D5.1 First Study Plan

Work Package	**WP5 Field Studies & Evaluation**
Task	**T5.1 Preparation First Field Study**
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Project PLAYTIME

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30/04/2018

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Part I: Study Plan Austria

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1 General Information

1.1 Protocol Identification

Study number: 1

Protocol-Number: 1.0

Date of protocol version: 30.09.2018

1.2 Statement of confidentiality

The content of this protocol has to be treated confidentially and should not be deliverd to third parties without the confirmation of the applicant.

1.3 Persons, Institutions, and Boards

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1.4 Summary

In the following, a summary of the proposed study/research line is given, including sufficient information on the data collection procedures, such as, the manipulations, stimuli, questionnaires, certainly when they may be ethically sensitive.

1.4.1 Background

Dementia is a broad category of neurocognitive disorders characterized by a long term and often gradual decrease in the ability to think and remember. Other symptoms include impaired language, personality changes, emotional problems, behavioral disturbances, and decreases in motivation (Prince, Albanese, Guerchet, & Prina, 2014). The most common forms of dementia are Alzheimer's disease (<70%), Vascular disease (<20%), Lewy Body Dementia (<5%) and frontotemporal dementia (2%) in descending order of occurrence (Prince et al., 2014). These diseases are progressive and slowly, but severely affect a person's brain, and thus affect his or her ability to live a normal live. Advancing age is the main risk factor for most forms of dementia, and with the ever increasingly aging population, the prevalence of dementia worldwide is expected to nearly double every 20 years to 65.7 million in 2030 and 115.4 million in 2050 (Prince et al., 2014). This expected increase will have profound societal challenges in the sense of costs connected to the care of dementia, the quality of life of people with dementia, and the burden on family care givers.

Currently, no disease modifying drugs for dementia are available and pharmacological treatment is limited to therapies that alleviate the symptoms. However, these treatments are not efficacious in all clients and may introduce undesirable side-effects (Galimberti & Scarpini, 2010). Non-pharmacological (or psychosocial) interventions, such as sensory stimulation, cognitive stimulation and physical exercise programs, are therefore appealing alternatives or add-ons as these were found to slow down cognitive decline (or even improved cognition) and/or to reduce behavioral and psychological symptoms once the clinical diagnosis of dementia has been established (e.g. Maseda et al., 2014; Woods, Aguirre, Spector, & Orrell, 2012; Groot et al., 2016; Farina, Rusted, Tabet, 2014; Teri, Logsdon, & McCurry, 2008; Oliveira et al., 2015). Most of these different interventions, however, have involved unimodal therapy and have demonstrated limited effectiveness (Buschert et al., 2011; Gräßel, Wiltfang, & Kornhuber, 2013). Therefore, non-pharmacological interventions for meaningful treatment of dementia should consists of multiple components, even being accompanied by social environments (Graessel et al., 2011; Luttenberger, Donath, Uter, & Graessel, 2012).

An Austrian project AktivDaheim[1], which redeveloped Schooltastic[2] into a playful interactive training for people with dementia, is the predecessor functionally and conceptionally for the project PLAYTIME that includes rich contribution from a consortium of European major players in the dementia health care and serious game communities.

[1] http://aktivdaheim.at/

[2] https://www.schooltastic.net/

The objective of the project PLAYTIME is to motivate people with dementia to enter a positive feedback cycle of periodic training with sensors that enable diagnostics on a daily basis, and to receive recommendations on the basis of these data that propose more personalized and better suited exercises for improved training. The motivation is primary triggered by the following three aspects of PLAYTIME: (1) positive affection achieved from social engagement in playful group gatherings, (2) multimodal online training modules, including a cognitive exercises (e.g. multiple choice, puzzles, spot-the-difference, memory), socio-emotional exercises (i.e. real-life scenarios), and a physical exercises, to offer the user playful experience at home and group gatherings, and (3) the involvement and improvement of activities of daily living. User feedback, in terms of physical performance, physical activity and eye movements, will provide indicators for diagnostics to determine personalized recommendations and, in turn, optimize user experience.

Furthermore, the PLAYTIME suite will contain an interactive mat for group gatherings, a mobile app with integrated trainings modules, a Tablet PC, a MoveMonitor, and software for web camera based eye movement analysis. In Figure 1, a schematic overview of the most important aspects of the PLAYTIME suite is provided.

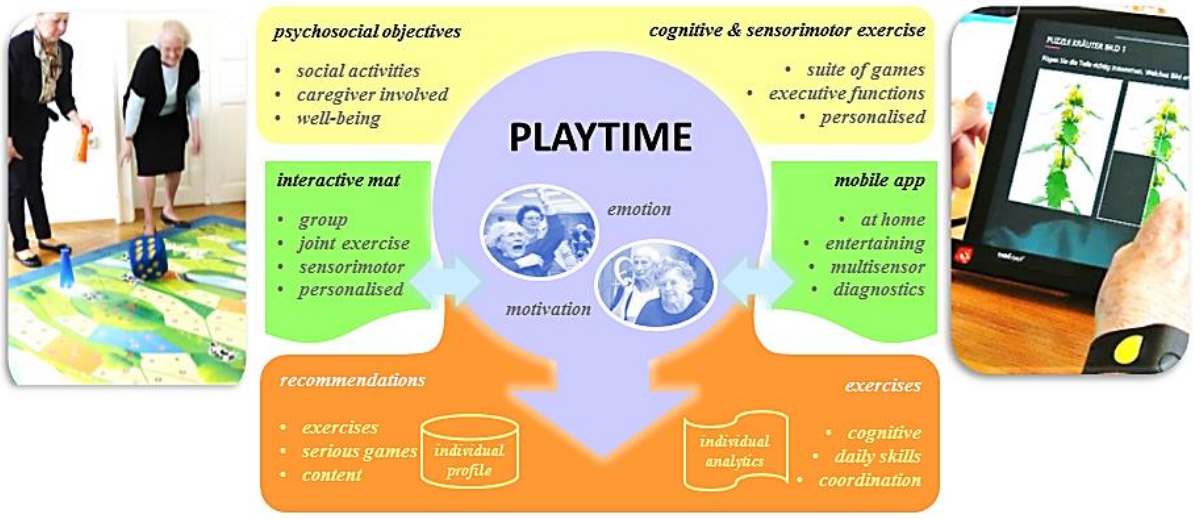

Figure 1. Schematic overview of the PLAYTIME suite for people living with dementia.

A carefully designed PLAYTIME suite may answer unmet needs of people living with dementia. Yet, research shows that the design of innovations for this target population still proves to be challenging as these are often too difficult to be used by them (Astell et al., 2010). For one, innovations for people living with dementia are seldom designed considering the users' needs and context (Bharucha et al., 2009). Understanding the daily context of users in the development of new innovations is essential to cater to their, often complex, needs and the acceptance of the innovation. Moreover, the first-hand perspective from the person with dementia itself is rarely sought in the design process of innovations (Topo, 2009). Instead, the designer or an informal caregiver generally voice product or service evaluations on their behalf. This absence of a first-hand perspective and the need to develop and evaluate innovations as an integral part of the home context of people with dementia motivates the use of the Living Lab

method for PLAYTIME. The Living Lab approach is described as a method to expose users to innovations in a natural context (Markopoulos & Rauterberg, 2000), with the goal to develop the innovation further for a market introduction (Leminen, Westerlund, & Nyström, 2012). We rarely see people with dementia getting involved in Living Lab studies, nevertheless, they are perfectly capable to do so when adequately prepared (Suijkerbuijk, Brankaert, Kort, Snaphaan, & Den Ouden, 2015).

1.4.2 Research questions

The research questions of this study can be formulated as follows:

(1) How do people living with dementia evaluate the alpha prototype of PLAYTIME with regard to usability, feasibility, appropriateness and acceptability?

(2) Which user feedback generated by the alpha prototype of PLAYTIME is usable for determining personalized recommendations?

1.4.3 Study design

For this study, an explorative study will be conducted to evaluate the experiences of users with the PLAYTIME alpha prototype and to look for improvement and personalization opportunities. The Living Lab method will be followed to evaluate the prototype in real-life environments: (i.e., homes and daycare centers). People living with dementia will therefore be involved as co-creators rather than test subjects of the study (Almirall et al., 2012). In addition, a mixed-method design will be used consisting of four phases: preparation, introduction, testing and evaluation. In doing so, we will be able to better understand the utility and relevance of PLAYTIME for people living with dementia, and learn how to improve the alpha prototype and provide personalized recommendations to continue development. In the preparation phase, people living with dementia will be recruited and informed about the aim and procedure of this study. In the introduction phase, the inclusion criteria of this study will be confirmed, the PLAYTIME suite will be demonstrated, and background information of people living with dementia will be collected by personal interviews. Based on this background information, each person with dementia and his or her informal caregiver will receive individual support and advice to fit the use of PLAYTIME to their own situation and preferences. Next, in the testing phase, people living with dementia will use PLAYTIME's **alpha prototype** at their home and during group gatherings. The **testing period will take two weeks** to overcome the short term effect and to still make it suitable for monitoring acceptance and integration in daily life (Brankaert, 2016). This is sufficient because the goal of this study is explorative in nature and focused on the creation of a beta prototype of PLAYTIME. In this phase, most user feedback for determining personalized recommendations will be automatically collected by the PLAYTIME suite. The final phase, evaluation, will involve a reflection interview to gather insights on user's testing experiences with PLAYTIME during these two weeks.

The study will be conducted in collaboration with the following partners of the project PLAYTIME: Sozialverein Deutschlandsberg (SVDL)[3], JOANNEUM RESEARCH Forschungsgesellschaft mbH (JR)[4], and FameL GmbH (FAM)[5].

[3] https://www.sozialverein-deutschlandsberg.at/

- The Austrian Sozialverein Deutschlandsberg (SVDL) has direct access to people living with dementia and healthcare professionals who are experienced with this target population. An appropriately trained healthcare professional of SVDL will perform several tasks in this study, namely:

  (1) She will build a Living Lab structure.

  (2) She will visit study participants at home to introduce PLAYTIME.

  (3) She will support and advice study participants in using PLAYTIME.

  (4) She will lead the PLAYTIME game during group gatherings.

  (5) She will be available to support study participants in case questions arise or problems occur.

  (6) She will report technical problems to the partners of PLAYTIME.

- The Austrian healthcare organization SVDL is knowledgeable about social innovation in healthcare. A researcher of SVDL will cooperate in the preparation of the evaluation with the Austrian applied research center JR. SVDL will particularly evaluate the usability, feasibility, appropriateness and acceptability of the PLAYTIME suite by conducting interviews with study participants and observing group gatherings. Therefore, study participants will only have contact with the healthcare professional of SVDL, making them feel more comfortable.

- The Austrian company FAM will provide the serious game that was developed in the Austrian project AktivDaheim. Their serious game, named “amicasa”, is the basis of the alpha prototype of PLAYTIME and consists of different trainings modules with several exercises: physical exercises, puzzles, memory, spot-the-difference, and knowledge-based questions. Each of these trainings modules covers one theme and can be played at three different levels (A, B or C). In this study, FAM is particularly interested in the usability, feasibility, appropriateness and acceptability of amicasa from users’ perspective. Next to this, the usability and appropriates of amicasa will also be evaluated by analyzing data of the event stream, including clickstream, time log, solution time and performance results.

- The Austrian company FAM will provide the socio-emotional trainings module of the PLAYTIME suite. The socio-emotional module is developed by the Belgian company Mindbytes, partner in the European project consortium of PLAYTIME, and the game is also referred to as SERES DementiaTM[6], consist of scenario-based serious games that intend to improve the coping skills of both people with dementia and their informal caregivers, and are therefore built around the ABC (antecedent-behavior-consequences) learning approach, which is a derivative of CBT (cognitive behavior therapy). This is realized by providing the study participant a realistic scenario (antecedent), three behavioral options directly derived from different coping styles (behavior), and quantitative feedback (consequences). In addition, the game also includes cognitive

[4] https://www.joanneum.at/
[5] https://firmen.wko.at/Web/DetailsKontakt.aspx?FirmaID=9e4ad4dc-6e57-4352-9e73-489715c872d2
[6] http://mindbytes.be/project/seres-dementia/

feedback related to best practices that are presented to the study participant after each module. In this study, MBY is interested in how people with dementia and their informal caregivers evaluate the usability, feasibility, appropriateness and acceptability of SERES Dementia™. The usability and appropriateness of SERES Dementia™ will also be evaluated by analyzing data from the event stream, including clickstream, time log, solution time and performance results. FAM will have the full responsibility for the implementation and operation of this module.

- The Austrian company FAM will provide the necessary equipment, training and knowledge to measure physical performance and physical activity during standardized tests and during daily life. The equipment provided by them will consist of the already existing MoveTest (short physical performance test) and MoveMonitor (physical activity in daily life). In this study, equipment is used that has been developed by the Dutch company McRoberts, partner in the European project consortium of PLAYTIME, and FAM will be responsible for the particularly evaluation of the usability, feasibility, appropriateness and acceptability of the MoveMonitor from users' perspective. Also the usability of the generated data by the MoveTest and the MoveMonitor for determining personalized recommendations will be evaluated.
- The contribution of the Austrian research institute JR to PLAYTIME is the implementation of measurement technologies that identify behavioral and psychophysiological markers for cognitive mechanisms in people with dementia during gameplay at home. Based on estimated mental state of the user, further game content will be personalized by adjusting the level of gameplay to the person with dementia. To do this, JR will provide a software for web camera based eye movement analysis at a Tablet PC. This software will analyze the video stream by detecting the face, localizing the eyes, and apply eye tracking for the estimation of orientation of eye balls towards the screen of the Tablet PC. The accuracy of the eye tracking is sufficient to conclude with simple statistics of eye movement features during gameplay at home and will estimate features of users' cognitive control. In this study, JR will evaluate the usability of the eye tracking calibration procedure and analyze the quality of the eye tracking data for determining personalized recommendations. The video of the user is only used for momentary – within the duration of a second - computation of the eye gaze and then immediately deleted: therefore video material of the user will be neither stored nor transmitted to another site.

Examples of amicasa, SERES Dementia™, the MoveMonitor and an eye tracking task are displayed in Appendix V.

A study design of several phases will be used to evaluate the alpha prototype of PLAYTIME. In Figure 2, a summary of the study procedure is provided, including the total amount of investment hours needed from each person with dementia and/or his or her informal caregiver.

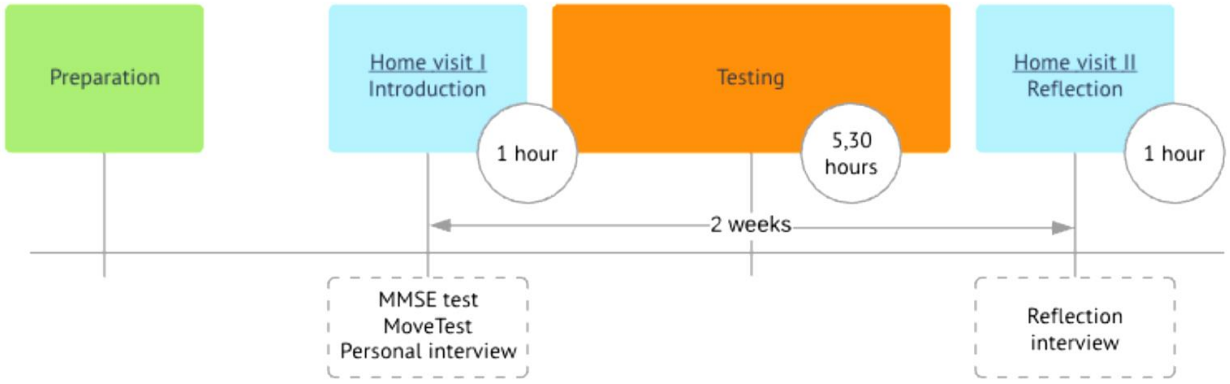

Figure 2. Summary of study procedure.

Phase 1 Preparation

From May 2018 till June 2018, a healthcare professional from SVDL will recruit 10 till 15 persons with dementia and their informal caregivers. Because PLAYTIME will be tested during groups gatherings, she will recruit one already existing group and one new group by three main methods, namely (1) asking healthcare professionals in her network if they have eligible participants and/or daycare groups in their caseload, (2) using the user platforms of SVDL, and (3) presenting PLAYTIME at discussion groups (i.e., Alzheimer café's) where people living with dementia can voluntary apply as participant. During recruitment, the healthcare professional will distribute information flyers and will emphasize that certain criteria needs to be satisfied in order to be able to participate in this study. A person with dementia will be included in this study if (s)he:

(1) Is diagnosed with dementia as formulated in DSM-IV or DSM-V: extended neurocognitive disorders caused by Alzheimer, lewy bodies, vascular diseases or multiple origins (frontotemporal lobar degeneration will be excluded).

(2) Is in an early stage of dementia (MMSE > 22).

(3) Still lives at home in the region of Western Styria (from Soboth to Graz, centered at Deutschlandsberg).

(4) Has involved informal caregiver.

(5) Speaks German.

(6) Has no severe visual and auditory processing disorders.

(7) Has sufficient physical abilities (at least 1 point on all three controlled tests of the MoveTest)

(8) Is willing to participate in and travel to group gatherings.

In the information flyer, contact information of the healthcare professional of SVDL is provided. This gives eligible participants the opportunity to have a personal conversation about the study and to ask questions. If both the person with dementia and his or her informal caregiver are interested in participating in the project, they have to contact the healthcare professional of SVDL. Subsequently, the healthcare professional of SVDL will send an information letter and informed consent to them (by post or email). In the information letter, the aim and procedure of the study are further explained. Next to this, the information letter will inform eligible participants

about their right to decline participation and withdraw from the research once participation has begun, without any negative consequences, and without providing any explanation. Two weeks after the information letter and informed consent were mailed (or a couple days longer in case these materials were sent by post), the healthcare professional of SVDL will contact eligible participants again by telephone. The purpose of the call is to verify if they received the information letter and informed consent, to address any remaining questions about the study, and to solicit their preliminary agreement to participate. If both the person with dementia and his or her informal caregiver agree, the healthcare professional of SVDL will make an appointment to visit them at home (see phase 2).

Before these home visits take place, the healthcare professional of SVDL will perform herself one 'friendly user' test to verify if the different trainings modules of the PLAYTIME suite are working properly. In doing so, it will be possible to provide the study participants with suitable instructions and manage their expectations on the PLAYTIME suite. Furthermore, as long as the trainings modules of the PLAYTIME suite are not working satisfactorily, the testing phase (phase 3) will not be initiated.

Phase 2 Introduction (Home visit I)

After scheduling an appointment, the healthcare professional of SVDL will visit a person with dementia and his or her informal caregiver at home. The main purposes of this home visit are:

(1) To obtain the informed consent.

(2) To verify if the inclusion criteria are met.

