first pilot-study explored the feasibility and usability of the newly developed exergame prototype in a living lab setting where training sessions were closely supervised. The results showed high feasibility and usability of the exergame prototype and, furthermore, delivered some suggestions for improvements and adaptations in a next iterative development step. The information gathered in the first feasibility trial are, therefore, used to develop the exergame intervention for application at older adults' homes by following a framework for the design and evaluation of complex interventions [51]. Therefore, the primary aim of this study was to evaluate the feasibility, usability, and user-experience of the modified Active@Home exergame in an in-home setting and to gain information from end-users about the system. A secondary aim was to explore whether this intervention effects on motor and/or cognitive functions as well as on cortical oscillatory activity.

3.2 Objectives

3.2.1 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.

3.2.2 Secondary Objective

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.

3.3 Methods

3.3.1 Study design and participants

This study is an exploratory trial (phase II study according to Campbell and colleagues) using a single arm pre-post design [51]. Recruitment of participants was conducted in March 2018 through public advertisements in a local newspaper (Höngger Zeitung, Zurich, Switzerland) and through contacting the pensioner community ETH Zurich (PVETH, Zurich, Switzerland). Assessments and the first half of the intervention were performed at ETH Hönggerberg (Zurich, Switzerland). The second half of the intervention took place at participants' home. The intervention period started in April 2018 and lasted until the beginning of June 2018. Measurements were conducted before and after the intervention. Ethical approval (protocol number EK 2018-N-07) was granted by the ETH Zurich Ethics Committee (Zurich, Switzerland). All participants were fully informed prior to participation and signed an informed consent form according to the Declaration of Helsinki before conducting any measurement.

For this trial, healthy and independent living older adults aged 65 years and above were recruited. To evaluate the eligibility of the potential participants, they were screened using the Mini Mental State Examination (MMSE) to assess cognitive status. In addition, the participants completed a health questionnaire including anthropometric data and questions about their health, medical history and physical activity level. Participants fulfilling all of the following inclusion criteria were eligible for the study: (1) age ≥ 65 years, (2) living independently, (3) healthy (self-reported), (4) able to stand at least for 10 minutes without assistance, (5) access to a TV with HDMI connection. Participants exhibiting one of the following criteria were excluded from the study: (1) mobility impairments that prevent from training participation, (2) severe health problems (e.g. recent cardiac infarction, uncontrolled diabetes or uncontrolled hypertension), (3) orthopaedic disease that prevents from training participation, (4) neurological disease (e.g. history of stroke or epilepsy, Parkinson's disease), (5) Alzheimer disease or other forms of dementia, (6) acute severe, rapidly progressive or terminal illness, (7) cognitive impairments (MMSE ≤ 23 points), (8) intake of any psychoactive substances (e.g. neuroleptics, antidepressants), (9) high alcohol, caffeine or nicotine consumption. The minimal intended study sample size of 20 participants starting with the training program was based on similar feasibility studies [52; 53], the "rule of 12" for continuous variables [54] and the expected compliance with the intervention [55].

3.3.2 Intervention (with the Active@Home exergame)

The Active@Home exergame consisted of four inertial measurement units (IMUs) providing both accelerometer and gyroscope assessments. For movement evaluation, participants wore the IMUs at wrists and ankles attached with a silicone slap band. The IMUs were connected via Bluetooth to a HDMI dongle that was inserted into a television (TV) and ran the game software. The game interface was presented on the TV screen. The story of the exergame was about travelling in Europe and to train in several different cities (London, Paris, Amsterdam, Rome, Porto, and Zurich). Exercises were instructed by a cartoon-based avatar and were accentuated with background music [56]. The training content of the Active@Home exergame was based on current recommendations for exercises to prevent falls in older adults [34; 57; 58; 59; 60; 61]. The exergame included Tai Chi-based, dance and, motor-cognitive exercises to train strength, balance, and cognition, respectively. Tai Chi-based training has been discussed as a suitable exercise for fall prevention [62; 63]. Tai Chi is a functional training involving bilateral and multidirectional movements [64], requiring whole body coordination [65], and improving strength of lower extremity muscles; e.g. m. iliopsoas, m. quadriceps femoris and m. tibialis anterior [66]. In the Active@Home exergame, several (four to five) Tai Chi levels were implemented in each city with increasing difficulty. Each level consisted of three practice sessions with ten exercise repetitions per session and a 20 seconds break between each session. This resulted in a duration of 2-3 minutes for each Tai Chi level. During the 20 seconds recovery break between sessions, participants were asked questions about the city in which they were exercising to entertain the participants. The initial positions of the Tai Chi-based exercises included squats, plies, lunges and single-leg stances. Furthermore, the Active@Home exergame contained dance exercises based on several different dancing styles (Bachata, Salsa, Cha-Cha-Cha, Waltz, Jive, and Disco Fox). Conducting rapid and well-directed steps has been shown to be an effective training for fall prevention [67; 68; 69; 70]. In each city of the exergame, one dancing style was trained in three levels of difficulty. Each dance level lasted around three minutes. Additionally, specific motor-cognitive exercises were included in the Active@Home exergame focussing on cognitive functions such as selective attention, divided attention, mental flexibility, inhibition/interference control, and working memory. Deficits in these cognitive functions contribute to gait disturbances and falls [71]. Each city of the exergame included three different motor-cognitive games, each game lasting between 1-2 minutes. Moreover, the exergame implemented some basic training principles (feedback, optimal load, progression, variability) which are important for effective training and for reaching the training goal of improvements in functioning [46]. A feedback system was included with a real-time colour code for achieved performance (red colour = "bad performance"; orange colour = "moderate performance"; green colour = "good performance") and performance scores during and after each exercise. In the motor-cognitive games, the visual feedback system described above was augmented with an auditory feedback system providing sounds to indicate the correctness of the answer. To ensure optimal load and progression, several difficulty levels for Tai Chi and dance exercises were developed. Progression was reached through more complex movements in the Tai Chi exercises (e.g. additional arm movements, upper body rotations, increased range of motion, longer time in unstable position) and through additional weights (e.g. filled water bottles), while faster and more complex motion sequences were performed in dance exercises. To increase difficulty in the motor-cognitive training, more complex games were used requiring e.g. faster reaction times or memorization of more information. Training variability was guaranteed through a high diversity of exercises in the different cities of the exergame.

