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MAKS aktiv! Multi-modal activating therapy for dementia patients in nursing homes (activating therapy concerning everyday activities, exercise, cognitive and spiritual elements)

Submission date
27/11/2008

Recruitment status
No longer recruiting

Registration date
16/01/2009

Overall study status
Completed

Last Edited
12/12/2012

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

Study website
http://www.maks-aktiv.de

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
LT-DEMENZ-44-059

Study information

Scientific Title
Multi-modal activating therapy for dementia patients in nursing homes: a randomised controlled trial with an intervention group (standard care plus non-pharmacological activating therapy) and a control group (standard care)

Acronym
MAKS aktiv!

Study objectives
Principal aim of the study:
To prove the effectiveness of an intensive intervention consisting of everyday activities, cognitive, motor and exercise elements on dementia patients' cognitive and activities of daily living (ADL) capacities in five nursing homes.

Principal hypothesis:
In the 6 months observation period the multi-modal activating therapy results in significantly better cognitive and ADL capacities within the intervention group compared to the control group in the way that the capacities of the intervention group remain on average on their initial level, whereas the control groups' capacities decrease according to the disease's progression.

As of 30/07/09 this trial has been updated. Please note that recruitment for this trial has been completed. Patients wishing to learn more about the trial may use the contact details below to request more information or get informed at the trial's official website http://www.maks-aktiv.de

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics committee of the Faculty of Medicine of the University Erlangen Nuremberg gave approval on 10th July 2008 (ref: 3232)

Study design
Multicentre randomised controlled single-blind intervention study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Quality of life

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

Health condition(s) or problem(s) studied
Dementia

Interventions
Intervention:
Multi-modal activating therapy, consisting of everyday activities, exercise, cognitive and spiritual elements, in five groups of ten persons each, two hours per day, six days per week, for at least six months.

Control:
Standard care (no changes in the care situation).

Baseline data (t0) is collected directly before the 6 months intervention period. After the 6 months the first follow up outcome data (t1) is collected. Further follow ups are planned at 1.5 and 2.5 years after t1. This design is equivalent for all treatment arms (intervention and control group).

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Competences in activities of daily living (ADL) operationalised with the Erlangen Test of Activities of Daily Living (E-ADL Test); score (0 = no ADL function, 30 = normal ADL function)
2. Cognitive abilities operationalised with the cognitive subtest of the Alzheimer's Disease Assessment Scale (ADAS-kog); score (0 = no cognitive impairment, 70 = severe impairment)

Primary and secondary outcome measures are collected for every participant individually in the week before (t0) and after (t1) the six months intervention period. For most of the participants the first measurements is from 20th to 31st October (t0) and again from 4th to 15th of May (t1). Participants who join the project at a later date to replace another participant who had to be excluded will have their t0 in the months of November 2008 until May 2009 and their t1 six months later, at the latest in November 2009.

Secondary outcome measures
1. Instrumental Activities of Daily Living (IADL) operationalised with the subscale IADL of the Nurses Observation Scale for Geriatric Patients (NOSGER); score (5 = full IADL function, 25 = no IADL function)
2. Global geriatric symptomatology operationalised with the NOSGER cumulative value; score (30 = no impairment, 150 = severe impairment)
3. Level of nursing care dependency operationalised with the level of care according to the criteria of the German Health Insurance companies (no level of care = no care necessary, level 3 =

highest level of care) and the Barthel-Index; score (0 = total care dependence, 100 = independent)
4. Care requirements and time cost operationalised with the Resource Utilisation in Dementia (RUD), items for ADL, IADL and supervision; score (time in minutes per day)

Primary and secondary outcome measures are collected for every participant individually in the week before (t0) and after (t1) the six months intervention period. For most of the participants the first measurements is from 20th to 31st October (t0) and again from 4th to 15th of May (t1). Participants who join the project at a later date to replace another participant who had to be excluded will have their t0 in the months of November 2008 until May 2009 and their t1 six months later, at the latest in November 2009.

Overall study start date
01/09/2008

Completion date
30/11/2009

Eligibility

Key inclusion criteria
102 inhabitants of 5 nursing homes in Germany:
1. Existence of an degenerative dementia syndrome (diagnosed by a physician according to International Classification of Diseases, version 10 [ICD-10])
2. Mini-Mental State Examination (MMSE): value less than 24 points
3. Level of care of 0, 1 or 2 (not 3) according to the criteria of the German Health Insurance companies
4. Existence of an informed consent of the patient or his/her legal guardian

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
102 complete data sets, i.e. about 135 participants

Key exclusion criteria
1. Psychiatric-neurological disease other than dementia that explains the cognitive impairment (e.g. schizophrenia)
2. Purely vascular dementia (diagnosed by physician)
3. Level of care equals 3
4. Blindness
5. Deafness
6. Being bed-ridden
7. Other severe obstacle for participating in the intervention group

Date of first enrolment
01/09/2008

Date of final enrolment
30/11/2009

Locations

Countries of recruitment
Germany

Study participating centre
University Hospital Erlangen
Erlangen
Germany
91054

Sponsor information

Organisation
German Federal Ministry of Health (Bundesministerium fur Gesundheit [BMG]) (Germany)

Sponsor details
c/o Dr. S. Gehring
Projektträger Gesundheitsforschung at the DLR
on behalf of the German Federal Ministry of Health
Heinrich-Konen-Str. 1
Bonn
Germany
53227

Sponsor type
Government

Website
http://www.bmg.bund.de/cln_117/nn_1168252/SharedDocs/Standardartikel/DE/AZ/L/Glossarbegriff-Leuchtturmprojekt-Demenz.html

ROR
https://ror.org/05vp4ka74

Funder(s)

Funder type
Government

Funder Name
German Federal Ministry of Health (Bundesministerium fur Gesundheit [BMG]) (Germany) (ref: LT Demenz 44-059)

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	01/05/2012		Yes	No
Results article	follow-up results	05/12/2012		Yes	No