(3) To introduce the PLAYTIME project step by step.

(4) To conduct a personal interview.

(5) To demonstrate and explain the PLAYTIME suite.

(6) To confirm the time and place of the group gatherings.

(7) To schedule an appointment for the second home visit.

Below, some of the these main purposes will be further described.

<u>Verifying the inclusion criteria</u>

To prevent that participating in this study may be too burdensome, the healthcare professional of SVDL will especially make sure that a person with dementia meets the inclusion criteria. She will do this by two tests: (1) the Mini-Mental State Examination (MMSE) (see Appendix V) and (2) the MoveTest. The MMSE test will be conducted to check if the person is still in the early stage of dementia: (s)he does have to score at least 22 out of 30 points (Folstein, Folstein, & McHugh, 1975). The second test, a MoveTest, will be conducted to check if the person with dementia has sufficient physical abilities to perform the physical exercises: (s)he does have to score at least one point on all three controlled tests of the MoveTest (balance, gait, chair rise). During these tests, the MoveTest collects data that will be analyzed on a cloud-based analysis platform. Basically, the healthcare professional of SVDL will perform the following actions:

(1) The healthcare professional will explain the test and the methodology to the person with dementia and his or her informal caregiver.

(2) When they are fully informed, the person with dementia will be fitted with a MoveTest device using a comfortable elastic belt around the waist.

(3) The healthcare professional will program the MoveTest using a secure online programming and analysis platform and starts a recording session.

(4) The person with dementia will have to perform three tests: (1) a balance test with three difficulty levels, (2) a gait test (four meters at comfortable speed) and (3) a five times repeated chair rise test (as fast as possible).

(5) After the tests, the healthcare professional will stop the measurement and will collect the MoveTest device.

(6) The healthcare professional will connect the MoveTest to a PC and logs in on the secure online programming and analysis platform and the data upload and analysis process will start automatically. Data will be transmitted in pseudo-anonymized form by a number.

(7) The healthcare professional will present the outcomes to the person with dementia and his or her informal caregiver in a report or in the PLAYTIME application.

When a person with dementia scores below the required minimum, s(he) will be excluded from participating in this study.

Conducting a personal interview

If all inclusion criteria are confirmed, the person with dementia and his or her informal caregiver will jointly be interviewed by a researcher of SVDL. The interview will average 15 minutes in time and deploy a semi-structured format. During the interview, the researcher of SVDL will attempt not to take any leading position, but will be a listener who gently directs the conservation to cover the main themes if necessary. In doing so, the possibility to discover verifying the inclusion criteria to prevent that participating in this study may be too burdensome, the healthcare professional of SVDL will especially make sure that a person with dementia meets the inclusion criteria. She will do this by two tests: (1) the Mini-Mental State Examination (MMSE) (see Appendix IV) and (2) the MoveTest.

The MMSE test will be conducted to check if the person is still in the early stage of dementia: (s)he does have to score at least 22 out of 30 points (Folstein, Folstein, & McHugh, 1975).

The second test, a MoveTest, will be conducted to check if the person with dementia has sufficient physical abilities to perform the physical exercises: (s)he does have to score at least one point on all three controlled tests of the MoveTest (balance, gait, chair rise). During these tests, the MoveTest collects data that will be analyzed on a cloud-based analysis platform. Basically, the healthcare professional of SVDL will perform the following actions:

(1) The healthcare professional will explain the test and the methodology to the person with dementia and his or her informal caregiver.

(2) When they are fully informed, the person with dementia will be fitted with a MoveTest device using a comfortable elastic belt around the waist.

(3) The healthcare professional will program the MoveTest using MCR’s secure online programming and analysis platform13 and starts a recording session.

(4) The person with dementia will have to perform three tests: (1) a balance test with three difficulty levels, (2) a gait test (four meters at comfortable speed) and (3) a five times repeated chair rise test (as fast as possible).

(5) After the tests, the healthcare professional will stop the measurement and will collect the MoveTest device.

(6) The healthcare professional will connect the MoveTest to a PC and logs in on the secure online programming and analysis platform and the data upload and analysis process will start automatically. Data will be transmitted in pseudo-anonymized form by a number.

(7) The healthcare professional will present the outcomes to the person with dementia and his or her informal caregiver in a report or in the PLAYTIME application.

When a person with dementia scores below the required minimum, s(he) will be excluded from participating in this study.

Demonstrating and explaining the PLAYTIME suite

As one of the final steps, the healthcare professional of SVDL will demonstrate and explain how PLAYTIME works at a Tablet PC, and make clear that the materials (MoveMonitor, Tablet PC and online trainings modules) cannot be kept after the testing period of two weeks. Next to this, each person with dementia and his or her informal caregiver will receive individual support and advice to fit the use of PLAYTIME to their own situation and preferences (based on the results of the personal interview). Particular attention will also be devoted to the MoveMonitor which will measure the physical activity of a person with dementia by using a comfortable elastic belt around the waist. In doing so, the healthcare professional of SVDL will perform the following steps:

(1) The healthcare professional will explains the test and the methodology to the person with dementia and his or her informal caregiver, and explains possible questions.

(2) When they are fully informed, the healthcare professional will program the MoveMonitor using the secure online programming and analysis platform11, and will start a recording session.

(3) The person with dementia will be fitted with the programmed MoveMonitor device using a comfortable elastic belt around the waist.

(4) The healthcare professional will explain that the MoveMonitor automatically stops after one week of measuring and that she will return the MoveMonitor during the next home visit.

After the home visit, study participants will start testing PLAYTIME at their home and during group gatherings for a period of two weeks. Contact information of the healthcare professional of SVDL will be provided to study participants in case questions arise or problems occur.

Phase 3 Testing

For the testing period of two weeks, study participants will be asked to test and experiment with the PLAYTIME suite at home and during two group gatherings. During gameplay at home, data regarding clickstream, time log, solution time and performance results will be automatically collected. The informal caregiver will be asked to support the person with dementia whenever necessary.

The testing period will basically look as follows:

Week 1

(1) The person with dementia will be asked to wear the MoveMonitor 24 hours per day, for seven days.

(2) The person with dementia will be asked to play 50 minutes the different trainings modules of PLAYTIME at a Tablet PC. When playing amicasa, the person with dementia will automatically perform one calibration exercise, in which the moderator is asking to fixate the eye to certain points on the screen that will be particularly displayed in that exercise.

(3) The person with dementia will be asked to participate in one group gathering to test the interactive mat and the different trainings modules of PLAYTIME.

(4) The informal caregiver will be asked to play 20 minutes the socio-emotional trainings module SERES Dementia™.

Week 2

(1) The person with dementia will be asked to play 50 minutes the different trainings modules of PLAYTIME at a Tablet PC.

(2) The person with dementia will be asked to participate in one group gathering to test the interactive mat and the different trainings modules of PLAYTIME.

(3) The informal caregiver will be asked to play 20 minutes the socio-emotional trainings module SERES Dementia™.

A number of five persons with dementia will participate in the group gatherings. Each of the two group gatherings will average 90 minutes in time (including 15 minutes break), consist of the same persons with dementia, and be held at the same location (preferably close to study participants' homes). The healthcare professional of SVDL will facilitate the PLAYTIME game, while the researcher of SVDL will observe the group sessions and make field notes.

To assist study participants in answering the questions of the reflective interview, an evaluation form to record their experiences is provided (optionally). The evaluation from will only request a description of the experience and the length of gameplay in order to not place any limits on their records. Study participants who use this evaluation form can consult these experiences during the reflective interview (see phase 4).

Phase 4 Evaluation (Home visit II)

After two weeks, the healthcare professional of and the researcher of SVDL will visit the person with dementia and his or her informal caregiver at home to collect the MoveMonitor and the Tablet PC. They will also reserve sufficient time to evaluate the PLAYTIME suite with study participants and address queries related to the research method and the project in general. To evaluate the PLAYTIME suite, a reflective semi-structured interview will be conducted with both the informal caregiver and the person with dementia. The topic list of this interview will contain several open and closed questions regarding the four evaluation areas (usability, feasibility, appropriateness and acceptability) and their experiences in general. Examples of open questions are: 'how long and often did you use PLAYTIME at home?', 'which trainings module did you use most?' and 'which function gave troubles?' and 'would you like to use PLAYTIME

again?'. The questions 'The physical exercises fit well to my physical abilities', 'Playing PLAYTIME with other persons with dementia has added value for me' and 'Wearing a MoveMonitor is no problem for me' are examples of closed questions. Their scale uses five response categories: strongly disagree, disagree, neither agree nor disagree, agree, or strongly agree, ranging from 1 (strongly disagree) to 5 (strongly agree). The interviews will average 60 minutes in time and will be audio-recorded for the convenience of transcribing.

Materials

The following materials will be required during this study:

(1) Information flyers

(2) Information letters (potential) study participants

(3) Informed consent forms

(4) Evaluation forms (optionally)

(5) 1 interactive mat with 5 cones

(6) 15 Tablet PCs

(7) 10 MoveMonitors

(8) Room(s) with large table(s) (preferably at a location close to study participants' homes)

1.4.4 Argumentation of effect and sample size

A total of 10 till 15 persons with dementia will be included in this study together with their informal caregivers (20 till 30 persons in total). The eventual total sample size will be determined by a saturation criterion, which is generally defined as the point were no new themes, findings, concepts or problems emerge from the data (Francis et al., 2009).

1.4.5 Proposed statistical analysis

For the interviews and observations of the group gatherings, a thematic analysis will be used as main method (Braun & Clarke, 2006). In this form of analysis, interview transcripts will be analyzed by the researcher from SVDL and discussed with the healthcare professional of SVDL. Using the software Atlas.ti, version 7.5.3, statements will be classified into categories using a priori codes regarding the four evaluation areas: usability, feasibility, appropriateness and acceptability. Emergent sub-codes will then be developed based on patterns within each concepts and which were relevant to the literature. In addition to the thematic analysis, descriptive statistics regarding interview responses and data from the event stream (frequencies/percentages, 95% confidence intervals CI, means/medians, standard deviations SD, interquartile ranges IQR, correlations) will be computed using the statistical analysis software package SPSS, version 19.

Data from eye tracking will first be filtered with respect to the frequency of available data. Data captures with frequencies below 5 Hz will be discarded. Filtered data from eye tracking will then be classified into fixations, saccades and blinks according to the methodology of (Salvucci & Goldberg, 2000). The time stamps associated with the fixations of the stored eye tracking data

will be matched with the training sessions and the corresponding areas of interest (AOI) on the screen. With respect to these AOIs, further eye movement features will be elaborated, such as, dwell time within a specific AOI. From the dwell time measures and related AOIs we will then estimate means/medians, standard deviations SD of dwell time. The quality of eye tracking data will be related to the mean dwell time that is being measured on a specific AOI, and comparing these values to those that have been received in lab like environments. If the difference is below a certain threshold the data quality evaluation will be positive.

Factor Analyses will used to present complex data of the MoveMonitor and Movetest into a simple number of parameters. Subsequently, these parameters will be compared to already collected data (age matched, control subjects) using T-test or Anova in order to determine if they are distinctive enough for persons with dementia and usable for personalized recommendations.

1.4.6 Scientific and societal relevance

Scientific relevance

Although some studies performed inclusive research with people living with dementia to develop and evaluate innovate interventions (i.e. Brankaert & den Ouden, 2013; Suijkerbuijk, et al., 2014; Brankaert, Snaphaan, & den Ouden, 2014), user-involvement of people living with dementia remains rather understudied. By testing and evaluating the alpha prototype of PLAYTIME with its users, more direct insights from persons living with dementia concerning the usability, feasibility, appropriateness and acceptability of the innovation can be generated.

Societal relevance

The World Alzheimer Report (2010) shows that the cost of dementia care worldwide was more than US$604 billion, or 1% of aggregated global Gross Domestic Product. Reducing transitions into professional care environments and providing care at home for as long as possible is an important strategy for containing the costs of dementia care (Prince et al., 2014). Whereas this strategy sometimes causes problems, it does generally align with older people's desire to live at home for as long as possible as well as with the global movement towards Person-Centred Care (Clarke, Jane Hanson, & Ross, 2003). This trend, however, will put further pressure on informal caregivers who already provide 60% of the accumulated care for people with dementia. This number is expected to increase majorly in western countries, and is already much higher in developing countries (Prince et al., 2014). This study aims to contribute to this global challenge of dementia by developing a beta prototype of PLAYTIME that fits with user's needs and context. In doing so, PLAYTIME may support people with dementia to live more independent at home, which in turn may reduce the burden on informal caregivers and increase the quality of life.

1.5 Subjects

1.5.1 Relevant study population

- General population with specific "complaints", i.e. stress, dementia, pregnancy, medically unexplained complaints

- Other, i.e. informal caregivers of people with dementia

1.5.2 Arguments to execute the study in the study population

To increase the ecological validity (Koskinen, Zimmerman, Binder, Redström, & Wensveen 2011) and to develop a beta prototype of PLAYTIME that fits with the user's needs and context, it is important that people diagnosed with dementia and their informal caregivers are included in this study.

1.5.3 Age category

Persons between 50 and 100 years of age.

1.5.4 Are the proposed participants able to give informed consent?

There will only be participants included that have given a written agreement to participate. In case of persons with dementia with a relative with power of representation or trustee there will be a procedure to gain a written agreement from representatives. In case of participants with dementia that are able to give informed consent and who are not able to sign due to physical limitations there will be an attestor (relative or professional caregiver) together with the person who will perform the interviews that will approve the oral agreement of the person with dementia. All participants can at any time stop and cancel the participation in the study.

1.5.5 Organization where the recruitment of participants will take place

Sozialverein Deutschlandsberg.

1.5.6 Reward for participation (per experiment)

None.

1.5.7 Describe in detail the expected burden of the experiment/assessment occasions for the study participants with respect to time, mental and physical burden.

We are aware that participating in this study requires some considerable time investment of five hours and 20 minutes to test PLAYTIME at home and during group gatherings (see Figure 1). As PLAYTIME will be tested in one already existing group, no additional time investments for participating in group gatherings is required for half of the study participants (3 hours). In addition, having the informal caregiver and/or the person(s) with dementia play a game together adds a social aspect to this study that may offset the perceived time burden of study participants. The game ambiance of this study could contribute to an informal setting, which is also important for the perceived time burden of study participants.

During gameplay, the physical and mental burden is minimal. For amicasa, the healthcare professional of SVDL will align the difficulty level of the exercises with the physical and cognitive

abilities of each individual person with dementia. There could be a mental burden associated with playing SERES Dementia™ due to reflection on the situation of the informal caregiver and person with dementia (e.g. relationships, health, condition, etc.). In case this game is played in group gatherings, this mental burden may be offset by the presence of the healthcare professional of SVDL and support from peers. When played at home, the presence of an informal caregiver is required, which also may be offset the mental burden of playing SERES Dementia™. There will be no burden for study participants with respect to the MoveMonitor and eye tracking calibration task because these are non-invasive and do not require any consideration or interaction of the person with dementia and their informal caregiver.

The burden associated with the personal interviews is minimal for study participants. It is not intend to discuss intimate or emotionally difficult information. The only goal of these interviews is to collect some background information (e.g. health, daytime activities, social contacts, motivation to test PLAYTIME, etc.) to fit the use of PLAYTIME to the individual situation and preferences of study participants, thereby reducing the mental and physical burden of study participation. The burden of the reflection interviews is also minimal. During these interviews, the focus will only be on how study participants evaluate the usability, feasibility, appropriateness and acceptability of the PLAYTIME suite and their experiences in general. Both the personal and reflection interviews will be conducted at study participants' home, contributing to a comfortable setting in which participants will feel at ease.

1.5.8 Potential negative consequences of participation for the study participants

Fatigue, however, this will be minimized through the attentive healthcare professional and by exercises.

1.5.9 Measures that have been taken to protect the study participant

All the participants will be informed about the study. Contact information of the healthcare professional of SVDL will be provided in case any questions arise or problems occur. Participation is voluntary and participants will be informed about their right to decline participation and withdraw from the research once participation has begun, without any negative consequences, and without providing any explanation. Next to this, several precautions were taken to protect the study participants with dementia in particular. First, only people in the early stage of dementia will be chosen because they still have a sense of self and are capable of understanding what the study means (Ettema et al., 2007). Second, only people with dementia who have an informal caregiving take care of them at their home are involved. In doing so, there is always another person nearby, which ensures a safe inclusion into the research. The main difficulty for research is that dementia is progressive, and the participant's perspective on the study might change. Therefore, the healthcare professional of SVDL will be involved to function, together with the informal caregivers, as gatekeepers. The gatekeepers will decide, continuously, whether participating in the study is still suitable for the person with dementia. The inform consent will thus not be seen as a one-time measure, rather it will be a continuous dialogue between researcher and participants (Coughlan et al., 2013).

Another measure that have been taken to protect study participants is by handling the data confidentially and anonymously. All subject-related data are transmitted and stored in pseudo-anonymized form by a number. Only the healthcare professional and the researcher of SVDL have permission to access the source data. Where it is necessary to be able to trace data to an individual subject, a subject identification code list will be used to link the data to the study participants. The key to the code is safeguarded by the researcher of TIU. The anonymous data will be stored in different databases for a period of 10 years and may only be acquired for purposes within the PLAYTIME project. The data collected by SVDL (MMSE scores, transcripts of interviews and field notes of observations) will be stored in a secure electronic information system of FAM. The eye tracking data of JR will be stored in association with time stamps in order to match eye movement statistics to training sessions played with the app on the Tablet PC. Neither video data nor any visual content about the study participant will be stored. IP addresses will also not be stored.

1.5.10 Subjects participate in more than one experiment within the same line?

No, this is a research proposal for one study only.

1.5.11 Participants subjected to procedures or experiment-related manipulations or tasks?

In this study, persons with dementia are mainly asked to test the PLAYTIME suite at home and during two group gatherings in order to be able to evaluate PLAYTIME from users' needs and context. Next to this, persons with dementia are subjected to the MMSE test and MoveTest, especially to prevent that participating in this study may be too burdensome for them.

(1) MMSE test: The MMSE test will be administered as part of determining the stage of dementia. Playing the different trainings modules of the PLAYTIME suite could be too difficult for a person with dementia, and hence too burdensome, when (s)he is in the late stage of dementia. A MMSE score will also be deployed to perform analyses on the difficulty level of cognitive, physical, and socio-emotional exercises.

(2) MoveTest: The MoveTest will measure the physical performance of a person with dementia during three short controlled tests (balance, gait, chair rise) which typically take five till ten minutes. One reason for including the MoveTest in this study is to determine if a person with dementia has sufficient physical abilities to perform the physical exercises of amicasa. In doing so, the MoveTest may prevent that there is not too much of a physical burden on study participants. Another reason for including the MoveTest in this study is to be able to evaluate the usability of the user feedback generated by this test.