From April to June 2018, each participant performed 24 training sessions in eight to ten weeks (a maximum of two weeks holiday interruption was allowed). Each week, three training sessions were performed, which were scheduled individually from Monday to Friday with a guideline of no more than one training session per day. Participants trained three to four weeks in a home-like setting (living lab) at ETH Hönggerberg (Zurich, Switzerland) and four to five weeks at their home. The differences in the number of training weeks at the two training locations (living lab, home) resulted from technical problems with the system leading to a delay of the training at home. The training sessions in the living lab were supervised by two postgraduate students supporting the participants if needed and systematically observing them while using and training with the exergame. During the intervention period at home, participants were called weekly to provide help when needed. Each session consisted of 40 minutes training with the Active@Home exergame including 15 minutes of Tai Chi-based training (four levels), 15 minutes of dance exercises (four levels), and 10 minutes of playing motor-cognitive games (six to eight games). It was recommended to play through all levels of one city before switching to the next city. Additionally, one level should be trained at least in two sessions before changing the level. The current difficulty level should always provide an optimal challenge avoiding under- or overload. The training intensity was thereby individually adapted to target a moderate training intensity level [72]. Intervention characteristics as frequency, duration, and training intensity were based on recommendations for fall prevention in elderly [60; 61; 73] and on studies showing positive training effects of exergame training in older adults [74].

3.3.3 Primary outcome measures

A mixed method approach in form of a combination of quantitative and qualitative data collection was used to evaluate the primary outcome of feasibility, usability, and game experience of the adapted Active@Home exergame [52]. Questionnaires were completed by participants after their last home training session of the intervention period (post-measurement).

Feasibility

Feasibility was assessed through adherence and attrition towards the training intervention. An attendance protocol was used to record the number of performed training sessions. During the intervention period in the “living lab”, the protocol was filled in by the supervisors after each training session, whereas participants were instructed to protocol the training sessions during the intervention period at home. Additionally, participants were called weekly by one of the supervisors to check the protocolling procedure and to provide help in case needed. The adherence rate was calculated using the number of performed training sessions as percentage of the maximum possible training sessions [53; 75]. Moreover, reasons for non-adherence were recorded. A 70% attendance rate (17 visited out of 24 total training sessions planned) was considered “being adherent” to the training program [55; 75]. The adherence rate was calculated for the two intervention periods (living lab, home) separately and in total. For attrition, the number of participants lost during the trial was recorded (drop-outs) and calculated as a percentage of the total sample size. Considering the median rate for attrition in fall prevention interventions for clinical trials, a 10% attrition rate (two drop-outs) was regarded acceptable [55]. Drop-outs were not considered in the calculation of the adherence rate.

Usability

For usability assessment, the System Usability Scale (SUS) and a usability protocol were used [76]. The SUS is a validated and reliable scale for evaluating subjective usability of newly developed devices and systems and includes 10 items rated on a 5-point Likert scale (0 = "strongly disagree" to 4 = "strongly agree") [76; 77]. The sum of all item scores was multiplied with 2.5 and led to the SUS score theoretically ranging between 0 and 100. Higher scores indicate better usability [76]. Based on the verbal categorization rate of Bangor [78], a SUS score ≥ 70 was expected for an "acceptable system". An additional question was added at the end of the SUS, asking participants about their general opinion of the Active@Home exergame. This question was also rated on a 5-point Likert scale (0 = "I don't like it" to 4 = "I like it a lot") and the mean was calculated over all participants.

The usability protocol was structured in several categories (functionality and interaction with the system, sensors, design, training principles, exercises, and emotions) and was filled in by the supervisors observing the participants during the intervention period in the "living lab". Furthermore, the protocol included requests for help and general feedback from participants. The participants were instructed to "think aloud" and mention all thoughts that came to their mind while using the exergame [79]. The collected observations and statements were separated in positive and negative aspects for each category.

Game experience

The Game Experience Questionnaire (GEQ) assesses several categories of subjective game experience (competence, immersion, flow, tension, challenge, negative affect, and positive affect) [45; 80]. The GEQ has been applied in several studies evaluating game experience of exergames for elderly [81; 82]. The GEQ core module, which was used in this study, includes in total 42 items rated on a 5-point Likert scale (0 = "not at all" to 4 = "extremely"). Competence implies feelings of being successful, strong or skilful in the game. Immersion includes the interest and pleasure of a player in the game. Flow summarizes the feelings of being deeply concentrated and absorbed, forgetting time, and losing connection to the world outside the game. Tension includes feelings of annoyance, frustration, and pressure. Challenge implies feelings of being stimulated and challenged. Negative affect summarizes feelings related to a bad mood and boredom, whereas positive affect includes feeling of happiness and enjoyment. The GEQ was analyzed by calculating the average rating for each of the seven categories [83]. Two categories involved only negative coded items (tension and negative affect) leading to reverse evaluation [80].

3.3.4 Secondary outcome measures

As secondary outcome, physical and cognitive functions as well as cortical oscillatory activity were measured before and after the intervention period (pre-measurement and post-measurement).

Physical functions

Parameters of gait kinematics (speed, cadence, stride length, and minimal toe clearance) were assessed using the Physilog5 IMU (Gait Up Sàrl, Lausanne, Switzerland), which has been shown to reliably and validly measure gait performance [84; 85; 86]. The Physilog5 IMUs were attached to the top of the right and left forefoot of participants using elastic straps. For further analysis, data was transferred to the computer via USB port. A walking protocol involving at least 50 gait cycles was applied [87]. Participants walked a straight distance of 80m under two conditions: (1) single-task condition (ST): participants were instructed to walk at preferred speed without talking; (2) dual-task condition (DT): participants had to walk at preferred speed and simultaneously count backwards (cognitive task) in steps of seven from a randomly given number between 200 and 250. In this condition, participants were asked to count out loud and perform both tasks concurrently and not to prioritise one task above the other. This is a common method to measure multitasking capabilities [32; 88]. Two walking steps for initiation and termination were discarded in order to analyse steady state walking [89]. Speed [m/s], cadence [steps/min], stride length [m], and minimal toe clearance [cm] were evaluated and expressed as mean values of both legs in the two walking conditions. For each parameter, the dual-task cost (DTC) of walking was calculated as a percentage of relative loss of the DT to the ST condition according to the formula: DTC [%] = (ST – DT)/ST × 100 [90].

