ISRCTN16412551 https://doi.org/10.1186/ISRCTN16412551

# 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?
Dr Katharina Luttenberger
katharina.luttenberger@uk-erlangen.de

# Contact information

### Type(s)
Scientific

### Contact name
Prof Elmar Graessel

### Contact details
University Clinic Erlangen
Department of Psychiatry and Psychotherapy
Medical Psychology and Medical Sociology
Erlangen
Germany
91054

# Additional identifiers

### Protocol serial number
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

## Primary study design
Interventional

## Study design
Cluster-randomised controlled intervention study

## Study type(s)
Treatment

## 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(s)
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

### Key secondary outcome(s)
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)

### 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

### Healthy volunteers allowed
No

### Age group
Adult

### Sex
All

### Total final enrolment

### 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)

### 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

## 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? |
|---|---|---|---|---|---|
| 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 |
| Protocol article | protocol | 17/07/2017 | 24/01/2019 | Yes | No |