The informal caregivers will not be subjected to procedures or experiment-related manipulations or tasks.

1.6 Information, Data, Archiving and Privacy

1.6.1 When applicable, are there terms/conditions set by the funding organization with respect to information, privacy and reporting?

Yes, i.e. guideline regarding Confidential Information.

1.6.2 Method of recruitment

- Conversation with medical doctor/psychiatrist/psychologist/social worker (or care professional).
- Voluntary application, i.e. via presentation(s) at Alzheimer Café(s).

1.6.3 Time given to eligible participants/parents/caretakers/guardians to decide about participation after the participant has received the participant information letter?

Eligible participants have two weeks to decide about participation.

1.6.4 Deviation from standard rules and regulation concerning information giving and privacy

Standard rules regarding information: participants or their legal representative are:

1. informed study in writing and in advance completely about the nature of the study

2. asked to give written informed consent by means of a consent form

3. debriefed afterwards (in writing and orally) about the goals of the study and reason for potential misleading elements during the experiment

Standard rules regarding research data:

4. data are processed in a coded fashion (and anonymous if possible) and stored confidentially

5. a participant may always look into their own data (except when a study is completely anonymous, then there is no link between personal information and study data)

6. all data must be available for inspection for all investigators involved in the project

In this sense, there will be no deviation from standard rules.

In this research no debriefing (in writing and orally) will take place as the information letter participants receive during recruitment already provides all information about the goals of the study. The study does not contain any misleading elements. Therefore, no further information needs to be debriefed to the participants.

1.7 Data use & publication

1.7.1 Use of the obtained data

The use of the data will be exclusively permitted for the following objectives,

- Scientific publication(s) in peer reviewed conferences or journals.
- Report for own organization (i.e. the PLAYTIME consortium).
- Other, i.e., to develop a beta prototype of PLAYTIME that will be tested in another field test.

1.8 Checklist information to patient

- Title (Title of the study, if necessary simplified, abbreviated or translated)
- Introduction
- Purpose
- Background
- Nature
- Duration
- Procedures
- Expected duration
- Possible advantage for the participant
- Voluntariness of participation.
- Right to decline to participate and withdraw from the research once participation has begun, without any negative consequences, and without providing any explanation.
- Confidentiality protection and limitations
- Period of time to which the consent applies (normally the length of the study)
- Deliberation time (if applicable)
- Processing results
- Period of time that date will be stored and encrypted (10 years)
- Approval Ethical Review Board
- Request for participation
- Closing / whom to contact in case of question or additional information (name and telephone number/ email address researchers)

1.9 Checklist Informed Consent

- Title (Title of the study, if necessary simplified, abbreviated or translated)
- Confirmation that the information is read
- Confirmation that there was room for questions
- Reminder on voluntariness of participation. Right to decline to participate and withdraw from the research once participation has begun, without any negative consequences, and without providing any explanation
- Permission processing of anonymous/coded data as mentioned in the information letter
- Permission for storing the research data for a period of ten years
- Permission participation in the study
- Date, name, signature participant (self-written, so not preprinted)
- Date, name, signature researcher (self-written, so not preprinted)
- Give the participant a copy of the signed informed consent form

1.10 Documents including the study plan / research proposal uploaded to the Ethics Committee

The committee would like to receive the following documents in addition to this study plan / research proposal:

- “Ethikantrag PLAYTIME 1” (document in the attachment)
- Study plan / research proposal (this document)
- Appendix I: Consortium agreement JR
- Appendix II: Information flyer (concept)
- Appendix III: Informed consent
- Appendix IV: Mini Mental State Examination (MMSE)
- Appendix V: Examples of stimulus materials
- Appendix VI: Template for final study results
- Appendix VII: Questionnaires

2 Appendix I: Consortium agreement of JR and SVDL

9 SIGNATURE PAGES

PLAYTIME Consortium Agreement - Signature Page 1/9

For and behalf of:

JOANNEUM RESEARCH Forschungsgesellschaft mbH

JOANNEUM RESEARCH
Geschäftsführung
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Univ.-Prof. DI Dr. Wolfgang Pribyl, MBA

Graz / AUSTRIA, 24. MRZ. 2017

PLAYTIME Consortium Agreement - Signature Page 4/9

For and behalf of:

Sozialverein Deutschlandsberg

Josef Steiner **Ingeborg Krainer**

Deutschlandsberg / AUSTRIA, 27.03.2017

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3 Appendix II: Information flyer (concept)

Entwicklung eines Spiels für Menschen mit Demenz

PLAY TIME

Vielen Dank für Ihr Interesse am PLAYTIME-Projekt. Wir würden Sie gerne über diese Broschüre informieren.

Worum geht es in dem Projekt?

Wissenschaftliche Untersuchungen haben gezeigt, dass die Stimulation von sozialen, kognitiven und physischen Funktionen dazu beitragen kann, den Prozess der Demenz zu verlangsamen. Das Projekt PLAYTIME entwickelt dafür ein interaktives Spiel für einen Tablet PC und stimuliert drei Funktionen gleichzeitig. Dieses interaktive Spiel wird in Zusammenarbeit mit mehreren Organisationen entwickelt aus dem In - und Ausland entwickelt, darunter dem Sozialverein Deutschlandsberg und JOANNEUM RESEARCH, dem wissenschaftlichen Exzellenzzentrum für Menschzentrierte Technologien in der Steiermark.

Was kannst du tun?

Es ist wichtig, dass wir ein Spiel entwickeln, das den Wünschen und Bedürfnissen von Menschen mit Demenz entspricht. Wir bitten Sie daher um Hilfe bei der Entwicklung und Erprobung des Spiels und möchten Ihre Erfahrungen aufzeichnen. Das Spiel wird zu Hause oder in einer Gruppe getestet werden. Sie können an diesem Projekt teilnehmen, wenn Sie zu Hause leben, eine Diagnose zu beginnender Demenz besitzen, sowie eine beteiligte Bezugsperson haben und das Spiel zu Hause durchführen können.

Haben Sie Fragen zu dieser Broschüre? Oder möchtest du am PLAYTIME-Projekt teilnehmen?

Name der Kontaktperson:	Dr.in Mariella Panagl (Psychologin)
erreichbar unter:	0664/2354629
Name der Kontaktperson:	Manuela Künstner (Leitung MAS Training)
erreichbar unter:	0664/2270244

4 Appendix III: Informed Consent

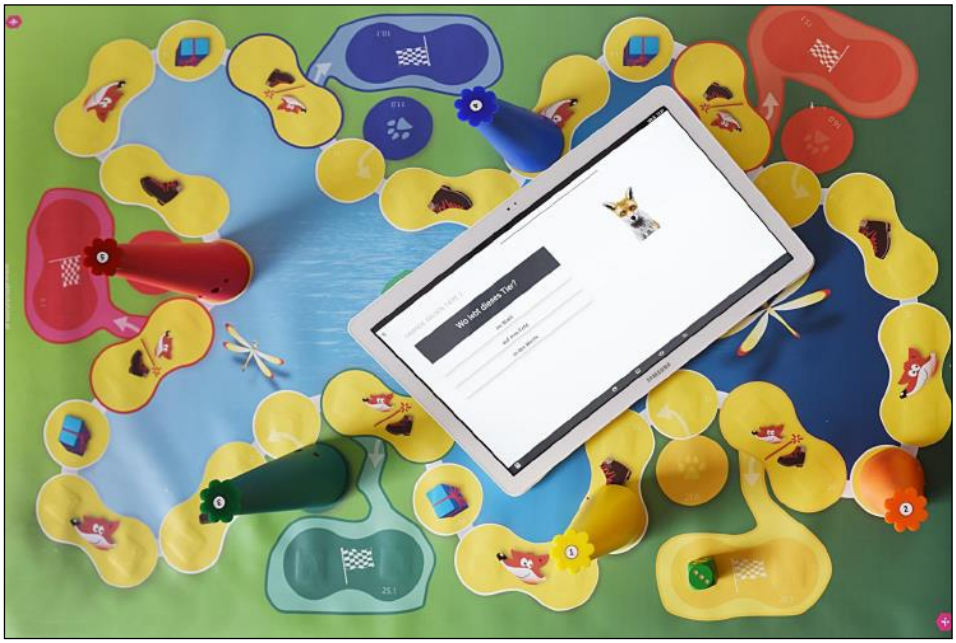
See attachment.

5 Appendix IV: Mini Mental State Examination (MMSE)

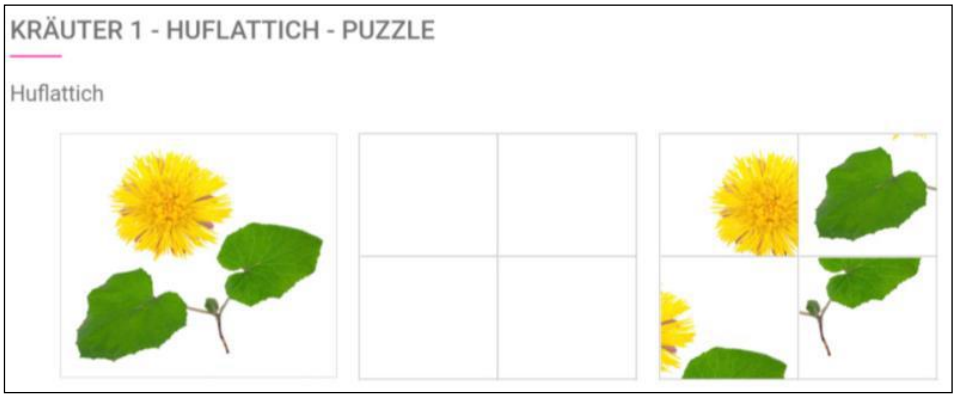
Mini Mental-Status (aus: CERAD-Plus Testbatterie)		**Falsch 0**	**Richtig 1**	**Nicht beurteilbar**
1. Welches Jahr haben wir?		☐	☐	☐
2. Welche Jahreszeit?		☐	☐	☐
3. Den wievielten des Monats?		☐	☐	☐
4. Welcher Wochentag ist heute?		☐	☐	☐
5. Welcher Monat?		☐	☐	☐
6. In welchem Land sind wir?		☐	☐	☐
7. In welchem Kanton?		☐	☐	☐
8. In welcher Ortschaft?		☐	☐	☐
9. Auf welchem Stockwerk?		☐	☐	☐
10. An welchem Ort (Name oder Adresse) befinden wir uns hier?		☐	☐	☐
11. Bitte sprechen Sie mir nach: "**Zitrone**", "**Schlüssel**", "**Ball**"		☐	☐	☐
12.		☐	☐	☐
13.		☐	☐	☐
14. Bitte buchstabieren Sie das Wort **PREIS** rückwärts	(S)	☐	☐	☐
15.	(I)	☐	☐	☐
16.	(E)	☐	☐	☐
17.	(R)	☐	☐	☐
18.	(P)	☐	☐	☐
19. Welches sind die drei Wörter, die Sie sich merken sollten?		☐	☐	☐
20.		☐	☐	☐
21.		☐	☐	☐
22. Was ist das? (Armbanduhr)		☐	☐	☐
23. Was ist das? (Bleistift)		☐	☐	☐
24. Sprechen Sie nach: "**Bitte keine Wenn und Aber**."		☐	☐	☐
25. Lesen Sie bitte was auf diesem Blatt steht und führen Sie es aus! (auf dem Blatt steht: „Schliessen Sie ihre Augen“).		☐	☐	☐
Ich gebe Ihnen nun ein Blatt Papier:		☐	☐	☐
26. Nehmen Sie das Blatt Papier in Ihre rechte Hand,		☐	☐	☐
27. falten Sie es mit beiden Händen und		☐	☐	☐
28. legen es dann auf Ihren Schoss!		☐	☐	☐
29. Schreiben Sie bitte irgendeinen vollständigen Satz auf dieses Blatt Papier!		☐	☐	☐
30. Hier ist eine Figur. Bitte zeichnen Sie diese Figur auf dem gleichen Blatt Papier ab!		☐	☐	☐
Punktezahl Total				

6 Appendix V: Examples of stimulus materials

Interactive mat and Tablet PC



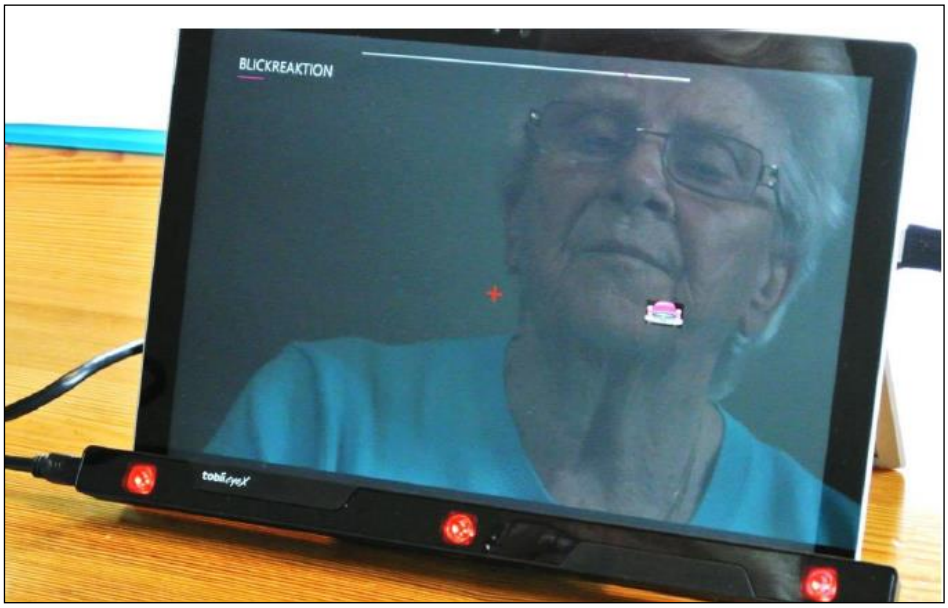
Example exercises amicasa


KRÄUTER 1 - HUFLATTICH - PUZZLE
Huflattich


KRÄUTER-MEMORY
Finden Sie die gleichen Bildpaare:
Salbei
Lorbeer
Petersilie
Rosmarin


KRÄUTER 1 - RÄTSEL - FRAGE 6
Um welches Kraut handelt es sich hierbei?
Spitzwegerich
Baldrian
Lavendel

Eye tracking task in amicasa



Examples of SERES DementiaTM[7]

[7] The text will be translated to German.

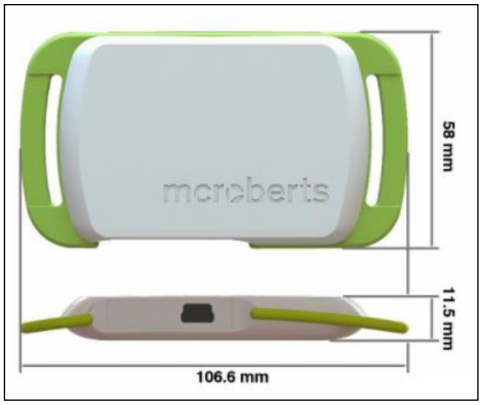
Emilie hat Schwierigkeiten mit dem Zuknöpfen ihrer Bluse. Sie fummelt ständig herum während du sie ungeduldig anguckst. Wenn ihr jetzt nicht losgeht, werdet ihr kaum noch Zeit im Supermarkt haben. Was machst du?

Du erklärst Emilie, dass der Laden geschlossen sein wird wenn ihr jetzt nicht losgeht. Danach gehst du selbst, ohne Emilie, fort. Das scheint ihr unbegründet und sie bleibt mit einer schlechten Laune zurück.

Du hilfst Emilie sich anzuziehen, obwohl sie am Anfang deine Hilfe nicht will. Bald danach seid ihr fertig und geht ihr los.

Du bevorzugst, dass Emilie sich selbstständig umzieht. Das könnte aber bedeuten, dass ihr nicht mehr rechtzeitig in den Supermarkt gehen könnt.

MoveMonitor



7 Appendix VI: Template for final study results

FINALES STUDIENRESULTAT

Person hat die Studie vollständig abgeschlossen ? ☐1	**Abschlussdatum** T T M M M J J J J
Wenn NICHT abgeschlossen, dann letztes Bearbeitungsdatum:	T T M M M J J J J

Grund für Abbruch:

(Nur **eine** Box ankreuzen)

- ☐1 Signifikante Nichterfüllung
- ☐2 Behandlungsfehler
- ☐3 Einverständnisbewilligung zurückgezogen
- ☐4 Nicht erreicht
- ☐5 Anderer (spezifizieren) _____

Bemerkungen:

_____

_____

_____

Monitoring Statement: Ich habe die Daten dieses Prüfbogens überprüft und bestätige dass diese Daten vollständig und präzise sind

Monitor (Vollständiger Name): _____

Unterschrift Monitor? ☐1

Unterschrift Datum: T T M M M J J J J

8 Appendix VII: Questionnaires

See documents in the attachment.

- „Quest1_Erstgespräch.1. Feldstudie“
- „Quest2_Evaluationsfragebogen“

9 References

Almirall, E., Lee, M., & Wareham, J. (2012). Mapping living labs in the landscape of innovation methodologies. Technology innovation management review, 2(9), 12.

Astell, A.J., Ellis, M.P., Bernardi, L., Alm, N., Dye, R., Gowans, G. and Campbell, J. (2010) Using a touch screen computer to support relationships between people with dementia and caregivers. Interact. Comput., 22, 267–275.

Bharucha, A. J., Anand, V., Forlizzi, J., Dew, M. A., Reynolds, C. F., Stevens, S., & Wactlar, H. (2009). Intelligent assistive technology applications to dementia care: current capabilities, limitations, and future challenges. The American journal of geriatric psychiatry, 17(2), 88-104.

Brankaert, R., & den Ouden, E. (2013). Setting up a LivingLab for innovation in the dementia care chain, a case study of the PhysiCAL. In ISPIM Conference Proceedings (p. 1). The International Society for Professional Innovation Management (ISPIM).

Brankaert, R., Snaphaan, L., & den Ouden, E. (2014). Stay in touch: an in context evaluation of a smartphone interface designed for people with dementia. In International Workshop on Ambient Assisted Living (pp. 288-295). Springer, Cham.

Brankaert, R. G. A. (2016). Design for dementia: a design-driven living lab approach to involve people with dementia and their context.

Braun, V., & Clarke, V. (2006). Using thematic analysis in psychology. Qualitative research in psychology, 3(2), 77-101.

Bryman, A. (2008). Social Research Methods. Oxford University Press. Oxford, New York.

Buschert, V. C., Friese, U., Teipel, S. J., Schneider, P., Merensky, W., Rujescu, D., ... & Buerger, K. (2011). Effects of a newly developed cognitive intervention in amnestic mild cognitive impairment and mild Alzheimer's disease: a pilot study. Journal of Alzheimer's disease, 25(4), 679-694.