To assess static balance, a subtest of the Short Physical Performance Battery (SPPB) was applied [91; 92]. The SPPB allows an objective and valid assessment of lower extremity functioning in elderly [91; 92]. The balance test of the SPPB includes the following tasks: standing in (1) feet side-by-side position, (2) semi-tandem stance, and (3) full-tandem stance. Each position should be held unsupported for 10 seconds. With a total score ranging from 0 (“not able to complete the tasks”) to 4 (“good balance function”), the performance can be evaluated. In line with previous studies [32; 93], we extended the balance test with two additional tasks to avoid ceiling effects. The first additional task was a 20 seconds single-leg stance (with preferred leg) where two points were achieved for reaching 20 seconds, one point for 10-20 seconds and zero points for < 10 seconds. The second additional task was a single-leg (with preferred leg) stance with eyes closed where one point was assigned for every five seconds of successful task achievement. Three trials were conducted for each additional task whereas the best trial counted. For the extended version of the subtest, the maximum point score is unlimited with higher scores meaning better balance functioning. The total score of the extended subtest was calculated for the analysis.

Dynamic balance was assessed with the Y-Balance Test™ (YBT, FunctionalMovement.com, Danville, Virginia, USA), a valid and reliable evaluation tool [94] often used in rather active populations [94; 95] and recently applied in several studies with older adults [96; 97; 98]. The testing kit consists of a stance platform to which three PVC bars are attached in the anterior, posteromedial, and posterolateral reach directions (the posterior bars are positioned at 135 degrees from the anterior bar with 45 degrees between both posterior bars). The participants were asked to push a target along the bars in every direction with one foot (barefoot), while standing on the other foot on the stance platform with hands on the pelvis. Thereby, the maximal reaching distance in every direction can be measured. When the personal limit was reached, participants had to return to the starting position. For familiarization, four practice trials were performed for each foot and direction. After a short break, three testing trials were accomplished using the following order: left anterior, right anterior, left posteromedial, right posteromedial, left posterolateral, and right posterolateral. Mean values of reaching distances were calculated over all testing trials for every direction and each foot. A testing trial was classified as invalid when participants (1) failed to maintain unilateral stance on the platform, (2) failed to maintain foot contact with the target while moving the target, (3) used the target for stance support, or (4) failed to return to the starting position. Invalid testing trials had to be repeated. For data analysis, the final score was calculated by taking the sum of the mean maximum reaching distances in each direction and for each foot (six values) divided by three times the sum of right and left lower limb length, and then multiplied by 100. With this calculation, the averaged maximal reaching distance was normalized to the limb length of both legs (anterior superior iliac spine to the most distal part of the medial malleolus) and expressed as percentage of limb length. Due to safety reasons, only participants who reached 20 seconds of single-leg stance in the extended version of the SPPB balance test were eligible for the YBT.

The Senior Fitness Test (SFT), a.k.a the Fullerton Fitness Test, was used to evaluate functional fitness of the participants [99]. In order to assess lower body strength and aerobic endurance, two subtests of the SFT test battery were chosen: the 30-seconds chair rises test and the 2-minutes stepping test. In the 30-seconds chair rises test, the participants had to cross their arms in front of the chest and perform as many full "chair rises" as possible in 30 seconds. A full chair rise was defined as sitting down on a chair and standing up, ending in an upright position again. The number of completed full chair rises in 30 seconds was counted. In the 2-minutes stepping test, the participants were asked to alternatingly step with both legs as many times as possible in two minutes while reaching a predefined individual height with the knees. This threshold height was calculated by means of the height from the floor to the middle of the thigh (midway between the iliac crest and the upper patella). For the analysis, the number of steps with the right leg was counted during the two minutes whereas a step was valid only when the right knee was reaching the required height.

Cognitive functions

To assess cognitive functions, one computer-based test and three paper-pencil tests were used. The Test of Attentional Performance (D-TAP 2.3 VL, PSYTEST, Psychologische Testsysteme, Herzogenrath, Germany) is a computerized test battery to validly assess various attentional and executive functions [100]. For this study, the subtest Divided attention was chosen to evaluate the capacity of dividing the attentional resources to stimuli in multiple modalities. The test was performed on a computer using an additional answer button and was preceded by a short familiarization session. Visual and acoustic signals were presented to the participants who had to react only to specific stimuli. Details about the protocol can be found elsewhere [100]. Reaction times [ms], number of errors, and omissions were assessed.

The Trail Making Test (TMT) is a widely used, valid and reliable neuropsychological paper-pencil test to assess mental flexibility [101; 102; 103]. In the first part of the test (TMT A), participants had to connect randomly allocated, encircled numbers from 1 to 25 in ascending order as fast as possible. In the second part of the test (TMT B), the stimuli comprise encircled letters and numbers. The randomly allocated numbers and letters have to be connected in ascending numerical and alphabetical order alternatingly as fast as possible (e.g. 1 – A – 2 – B – 3 – C – ...). In both parts, a short practice session was conducted. Time [s] for completing the tasks was recorded and errors were counted.

To assess response inhibition and interference control, the Victoria Stroop Test (VST) was used, a tool to validly and reliably measure executive functions [104; 105; 106]. The VST compromises three parts: (1) VST 1: naming the colour of dots (red, blue, green, or yellow), (2) VST 2: naming the colour of neutral words (e.g. words like "when" or "hardly" coloured in red, blue, green, or yellow), and (3) VST 3: naming the colour of colour words printed in incongruent colours (e.g. word = red while word colour = blue, etc.). In VST 3, interfering information is provided which requires interference control and response inhibition; the fast and automatic response of reading the words has to be inhibited and a more effortful colour-naming response has to be produced [107]. Each part contains 24 stimuli. Performance time [s] was recorded for each task and errors were counted.

Further cognitive performance was evaluated with two subtests of the Wechsler Memory Scale-Revised (WMS-R) [108; 109]. The first subtest, the digit forward task of the WMS-R, assessed the short-term attention span and information processing speed [109; 110]. Participants had to remember and repeat digit sequences, which were read out loud by the tester, in the correct order. The first two sequences consisted of three digits. Then the sequence was extended with an additional number for another two trials, and so on, until a maximum sequence length of eight digits was reached. The second subtest, the digit backward task of the WMS-R, was used to evaluate working memory capacity [109]. Participants had to repeat the digit sequences in reversed order. Initially, the sequence consisted of two digits with the same extending procedure as described above whereas the maximum sequence length was seven digits for this task. For every correct replication of a digit sequence, one point was scored, summing up to a total point score for each subtest [111].

