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Non-drug therapy for persons with cognitive decline in day-care institutions

Submission date
04/07/2014

Recruitment status
No longer recruiting

Registration date
30/07/2014

Overall study status
Completed

Last Edited
19/08/2022

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
To date, two thirds of people suffering from cognitive decline or dementia are cared for at home. Informal caregivers are often spouses, and a growing number of them are children of the affected person. These caregivers often have to work as well and suffer from the double work load. The DeTaMAKS project aims to find ways to reduce the burden for informal caregivers, helping them to cope with their joint care and home responsibilities though counselling, and offering a proven drug-free therapy called MAKS for those affected by dementia in day-care centres.

Who can participate?
Visitors of day-care centres with mild cognitive impairment or early dementia and their informal caregiver.

What does the study involve?
Participants are randomly allocated into one of two groups. Those in group 1 (intervention group) receive the treatment. MAKS therapy involves a combination of physical activities, practice in daily living activities, cognitive stimulation exercises and a spiritual element - for example a group song or discussion of a topic. Participants in group 1 have daily sessions of MAKS therapy for six months. Those in group 2 (control group) receive their usual care offered by the day centre. Informal caregivers of those participants in group 1 are offered up to 3 telephone counselling sessions designed to help them develop strategies of stress management and how to cope with any challenging behavior from their affected relative.

What are the possible benefits and risks of participating?
Not provided at registration

Where is the study run from?
Fredrich Alexander University, Erlangen (Germany)

When is the study starting and how long is it expected to run for?
July 2014 to December 2016

Who is funding the study?
The German National Association of the Statutory Health Insurance and Long-Term Care Insurance Funds (GKV-Spitzenverband) (Germany) and the Bavarian State Ministry of Health and Care (Germany)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
GKV-SV201

Study information

Scientific Title
Multimodal non-drug therapy for persons with cognitive decline in day-care institutions with short-term interventions for informal caregivers by telephone to strengthen the compatibility of care and work

Acronym
DeTaMAKS

Study objectives
1. Advancement of preventive and rehabilitative approaches. Compared with the control group (treatment as usual), MAKS-T will lead to improved stabilization of abilities in activities of daily living for people with dementia and to better preservation of independence.

2. Decreases in the stress caused by giving care for informal caregivers. Compared with the control group, the stress caused by caring for relatives will decrease with the administration of the combination of MAKS-T and the short intervention for family caregivers by telephone.
3. In the medium and long term, targets 1 and 2 will lead to an improvement in the compatibility of care and work and to an improvement in cost efficiency (day care instead of nursing home). The intervention will lead to a longer stay in day-care institutions, beginning with the two-year-data acquisition (which means that institutionalization will not be necessary because of the compatibility of care and work).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics board of the Friedrich-Alexander-University Erlangen-Nuremberg,03/06/2014. ref. 170_14 B

Study design
Cluster-randomised controlled intervention study

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 the contact details below to request a patient information sheet (in German only)

Health condition(s) or problem(s) studied
Mild cognitive impairment, mild or moderate dementia (degenerative type, not solely vascular)

Interventions
Treatment consists of two parts:
1. Activation therapy for cognitively affected day-care visitors
1.a. Intervention group: The well-examined MAKS therapy (see http://www.biomedcentral.com /1741-7015/9/129) will be adapted to the day-care situation. During the intervention time of six months, MAKS therapy will be performed every day in the day care in groups of a maximum of 12 persons with two therapists. MAKS is a multicomponent group therapy consisting of tasks organised into three categories motor stimulation (M), ADL (A), and cognition (K) preceded by a short introduction to create a feeling of social cohesion within the group (S). Each daily session will begin with this introduction, which lasts approximately 10 minutes and was designed to help the dementia patients feel that they are a part of the group. This is followed by about 30 minutes of motor exercises, such as bowling, croquet, or balancing a tennis ball on a frisbee and passing it to ones neighbour. After a 10 minute break, the patients spend approximately 30

minutes completing a variety of cognitive tasks, ranging from paper and pencil exercises, such as solving word jumbles or matching symbols in pairs, to picture puzzles projected digitally onto a large screen to be solved by the group. MAKS was designed to promote activities that take place at an individuals performance limit. Therefore, therapists place all participants into three homogenous groups according to their individual performance levels (operationalised as their MMSE score) and assign the cognitive tasks from one of three difficulty levels to the appropriate group. This is followed by about 40 minutes during which patients carry out ADL (such as preparing a snack), engage in creative tasks (such as working with wood, paper, or other natural materials), or perform simple gardening work.
1.b. Control group: The control group receives the usual care offered in each day care (treatment as usual).
2. Telephone intervention for informal caregiver:
Each informal caregiver in the intervention groups will receive up to 3 telephone counselling sessions in which skilled psychologists help her or him to elaborate strategies of stress management and to cope with any challenging behaviour exhibited by the affected relative.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Abilities of daily living assessed at baseline and after 6 months:
Performance test E-ADL
2. Cognition assessed at baseline and after 6 months:
MMSE and MOCA

Secondary outcome measures
All assessed at baseline, after 6, 12, and 24 months
1. Life quality of informal caregiver and relative:
EQ-5 D questionnaire
2. Care Situation:
2.a. RUD Questionnare
2.b. FIMA
2.c. Health care utilisation
3. Caregiver Burden:
3.a. HPS-K
3.b. BIZA-D
4. Dementia symptoms
4.a. NPI-Q
4.b. NOSGER (social behaviour)

Overall study start date
01/07/2014

Completion date
31/12/2016

Eligibility

Key inclusion criteria
1. Visitors of day-care centres with mild cognitive impairment or early dementia who have an informal caregiver
2. Informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
350

Total final enrolment
362

Key exclusion criteria
1. Completely blind or deaf
2. No informal caregiver at all
3. Severe dementia
4. Cognitive decline due to diseases other than dementia (e.g. schizophrenia or Korsakov)

Date of first enrolment
01/07/2014

Date of final enrolment
31/12/2016

Locations

Countries of recruitment
Germany

Study participating centre
University Clinic Erlangen
Erlangen
Germany
91054

Sponsor information

Organisation
Statutory Health Insurance Funds Association (GKV-Spitzenverband) (Germany)

Sponsor details
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Sponsor type
Industry

ROR
https://ror.org/03psr2094

Funder(s)

Funder type
Other

Funder Name
German National Association of the Statutory Health Insurance and Long-Term Care Insurance Funds (GKV-Spitzenverband) reference No.: GKV-SV201(Germany)

Funder Name
Bavarian State Ministry of Health and Care (Germany)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	17/07/2017	24/01/2019	Yes	No
Results article	results	01/12/2017	24/01/2019	Yes	No
Results article	results	24/09/2018	17/09/2019	Yes	No
Results article	results	25/07/2019	15/04/2020	Yes	No
Results article		18/08/2022	19/08/2022	Yes	No