Clarke, A., Jane Hanson, E., & Ross, H. (2003). Seeing the person behind the patient: enhancing the care of older people using a biographical approach. Journal of clinical nursing, 12(5), 697-706.

Coughlan, T., Leder Mackley, K., Brown, M., Martindale, S., Schloegl, S., Mallaband, B., Arnott, J., et al. (2013). Current issues and future directions in methods for studying technology in the home. PsychNology, 11(2), 159 – 184.

Ettema, T. P., Dröes, R. M., de Lange, J., Mellenbergh, G. J., & Ribbe, M. W. (2007). QUALIDEM: development and evaluation of a dementia specific quality of life instrument—validation. International journal of geriatric psychiatry, 22(5), 424-430.

Farina, N., Rusted, J., & Tabet, N. (2014). The effect of exercise interventions on cognitive outcome in Alzheimer's disease: a systematic review. International Psychogeriatrics, 26(1), 9-18.

Francis, J. J., Johnston, M., Robertson, C., Glidewell, L., Entwistle, V., Eccles, M. P., & Grimshaw, J. M. (2010). What is an adequate sample size? Operationalising data saturation for theory-based interview studies. Psychology and Health, 25(10), 1229-1245.

Galimberti, D., & Scarpini, E. (2010). Inflammation and oxidative damage in Alzheimer's disease: friend or foe?. Frontiers in bioscience (Scholar edition), 3, 252-266.

Graessel, E., Stemmer, R., Eichenseer, B., Pickel, S., Donath, C., Kornhuber, J., & Luttenberger, K. (2011). Non-pharmacological, multicomponent group therapy in patients with degenerative dementia: a 12-month randomized, controlled trial. BMC medicine, 9(1), 129.

Gräsel, E., Wiltfang, J., & Kornhuber, J. (2003). Non-drug therapies for dementia: an overview of the current situation with regard to proof of effectiveness. Dementia and geriatric cognitive disorders, 15(3), 115-125.

Groot, C., Hooghiemstra, A. M., Raijmakers, P. G. H. M., van Berckel, B. N. M., Scheltens, P., Scherder, E. J. A., ... & Ossenkoppele, R. (2016). The effect of physical activity on cognitive function in patients with dementia: a meta-analysis of randomized control trials. Ageing research reviews, 25, 13-23.

Koskinen, I., Zimmerman, J., Binder, T., Redstrom, J., & Wensveen, S. (2011). Design research through practice: From the lab, field, and showroom. Elsevier.

Leminen, S., Westerlund, M., & Nyström, A. G. (2012). Living Labs as open-innovation networks. Technology Innovation Management Review, 2(9).

Luttenberger, K., Donath, C., Uter, W., & Graessel, E. (2012). Effects of Multimodal Nondrug Therapy on Dementia Symptoms and Need for Care in Nursing Home Residents with Degenerative Dementia: A Randomized-Controlled Study with 6-Month Follow-Up. Journal of the American Geriatrics Society, 60(5), 830-840.

Maseda, A., Sánchez, A., Marante, M. P., González-Abraldes, I., Buján, A., & Millán-Calenti, J. C. (2014). Effects of multisensory stimulation on a sample of institutionalized elderly people with dementia diagnosis: a controlled longitudinal trial. American Journal of Alzheimer's Disease & Other Dementias®, 29(5), 463-473.

Markopoulos, P., & Rauterberg, G. W. M. (2000). LivingLab: A white paper. IPO Annual Progress Report, 35, 53-65.

Oliveira, A. M. D., Radanovic, M., Mello, P. C. H. D., Buchain, P. C., Vizzotto, A. D. B., Celestino, D. L., ... & Forlenza, O. V. (2015). Nonpharmacological interventions to reduce behavioral and psychological symptoms of dementia: a systematic review. BioMed research international, 2015.

Prince, M., Albanese, E., Guerchet, M., & Prina, M. (2014). World Alzheimer Report 2014: Dementia and

Salvucci, D. D., & Goldberg, J. H. (2000). Identifying fixations and saccades in eye-tracking protocols. In Proceedings of the 2000 symposium on Eye tracking research & applications(pp. 71-78). ACM.

Suijkerbuijk, S., Brankaert, R., de Kort, Y. A., Snaphaan, L. J., & den Ouden, E. (2014). Seeing the first-person perspective in dementia: a qualitative personal evaluation game to evaluate assistive technology for people affected by dementia in the home context. Interacting with Computers, 27(1), 47-59.

Teri, L., Logsdon, R. G., & McCurry, S. M. (2008). Exercise interventions for dementia and cognitive impairment: the Seattle Protocols. The journal of nutrition, health & aging, 12(6), 391-394.

Topo, P. (2009). Technology studies to meet the needs of people with dementia and their caregivers: a literature review. Journal of applied Gerontology, 28(1), 5-37.

Woods, B., Aguirre, E., Spector, A. E., & Orrell, M. (2012). Cognitive stimulation to improve cognitive functioning in people with dementia. The Cochrane Library.

World Alzheimer report (2010). The global economic impact of dementia. Alzheimer's Disease International.

Part II: Study Plan the Netherlands

- ETHICS REVIEW BOARD TSB –

SUBMISSION FORM RESEARCH PROPOSAL

1. General guidelines of use

- **This submission form may be used for an individual research proposal and for experimental research lines. Only principal investigators of a project can submit a proposal for evaluation. At least one of the principal investigators with a PhD has to be employed by Tilburg University.**
  NB. When you are planning a series of experiments that are similar in content in similar populations and with similar procedures, it is sometimes to be preferred to submit a research line, as this saves time and effort. This is not obligatory though. The submission of a research line does cost more work, as the committee expects a more extensive description of the series of experiments.

- Ethical approval of a research project is valid for the indicated duration of the project or until a change occurs in study population, data collection or other procedures. The ethical approval of a research line is valid for a maximum of 5 years (or until a change occurs in study population, data collection or other procedures) after which a new proposal needs to be submitted.

- Below mentioned researchers and other involved personnel commit themselves to treat all study participants according to the most recent version of the Helsinki declaration (http://www.wma.net/en/30publications/10policies/b3/) as well as the Code of Ethics for the Social & Behavioral Sciences (www.tilburguniversity.edu/erb).

- Researchers and other involved personnel also guarantee that the study participant may discontinue their participation at all times without any consequences. The researchers and other involved personnel commit themselves to maximize the quality of the research, statistical analysis and the reports and to respect specific rules and regulations concerning specific methodologies (e.g., fMRI).

- With this electronic signature the undersigned declares to have described the research project truthfully, with special attention to the ethical aspects of the project.

For agreement:

Name:	Prof. Dr. I.M.B. Bongers
ANR (employee number):	2 5 4 7 8 9
Date:	24-01-2018

- ETHICS REVIEW BOARD TSB –

Title: Playtime: a first field study on developing an integrated theratainment innovation for people living with dementia

Main investigators: I.A.G.M. Geerts MSc
Dr. L.J.A.E. Snaphaan
Prof. Dr. I.M.B. Bongers

1. SUMMARY

Give a summary of the proposed study/research line. Make sure you give sufficient information on the data collection procedures (manipulations, stimuli, questionnaires, certainly when they may be ethically sensitive).

1.1 Background (Max. 1500 words):

Dementia is a broad category of neurocognitive disorders characterized by a long term and often gradual decrease in the ability to think and remember. Other symptoms include impaired language, personality changes, emotional problems, behavioral disturbances, and decreases in motivation (Prince, Albanese, Guerchet, & Prina, 2014). The most common forms of dementia are Alzheimer's disease (<70%), Vascular disease (<20%), Lewy Body Dementia (<5%) and frontotemporal dementia (2%) in descending order of occurrence (Prince et al., 2014). These diseases are progressive and slowly, but severely affect a person's brain, and thus affect his or her ability to live a normal live. Advancing age is the main risk factor for most forms of dementia, and with the ever increasingly aging population, the prevalence of dementia worldwide is expected to nearly double every 20 years to 65.7 million in 2030 and 115.4 million in 2050 (Prince et al., 2014). This expected increase will have profound societal challenges in the sense of costs connected to the care of dementia, the quality of life of people with dementia, and the burden on family care givers.

Currently, no disease modifying drugs for dementia are available and pharmacological treatment is limited to therapies that alleviate the symptoms. However, these treatments are not efficacious in all clients and may introduce undesirable side-effects (Galimberti & Scarpini, 2010). Non-pharmacological (or psychosocial) interventions, such as sensory stimulation, cognitive stimulation and physical exercise programs, are therefore appealing alternatives or add-ons as these were found to slow down cognitive decline (or even improved cognition) and/or to reduce behavioral and psychological symptoms once the clinical diagnosis of dementia has been established (e.g. Maseda et al., 2014; Woods, Aguirre, Spector, & Orrell, 2012; Groot et al., 2016; Farina, Rusted, Tabet, 2014; Teri, Logsdon, & McCurry, 2008; Oliveira et al., 2015). Most of these different interventions, however, have involved unimodal therapy and have demonstrated limited effectiveness (Buschert et al., 2011; Gräßel, Wiltfang, & Kornhuber, 2013). Therefore, non-pharmacological interventions for meaningful treatment of dementia should consists of multiple components, even being accompanied by social environments (Graessel et al., 2011; Luttenberger, Donath, Uter, & Graessel, 2012).

The AAL funded project Playtime[8] consisting of partners within Austria, Belgium and the Netherlands intends to achieve this by developing an integrated theratainment innovation of personalized emotion-oriented training

[8] http://aal-playtime.eu/

modules to stimulate cognitive processes, to address physical activities and foster social inclusion. The targeted innovation of Playtime is based on an Austrian project AktivDaheim[9], which redeveloped Schooltastic[10] into a playful interactive training for people with dementia. The objective of the project Playtime is to motivate people with dementia to enter a positive feedback cycle of periodic training with sensors that enable diagnostics on a daily basis, and to receive recommendations on the basis of these data that propose more personalized and better suited exercises for improved training. The motivation is primary triggered by the following three aspects of Playtime: (1) positive affection achieved from social engagement in playful group gatherings, (2) multimodal online training modules, including a cognitive exercises (e.g. multiple choice, puzzles, spot-the-difference, memory), socio-emotional exercises (i.e. real-life scenarios), and a physical exercises, to offer the user playful experience at home and group gatherings, and (3) the involvement and improvement of activities of daily living. User feedback, in terms of physical performance, physical activity and eye-tracking movements, will provide diagnostics to determine personalized recommendations and, in turn, optimize user experience. The Playtime suite will contain an interactive mat for group gatherings, a mobile app with integrated trainings modules, a Tablet PC, a MoveMonitor, and software for web camera based eye movement analysis. In figure 1, a schematic overview of the most important aspects of the Playtime suite is provided.

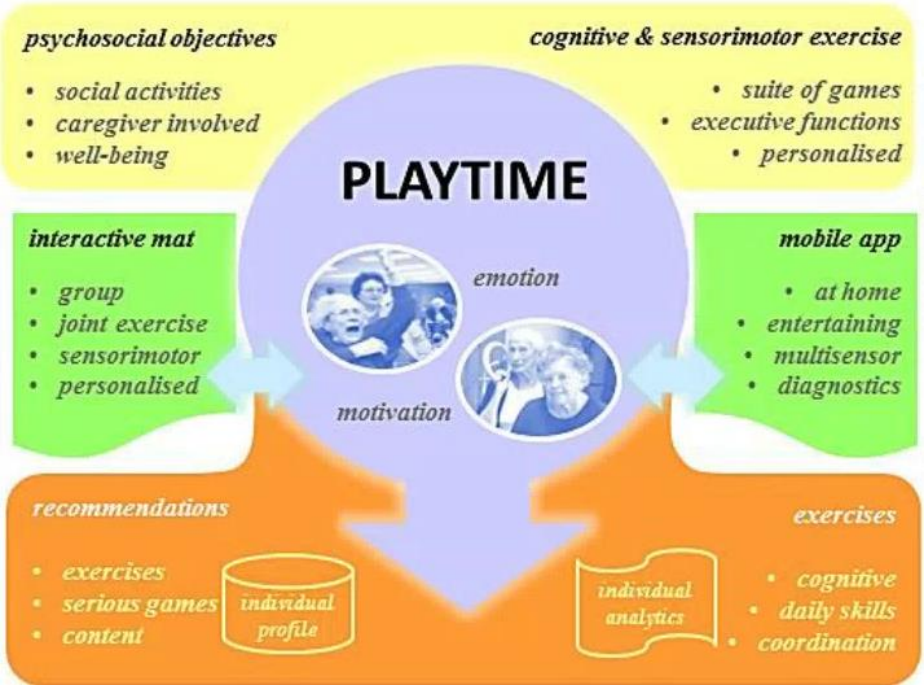


Figure 1. *Schematic overview of the Playtime suite for people living with dementia.*

A carefully designed Playtime suite may answer unmet needs of people living with dementia. Yet, research shows that the design of innovations for this target population still proves to be challenging as these are often too difficult to be used by them (Astell et al., 2010). For one, innovations for people living with dementia are seldom designed considering the users' needs and context (Bharucha et al., 2009). Understanding the daily context of

[9] http://aktivdaheim.at/

[10] https://www.schooltastic.net/

users in the development of new innovations is essential to cater to their, often complex, needs and the acceptance of the innovation. Moreover, the first-hand perspective from the person with dementia itself is rarely sought in the design process of innovations (Topo, 2009). Instead, the designer or an informal caregiver generally voice product or service evaluations on their behalf. This absence of a first-hand perspective and the need to develop and evaluate innovations as an integral part of the home context of people with dementia motivates the use of the Living Lab method for Playtime. The Living Lab approach is described as a method to expose users to innovations in a natural context (Markopoulos & Rauterberg, 2000), with the goal to develop the innovation further for a market introduction (Leminen, Westerlund, & Nyström, 2012). We rarely see people with dementia getting involved in Living Lab studies, nevertheless, they are perfectly capable to do so when adequately prepared (Suijkerbuijk, Brankaert, Kort, Snaphaan, & Den Ouden, 2015).

Given the preceding paragraph, it is clear why the Playtime suite needs to be carefully evaluated by the use of a Living Lab method. Therefore, this first field study aims to evaluate the alpha prototype of Playtime in order to retrieve insights on its usability, feasibility, appropriateness and acceptability in real-life environments. Furthermore, it will evaluate the usability of the user feedback, in terms of physical performance, physical activity and eye-tracking movements, for determining personalized recommendations. The results of this study are input for the development of a beta prototype of Playtime that fits with the user's needs and context.

1.2 Research question(s):

The research questions of this study can be formulated as follows:

(1) How do people living with dementia evaluate the alpha prototype of Playtime with regard to usability, feasibility, appropriateness and acceptability?

(2) Which user feedback generated by the alpha prototype of Playtime is usable for determining personalized recommendations?

1.3 Study design:

For this study, an explorative study will be conducted to evaluate the experiences of users with the Playtime alpha prototype and to look for improvement and personalization opportunities. The Living Lab method will be followed to evaluate the prototype in real-life environments: (i.e. homes and daycare centers). People living with dementia will therefore be involved as co-creators rather than test subjects of the study (Almirall et al., 2012). In addition, a mixed-method design will be used consisting of four phases: preparation, introduction, testing and evaluation. In doing so, we will be able to better understand the utility and relevance of Playtime for people living with dementia, and learn how to improve the alpha prototype and provide personalized recommendations to continue development. In the preparation phase, people living with dementia will be recruited and informed about the aim and procedure of this study. In the introduction phase, the inclusion criteria of this study will be confirmed, the Playtime suite will be demonstrated, and background information of people living with dementia will be collected by personal interviews. Based on this background information, each person with dementia and his or her informal caregiver will receive individual support and advice to fit the use of Playtime to their own situation and preferences. Next, in the testing phase, people living with dementia will use Playtime's alpha prototype at their home and during group gatherings. The testing period will take two weeks to overcome the short term effect and to still make it suitable for monitoring acceptance and integration in daily life (Brankaert, 2016). This is sufficient because the goal of this study is explorative in nature and focused on the creation of a beta prototype of Playtime. In this phase, most user feedback for determining personalized recommendations will be automatically collected by the Playtime suite. The final phase, evaluation, will involve a reflection interview to gather insights on user's testing experiences with Playtime during these two weeks.

1.4 Procedure & materials:

The study will be conducted in collaboration with the following partners of the project Playtime: Geestelijke Gezondheidszorg Eindhoven en de Kempen (GGZ)[11], Tilburg University (Tranzo) (TIU), FAMEL (FAM)[12], Sozialverein Deutschlandsberg (SVD)[13], MindBytes (MBY)[14], McRoberts (MCR)[15], and JOANNEUM RESEARCH (JR)[16].

- The Dutch mental healthcare organization GGZ has direct access to people living with dementia and healthcare professionals who are experienced with this target population. An appropriately trained healthcare professional of GGZ will perform several tasks in this study, namely:
  (1) She will build a Living Lab structure.
  (2) She will visit study participants at home to introduce Playtime.
  (3) She will support and advice study participants in using Playtime.
  (4) She will lead the Playtime game during group gatherings.
  (5) She will be available to support study participants in case questions arise or problems occur.
  (6) She will report technical problems to the partners of Playtime.
- The Dutch research institute Tranzo of TIU is knowledgeable about social innovation in healthcare. A researcher of TIU will particularly evaluate the usability, feasibility, appropriateness and acceptability of the Playtime suite by conducting interviews with study participants and observing group gatherings. Therefore, study participants will only have contact with the researcher of TIU and the healthcare professional of GGZ, making them feel more comfortable.
- The Austrian company FAM will provide the serious game that was developed in the Austrian project AktivDaheim. Their serious game, named Amicasa, is the basis of the alpha prototype of Playtime and consists of different trainings modules with several exercises: physical exercises, puzzles, memory, spot-the-difference, and knowledge-based questions. Each of these trainings modules covers one theme and can be played at three different levels (A, B or C). In this study, FAM is particularly interested in the usability, feasibility, appropriateness and acceptability of Amicasa from users' perspective. Next to this, the usability and appropriates of Amicasa will also be evaluated by analyzing data of the event stream, including clickstream, time log, solution time and performance results.
- The Austrian healthcare organization SVD has already evaluated Amicasa with their clients and has shared these experiences with GGZ and TIU. Although healthcare professionals of SVD will perform the same tasks in Austria as the healthcare professional of GGZ and the researcher of TIU in the Netherlands, this proposal *only* applies to the study that will be conducted in the Netherlands. The first field study in Austria will be reviewed by a local Austrian ethical committee.
- The Belgian company MBY will provide the socio-emotional trainings module of the Playtime suite. Their socio-emotional module, also referred to as SERES Dementia™ [17], consist of scenario-based serious games that intend to improve the coping skills of *both* people with dementia and their informal caregivers, and

[11] https://www.ggze.nl/

12https://firmen.wko.at/Web/DetailsInfos.aspx?Suchbegriff=FameL%20GmbH&StandortName=Steiermark%20(Bundesland)&FirmaID=bf154e05-7a01-4746-9c51-e5524b462ba0

13 https://www.sozialverein-deutschlandsberg.at/

14 http://mindbytes.be/

15 https://www.mcroberts.nl/

16 https://www.joanneum.at/

17 http://mindbytes.be/project/seres-dementia/

are therefore built around the ABC (antecedent-behavior-consequences) learning approach, which is a derivative of CBT (cognitive behavior therapy). This is realized by providing the study participant a realistic scenario (antecedent), three behavioral options directly derived from different coping styles (behavior), and quantitative feedback (consequences). In addition, the game also includes cognitive feedback related to best practices that are presented to the study participant after each module. In this study, MBY is interested in how people with dementia and their informal caregivers evaluate the usability, feasibility, appropriateness and acceptability of SERES Dementia™. The usability and appropriateness of SERES Dementia™ will also be evaluated by analyzing data from the event stream, including clickstream, time log, solution time and performance results.