Cortical activity

To assess cortical oscillatory activity, five minutes of resting state electroencephalography (EEG) were recorded at 500Hz sampling rate, using a 20-channels dry-electrodes cap (ENOBIO 20, Neuroelectrics, Barcelona, Spain) placed according to the international 10-20 system [112] and referenced using the Driven-Right-Leg (DRL) / Common Mode Sense (CMS) technique (two external electrodes placed on either side of the left earlobe with an ear-clip). Before electrode placement on the forehead and earlobe, the skin was prepared with abrasive paste (H+H Medizinprodukte GbR, Münster, Germany).

EEG data analysis was performed using custom scripts written in MATLAB R2017b (The Mathworks, Natick, Massachusetts, USA) and using the EEGLAB 14.1.0b open source toolbox [113]. EEG data was first high-pass filtered [zero-phase Hamming windowed sinc FIR, cut-off frequency (−6dB) 0.5Hz, passband edge 1Hz, transition bandwidth 1Hz, order 1651] and subsequently low-pass filtered [zero-phase Hamming windowed sinc FIR, cut-off frequency (−6dB) 45Hz, passband edge 40Hz, transition bandwidth 10Hz, order 167]. Further analysis was performed to seven parieto-occipital EEG electrodes (Pz, P3/4, P7/8, and O1/2) only, since this cortical area is widely used to reliably detect individual alpha frequency (IAF) [114; 115]. Channel rejection was performed using the automatic procedure supplied by the clean_rawdata EEGLAB extension by taking into account whether the correlation of a channel to a reconstruction of it based on other channels, in a given time window, was less than 0.4, and whether a channel was flat for more than five seconds. On average, ~98% of the parieto-occipital channels in the pre-measurement EEG recordings remained for further analysis (σ: ~5%; range: ~86-100%) and ~95% (σ: ~9%; range: ~71-100%) in the post-measurement EEG recordings. Artifactual data points were rejected when their amplitude was higher than ±75μV within a 500ms width time window as detected by the trimOutlier EEGLAB plugin. On average, ~5% of data was rejected in the pre-measurement EEG recordings (σ: ~11%; range: ~0-43%) and ~6% (σ: ~14%; range: ~0-17%) in the post-measurement EEG recordings. Afterwards, two IAF measures were estimated: peak alpha frequency (PAF) and center of gravity (CoG), by means of the resting IAF v1.0 open source package available from https://github.com/corcorana/restingIAF. This allowed a fully automatic and reliable strategy to determine IAF estimates during resting state EEG recordings, of which a more detailed and extensive description can be found elsewhere [115; 116]. Briefly, one-sided channel-wise power spectral density (PSD) was first calculated in the 1-40Hz frequency range by the Welch's modified periodogram method, using a 2048 sample (~4s) Hamming window (50% overlap) across segments (frequency resolution = 0.244Hz) and normalized by dividing each PSD channel estimate (within the passband) by the mean spectral power. Then, each PSD estimate was smoothed using a Savitzky-Golay filter with frame length equals to 11 frequency bins and polynomial degree of five. From the smoothed PSD used to detect evident frequency peaks within the a priori defined alpha frequency band (7-13Hz), yielding to spectral peaks' boundaries from which IAF estimates can be computed. Using the first derivative to detect spectral peaks seemingly yields true estimates compared to simply searching from maximal values within a predefined alpha frequency band [114]. Finally, IAF estimates were computed by averaging the obtained spectral peaks estimates across channels. The minimum number of valid channels necessary to estimate IAF was set to one, given the relatively low-density parieto-occipital EEG channels used for this analysis. Additionally, spectral power within the alpha frequency band was calculated by averaging in each participant the PSD estimates of all the included channels, and then summing the obtained channels mean power across the alpha frequency band. Alpha spectral bandwidth was defined as the individual PAF ±2Hz.

3.3.5 Other outcome measures

The participants rated their current training motivation on a Visual Analog Scale (1 = unmotivated lethargic smiley to 5 = motivated happy smiley) before each training session. The average training motivation was separately calculated for the training period in the living lab and at home. Subjective exercise intensity was reported after each training session during the whole intervention period. The participants estimated their perceived exertion on the 20-point Borg scale that ranges from 6-20 (6 = "less than very light", 20 = "more than very hard") for Tai Chi and dance exercises, respectively [117; 118]. To target a moderate training intensity, Borg scale ratings in the range of 12-14 were expected. Furthermore, objective exercise intensity was assessed by heart rate (HR) measurements during at least three training sessions performed in the living lab. A Polar M400 (Polar Electro Oy, Kempele, Finland) was used to record HR for Tai Chi and dancing training separately. The resting state heart rate (HRrest) was measured once to enable relative comparison with the average HR measured during training (HRtrain). The HRrest was calculated by averaging the HR of one minute after participants have been resting in a sitting position for five minutes. A relative increase of the average HR while training was calculated as follows: HR increase [%] = (HRtrain – HRrest)/ HRrest. Furthermore, the individual maximal HR (HRmax) was estimated with the formula: HRmax = 220 – age [QUELLE]. The average HR while training was compared to the individual estimated HRmax by calculating the HRtrain as percentage of the HRmax. To target a moderate training intensity, an average training HR about 60% of HRmax was expected [60; 61].

3.3.6 Statistical analysis

SPSS 23.0 for Windows (SPSS Inc, Chicago, Illinois, USA) was used for statistical analysis. Descriptive statistics were generated for all variables. Following a conservative approach and due to non-normality of some of the data, confirmed by both Shapiro-Wilk test and Q-Q-plots, non-parametric testing was applied. Intragroup differences between pre- and post-measurements were analysed by Wilcoxon signed-rank test. A significance level of $\alpha = 0.05$ was applied. Correlational effect sizes (r), according to the following equation: $r = z/\sqrt{(n1+n2)}$ with n1 = n at pre-measurement and n2 = n at post-measurement, were calculated in MS Office Excel (version 2016) and reported according to Cohen [119]: an effect size of r = 0.10-0.24 indicates a small effect, r = 0.25-0.39 a medium effect, and $r \geq 0.40$ a large effect. For pre- and post-measurement comparisons, drop-outs were excluded from analysis (per-protocol analysis). The analysis does not consider intention-to-treat analysis because of a clear description of the drop-out reasons [120]. Moreover, only participants who reached 70% of the maximal possible training sessions were included in the pre-post-comparison.

