PLEASE NOTE: *This trial has been registered retrospectively.*

Trial Description

Title

Assistant to activate patients with dementia and their caregivers

Trial Acronym

MobiAssist

URL of the trial

http://www.mobiassist.info

Brief Summary in Lay Language

In the course of dementia physical and mental abilities are declining. In the project MobiAssist an exergame is developed in order to improve and maintain the physical and mental performance of patients with dementia. The exercise program includes strength and coordination exercises as well as mental and biographical stimulation. Training takes place in front of the TV; control is based on MS Kinect. This makes it easy for users to engage in physical activity. Thus, MobiAssist helps to improve the quality of life of people with dementia and to support the disease prevention of dementia patients in their home.

Brief Summary in Scientific Language

Symptoms of dementia are not only the decline of mental but also physical abilities. Activities of daily living decreases as the degree of dementia increases, and the scope of support and care requirements increases accordingly. Activities that stimulate or train mental and physical performance are reduced or even abandoned. The vast majority of care for those suffering from dementia, especially with incipient dementia, is managed in private, i.e. implemented in the respective domestic environment and in many cases carried out by family members. Studies addressing home care of dementia patients have revealed that caregivers of dementia sufferers are significantly more burdened than those of non-dementia patients.
Objectives of the project are to improve or maintain physical and cognitive functions and thus to strengthen independence and everyday skills. Furthermore, the work of caring relatives and caregivers is facilitated.
This is realized with the help of information and communication technology. For the exercise program exergames were developed in which power and coordination as well as cognitive exercises are playfully implemented. The exercises of the training can be planned in the system, documented and subjected to a monitoring procedure. Training takes place at the patient's home or in care facilities. Integration into the nursing planning of an outpatient or semi-stationary service is possible. The system is connected to various terminals (e.g., tablet) through a secure cloud server, allowing information about the current level of training to be shared by all concerned. MobiAssist also includes an information and training

**system that can be used to design and deliver training for informal caregivers and caregivers.
Feasibility/usability of the system and effects of the program on physical and cognitive functions, daily activities, and carers burden will be studied in a controlled trial. Procedure: Participants were assessed before, between, and after the control and intervention phase of 16 weeks each. Participants serve as their own controls.**

Organizational Data

- DRKS-ID: **DRKS00013638**
- Date of Registration in DRKS: **2018/02/01**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **160/2017 , Deutsche Sporthochschule Köln**

Secondary IDs

Health condition or Problem studied

- ICD10: **F00 - Dementia in Alzheimer disease**
- ICD10: **F01 - Vascular dementia**

Interventions/Observational Groups

- Arm 1: **Control phase of 16 weeks, no treatment, usual care (prescribed medications, exercise therapy and other therapies will be retained, continuation of all activities as far as possible). Afterwards intervention phase, 16 weeks, MobiAssist-training: at least 3 sessions per week with at least 20 minutes training each session, strength exercises, coordination exercises, and cognitive exercises.**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Non-randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***

Study Type: **Interventional**

Study Type Non-Interventional: **[---]***

Allocation: **Non-randomized controlled trial**

Blinding: **[---]***

Who is blinded: **[---]***

- Control: **Active control (effective treament of control group)**
- Purpose: **Prevention**
- Assignment: **Other**
- Phase: **II**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Functional status and the extent of support effort using Barthel-Index (Hamburg Classification Manual). Periods: December 2017 until January 2018 (T0), March until April 2018 (T1), July until August 2018 (T2).

Secondary Outcome

1) Extended Barthel-Index (Mahoney & Barthel, 1965).
2) Physical performance (endurance, strength, balance, gait speed, chair stand, mobility) using Short Physical Performance Battery (Guralnik et al., 1994) and Senior Fitness Test (Rikli & Jones, 1999).
3) Cognitive performance (processing speed, memory, working memory, word fluency) using Trail-Making-Test A (Tischler & Petermann, 2010) and DemTect (Kalbe et al., 2004; Kessler et al., 2000).
4) Quality of Life using Quality of Living-AD (Logsdon, 1999).
5) Leasure time activities using PASE (Washburn et al., 1991).
6) Aspects of Usability using System Usability Scale (Brooke, 1996), DART (Amberg et al., 2003) and User Experience Questionnaire (Laugwitz et al., 2008).
7) Trainingadherence (Mode, frequency, duration, level of all single Exergames).
8) Effects of the system/using of technology on aspects of care and daily life using interviews.
Periods: 1)-5): December 2017 until January 2018 (T0), March until April 2018 (T1), July until August 2018 (T2). 6)+7) March until August 2018 (Interventionphase). 8): July until August 2018 (T2).

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- other **Deutsche Sporthochschule Köln, Köln**
- University Medical Center **Charité - Geriatrie, Berlin**
- other **Universität Siegen, Siegen**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2017/12/01**
- Target Sample Size: **45**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **no minimum age**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

1) type of dementia: Alzheimer’s disease or vascular dementia; diagnosed by professionals in memory clinic (CERAD neuropsychological battery); alternative for Siegen: Clinical Dementia Rating (CDR; Morris, 1993) value > 0.5
2) give consent
3) participants are retired
4) participants are mobile and able to stand up from a chair without support and walk 6m
5) care dependency measured by barthel index (BI): criteria: BI< 60 points (Mahoney & Barthel, 1965)
6) support by a professional caregiver or by an informal caregiver
7) written informed consent from patient with dementia and the informal caregiver
8) medical certification
9) cognitive and social requirements (interested, motivated, no aggressive behavior, can imitate exercises, understand simple verbal information, control of emotional reactions)
10) physical requirements (routine actions can be completed; also he/she can: see, hear, speak, sit and stand up, walk, grab and hold on a chair)
11) conditions of the environments (TV with HDMI, wireless internet at home)

Exclusion criteria

1) other types of dementia (frontotemporal dementia, dementia with Lewy bodies, alcohol-relates brain damage (Korsakoff´s syndrome), familial Alzheimer's disease)
2) mental disorders like depression or generalized anxiety disorder who have not been satisfactorily medicated for at least six months; substance-related disorders in the last 2 years; schizophrenia and other psychological disorders
3) neurodegenerative diseases of the Central Nervous System (CNS), Parkinson’s

disease, multiple sclerosis, Amyotrophic Lateral Sclerosis (ALS)
4) cardiovascular diseases: acute cardiac failure, acute cardiac insufficiency, angina pectoris, untreated cardiac arrhythmia or heart valve disease, pacemaker, untreated hypertension - systolic blood pressure >180 mm Hg or diastolic blood pressure > 110 mm Hg; untreated hypotension - < 90/60 mm Hg
5) untreated cancer disease
6) untreated hormone diseases
7) badly controlled diabetes (blood glucose < 6 mmol/L or >15 mmol/L)
8) epilepsy
9) Chronic Obstructive Pulmonary Disease (COPD) grade 4
10) acute infection or fever
11) acute renal insufficiency
12) osteoporosis
13) surgical interventions in the last 6 months
14) taking neuroleptics or benzodiazepine
15) participation in another study for dementia

Addresses

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Sources of Monetary or Material Support

- **Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)**

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URL: **www.bmbf.de**

Status

- Recruitment Status: **Recruiting complete, follow-up continuing**
- Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

- Approval of ethics comm. (mandatory for transfer to Studybox) **Ethikvotum der DSHS**

** This entry means the parameter is not applicable or has not been set.*

**** This entry means that data is not displayed due to insufficient data privacy clearing.*