- The Dutch company MCR will provide the necessary equipment, training and knowledge to measure physical performance and physical activity during standardized tests and during daily life. The equipment provided by them will consist of the already existing MoveTest (short physical performance test) and MoveMonitor (physical activity in daily life). In this study, MCR will particularly evaluate the usability, feasibility, appropriateness and acceptability of the MoveMonitor from users' perspective. Also the usability of the generated data by the MoveTest and the MoveMonitor for determining personalized recommendations will be evaluated.
- The contribution of the Austrian research institute JR to Playtime is the implementation of measurement technologies that identify behavioral and psychophysiological markers for cognitive mechanisms in people with dementia during gameplay at home. Based on estimated mental state of the user, further game content will be personalized by adjusting the level of gameplay to the person with dementia. To do this, JR will provide a software for web camera based eye movement analysis at a Tablet PC. This software will analyze the video stream by detecting the face, localizing the eyes, and apply eye tracking for the estimation of orientation of eye balls towards the screen of the Tablet PC. The accuracy of the eye tracking is sufficient to conclude with simple statistics of eye movement features during gameplay at home and will estimate features of users' cognitive control. In this study, JR will evaluate the usability of the eye tracking calibration procedure and analyze the quality of the eye tracking data for determining personalized recommendations.

Examples of Amicasa, SERES Dementia™, the MoveMonitor and an eye tracking task are displayed in Appendix III.

A study design of several phases will be used to evaluate the alpha prototype of Playtime. In the figure below, a summary of the study procedure is provided, including the total amount of investment hours needed from each person with dementia and/or his or her informal caregiver.

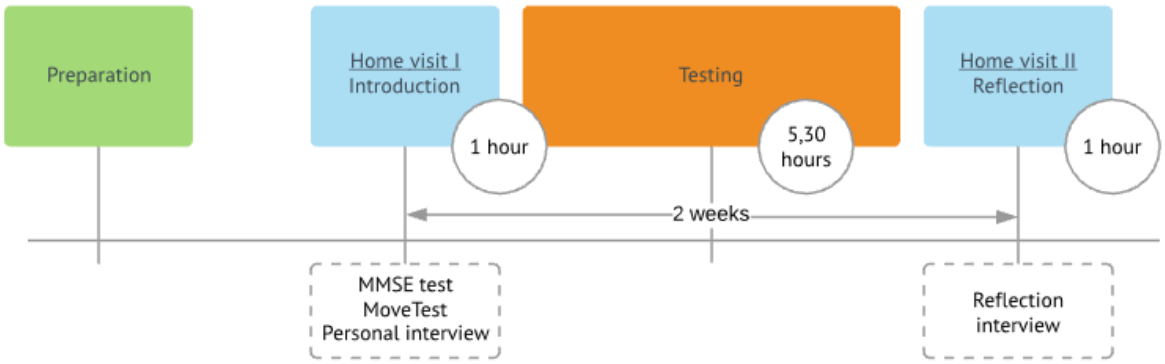


Figure 2. *Summary of study procedures*.

Phase 1 Preparation

From February 2018 till April 2018, a healthcare professional from GGZ will recruit 10 till 15 persons with dementia and their informal caregivers. Because Playtime will be tested during groups gatherings, she will recruit one already existing group and one new group by four main methods, namely (1) asking healthcare professionals in her network if they have eligible participants and/or daycare groups in their caseload, (2) using the Innovate Dementia[18] user platform of GGZ, (3) using the ecosystem of Brabantse Proeftuin Dementie[19], and (4) presenting Playtime at discussion groups (i.e. Alzheimer café's) where people living with dementia can voluntary apply as participant. During recruitment, the healthcare professional will distribute information flyers and will emphasize that certain criteria needs to be satisfied in order to be able to participate in this study. A person with dementia will be included in this study if (s)he:

(1) Is diagnosed with dementia as formulated in DSM-IV or DSM-V: extended neurocognitive disorders caused by Alzheimer, lewy bodies, vascular diseases or multiple origins (frontotemporal lobar degeneration will be excluded).
(2) Is in an early stage of dementia (MMSE>22).
(3) Still lives at home in the region of Eindhoven or Tilburg.
(4) Has involved informal caregiver.
(5) Speaks Dutch.
(6) Has no severe visual and auditory processing disorders.
(7) Has sufficient physical abilities (at least 1 point on all three controlled tests of the MoveTest)
(8) Is willing to participate in and travel to group gatherings.

In the information flyer, contact information of the healthcare professional of GGZ and the researcher of TIU is provided. This gives eligible participants the opportunity to have a personal conversation about the study and to ask questions. If both the person with dementia and his or her informal caregiver are interested in participating in the project, they have to contact the healthcare professional of GGZ. Subsequently, the healthcare professional of GGZ will sent an information letter and informed consent to them (by post or email). In the information letter, the aim and procedure of the study are further explained. Next to this, the information letter will inform eligible participants about their right to decline participation and withdraw from the research once participation has begun, without any negative consequences, and without providing any explanation. Two weeks after the information letter and informed consent were mailed (or a couple days longer in case these materials were sent by post), the healthcare professional of GGZ will contact eligible participants again by telephone. The purpose of the call is to verify if they received the information letter and informed consent, to address any remaining questions about the study, and to solicit their preliminary agreement to participate. If both the person with dementia and his or her informal caregiver agree, the healthcare professional of GGZ will make an appointment to visit them at home together with the researcher of TIU (see phase 2).

Before these home visits take place, the healthcare professional of GGZ will perform herself one 'friendly user' test to verify if the different trainings modules of the Playtime suite are working properly. In doing so, it will be possible to provide the study participants with suitable instructions and manage their expectations on the Playtime suite. Furthermore, as long as he trainings modules of the Playtime suite are not working satisfactorily, the testing phase (phase 3) will not be initiated.

Phase 2 Introduction (Home visit I)

After scheduling an appointment, the healthcare professional of GGZ and the research of TIU will visit a person

[18] http://www.innovatedementia.eu/nl

[19] http://www.brabantseproeftuindementie.nl/

with dementia and his or her informal caregiver at home. The main purposes of this home visit are:

(1) To obtain the informed consent.
(2) To verify if the inclusion criteria are met.
(3) To introduce the Playtime project step by step.
(4) To conduct a personal interview.
(5) To demonstrate and explain the Playtime suite.
(6) To confirm the time and place of the group gatherings.
(7) To schedule an appointment for the second home visit.

Below, some of the these main purposes will be further described.

Verifying the inclusion criteria

To prevent that participating in this study may be too burdensome, the healthcare professional of GGZ will especially make sure that a person with dementia meets the inclusion criteria. She will do this by two tests: (1) the Mini-Mental State Examination (MMSE) (see Appendix V) and (2) the MoveTest. The MMSE test will be conducted to check if the person is still in the early stage of dementia: (s)he does have to score at least 22 out of 30 points (Folstein, Folstein, & McHugh, 1975). The second test, a MoveTest, will be conducted to check if the person with dementia has sufficient physical abilities to perform the physical exercises: (s)he does have to score at least one point on all three controlled tests of the MoveTest (balance, gait, chair rise). During these tests, the MoveTest collects data that will be analyzed on a cloud-based analysis platform. Basically, the healthcare professional of GGZ will perform the following actions:

(1) The healthcare professional will explain the test and the methodology to the person with dementia and his or her informal caregiver.
(2) When they are fully informed, the person with dementia will be fitted with a MoveTest device using a comfortable elastic belt around the waist.
(3) The healthcare professional will program the MoveTest using MCR's secure online programming and analysis platform[20] and starts a recording session.
(4) The person with dementia will have to perform three tests: (1) a balance test with three difficulty levels, (2) a gait test (four meters at comfortable speed) and (3) a five times repeated chair rise test (as fast as possible).
(5) After the tests, the healthcare professional will stop the measurement and will collect the MoveTest device.
(6) The healthcare professional will connect the MoveTest to a PC and logs in on MCR's secure online programming and analysis platform and the data upload and analysis process will start automatically. Data will be transmitted in pseudo-anonymized form by a number.
(7) The healthcare professional will present the outcomes to the person with dementia and his or her informal caregiver in a report or in the Playtime application.

When a person with dementia scores below the required minimum, s(he) will be excluded from participating in this study.

Conducting a personal interview

If all inclusion criteria are confirmed, the person with dementia and his or her informal caregiver will jointly be interviewed by the researcher of TIU. The interview will average 15 minutes in time and deploy a semi-structured format. The topic list will be based on an abridged version of the Innovate Dementia protocol, which maps the general welfare of a person with dementia and his or her informal caregiver by five standardized questionnaires,

[20] www.mcroberts.nl/mymcroberts

including: (1) IQcode, (2) NPI, (3) Katz, (4) IADL, and (5) EDIZ. During the interview, the researcher of TIU will attempt not to take any leading position, but will be a listener who gently directs the conservation to cover the main themes if necessary. In doing so, the possibility to discover information that is important to participants but may not have previously been thought of as pertinent will be enhanced (Bryman, 2008).

Demonstrating and explaining the Playtime suite

As one of the final steps, the healthcare professional of GGZ will demonstrate and explain how Playtime works at a Tablet PC, and make clear that the materials (MoveMonitor, Tablet PC and online trainings modules) cannot be kept after the testing period of two weeks. Next to this, each person with dementia and his or her informal caregiver will receive individual support and advice to fit the use of Playtime to their own situation and preferences (based on the results of the personal interview). Particular attention will also be devoted to the MoveMonitor which will measure the physical activity of a person with dementia by using a comfortable elastic belt around the waist. In doing so, the healthcare professional of GGZ will perform the following steps:

(1) The healthcare professional will explains the test and the methodology to the person with dementia and his or her informal caregiver, and explains possible questions.
(2) When they are fully informed, the healthcare professional will program the MoveMonitor using MCR's secure online programming and analysis platform[11], and will start a recording session.
(3) The person with dementia will be fitted with the programmed MoveMonitor device using a comfortable elastic belt around the waist.
(4) The healthcare professional will explain that the MoveMonitor automatically stops after one week of measuring and that she will return the MoveMonitor during the next home visit.

After the home visit, study participants will start testing Playtime at their home and during group gatherings for a period of two weeks. Contact information of the healthcare professional of GGZ will be provided to study participants in case questions arise or problems occur.

Phase 3 Testing

For the testing period of two weeks, study participants will be asked to test and experiment with the Playtime suite at home and during two group gatherings. During gameplay at home, data regarding clickstream, time log, solution time and performance results will be automatically collected. The informal caregiver will be asked to support the person with dementia whenever necessary.

The testing period will basically look as follows:

Week 1

(1) The person with dementia will be asked to wear the MoveMonitor 24 hours per day, for seven days.
(2) The person with dementia will be asked to play 50 minutes the different trainings modules of Playtime at a Tablet PC. When playing Amicasa, the person with dementia will automatically perform one calibration exercise, in which the moderator is asking to fixate the eye to certain points on the screen that will be particularly displayed in that exercise.
(3) The person with dementia will be asked to participate in one group gathering to test the interactive mat and the different trainings modules of Playtime.
(4) The informal caregiver will be asked to play 20 minutes the socio-emotional trainings module SERES Dementia™.

Week 2

(1) The person with dementia will be asked to play 50 minutes the different trainings modules of Playtime at a Tablet PC.
(2) The person with dementia will be asked to participate in one group gathering to test the interactive mat and the different trainings modules of Playtime.
(3) The informal caregiver will be asked to play 20 minutes the socio-emotional trainings module SERES Dementia™.

A number of five persons with dementia will participate in the group gatherings. Each of the two group gatherings will average 90 minutes in time (including 15 minutes break), consist of the same persons with dementia, and be held at the same location (preferably close to study participants' homes). The healthcare professional of GGZ will facilitate the Playtime game, while the researcher of TIU will observe the group sessions and make field notes.

To assist study participants in answering the questions of the reflective interview, an evaluation form to record their experiences is provided (optionally). The evaluation from will only request a description of the experience and the length of gameplay in order to not place any limits on their records. Study participants who use this evaluation form can consult these experiences during the reflective interview (see phase 4).

Phase 4 Evaluation (Home visit II)

After two weeks, the healthcare professional of GGZ and the researcher of TIU will visit the person with dementia and his or her informal caregiver at home to collect the MoveMonitor and the Tablet PC. They will also reserve sufficient time to evaluate the Playtime suite with study participants and address queries related to the research method and the project in general. To evaluate the Playtime suite, a reflective semi-structured interview will be conducted with both the informal caregiver and the person with dementia. The topic list of this interview will contain several open and closed questions regarding the four evaluation areas (usability, feasibility, appropriateness and acceptability) and their experiences in general. Examples of open questions are: 'how long and often did you use Playtime at home?', 'which trainings module did you use most?' and 'which function gave troubles?' and 'would you like to use Playtime again?'. The questions 'The physical exercises fit well to my physical abilities', 'Playing Playtime with other persons with dementia has added value for me' and 'Wearing a MoveMonitor is no problem for me' are examples of closed questions. Their scale uses five response categories: strongly disagree, disagree, neither agree nor disagree, agree, or strongly agree, ranging from 1 (strongly disagree) to 5 (strongly agree). The interviews will average 60 minutes in time and will be audio-recorded for the convenience of transcribing.

Materials

The following materials will be required during this study:

(1) Information flyers
(2) Information letters (potential) study participants
(3) Informed consent forms
(4) Evaluation forms (optionally)
(5) 1 interactive math with 5 cones
(6) 15 Tablet PCs
(7) 10 MoveMonitors
(8) Room(s) with large table(s) (preferably at a location close to study participants' homes)

1.5 Calculation and *argumentation* of effect and sample size (per experiment in case of a research line) (please try to use appropriate software (e.g. G*Power) for the calculation of sample sizes). In case of qualitative studies, we will need a reasoning of the sample size, as related to for example data saturation:

A total of 10 till 15 persons with dementia will be included in this study together with their informal caregivers (20 till 30 persons in total). The eventual total sample size will be determined by a saturation criterion, which is generally defined as the point were no new themes, findings, concepts or problems emerge from the data (Francis et al., 2009).

1.6 Proposed statistical analyses:

For the interviews and observations of the group gatherings, a thematic analysis will be used as main method (Braun & Clarke, 2006). In this form of analysis, interview transcripts will be analyzed by the researcher from TIU and discussed with the healthcare professional of GGZ. Using the software Atlas.ti, version 7.5.3, statements will be classified into categories using a priori codes regarding the four evaluation areas: usability, feasibility, appropriateness and acceptability. Emergent sub-codes will then be developed based on patterns within each concepts and which were relevant to the literature. In addition to the thematic analysis, descriptive statistics regarding interview responses and data from the event stream (frequencies/percentages, 95% confidence intervals CI, means/medians, standard deviations SD, interquartile ranges IQR, correlations) will be computed using the statistical analysis software package SPSS, version 19.

Data from eye tracking will first be filtered with respect to the frequency of available data. Data captures with frequencies below 5 Hz will be discarded. Filtered data from eye tracking will then be classified into fixations, saccades and blinks according to the methodology of (Salvucci & Goldberg, 2000). The time stamps associated with the fixations of the stored eye tracking data will be matched with the training sessions and the corresponding areas of interest (AOI) on the screen. With respect to these AOIs, further eye movement features will be elaborated, such as, dwell time within a specific AOI. From the dwell time measures and related AOIs we will then estimate means/medians, standard deviations SD of dwell time. The quality of eye tracking data will be related to the mean dwell time that is being measured on a specific AOI, and comparing these values to those that have been received in lab like environments. If the difference is below a certain threshold the data quality evaluation will be positive.

Factor Analyses will used to present complex data of the MoveMonitor and Movetest into a simple number of parameters. Subsequently, these parameters will be compared to already collected data (age matched, control subjects) using T-test or Anova in order to determine if they are distinctive enough for persons with dementia and usable for personalized recommendations.

1.7 Scientific and societal relevance:

Scientific relevance

Although some studies performed inclusive research with people living with dementia to develop and evaluate innovate interventions (i.e. Brankaert & den Ouden, 2013; Suijkerbuijk, et al., 2014; Brankaert, Snaphaan, & den Ouden, 2014), user-involvement of people living with dementia remains rather understudied. By testing and evaluating the alpha prototype of Playtime with its users, more direct insights from persons living with dementia concerning the usability, feasibility, appropriateness and acceptability of the innovation can be generated.

Societal relevance
The World Alzheimer Report (2010) shows that the cost of dementia care worldwide was more than US$604 billion, or 1% of aggregated global Gross Domestic Product. Reducing transitions into professional care environments and providing care at home for as long as possible is an important strategy for containing the costs of dementia care (Prince et al., 2014). Whereas this strategy sometimes causes problems, it does generally align with older people's desire to live at home for as long as possible as well as with the global movement towards Person-Centred Care (Clarke, Jane Hanson, & Ross, 2003). This trend, however, will put further pressure on informal caregivers who already provide 60% of the accumulated care for people with dementia. This number is expected to increase majorly in western countries, and is already much higher in developing countries (Prince et al., 2014). This study aims to contribute to this global challenge of dementia by developing a beta prototype of Playtime that fits with user's needs and context. In doing so, Playtime may support people with dementia to live more independent at home, which in turn may reduce the burden on informal caregivers and increase the quality of life.

2. SUBJECTS

2.1. Please check the relevant study population:

☐ Students
☐ General population without complaints
☑ General population with specific "complaints", i.e. stress, dementia, pregnancy, medically unexplained complaints
☐ Patients
☑ Other, i.e. informal caregivers of people with dementia

2.2 Do you use patients or persons from the general population with specific "complaints"? Please indicate below why it is necessary to execute your study in this study population.