3.4 Results

A total of 21 participants signed informed consent and were included in the study. Fifteen participants completed the eight-week training intervention. Six participants prematurely terminated study participation. The study flow chart is presented in Figure 3. Three drop-out reasons were associated with technical problems and malfunctions of the training systems which led to a decreased training motivation. The other reasons for terminating were related to personal and health issues. Table 5 summarizes the demographic characteristics and screening measures of the drop-outs and the remaining participants separately. The drop-outs were comparable to the rest of the sample regarding their characteristics except of the age (U = 75.50, p = .017) and self-evaluated balance at baseline (□2(df) = 9.64(3), p = .022). No adverse events occurred during the intervention period.

Table 5. Demographic characteristics of participants and screeing values.

Participant characteristics	n = 21	n = 6 (Dropouts)
Age in years	74.4 ± 7.0 (65-92)	80.2 ± 7.1 (70-92)
Weight [kg]	73.2 ± 19.8 (42-120)	66.0 ± 20.0 (42-95)
Height [cm]	168.0 ± 9.4 (155-187)	168.0 ± 12.4 (155-187)
Education in years	14.1 ± 4.2 (4-20)	13.8 ± 6.1 (4-20)
MMSE Score	29.0 ± 1.6 (24-30)	27.8 ± 2.6 (24-30)
Female [n, %]	11 (52.4)	2 (33.3)
Fear of falling [n, %]		
Never	17 (81.0)	6 (100.0)
Sometimes	3 (14.3)	0 (0.0)
Often	1 (4.8)	0 (0.0)
Always	0 (0.0)	0 (0.0)
Number of falls during last month^{+} [n, %]		
Never	18 (85.7)	6 (100.0)
Once	2 (9.5)	0 (0.0)
More than once	1 (4.8)	0 (0.0)
Self-evaluation of health state [n, %]		
Very good	5 (23.8)	1 (16.7)
Good	12 (57.1)	2 (33.3)
Medium	4 (19.0)	3 (50.0)
Bad	0 (0.0)	0 (0.0)
Self-evaluation of balance [n, %]		
Very good	3 (14.3)	3 (50.0)
Good	9 (42.9)	1 (16.7)
Medium	7 (33.3)	2 (33.3)
Bad	2 (9.5)	0 (0.0)
Self-evaluation of muscle strength [n, %]		
Very good	2 (9.5)	1 (16.7)
Good	12 (57.1)	4 (66.7)
Medium	7 (33.3)	1 (16.7)
Bad	0 (0.0)	0 (0.0)

Data are mean values ± standard deviations (ranges) or number of participants per category (absolute and relative frequency). MMSE = Mini Mental State Examination. $^{+}$Self-stated.

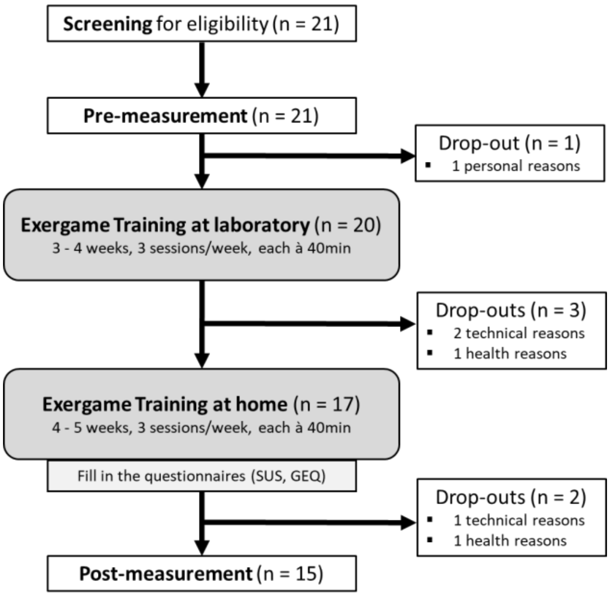

Figure 3. Study flow chart. Screening of participants for eligibility included an assessment of cognitive and health state. Physical and cognitive functions as well as brain activity were measured at pre- and post-measurement. Questionnaires assessing usability and game experience were filled in after the training period.

3.4.1 Primary outcome results: Feasibility, usability, and game experience

The adherence rate over the whole intervention period was 91.1% (n = 15). For the training period in the living lab, the attendance rate reached 91.7% whereas 91.0% of all training sessions were attended during the training period at home. Both attendance rates were above the predefined 70% threshold rate considered as acceptable adherence. Ten participants completed all planned 24 training sessions. Reasons for not attending training sessions were: holidays, being busy, work, family affairs, and temporary health issues (e.g. catching a cold). After the eight-week training intervention, the attrition rate of 28.6% (six drop-outs) was higher than the predefined expectable drop-out rate of 10% (two drop-outs due to the sample size in this study). Nevertheless, the number required for gaining valuable preliminary information from the width of the confidence intervals for the mean responses remained well above the recommended 12 individuals. The SUS score was 70.6 ± 19.8 (n = 17) showing acceptable usability (a 70 points-score was predefined and considered acceptable for usability). In the additional question, asking the participants about their general opinion of the Active@Home exergame, the mean score was 3.2 ± 1.0 (on a scale from 0 = "I don't like it" to 4 = "I like it a lot"). Figure 4 presents the results of the GEQ (n = 17) indicating positive game experience based on the above-average score of positive affect (2.3 ± 1.0) and the low scores of negative affect (0.3 ± 0.5) and tension (0.8 ± 0.7). The ratings for competence (2.2 ± 0.9) and immersion (2.0 ± 0.7) were around average whereas the scores of challenge (1.6 ± 0.6) and flow (1.3 ± 0.8) were slightly lower. Table 6 summarizes the main feedback of the participants and the observations of the supervisors during the training in the living lab setting.

