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Improving the treatment of neuropsychiatric symptoms in nursing home residents suffering from dementia

Submission date
30/01/2010

Registration date
10/06/2010

Last Edited
25/04/2014

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Michael Rapp

Contact details
Psychiatric University Hospital St. Hedwig
Grosse Hamburger Str. 5-11
Berlin
Germany
10115
+49 2311 2057
michael.rapp@charite.de

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
LT 44-076

Study information

Scientific Title
Evaluation of a combined guideline implementation protocol for neuropsychiatric symptoms in nursing home residents suffering from dementia

Acronym
VIDEANT

Study objectives
The implementation of guideline-driven training and occupational therapy interventions will reduce neuropsychiatric symptoms, specifically, agitation, depression, and apathy, in nursing home residents suffering from dementia

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of Charite - University Medicine Berlin approved on the 17th of July 2008 (ref: EA1/065/08)

Study design
Cluster randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details below to request a patient information sheet (in German)

Health condition(s) or problem(s) studied
Neuropsychiatric symptoms in dementia

Interventions
18 care centres in Berlin will be randomised to the intervention or control conditions:
1. Intervention centres:
1.1. 20 hours of training for nursing staff on causes, symptomatology and treatment of neuropsychiatric symptoms in dementia
1.2. 4 hours of training for primary care psychiatrists on causes and medical treatment of

neuropsychiatric symptoms in dementia
1.3. 15 minute individual occupational therapy sessions twice a week
1.4. Provision of and training in standardized assessments of neuropsychiatric symptoms in dementia (nursing staff)
2. Control centres: treatment as usual

The total duration of the intervention and follow up will be 9 months

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Agitation as measured with the Cohen-Mansfield Agitation inventory (CMAI)
2. Depression as measured with the Dementia Mood Assessment Scale (DMAS)
3. Apathy as measured with the Apathy Evaluation Scale (AES)
All primary outcomes are measured at baseline and at 12 months.

Secondary outcome measures
1. Psychotropic medication in defined daily dosages
2. Number of hospital admissions
3. Caregiver burden as measured with the Perceived Stress Scale (PSS)
4. Mortality
All secondary outcomes are measured at baseline, months 3, 6, and 12, and mortality dates are ascertained retrospectively.

Overall study start date
01/11/2008

Completion date
01/05/2010

Eligibility

Key inclusion criteria
Both male and female dementia patients aged 60 or older who live in a nursing home

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
400 (from 18 Berlin nursing homes)

Key exclusion criteria
1. Inability to give informed consent and absence of a caregiver holding power of attorney
2. Any of the following conditions as defined by ICD-10 criteria
2.1. Presence of substance abuse (F 10)
2.2. Schizophrenia and associated conditions (F20)
2.3. Bipolar disorder (F30,31)

Date of first enrolment
01/11/2008

Date of final enrolment
01/05/2010

Locations

Countries of recruitment
Germany

Study participating centre
Psychiatric University Hospital St. Hedwig
Berlin
Germany
10115

Sponsor information

Organisation
Federal Office of Administration (Bundesverwaltungsamt [BVA]) (Germany)

Sponsor details
Eupener Str. 125
Koeln
Germany
50728

Sponsor type
Government

Website
http://www.bundesverwaltungsamt.de

ROR
https://ror.org/04n9aye53

Funder(s)

Funder type
Government

Funder Name
German Federal Ministry of Health (Bundesministerium für Gesundheit [BMG]) (ref: LT 44-076)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2013		Yes	No