☐ N/A

To increase the ecological validity (Koskinen, Zimmerman, Binder, Redström, & Wensveen 2011) and to develop a beta prototype of Playtime that fits with the user's needs and context, it is important that people diagnosed with dementia and their informal caregivers are included in this study.

2.3. Age category of the study population:

☐ <12 yrs.
☐ 12-17 yrs.
☑ ≥ 18 yrs.

2.4. Are the proposed participants able to give informed consent?

☑ Yes

☐ No *

* *Ability to give informed consent: According to Dutch law, persons younger than 12 are not able to give informed consent, and both parents or caretakers need to sign for participation. In the age category of 12-17 yrs. one of the parents as well as the adolescent need to sign the informed consent to be able to participate. In case an adult is unable to give informed consent, the legal guardian needs to sign for participation.*

2.5. Is your study population younger than 12 years of age? Please give a reason for the inclusion of this young research population in your study.

☑ N/A

2.6. Organization where the recruitment of participants will take place:

☐ Tilburg University
☑ Other, GGZ as participating organization in the Playtime consortium (see Appendix IV for consortium agreement).
☐ N/A

2.7. Reward for participation (per experiment):

☑ None
☐ Reimbursement of travel expenses
☐ Course credit
☐ Financial reward, i.e. ……. €/hours

2.8. Describe in detail the expected burden of the experiment/assessment occasions for the study participants with respect to time, mental and physical burden.

We are aware that participating in this study requires some considerable time investment of five hours and 20 minutes to test Playtime at home and during group gatherings (see Figure 1). As Playtime will be tested in one already existing group, no additional time investments for participating in group gatherings is required for half of the study participants (3 hours). In addition, having the informal caregiver and/or the person(s) with dementia play a game together adds a social aspect to this study that may offset the perceived time burden of study participants. The game ambiance of this study could contribute to an informal setting, which is also important for the perceived time burden of study participants.

During gameplay, the physical and mental burden is minimal. For Amicasa, the healthcare professional of GGZ will align the difficulty level of the exercises with the physical and cognitive abilities of each individual person with dementia. There could be a mental burden associated with playing SERES Dementia™ due to reflection on the situation of the informal caregiver and person with dementia (e.g. relationships, health, condition, etc.). In case this game is played in group gatherings, this mental burden may be offset by the presence of the healthcare professional of GGZ and support from peers. When played at home, the presence of an informal caregiver is required, which also may be offset the mental burden of playing SERES Dementia™. There will be no burden for study participants with respect to the MoveMonitor and eye tracking calibration task because these are non-

invasive and do not require any consideration or interaction of the person with dementia and their informal caregiver.

The burden associated with the personal interviews is minimal for study participants. It is not intend to discuss intimate or emotionally difficult information. The only goal of these interviews is to collect some background information (e.g. health, daytime activities, social contacts, motivation to test Playtime, etc.) to fit the use of Playtime to the individual situation and preferences of study participants, thereby reducing the mental and physical burden of study participation. The burden of the reflection interviews is also minimal. During these interviews, the focus will only be on how study participants evaluate the usability, feasibility, appropriateness and acceptability of the Playtime suite and their experiences in general. Both the personal and reflection interviews will be conducted at study participants' home, contributing to a comfortable setting in which participants will feel at ease.

2.9. Describe potential negative consequences of participation for the study participants:

☑ N/A because no negative consequences are expected

2.10. Describe measures that have been taken to protect the study participant (e.g. insurance, debriefing, etc.):

☐ N/A

All the participants will be informed about the study. Contact information of the healthcare professional of GGZ will be provided in case any questions arise or problems occur. Participation is voluntary and participants will be informed about their right to decline participation and withdraw from the research once participation has begun, without any negative consequences, and without providing any explanation. Next to this, several precautions were taken to protect the study participants with dementia in particular. First, only people in the early stage of dementia will be chosen because they still have a sense of self and are capable of understanding what the study means (Ettema et al., 2007). Second, only people with dementia who have an informal caregiving take care of them at their home are involved. In doing so, there is always another person nearby, which ensures a safe inclusion into the research. The main difficulty for research is that dementia is progressive, and the participant's perspective on the study might change. Therefore, the healthcare professional of GGZ will be involved to function, together with the informal caregivers, as gatekeepers. The gatekeepers will decide, continuously, whether participating in the study is still suitable for the person with dementia. The inform consent will thus not be seen as a one-time measure, rather it will be a continuous dialogue between researcher and participants (Coughlan et al., 2013).

Another measure that have been taken to protect study participants is by handling the data confidentially and anonymously. All subject-related data are transmitted and stored in pseudo-anonymized form by a number. Only the healthcare professional of GGZ and the researcher of TIU has permission to access the source data. Where it is necessary to be able to trace data to an individual subject, a subject identification code list will be used to link the data to the study participants. The key to the code is safeguarded by the researcher of TIU. The anonymous data will be stored in different databases for a period of 10 years and may only be acquired for purposes within the Playtime project. The data collected by GGZ and TIU (MMSE scores, transcripts of interviews and field notes of observations) will be stored in a secure electronic information system of GGZ. The eye tracking data of JR will be stored in association with time stamps in order to match eye movement statistics to training sessions played with the app on the Tablet PC. Neither video data nor any visual content about the study participant will be stored. IP addresses will also not be stored.

2.11. In case of a research line, is it allowed for subjects to participate in more than one experiment within the same line?

☑ N/A this is a research proposal for one study only
☐ Yes
☐ No

2.12. Are participants subjected to procedures or experiment-related manipulations or tasks? Indicate which ones, and with what purpose.

Examples: intervention, denials (subjects are asked not to smoke, drink alcohol or eat within a certain time frame preceding the experiment), dietary requests, invasive procedures (venipuncture to draw blood), medical (e.g. exercise test, fMRI or PET scans) or neuropsychological tests, admissions into hospital/institution, intelligence tests.

In this study, persons with dementia are mainly asked to test the Playtime suite at home and during two group gatherings in order to be able to evaluate Playtime from users' needs and context. Next to this, persons with dementia are subjected to the MMSE test and MoveTest, especially to prevent that participating in this study may be too burdensome for them.

(1) MMSE test: The MMSE test will be administered as part of determining the stage of dementia. Playing the different trainings modules of the Playtime suite could be too difficult for a person with dementia, and hence too burdensome, when (s)he is in the late stage of dementia. A MMSE score will also be deployed to perform analyses on the difficulty level of cognitive, physical, and socio-emotional exercises.
(2) MoveTest: The MoveTest will measure the physical performance of a person with dementia during three short controlled tests (balance, gait, chair rise) which typically take five till ten minutes. One reason for including the MoveTest in this study is to determine if a person with dementia has sufficient physical abilities to perform the physical exercises of Amicasa. In doing so, the MoveTest may prevent that there is not too much of a physical burden on study participants. Another reason for including the MoveTest in this study is to be able to evaluate the usability of the user feedback generated by this test.

The informal caregivers will not be subjected to procedures or experiment-related manipulations or tasks.

3. INFORMATION, DATA, ARCHIVING AND PRIVACY

3.1. When applicable, are there terms/conditions set by the funding organization with respect to information, privacy and reporting?

☑ Yes, i.e. guideline regarding Confidential Information
☐ No
☐ N/A

3. 2. Method of recruitment (multiple options may be checked):

☑ Advertisement
☑ Conversation with medical doctor/psychiatrist/psychologist/social worker (or care professional)
☑ Voluntary application, i.e. via presentation(s) at Alzheimer Café(s)
☐ Other

3.3. How much time is given to eligible participants/parents/caretakers/guardians to decide about participation after the participant has received the participant information letter?
Eligible participants have two weeks to decide about participation.

3.4a. Does this study deviate from standard rules and regulation concerning information giving and privacy?

Standard rules regarding information: participants or their legal representative are:

1. informed study in writing and in advance completely about the nature of the study
2. asked to give written informed consent by means of a consent form
3. debriefed afterwards (in writing and orally) about the goals of the study and reason for potential misleading elements during the experiment

Standard rules regarding research data:
4. data are processed in a coded fashion (and anonymous if possible) and stored confidentially
5. a participant may always look into their own data (except when a study is completely anonymous, then there is no link between personal information and study data)
6. all data must be available for inspection for all investigators involved in the project

☑ No
☐ Yes, this study deviates with respect to rule(s):

☐ 1 ☐ 2 ☑ 3 ☐ 4 ☐ 5 ☐ 6 (multiple options possible)

3.4b. If the study deviates from the above stated rules on one or more points, please describe how the study deviates from the standard rules per deviation:

In this research no debriefing (in writing and orally) will take place as the information letter participants receive during recruitment already provides all information about the goals of the study. The study does not contain any misleading elements. Therefore, no further information needs to be debriefed to the participants.

4. DATA USE & PUBLICATION

4.1 What do the researchers plan to use the obtained data for (you may check multiple answers)?

☑ Scientific publication(s) in peer reviewed journal
☐ Educational purposes only
☐ Report for external organization
☑ Report for own organization (i.e. the Playtime consortium)
☐ Pilot data only to substantiate grant applications
☑ Other, i.e. to develop a beta prototype of Playtime that will be tested in another field test

5. ADDITIONAL INFORMATION

Please use this space to add information that is important to your project but was not asked about in the form.

6. CHECKLIST INFORMATION TO PARTICIPANT

Please check each applicable box to confirm that the information letter contains the required elements

☑ Title (Title of the study, if necessary simplified, abbreviated or translated)
☑ Introduction

6.1 What does the study entail

☑ Purpose
☑ Background
☑ Nature
☑ Duration

6.2 What does participating in the study entail

☑ Procedures
☑ Expected duration
☐ Disadvantages/consequences/risks
☑ Possible advantage for the participant

6.3 Information about the participation

☑ Voluntariness of participation.
☑ Right to decline to participate and withdraw from the research once participation has begun, without any negative consequences, and without providing any explanation.
☑ Confidentiality protection and limitations

☐ Applicable insurance guarantees (only if there is additional insurance to the standard insurance)
☑ Period of time to which the consent applies (normally the length of the study)
☐ Re-use of specified data in the current, future or other research, where applicable
☑ Deliberation time (if applicable)
☑ Processing results
☑ Period of time that date will be stored and encrypted (10 years)
☐ Incentives for participation (traveling expense, pp hours)
☑ Approval Ethical Review Board (ERB)
☑ Request for participation
☑ The following text should be included:
Voor eventuele opmerkingen of klachten over dit onderzoek kunt u ook contact opnemen met de "Ethics Review Board" van Tilburg School of Social and Behavioral Sciences via ERB@tilburguniversity.edu.

If you have any remarks or complaints regarding this research, you may also contact the Ethics Review Board of Tilburg School of Social and Behavioral Sciences via ERB@tilburguniversity.edu.
☑ Closing / whom to contact in case of question or additional information (name and telephone number/ email address researchers)
☑ Appendices: Informed Consent

7. CHECKLIST INFORMED CONSENT

Please check each applicable box to confirm that the informed consent contains the required elements

7.1 Mentally competent participants and minors 12-17 year

☑ Title (Title of the study, if necessary simplified, abbreviated or translated)
☑ Confirmation that the information is read
☑ Confirmation that there was room for questions
☑ Reminder on voluntariness of participation. Right to decline to participate and withdraw from the research once participation has begun, without any negative consequences, and without providing any explanation
☑ Permission processing of anonymous/coded data as mentioned in the information letter
☑ Permission for storing the research data for a period of ten years
☑ Permission participation in the study
☑ Date, name, signature participant (self-written, so not preprinted)
☑ Date, name, signature researcher (self-written, so not preprinted)
☑ Give the participant a copy of the signed informed consent form

7.2 Addition/correction for mentally incompetent adults

☑ Date, name, signature legal representative, relation to participant

7.3 Addition/correction for minors

☐ Date of birth participant

☐ Date, name, signature (if possible both) parents/guardians

8. UPLOADING THE PROPOSAL TO THE ETHICS COMMITTEE VIA THE ERB WEBSITE

The committee would like to receive the following documents in addition to this research proposal (if applicable):

☑ Survey

☑ Examples of stimulus materials if unusual

☑ Advertisement

☑ Participant information letter (precedes participation)

☑ Informed consent form

☐ Written debriefing

☑ Written consent of external (outside university) institution to recruit participants

REFERENCES

Almirall, E., Lee, M., & Wareham, J. (2012). Mapping living labs in the landscape of innovation methodologies. *Technology innovation management review*, *2*(9), 12.

Astell, A.J., Ellis, M.P., Bernardi, L., Alm, N., Dye, R., Gowans, G. and Campbell, J. (2010) Using a touch screen computer to support relationships between people with dementia and caregivers. *Interact. Comput*., 22, 267–275.

Bharucha, A. J., Anand, V., Forlizzi, J., Dew, M. A., Reynolds, C. F., Stevens, S., & Wactlar, H. (2009). Intelligent assistive technology applications to dementia care: current capabilities, limitations, and future challenges. *The American journal of geriatric psychiatry*, *17*(2), 88-104.

Brankaert, R., & den Ouden, E. (2013). Setting up a LivingLab for innovation in the dementia care chain, a case study of the PhysiCAL. In *ISPIM Conference Proceedings* (p. 1). The International Society for Professional Innovation Management (ISPIM).

Brankaert, R., Snaphaan, L., & den Ouden, E. (2014). Stay in touch: an in context evaluation of a smartphone interface designed for people with dementia. In *International Workshop on Ambient Assisted Living* (pp. 288-295). Springer, Cham.

Brankaert, R. G. A. (2016). Design for dementia: a design-driven living lab approach to involve people with dementia and their context.

Braun, V., & Clarke, V. (2006). Using thematic analysis in psychology. *Qualitative research in psychology*, *3*(2), 77-101.

Bryman, A. (2008). *Social Research Methods.* Oxford University Press. Oxford, New York.

Buschert, V. C., Friese, U., Teipel, S. J., Schneider, P., Merensky, W., Rujescu, D., ... & Buerger, K. (2011). Effects of a newly developed cognitive intervention in amnestic mild cognitive impairment and mild Alzheimer's disease: a pilot study. *Journal of Alzheimer's disease*, 25(4), 679-694.

Clarke, A., Jane Hanson, E., & Ross, H. (2003). Seeing the person behind the patient: enhancing the care of older people using a biographical approach. *Journal of clinical nursing*, *12*(5), 697-706.

Coughlan, T., Leder Mackley, K., Brown, M., Martindale, S., Schloegl, S., Mallaband, B., Arnott, J., et al. (2013). Current issues and future directions in methods for studying technology in the home. *PsychNology*, 11(2), 159 – 184.

Ettema, T. P., Dröes, R. M., de Lange, J., Mellenbergh, G. J., & Ribbe, M. W. (2007). QUALIDEM: development and evaluation of a dementia specific quality of life instrument—validation. *International journal of geriatric psychiatry*, *22*(5), 424-430.

Farina, N., Rusted, J., & Tabet, N. (2014). The effect of exercise interventions on cognitive outcome in Alzheimer's disease: a systematic review. *International Psychogeriatrics*, 26(1), 9-18.

Francis, J. J., Johnston, M., Robertson, C., Glidewell, L., Entwistle, V., Eccles, M. P., & Grimshaw, J. M. (2010). What is an adequate sample size? Operationalising data saturation for theory-based interview studies. *Psychology and Health*, *25*(10), 1229-1245.

Galimberti, D., & Scarpini, E. (2010). Inflammation and oxidative damage in Alzheimer's disease: friend or foe?. *Frontiers in bioscience (Scholar edition),* 3, 252-266.

Graessel, E., Stemmer, R., Eichenseer, B., Pickel, S., Donath, C., Kornhuber, J., & Luttenberger, K. (2011). Non-pharmacological, multicomponent group therapy in patients with degenerative dementia: a 12-month randomized, controlled trial. *BMC medicine*, 9(1), 129.

Gräsel, E., Wiltfang, J., & Kornhuber, J. (2003). Non-drug therapies for dementia: an overview of the current situation with regard to proof of effectiveness. *Dementia and geriatric cognitive disorders*, 15(3), 115-125.

Groot, C., Hooghiemstra, A. M., Raijmakers, P. G. H. M., van Berckel, B. N. M., Scheltens, P., Scherder, E. J. A., ... & Ossenkoppele, R. (2016). The effect of physical activity on cognitive function in patients with dementia: a meta-analysis of randomized control trials. *Ageing research reviews*, 25, 13-23.

Koskinen, I., Zimmerman, J., Binder, T., Redstrom, J., & Wensveen, S. (2011). *Design research through practice: From the lab, field, and showroom*. Elsevier.

Leminen, S., Westerlund, M., & Nyström, A. G. (2012). Living Labs as open-innovation networks. *Technology Innovation Management Review*, *2*(9).

Luttenberger, K., Donath, C., Uter, W., & Graessel, E. (2012). Effects of Multimodal Nondrug Therapy on Dementia Symptoms and Need for Care in Nursing Home Residents with Degenerative Dementia: A Randomized-Controlled Study with 6-Month Follow-Up. *Journal of the American Geriatrics Society*, 60(5), 830-840.

Maseda, A., Sánchez, A., Marante, M. P., González-Abraldes, I., Buján, A., & Millán-Calenti, J. C. (2014). Effects of multisensory stimulation on a sample of institutionalized elderly people with dementia diagnosis: a controlled longitudinal trial. *American Journal of Alzheimer's Disease & Other Dementias®*, 29(5), 463-473.

Markopoulos, P., & Rauterberg, G. W. M. (2000). LivingLab: A white paper. *IPO Annual Progress Report*, 35, 53-65.

Oliveira, A. M. D., Radanovic, M., Mello, P. C. H. D., Buchain, P. C., Vizzotto, A. D. B., Celestino, D. L., ... & Forlenza, O. V. (2015). Nonpharmacological interventions to reduce behavioral and psychological symptoms of dementia: a systematic review. *BioMed research international*.

Prince, M., Albanese, E., Guerchet, M., & Prina, M. (2014). World Alzheimer Report 2014: Dementia and risk reduction: An analysis of protective and modifiable risk factors. *London: Alzheimer Disease International*.

Salvucci, D. D., & Goldberg, J. H. (2000). Identifying fixations and saccades in eye-tracking protocols. In *Proceedings of the 2000 symposium on Eye tracking research & applications*(pp. 71-78). ACM.

Suijkerbuijk, S., Brankaert, R., de Kort, Y. A., Snaphaan, L. J., & den Ouden, E. (2014). Seeing the first-person perspective in dementia: a qualitative personal evaluation game to evaluate assistive technology for people affected by dementia in the home context. *Interacting with Computers*, *27*(1), 47-59.

Teri, L., Logsdon, R. G., & McCurry, S. M. (2008). Exercise interventions for dementia and cognitive impairment: the Seattle Protocols. *The journal of nutrition, health & aging,* 12(6), 391-394.

Topo, P. (2009). Technology studies to meet the needs of people with dementia and their caregivers: a literature review. *Journal of applied Gerontology*, *28*(1), 5-37.

