Trial Description

Title

Exercise-carroussel in inpatient dementia care

Trial Acronym

ExCaDem-Trial

URL of the trial

[---]*

Brief Summary in Lay Language

Behavioral symptoms in Alzheimer’s disease like aggression, restlessness, shouting and resistance to nursing staff are most challenging burden for caregivers and clinical staff. Observational studies describe a direct link between physical inactivity and behavioral dirsturbances in these patients. Therefore it is strongly reccomended to treat behavioral disturbances not by physical or chemical immobilization but through participartion in exercise programs.
The main objective of this trial is to translate this link between physical inactivity and behavioral symptoms in inpatient dementia care and to investigate, if participation in an tailored exercise program leads to a reduction in behavioral symptoms. Compared to a control-group, carrying out a social stimulation programme, the effects on behavioral symptoms of a special exercise program, the exrcise-carrousel, are ivnestigated.
In this trial a day-structuring exercise program, the exercise-carrousel, is conducted for two weeks in inpatient geriatric psychiatry care. The special exercise-schedule with four daily exercise session thrice a week submits rest and activity cycles in motor behavior of the patients. Effects on behavioral symptoms will be assessed via observational scales, motion sensors, mouth-salivary- and blood-probes.

Brief Summary in Scientific Language

The decline of cognitive functioning is the main symptom of different dementia syndromes and underlying diseases. In the course of illness, behavioural disturbances affect a large proportion of the patients. Behavioural and psychological symptoms of dementia (BPSD) include affective disturbances, including depression and anxiety, psychotic features with delusions and hallucinations, hyperactivity including irritability and aggression or euphoria. These symptoms are perceived as a greater burden and challenge for the caregivers than the cognitive decline itself.
Observational studies describe a link between physical inactivity and BPSD in dementia care. Therefore, it is recommended to treat BPSD not by physical or chemical immobilization, but by an increase in physical activity. This trial seeks to

translate the link between physical activity and BPSD into clinical dementia care. In addition to usual care, the study group will run a 2-week exercise program. The participants will be offered a novel exercise program four times daily thrice a week . A single exercise-session will be held for a net time of 20 minutes. After one exercise session, there will be a scheduled break of one hour. This specific time schedule will be run four times a day. Due to provision of recurrent rest-activity periods throughout the day, this activation program is called exercise-carrousel.Two exercise sessions will include weight-lifting exercise for the upper and lower limb (ankle- / wrist-worn weights). In two sessions an aerobe exercise-program on ergometers will be conducted. The control group will recieve a social stimulation programme in addition to routine care. Compared to the control group, the effects on BPSD, motion behaviour, day-structure and neurotrophe factors will be assessed.
It is hypothesized that a structured increase in physical activity would lead to a decrease in BPSD, a stabilization in circadian rhythms of motor behavior and cortisol stress levels.

Organizational Data

- DRKS-ID: **DRKS00006740**
- Date of Registration in DRKS: **2014/10/28**
- 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.: **2014216 , Ethikkommission der Ärztekammer Nordrhein**

Secondary IDs

Health condition or Problem studied

- ICD10: **F00 - Dementia in Alzheimer disease**
- ICD10: **F01 - Vascular dementia**
- ICD10: **F02 - Dementia in other diseases classified elsewhere**
- ICD10: **F03 - Unspecified dementia**
- ICD10: **G30 - Alzheimer disease**

Interventions/Observational Groups

- Arm 1: **Study-group:**
  In addition to usual care, the participants enrolled to the study group will run a two-week exercise program. The participants will be offered a novel exercise program four times daily thrice a week . A single exercise-session will be held

for a net time of 20 minutes. After one exercise session, there will be a scheduled break of one hour. Two exercise sessions will include weight-lifting exercise for the upper and lower limb (ankle- / wrist-worn weights). In two sessions an aerobe exercise-program on ergometers will be conducted.

- Arm 2: **Control-group:**
  In addition to usual care, the participants enrolled to the control-group will recieve a two-week social stimulation programme, conducted by an occupational therapist.

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **assessor**
- Control: **Active control (effective treament of control group)**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

behavioral and psychological symptoms (measured via standardised interview with the primary nurse of the patient):
- Neuropsychiatric Inventory (pre and post 2-weeks-intervention)
- Cohen-Mansfield-Agitation Inventory (pre and post 2-weeks-intervention)
- ADCS-CGIC (Alzheimer-Cohort-Study clinical global impression of change) (post 2-weeks intervention)

Secondary Outcome

- caregiver-burden, measured via NPI-Caregiver-Version (structured interview); carried out pre and post two-week intervention
- PRN-Medication while intervention-phase
- functional performance assessed via Timed Up and Go-Test + 10m Gaitspeed; pre and post two-week-intervention
- motion behavior measured via body-fixed sensors (Stepwatch + uSense-Sensor) on four days pre and post two-week intervention
- day-structure (cortisol-profiles) measured via saliva probes on two consecutive days pre and post two-week intervention
- brain derieved neurotrophic factor (BDNF): measured via one blood probe pre and post two-week intervention
- falls and use of physical constraints while the two-week-intervention (as registered in the clinical information system)

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Medical Center **LVR-Klinik Köln, Köln**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2015/01/01**
- Target Sample Size: **80**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **60 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

- diagnosis of dementia following ICD-10-Criteria
- minimum length of stay: 1 week in order to submit familiarization to the new setting
- exclusion of delirium (Confusion Assessment Method)
- ability to perform the timed-up and go-test [19] without human assistance
- written consent of the legal guardians

Exclusion criteria

- acute cardial instability, that allows no physical exercise
- behavior that allows no group exercise

Addresses

- **Primary Sponsor**

  LVR-Klinik KölnAbt. für Gerontopsychiatrie und -psychotherapie

Primary Sponsor

LVR-Klinik KölnAbt. für Gerontopsychiatrie und -psychotherapie
Wilhelm-Griesinger-Straße 23
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■ **Contact for Scientific Queries**

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Sources of Monetary or Material Support

- **Institutional budget, no external funding (budget of sponsor/PI)**

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- **Institutional budget, no external funding (budget of sponsor/PI)**

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  E-mail: **[---]***
  URL: **[---]***

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2015/12/31**

Trial Publications, Results and other documents

- Paper **Veröffentlichen Studienprotokoll in Trials (open access)**
- Trial results <style fontName='DejaVu Sans' isBold='true'>Veröffentlichung der Hauptergebnisse: Fleiner et al., 2017 in Alzheimer's Research & Therapy</style>

** 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.*