Table 6. Primary outcome results of usability (qualitative measurement): Summary of usability protocol with observations and participants' feedback.

Criteria	Positive aspects	Negative aspects
Functionality and interaction with the system	– Simple set up – Easy usable game composition	– Very specific movements/steps needed for motor-cognitive games (specific and strict step detecting algorithm) – Technical malfunctions of HDMI dongles
Sensors	– Comfortable to wear – Easy to attach (slap band) to wrists and ankles – Slap bands are easy to clean (e.g. from sweat) – Feasible navigation with the right hand sensor ("hand mouse") – Battery can be easily charged	– Instable sensor connection (via Bluetooth) – Activation of the "hand mouse" in inappropriate situations (e.g. during dancing) – Suboptimal navigation for left-hander – Technical malfunctions of sensors (switching into a "lock-state")
Design	– Appealing game design – Pleasant and diverse music – Cute and funny cartoon-based avatar as virtual coach	– Avatar could be more motivating (gestures as "thumps up", comment etc.)
Training principles	– Real-time feedback while exercising (auditory and visual, positive and negative) – Performance points as feedback after exercising are motivating – High variability of exercises – Levels are built on one another – Higher levels are exciting and challenging	– Auditory feedback (sounds for "right" and "wrong") could be louder in relation to background music – Feedback not always traceable (visual colour code feedback, performance point scores) – Partly inaccurate evaluation of movements
Exercises	– Clear structure of exercise levels – Quiz questions between strength exercises for cognitive stimulating and educating recovery – Challenging strength and balance exercises (especially higher levels) – Exciting, funny and challenging motor-cognitive games – Duration of the exercise is displayed – Helpful cues (arrows) to prepare the next movement	– Dance steps for balance training sometimes not perfectly instructed (difficult to reproduce) – Turns in dancing are difficult as no view on TV while turning – No perfect synchronization of music and movements – Instructions in English (difficult to understand for German-speaking participants) – Only frontal view of exercises (side view missing)
Emotions	– Motivation and fun (despite of technical malfunctions) – Curiosity about what is coming in the next levels – Happiness when seeing progress or achieving more performance points	– Frustration and displeasure because of technical issues and inaccurate evaluation of movements – Impatience with navigation

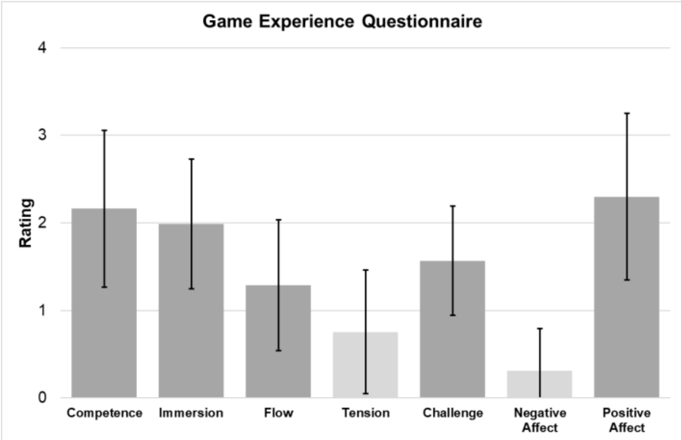

Figure 4. Primary outcome result of game experience (quantitative measurement). Data shown in the figure are means with standard deviations in each emotional category of the GEQ (n = 17). Two categories (tension, negative affect) have to be evaluated reversely which means a low score is favorable. GEQ scale ranges from 0 = "not at all" to 4 = "extremly".

3.4.2 Secondary outcome results: Effectiveness of the intervention

Table 7 summarises median and variability values next to reporting the confidence intervals for the measures. For gait analysis, the minimal toe clearance under single-task walking condition increased significantly (z = -2.158, p = .030, r = 0.39) comparing pre- and post-measurement. Considering the balance assessments, nine participants reached 20 seconds or more for the single-leg stance and, thus, were eligible for the YBT test. A large effect size (z = -1.836, p = .074, r = 0.43) was evident for these individuals with a tendency of higher dynamic balance scores after the intervention. In the digit forward task of the WMS-R, a significant increase in the performance score was found (z = -2.859, p = .002, r = 0.52) comparing pre- and post-measurement. Furthermore, reaction time in the first task of the VST (VST 1) was significantly faster (z = -2.727, p = .004, r = 0.50) after the training intervention. No significant changes in resting state EEG were found for the pre- and post-measurement comparison. However, a large effect size was evident for the alpha spectral power (z = -1.955, p = .055, r = 0.44) with a tendency of increased spectral power in the individual alpha frequency band after training.

3.4.3 Other outcome results

Participants rated their training motivation on average with 4.2 ± 0.7 (n = 20). The motivation for the training in the living lab was 4.2 ± 0.6 (n = 20) and the motivation for the home-based training was 4.1 ± 0.8 (n = 17). The average rating of participants' perceived exertion for Tai Chi exercises was 11.9 ± 1.5 (n = 20) and for dance exercises 11.0 ± 1.5 (n = 20). Both ratings reflect an intensity on the 20-point Borg scale that corresponds from "fairly light" (11) to "somewhat hard" (13). Heart rate analysis showed a relative increase of 22 ± 16% for the average HR during training compared to the resting state HR. The average HR during Tai Chi training was 60 ± 10% of the individual maximal HR, the average HR during dancing training was also 61 ± 11% of the maximal HR.

Table 7. Secondary outcome results.