Woods, B., Aguirre, E., Spector, A. E., & Orrell, M. (2012). Cognitive stimulation to improve cognitive functioning in people with dementia. *The Cochrane Library.*

World Alzheimer report (2010). The global economic impact of dementia. *Alzheimer's Disease International.*

APPENDICES

Appendix I: Participant information letter and informed consent
Appendix II: Information flyer (concept)
Appendix III: Examples of stimulus materials
Appendix IV: Consortium agreement GGZ
Appendix V: Mini Mental State Examination (MMSE)
Appendix VI: Vragenlijst intake
Appendix VII: Vragenlijst evaluatie

Appendix I
Participant information letter and informed consent

April 2018

Informatiebrief deelname project Playtime
Ontwikkeling van een spel voor mensen met dementie

Geachte heer, mevrouw,

Hartelijk dank voor uw belangstelling in het project Playtime. In deze brief willen wij vragen of u wilt deelnemen aan dit project. Mochten er vragen ontstaan, dan kunt u deze zowel telefonisch als per e-mail stellen aan de projectmedewerkers Linda Burgmans of Iris Geerts. U hoeft niet meteen een besluit te nemen over deelname. Denk hier vooral rustig over na en bespreek het, als u dit fijn vindt, met mensen om u heen.

Waar gaat het project over?
Wetenschappelijk onderzoek heeft aangetoond dat de stimulatie van sociale, cognitieve en fysieke functies helpen om het proces van dementie te vertragen. Het project Playtime ontwikkelt een interactief spel voor een tablet dat deze drie functies tegelijkertijd stimuleert. Dit interactieve spel wordt ontwikkeld in samenwerking met verschillende organisaties uit binnen- en buitenland, waaronder GGZ Eindhoven en De Kempen (GGzE) en Tranzo, het wetenschappelijk centrum voor zorg en welzijn van Tilburg University.

Het is belangrijk dat we een spel ontwikkelen dat aansluit bij de wensen en behoeften van mensen met dementie. Wij vragen daarom uw hulp bij het ontwikkelen en testen van het spel en brengen graag uw ervaringen in kaart. Het spel zal zowel bij mensen thuis als in een groepsverband getest gaan worden.

Wanneer kunt u meedoen?
- Als u het spel op een tablet wilt testen (voor een duur van twee weken)
- Als u bereid bent twee keer in een groepsverband samen te komen
- Als u thuiswonend bent
- Als u de diagnose beginnende dementie heeft
- Als u een betrokken mantelzorger heeft (bijvoorbeeld een familielid of vriend(in))
- Als u de Nederlandse taal vaardig bent
- Als u in staat bent een korte bewegingstest uit te voeren (maximaal 10 minuten)

Wat gaan we doen?
- Tijdens het eerste huisbezoek zal er een intake plaatsvinden en worden uw cognitieve, fysieke en sociale mogelijkheden in kaart gebracht. Daarnaast krijgt u uitgebreide informatie over het testen van het spel en wordt het spel gedemonstreerd. Het huisbezoek zal ongeveer 1 uur duren.
- Tijdens de testperiode zult u eenmaal per week in een groep bijeen komen om het spel te testen. Daarnaast kunt u het spel thuis op een tablet testen. Wanneer u het spel speelt, zullen er verschillende gegevens over uw cognitieve, fysieke en sociale mogelijkheden verzameld worden. Deze gegevens zijn door u in te zien en worden gebruik voor de verdere ontwikkeling van het spel. De testperiode zal twee

weken duren.

- Na de testperiode wordt het spel bij u thuis opgehaald en wordt samen met u besproken wat uw ervaringen met spel het spel zijn. Ook dit zal ongeveer 1 uur in beslag nemen.

Wat vergt het van u?
Uw deelname aan dit project vergt enige tijd, onder andere door de contactmomenten met de projectmedewerkers van Playtime en het testen van het spel zowel thuis als in groepsverband. Het tijdstip van de bezoeken wordt vanzelfsprekend in overleg met u gepland. Ook wordt u gevraagd om gedurende een week een band te dragen die uw lichamelijke activiteiten meet. Deze band kan als een riem gedragen worden.

Wat levert het op?
Met deelname aan dit project levert u een bijdrage aan de ontwikkeling van een spel voor mensen met dementie. Het testen van dit spel geeft inzicht in uw eigen cognitieve, fysieke en sociale mogelijkheden en zou u kunnen stimuleren om actief te blijven op deze drie gebieden. Ook kunt u uw ervaringen delen met lotgenoten en zorgprofessionals en kunt u tips/informatie van hen ontvangen.

Belangrijk om te weten

- Deelname aan dit project is geheel vrijwillig en er worden geen vergoedingen aan u verstrekt. Indien u niet wilt deelnemen, zal dit op geen enkele manier nadelige gevolgen hebben voor u of voor uw mantelzorger. Mocht u besluiten deel te nemen en u bedenkt zich later, dan kunt u ten alle tijden stoppen met deelname aan dit project door contact op te nemen met Linda Burgmans of Iris Geerts.
- De ethische toetsingscommissie van Tilburg University (<kenmerk>) heeft toestemming gegeven voor het uitvoeren van dit project. Uw gegevens worden vertrouwelijk behandeld en anoniem verwerkt. Na afloop van het onderzoek worden deze geanonimiseerde gegevens conform de richtlijnen van Tilburg University 10 jaar bewaard in een beveiligde omgeving.

Hoe nu verder?
Twee weken na ontvangst van deze brief zal een projectmedewerker telefonisch contact met u opnemen. Wanneer u dan besluit mee te werken aan dit onderzoek, wordt u gevraagd het bijgesloten toestemmingsformulier te onderteken. Daarnaast zal de projectmedewerker de tijdsplanning van dit onderzoek verder toelichten en met u een huisbezoek plannen om het spel te demonstreren. Tijdens het eerste huisbezoek zal het ingevulde toestemmingsformulier opgehaald worden.

Voor eventuele opmerkingen of klachten over dit onderzoek kunt u ook contact opnemen met de “Ethics Review Board” van Tilburg School of Social and Behavioral Sciences via ERB@tilburguniversity.edu.

Alvast hartelijk dank voor uw tijd.
Met vriendelijke groeten,

Linda Burgmans
✉ Linda.Burgmans@GGZE.nl
☏ 06 51632735

Iris Geerts
I.A.G.M.Geerts@tilburguniversity.edu
☏ 06 23719009

April 2018

Toestemmingsformulier deelname project Playtime
Ontwikkeling van een spel voor mensen met dementie

Ondergetekende,

Naam: dhr/mevr* _____

Geboortedatum: _____

Verklaart de informatiebrief 'deelname project Playtime' te hebben gelezen, in de gelegenheid te zijn geweest om vragen over het project te stellen en om voldoende tijd te hebben gehad voor beslissing over deelname. Ik ben bereid om mee te werken aan het onderzoek door het spel zowel thuis als in groepsverband uit te testen voor een periode van twee weken.

Tevens geef ik toestemming om mijn gegevens te gebruiken voor de doelen die in de informatiebrief vermeld staan. De verzamelde data wordt anoniem verwerkt en uitsluitend gebruikt voor ontwikkeling van het spel door de partners van het project Playtime. Na afloop van het project wordt de verzamelde data conform de richtlijnen van Tilburg University 10 jaar bewaard in een beveiligde omgeving.

Mochten er redenen zijn waarom ik niet verder wil meewerken aan het onderzoek, behoud ik te allen tijde het recht om mijn toestemming in te trekken.

Voor akkoord,

	Deelnemer project Playtime	Projectmedewerker Playtime
Datum		
Handtekening		

April 2018

Toestemmingsformulier deelname project Playtime
Ontwikkeling van een spel voor mensen met dementie

Ondergetekende,

Naam: dhr/mevr* _____

Geboortedatum: _____

Verklaart de informatiebrief 'deelname project Playtime' te hebben gelezen en in de gelegenheid te zijn geweest om vragen over het project te kunnen stellen en om voldoende tijd te hebben gehad voor beslissing over deelname. Ik ben bereid om mee te werken aan het onderzoek door het spel zowel alleen als samen met mijn naaste uit te testen voor een periode van twee weken.

Tevens geef ik toestemming om de gegevens te gebruiken voor de doelen die in de informatiebrief staan. De verzamelde data wordt anoniem verwerkt en uitsluitend gebruikt voor ontwikkeling van het spel door de partners van het project Playtime. Na afloop van het project wordt de verzamelde data conform de richtlijnen van de universiteit 10 jaar bewaard in een beveiligde omgeving.

Mochten er redenen zijn waarom ik niet verder wil meewerken aan het onderzoek, behoud ik te allen tijde het recht om mijn toestemming in te trekken.

Voor akkoord,

	Deelnemer project Playtime (mantelzorger)	Projectmedewerker Playtime
Datum		
Handtekening		

Appendix II
Information flyer (concept)

PLAY TIME

Ontwikkeling van een spel voor mensen met dementie

Hartelijk dank voor uw belangstelling in het project Playtime. Via deze folder willen wij u graag informeren over dit project.

Waar gaat het project over?

Wetenschappelijk onderzoek heeft aangetoond dat de stimulatie van sociale, cognitieve en fysieke functies helpen om het proces van dementie te vertragen. Het project Playtime ontwikkelt een interactief spel voor een tablet dat deze drie functies tegelijkertijd stimuleert. Dit interactieve spel wordt ontwikkeld in samenwerking met verschillende organisaties uit binnen- en buitenland, waaronder GGZ Eindhoven en De Kempen (GGzE) en Tranzo, het wetenschappelijk centrum voor zorg en welzijn van Tilburg University.

Wat kunt u doen?

Het is belangrijk dat we een spel ontwikkelen dat aansluit bij de wensen en behoeften van mensen met dementie. Wij vragen daarom uw hulp bij het ontwikkelen en testen van het spel en brengen graag uw ervaringen in kaart. Het spel zal zowel bij mensen thuis als in een groepsverband getest gaan worden. U kunt deelnemen aan dit project als u thuiswonend bent, de diagnose beginnende dementie heeft, een betrokken mantelzorger heeft, en het spel thuis op een tablet wilt testen.

Heeft u naar aanleiding van deze folder vragen? Of wil u deelnemen aan het project Playtime? Laat het ons weten! U kunt de bijgevoegde antwoordkaart opsturen naar en/of contact opnemen met de onderstaande contactpersonen.

Contactpersonen

Linda Burgmans
✉ Linda.Burgmans@GGZE.nl
☎ 06 51632735

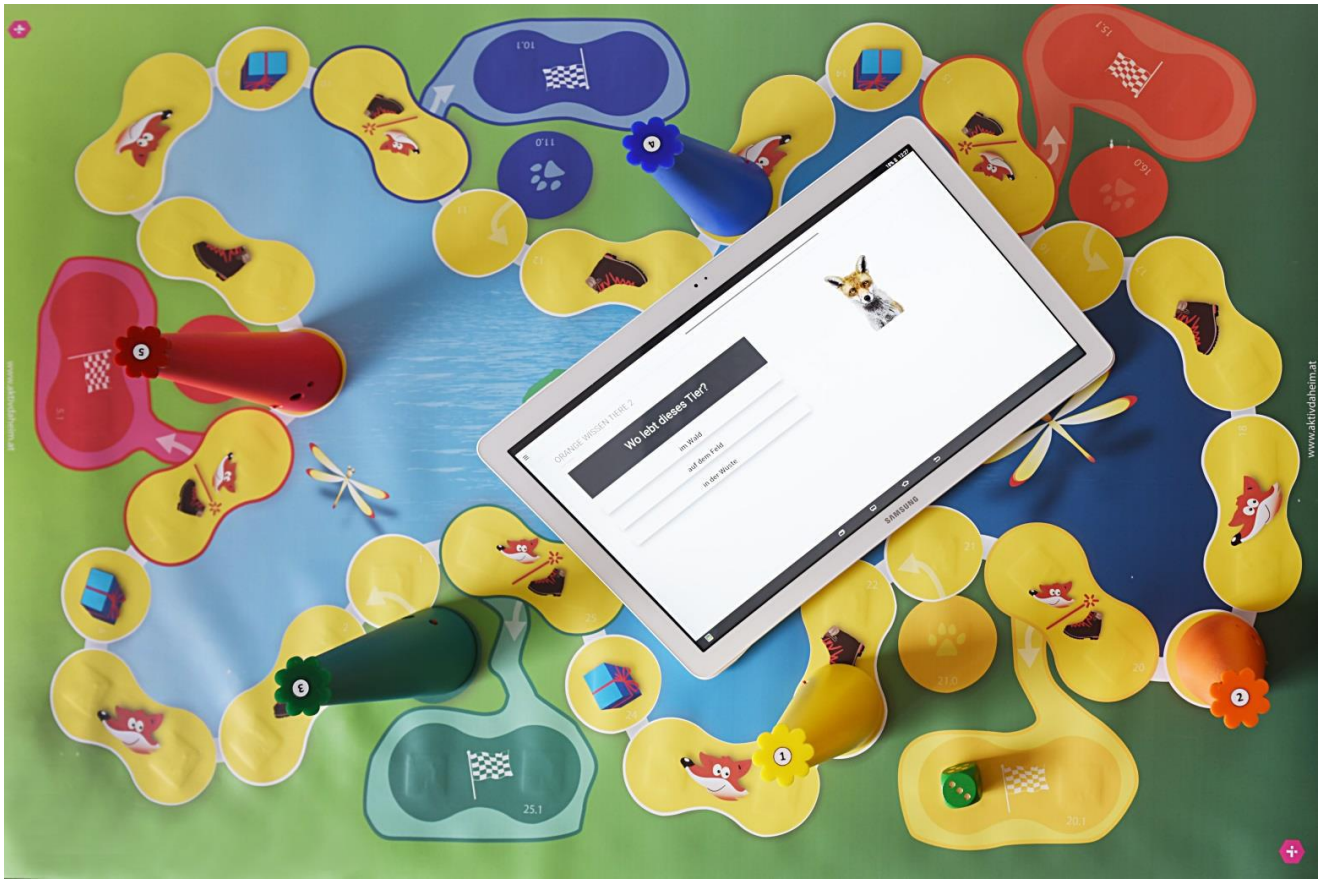
Iris Geerts
✉ I.A.G.M.Geerts@tilburguniversity.edu
☎ 06 23719009

Partners

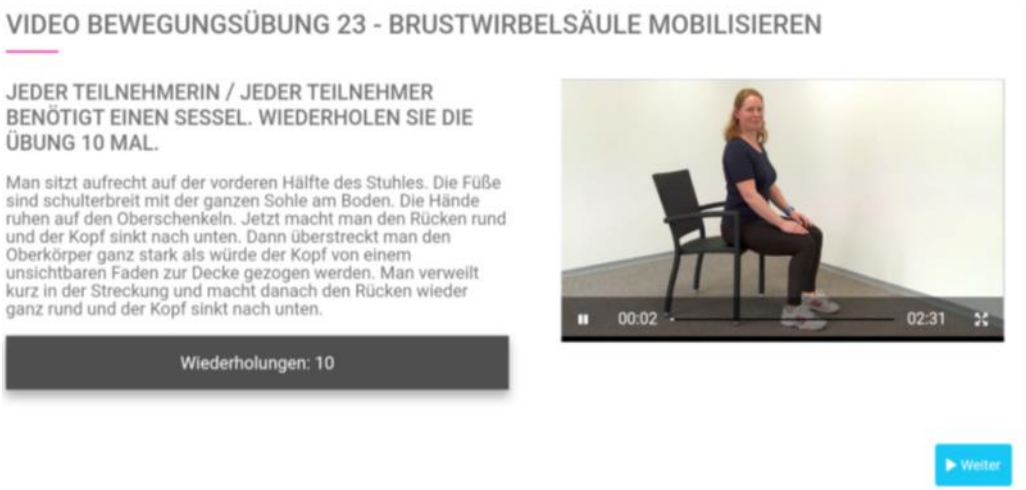
Appendix III

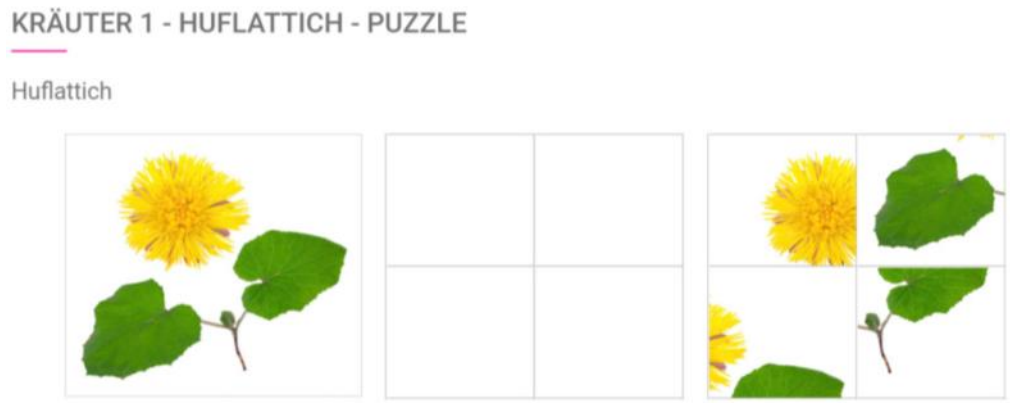
Examples of stimulus materials

Interactive mat and Tablet PC



Example exercises Amicasa[21]





[21] Note: Exercises will be translated to Dutch

KRÄUTER-MEMORY

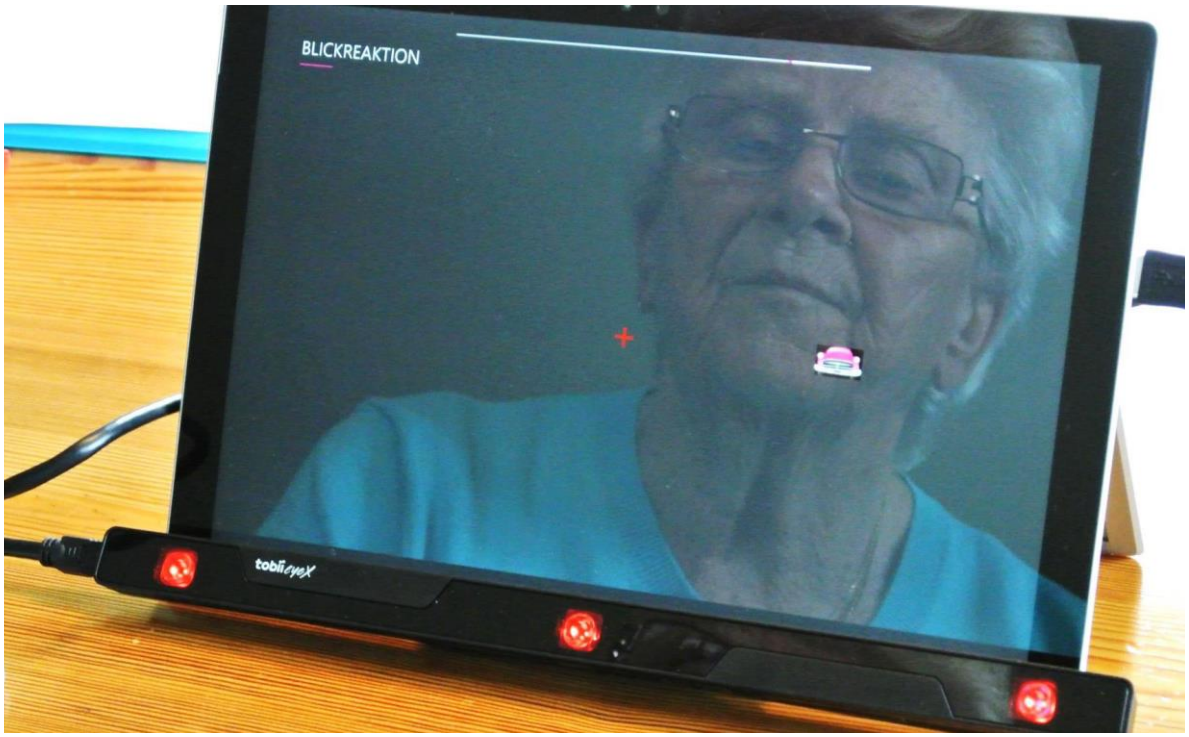
Finden Sie die gleichen Bildpaare:
Salbei
Lorbeer
Petersilie
Rosmarin

KRÄUTER 1 - RÄTSEL - FRAGE 6

Um welches Kraut handelt es sich hierbei?