Secondary Outcomes	Assessed by	Pre	Post	z	p	r
Physical functions	**Gait analysis with Physilog®**					
	Speed [m/s]					
	ST walking	1.41 (1.32; 1.49)	1.43 (1.23; 1.55)	-0.454	.679	0.08
	DT walking	1.23 (1.13; 1.42)	1.34 (1.12; 1.44)	-1.590	.121	0.29
	DT costs in %	9.4 (6.5; 18.3)	10.1 (2.5; 17.2)	-1.477	.151	0.27
	Cadence [steps/min]					
	ST walking	119.4 (114.8; 120.7)	118.9 (111.3; 123.3)	-0.909	.389	0.17
	DT walking	112.9 (103.1; 114.8)	113.3 (104.7; 117.3)	-1.704	.095	0.31
	DT costs in %	6.8 (3.6; 12.1)	5.1 (3.2; 12.0)	-1.533	.135	0.28
	Stride length [m]					
	ST walking	1.40 (1.35; 1.51)	1.41 (1.33; 1.47)	-0.341	.762	0.06
	DT walking	1.30 (1.25; 1.52)	1.40 (1.25; 1.51)	-1.022	.330	0.19
	DT costs in %	4.7 (0.1; 6.9)	3.1 (-1.6; 5.9)	-0.795	.454	0.15
	Toe clearance min [cm]					
	ST walking	1.9 (1.5; 2.4)	2.3 (1.9; 3.0)	-2.158	.030*	0.39
	DT walking	2.0 (1.5; 2.7)	2.4 (1.5; 3.1)	-1.306	.208	0.24
	DT costs in %	-4.5 (-36.3; 2.4)	6.2 (-10.5; 16.4)	-0.852	.421	0.16
	Extended Short Physical Performance Battery (SPPB)					
	Balance score	7 (6; 7)	7 (6; 7)	-0.857	.488	0.16
	Senior Fitness Test (SFT)					
	30sec chair rises test	15 (13; 20)	18 (15; 22)	-1.603	.110	0.29
	2min stepping test	94 (74; 114)	100 (79; 113)	-1.137	.270	0.21
	Y-Balance Test (YBT)					
	YBT score [%]+	76.8 (73.7; 85.2)	87.1 (73.9; 91.1)	-1.836	.074	0.43
Cognitive functions	**Test of Attentional Performance (TAP) – Divided attention**					
	RT auditory [ms]	624 (577; 675)	648 (617; 691)	-0.057	.966	0.01
	RT visual [ms]	834 (798; 980)	892 (813; 1012)	-0.454	.679	0.08
	Errors	3 (1; 5)	3 (1; 5)	-0.466	.730	0.09
	Omissions	2 (1; 3)	2 (0; 3)	-0.051	.953	0.01
	Trial Making Test (TMT)					
	TMT A					
	Time [s]	38.3 (35.1; 46.5)	33.6 (31.2; 50.0)	-0.625	.561	0.11
	Errors	0 (0; 0)	0 (0; 0)	-1.000	1.000	0.18
	TMT B					
	Time [s]	85.9 (72.0; 107.8)	85.5 (70.5; 109.0)	-0.511	.639	0.09
	Errors	0 (0; 2)	1 (0; 2)	-0.520	.656	0.09
	Wechsler Memory Scale-Revised (WMS-R)					
	Digit forward task	6 (6; 8)	8 (6; 9)	-2.859	.002*	0.52
	Digit backward task	5 (5; 6)	6 (6; 7)	-0.890	.434	0.16
	Victoria Stroop Test (VST)					
	VST 1					
	Time [s]	13.2 (12.4; 15.2)	12.5 (11.4; 14.5)	-2.727	.004*	0.50
	Errors	0 (0; 0)	0 (0; 0)	-0.707	.750	0.13
	VST 2					
	Time [s]	16.5 (14.1; 19.2)	15.2 (14.6; 16.1)	-1.789	.075	0.33
	Errors	0 (0; 0)	0 (0; 0)	-1.414	.500	0.26
	VST 3					
	Time [s]	25.0 (22.0; 29.0)	22.8 (19.0; 27.2)	-1.533	.135	0.28
	Errors	0 (0; 1)	0 (0; 1)	-1.023	.328	0.19
Cortical activity	**Resting state EEG**					
	Peak alpha frequency [Hz]	9.3 (8.7; 9.5)	9.7 (9.0; 9.8)	-1.104	.375	0.25
	Center of gravity [Hz]	8.8 (8.5; 9.5)	9.2 (8.8; 9.5)	-1.682	.105	0.36
	Alpha spectral power [μV^2]	23.4 (20.1; 39.2)	27.8 (19.8; 63.9)	-1.955	.055	0.44

Data are median values (interquartile range). n = 15 (+exepct of the YBT with n = 9) . *p < .05, p-values are exact sig. two-tailed. Pre-post differences were evaluated using Wilcoxon signed-rank test. For effect size r, r = 0.10-0.24 indicates a small effect, r = 0.25-0.39 a medium effect and r = ≥ 0.40 indicates a large effect (Cohen, 1988). ST = single-task. DT = dual-task. RT = reaction time. DT costs are calculated as (ST – DT)/ST × 100.

3.5 Discussion

The primary aim of this study was to test the feasibility and usability of a technology-based in-home exergame training for older adults. Furthermore, mean changes, variability measures, and confidence intervals for potential training-related changes, both in physical and cognitive aspects of functioning, were assessed. In summary, the study results showed a general feasible and well accepted exergame that indicates to endorse measurable training effects in physical and cognitive functions.

3.5.1 Feasibility, usability, and game experience

The conclusion of a feasible training system is based on the high total adherence rate of over 90% (91.1%). Interestingly, the adherence rates for the training periods in the living lab and at home were almost the same (91.7% and 91.0%, respectively). Therefore, we might conclude that the presence of a supervisor during the living lab training sessions might not have promoted the training adherence compared to the in-home setting. Although, a widespread opinion is that social interaction increases training motivation in older adults. The high adherence rate found in this study is in line with the result of the first feasibility study testing the newly developed exergame in living lab setting. Furthermore, previous studies evaluating exergame interventions in older adults showed high training attendance [53; 75]. Moreover, adherence has been shown to be often higher in interventions using exergames compared to standard fall prevention exercises [53; 75; 121]. One reason might be the high motivational potential and playfulness of exergames leading to a captivating and entertaining training [77; 80; 122]. Accordingly, the motivation ratings were equally high for the training in the living lab and at home. In general, high motivation seems to be crucial for the success of an exergame and training interventions as motivation might lead to a high training compliance and, therefore, training related benefits can reach their full potential [123; 124]. The attrition rate in this study has shown to be higher than the predefined rate [55]. Even after subtracting the drop-outs resulting from reasons not related to the training system itself (e.g. due to health issues), attrition was still higher than the predefined rate. Although, the drop-out rate is about 10% on average in exergame studies [47], it can reach up to 40% in individual studies [125]. Exergames might be more prone to technical issues (e.g. system crashes or unstable connections to sensors) that might, in some cases, lead to higher drop-out rates.