- Spitzwegerich
- Baldrian
- Lavendel

Eye tracking task in Amicasa



Examples of SERES Dementia™

Emilie heeft moeite met haar blouse dicht te knopen en blijft friemelen terwijl je haar ongeduldig aankijkt.

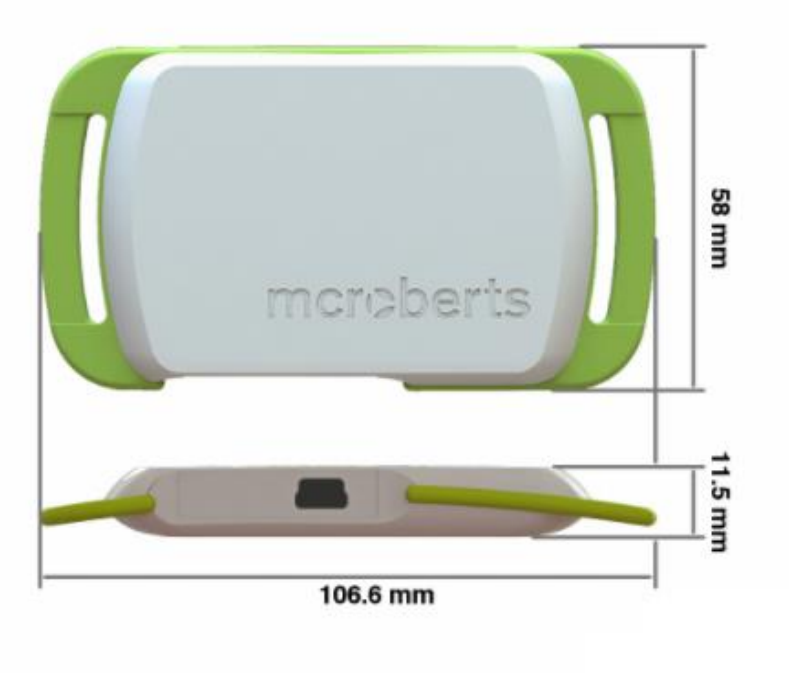
Wat doe je?

Je legt uit aan Emilie dat de winkel gesloten zal zijn als je nu niet vertrekt en vertrekt alleen. Emilie vindt dit onredelijk en blijft slechtgezind thuis achter.

Je accepteert het feit dat Emilie voortdurend je ondersteuning nodig heeft en je helpt haar zich aan te kleden. Hoewel Emilie aanvankelijk je assistentie afweert, overtuig je haar dat ze je hulp nodig heeft. Kort nadien zijn jullie klaar om naar de supermarkt te vertrekken.

Je verkiest Emilie zelfstandig te laten zijn en je laat haar zich alleen verder klaarmaken. Jammer genoeg betekent dit dat je te laat toekomt bij de supermarkt. Je neemt jezelf voor toekomstige uitstapjes met Emilie anders aan te pakken.

MoveMonitor



Appendix IV

Consortium agreement GGZ

AAL PROGRAMME

PLAYTIME Consortium Agreement - Signature Page 5/9

For and behalf of:

Stichting Geestelijke Gezondheidszorg Eindhoven en de Kempen , 27/3/2017

mevrouw drs. Marie-Louise Vossen, Board GGzE

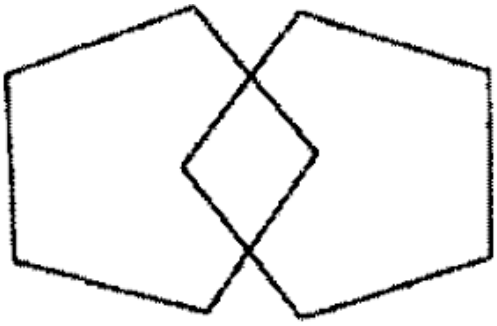
Eindhoven – THE NETHERLANDS, ...

- ETHICS REVIEW BOARD TSB –

Appendix V

Mini Mental State Examination (MMSE)

Naam: Datum:		
Ik ga u nu enkele vragen stellen en geef u enkele problemen om op te lossen. Wilt u alstublieft uw best doen om zo goed mogelijk antwoord te geven.		
Noteer antwoord		**Score**
1.	a. Welk jaar is het? b. Welk seizoen is het? c. Welke maand van het jaar is het? d. Wat is de datum van vandaag? e. Welke dag van de week is het? Eén punt voor elk juist antwoord.	(0 – 5)
2.	a. In welke provincie zijn we nu? b. In welke plaats zijn we nu? c. In welke straat zijn we nu? d. In welk gebouw zijn we nu? e. In welke ruimte/kamer zijn we nu? Eén punt voor elk juist antwoord.	(0 – 5)
3.	Ik noem u nu drie voorwerpen. Wilt u die herhalen nadat ik ze alle drie heb gezegd? Onthoud ze, want ik vraag u over enkele minuten ze opnieuw te noemen. (Noem "appel, sleutel, tafel", neem 1 seconde per woord). Herhaal maximaal 5 keer tot de patiënt de drie woorden weet Eén punt voor elk goed antwoord.	(0 – 3)
4.	Wilt u van de 100 zeven aftrekken en van wat overblijft weer zeven aftrekken en zo doorgaan tot ik stop zeg? (Herhaal eventueel 3 maal als de persoon stopt, herhaal dezelfde instructie, geef maximaal 1 minuut de tijd). Of: wilt u het woord "'worst" achterstevoren spellen?	(0 – 5)
5.	Noemt u nogmaals de drie voorwerpen van zojuist. Eén punt voor elk goed antwoord.	(0 – 3)
6.	Wat is dit? En wat is dat? (Wijs een pen en een horloge aan). Eén punt voor elk goed antwoord.	(0 – 3)
7.	Wilt u de volgende zin herhalen: " Nu eens dit en dan weer dat ". Eén punt als de complete zin goed is.	(0 -1)

8.	Wilt u deze woorden lezen en dan doen wat er staat'? (papier met daarop in grote letters: "Sluit uw ogen")	(0 – 1)
9.	Wilt u dit papiertje pakken met uw rechterhand, het dubbelvouwen en het op uw schoot leggen? Eén punt voor iedere goede handeling.	(0 – 3)
10.	Wilt u voor mij een volledige zin opschrijven op dit stuk papier? Eén punt wanneer de zin een onderwerp en een gezegde heeft en betekenis heeft.	(0 – 1)
11.	Wilt u deze figuur natekenen?  Eén punt als figuur geheel correct is nagetekend. Er moet een vierhoek te zien zijn tussen de twee vijfhoeken.	(0 – 1)
		(0 – 30)

Appendix VI
Vragenlijst intake

Gegevens deelnemer

ID nr:…… Tablet nr:……..dinaport nr:……

MoveTest score:…….. MMSE:……..(score afgenomen / minder dan 6 maanden oud)*

Diagnose:……

Geslacht: Dhr/ Mw*

Geboortedatum:……

Vragen over uw fysieke gezondheid

1 Doet u aan een vorm van lichaamsbeweging, zo ja, wat en hoe vaak per week?
……

……

2 Is er iets wat u zou willen veranderen in uw fysieke activiteiten? ……

……

……

3 Gebruikt u een bril, leesbril of gehoorapparaat?……

4 Gebruikt u hulpmiddelen zoals bijvoorbeeld een rollator of stok, zo ja welke? ……..

……

Vragen over uw sociale activiteiten

5 Wat is uw woonsituatie? ……

6 Krijgt u regelmatig bezoek van naasten?……

7 Hoe geeft u vorm aan uw dag invulling? Denk bv aan hobby's ……

……

8 Bent u lid van een vereniging of groep, en zo ja welke?.....

……

9 Bent u tevreden met uw daginvulling?.....

10 Hoe is uw stemming over het algemeen?.....

11 Is er iets wat u zou willen veranderen in uw sociale bezigheden?.....

……

……

Vragen over uw cognitieve vaardigheden

12 Wat is uw hoogst genoten opleiding?.....

13 Weet u hoe uw dagplanning er vandaag uit ziet?.....

14 Gebruikt u hiervoor een hulpmiddel zoals b.v. een kalender? En kunt u deze zelfstandig gebruiken?

……

……

15 Kunt u apparaten goed bedienen, zoals een telefoon of wasmachine?.....

……

16 Kunt u over het algemeen goed uit uw woorden komen? B.v. het op woorden komen, en een zin vormen?

……

17 Op welke gebieden ervaart u over het algemeen achteruitgang in uw cognitie? B.v. taal, initiatief ,praxis

……

……

Veiligheid

18 Hebben zich weleens onveilige situaties voorgedaan, waar rekening mee gehouden kan worden? (denk bijvoorbeeld aan valgevaar, verdwalen binnen vreemde gebouwen) ……

……

19 Zijn er weleens situaties, waarin u zichzelf niet veilig voelt?……

……

Vragen voor de mantelzorger

20 Geboortedatum……

21 Welke hobby's heeft u, en heeft u hier voldoende tijd voor ?……

……

22 Welke veranderingen ervaart u in uw dagelijkse leven?……

……

……

Vragen over uw deelname aan Playtime

23 Wat zijn uw verwachtingen van Playtime? ……

……

……

24 Wat is uw motivatie om deel te nemen aan Playtime?……

……

……

25 Zijn er lichamelijke/mentale/sociale aspecten waar we rekening mee kunnen houden?……

……

Tot slot

26 Heeft een van u nog vragen of opmerkingen?.....

.....

.....

.....

*= doorhalen wat niet van toepassing is.

- ETHICS REVIEW BOARD TSB –

Appendix VII
Vragenlijst evaluatie

Persoonlijke gegevens

ID nummer: .....

Testperiode: .....

Evaluatie Playtime

Onlangs heeft u Playtime twee weken getest. Door onderstaande vragen te beantwoorden kunnen wij uw ervaringen in kaart brengen en het product verbeteren. Wanneer u een dagboek bijgehouden hebt, dan kunt u deze raadplegen bij het beantwoorden van de vragen.

Deel 1: Algemene vragen

1. Playtime meet uw lichamelijk activiteiten. Hiervoor heeft u een bewegingstest gedaan en een band gedragen.
    a. Wat zijn uw ervaringen met het dragen van deze band en wat zou u eventueel anders willen zien?
    b. Zijn de verkregen resultaten (verstrekt in het rapport) duidelijk en helpen ze u?

2. Playtime bevat de SERES game, waarin u een aantal alledaagse situaties doorloopt. Wat zijn uw ervaringen met deze game en wat zou u eventueel anders willen zien?

3. Playtime bevat de Amicasa game, waarin u geheugen- en lichamelijke opdrachten kunt doen. Wat zijn uw ervaringen met deze game en wat zou u eventueel anders willen zien?

4. Heeft U meerdere keren gespeeld met SERES en Amicasa?
    a. Hoe vaak en hoe lang was dit (ongeveer) voor SERES?
    b. Hoe vaak en hoe lang was dit (ongeveer) voor Amicasa?

5. Wat is volgens u de ideale tijd om aan SERES en Amicasa te besteden?

6. Tijdens het eerste huisbezoek heeft u een kalibrering opdracht uitgevoerd, waarbij u steeds op de roos moest tikken. Wat vond u van deze opdracht?
    a. Wat waren de grootste problemen bij deze kalibrering opdracht?

b. Hebt u nog ideeën voor verbeteringen?
c. Stel voor dat u Playtime voor een langere periode getest zou hebben, zou u deze kalibrering opdracht dan één keer per maand willen uitvoeren?

Deel 2: Stellingen

Nu volgen er 19 stellingen. Kunt u aangeven in hoeverre u het met deze stellingen eens of oneens bent? Zou u dit antwoordt eventueel kunnen toelichten?

Voor de volgende vragen verstaan wij onder Playtime de SERES en Amicasa applicatie.

1. Ik zou Playtime graag vaker willen gebruiken.

Helemaal mee oneens	Mee oneens	Niet mee oneens/niet mee eens	Mee eens	Helemaal mee eens
1	2	3	4	5

Zo nee, wanneer zou u Playtime wel voor een langere periode willen blijven gebruiken?

Toelichting:

.....

.....

2. Ik vind Playtime onnodig ingewikkeld.

Helemaal mee oneens	Mee oneens	Niet mee oneens/niet mee eens	Mee eens	Helemaal mee eens
1	2	3	4	5

Toelichting:

.....

.....

3. Ik kan Playtime makkelijk gebruiken.

Helemaal mee oneens	Mee oneens	Niet mee oneens/niet mee eens	Mee eens	Helemaal mee eens
1	2	3	4	5

Toelichting:

.....

.....

4. Ik heb ondersteuning nodig om Playtime te kunnen gebruiken.

Helemaal mee oneens	Mee oneens	Niet mee oneens/niet mee eens	Mee eens	Helemaal mee eens
1	2	3	4	5

Zo ja, wat voor ondersteuning?

Toelichting:

.....

.....

5. De onderdelen van Playtime vormen een mooi geheel.

Helemaal mee oneens	Mee oneens	Niet mee oneens/niet mee eens	Mee eens	Helemaal mee eens
1	2	3	4	5

Toelichting:

.....

.....

6. De besturing van Playtime is voor de hand liggend.

Helemaal mee oneens	Mee oneens	Niet mee oneens/niet mee eens	Mee eens	Helemaal mee eens
1	2	3	4	5

Toelichting:

.....

.....

7. Ik kan me voorstellen dat de meeste mensen snel door hebben hoe ze Playtime moeten gebruiken.

Helemaal mee oneens	Mee oneens	Niet mee oneens/niet mee eens	Mee eens	Helemaal mee eens
1	2	3	4	5

Toelichting:

.....

.....

8. Ik vind Playtime erg onpraktisch om te gebruiken.

Helemaal mee oneens	Mee oneens	Niet mee oneens/niet mee eens	Mee eens	Helemaal mee eens
1	2	3	4	5

Toelichting:

.....

.....

9. Ik heb er vertrouwen in dat ik Playtime kan spelen.

Helemaal mee oneens	Mee oneens	Niet mee oneens/niet mee eens	Mee eens	Helemaal mee eens
1	2	3	4	5

Toelichting:

.....

.....

10. Ik moet veel leren over Playtime voordat ik het goed kan gebruiken.

Helemaal mee oneens	Mee oneens	Niet mee oneens/niet mee eens	Mee eens	Helemaal mee eens
1	2	3	4	5

Toelichting:

.....

.....

11. De handleiding is duidelijk en geeft voldoende ondersteuning.

Helemaal mee oneens	Mee oneens	Niet mee oneens/niet mee eens	Mee eens	Helemaal mee eens
1	2	3	4	5

Toelichting:

.....

.....

12. De tekst in de apps is niet goed leesbaar voor mij.

Helemaal mee oneens	Mee oneens	Niet mee oneens/niet mee eens	Mee eens	Helemaal mee eens
1	2	3	4	5

Toelichting:

.....

.....

13. Het taalgebruik kan ik goed begrijpen.

Helemaal mee oneens	Mee oneens	Niet mee oneens/niet mee eens	Mee eens	Helemaal mee eens
1	2	3	4	5

Toelichting:

.....

.....

14. Het geluid van de SERES en Amicasa is goed.

Helemaal mee oneens	Mee oneens	Niet mee oneens/niet mee eens	Mee eens	Helemaal mee eens
1	2	3	4	5

Toelichting:

.....

.....

15. De opdrachten en oefeningen zijn te moeilijk.

Helemaal mee oneens	Mee oneens	Niet mee oneens/niet mee eens	Mee eens	Helemaal mee eens
1	2	3	4	5

Toelichting:

.....

.....

16. Playtime stimuleert mijn mogelijkheden op sociaal, geheugen en lichamelijk gebied.

Helemaal mee oneens	Mee oneens	Niet mee oneens/niet mee eens	Mee eens	Helemaal mee eens
1	2	3	4	5

Toelichting:

.....

.....

17. Playtime is geschikt voor mensen met dementie.

Helemaal mee oneens	Mee oneens	Niet mee oneens/niet mee eens	Mee eens	Helemaal mee eens
1	2	3	4	5

Toelichting:

.....

.....

18. Het spelen van Playtime in een groep heeft geen meerwaarde voor mij.

Helemaal mee oneens	Mee oneens	Niet mee oneens/niet mee eens	Mee eens	Helemaal mee eens
1	2	3	4	5

Toelichting:

.....

.....

19. Ik vond het leuk om Playtime te spelen.

Helemaal mee oneens	Mee oneens	Niet mee oneens/niet mee eens	Mee eens	Helemaal mee eens
1	2	3	4	5

Toelichting:

.....

.....

Deel 3: afsluitende vragen

1. Als u Playtime een cijfer mag geven (1-5), welk cijfer zou dat zijn?

   1=uitstekend 2=goed 3=voldoende 4=matig 5=onvoldoende

2. Wanneer Playtime straks beschikbaar is, zou dat dan iets mogen kosten? Zo ja, hoeveel?

   € …….

3. Zou u Playtime nog een keer willen testen?

   Ja / Nee

4. Tot slot, heeft u nog vragen en/of opmerkingen?

Namens het team van Playtime: hartelijke dank voor uw medewerking aan dit onderzoek.