Despite the rather high attrition rate, the usability of the exergame was rated with an acceptable score (SUS score of 70.6) and a general positive feedback was given by the participants. However, some discrepancies were evident comparing the participants' feedback and the supervisors' observations during the training in the living lab. Difficulties in using the system (e.g. navigating through the game) have been observed, whereas help was occasionally requested by participants. Nevertheless, the supervisors' observations and the participants' feedback gave insights in the positive user experiences, e.g. easy usable system set up and simple attachment of the IMUs. Previous experiences with technology might have been beneficial as for example the navigation of the hand IMU seemed to be partly related to previous experiences with navigation systems like a computer mouse. Additionally, the participants were satisfied with the game story, the virtual coach, and the training content including diverse and challenging exercises and cognitive stimulation. Comparing to existing literature, exergames in general have been shown to be well accepted and usable for healthy older adults [36; 52; 77]. Considering the potentially restricted technology knowledge of older adults, providing a technology-based system with flawless functionality and age-appropriate design may be crucial especially when the system is expected to be deployed at seniors' home [77; 126; 127]. Yet, the most threatening aspect for the feasibility and usability of the Active@Home exergame was related to technical malfunctions of the system. Participants often were frustrated and disappointed when the IMU connections were unstable or movement detection was incorrect. These emotional reactions evident in the observations were also reflected in the results of a questionnaire assessing emotions and game experience (GEQ). Compared to other studies evaluating exergames with this questionnaire [81; 82; 128], positive affect was rated slightly lower whereas tension was rated slightly higher. Nevertheless, the emotional experience during training with the Active@Home exergame can be interpreted as general positive with ratings of positive emotions above average (e.g. feeling captivated and pleased) and a low rating of negative affect (e.g. feeling tensed and annoyed). Emotions related to challenge and flow were rated rather low which might be explained by not providing the appropriate training load for everyone and by interrupting the game flow due to technical problems. In sum, we concluded that the Active@Home exergame provided mainly positive emotional experiences which might be linked to the high training motivation and adherence.

3.5.2 Effectiveness of the intervention

Our study results showed a significant improvement in minimal toe clearance under single-task walking leading to higher "foot lifting" after training which might be related to a decreased risk of tripping and falling in older adults [129]. Improvements in gait parameters after exergame training have been found in several previous studies, mainly in dual-task walking [88; 130; 131]. These effects on multitasking capabilities are discussed to be due to the characteristics of exergame training targeting motor as well as cognitive functions and the motor-cognitive interplay [21; 132]. Even though the Active@Home exergame included training of motor and cognitive functions, no significant improvements in gait parameters under dual-task walking have been found in this study. Regarding further physical functions, analysis did not reveal any significant changes after the training intervention. Nevertheless, a large effect size was found for dynamic balance assessed by the YBT despite the small sample size in this test due to restricted eligibility of participants to perform the demanding test. In contrast, measures of static balance assessed by the SPPB showed no improvement which is in line with the results of the first study using the Active@Home exergame. We might conclude that the Active@Home exergame has a stronger focus on training of dynamic balance or that the SPPB seems to be not sensitive enough to assess balance differences in an upper range of static balance performance. Moreover, considering the subjective ratings of perceived exertion during training (Borg scale ratings) and the objectively assessed training intensity (heart rate measurements), optimal training load in a moderate to vigorous exercise intensity might be questioned [60; 61]. The suboptimal training load and the rather short training period might have restricted the training impact on additional physical outcomes. Therefore, further studies should focus on ensuring optimal training intensity as well as extended training duration.

In the cognitive tests, study results showed a significant change in the short-term attentional span (digit forward task of WMS-R) whereas an improvement in general attentional focus and information processing speed might be hypothesized. Accordingly, information processing speed in another task (VST 1) significantly improved after the training intervention resulting in faster reaction times. These positive effects might be attributed to the cognitive training components and the motor-cognitive interaction required in the exergame training. Similarly, recent studies showed significant enhancement of cognitive abilities including information processing speed after exergame training [133; 134; 135; 136]. Interestingly, a cognitive training alone (e.g. computer-based training) without elements of physical activity might not be sufficient enough to improve cognitive functions [137] leading to the suggestion that exergames have a greater impact on cognitive functions than computer-based training without a physical component. Nevertheless, no significant changes were evident in the classical executive functions as mental flexibility and inhibition. Again, a link to the rather short training period can be assumed.

Our study results of the neuronal activity measurements showed a large effect size for alpha spectral power with a tendency to a power increase after the training intervention. A variety of studies reported age-related changes in cortical oscillatory activity [138]. Mainly a general "slowing" of the resting state EEG with a power increase in the slow frequency ranges (< 7Hz) and a power decrease in higher frequencies (e.g. alpha power frequency band: ~7-13Hz) has been described, especially in posterior brain regions [31; 139]. Moreover, the individual alpha frequency peak is known to decrease in the later part of lifespan [138]. A positive correlation between alpha power and global cognitive status in healthy as well as in impaired older adults is considered [138; 140; 141; 142]. Our study results are supporting the suggestions/hypothesis that the age-related "slowing" in cortical oscillatory activity can be counteracted with physical and cognitive training [139]. However, we found no significant changes in measurements of the individual alpha frequency.

3.5.3 Conclusion

Our study results showed a general high feasibility and usability of the adapted Active@Home exergame and an overall positive emotional game experience in a living lab and in a home-based setting. These results lead to the conclusion that the presence of a supervisor might not be a crucial factor regarding training compliance and motivation. Furthermore, this study demonstrated that older adults were able to use the technology-based exergame in an in-home setting. However, simplicity and flawless technical functionality of the system should be a mandatory development consideration. Moreover, a rather high variability in participants' general feedback about the exergame training was present reflecting personal experiences and preferences. Thus, we might conclude that the Active@Home exergame is a general feasible and usable in-home training satisfying the needs and requirements of at least a part of the older population. Additionally, results of motor and cognitive testing indicate that the exergame seems to have potential positive influence on crucial functioning in older adults. However, the efficacy has to be further evaluated in a future randomized controlled trail.

4. Randomized Controlled Trial (RCT)

The RCT was running in Switzerland and in the Netherlands. Data collection is finished in Switzerland whereas the trial in the Netherlands is still running (until the end of April 2019). Data analysis will be finished in May and this chapter will be added to the document in June.

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