

MAKS-s – multimodal psychosocial intervention for people with severe dementia in inpatient care: a cluster-randomized controlled trial

Submission date 11/07/2019	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 07/08/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 29/12/2022	Condition category Nervous System Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

There are currently very few therapies available for people with severe dementia. Therefore, the multimodal, psychosocial, evidence-based MAKS therapy for people with mild to moderate dementia and mild cognitive impairment should be adapted to the needs of people with severe dementia. The main objective of MAKS-s is a reduction of behavioral and psychological symptoms as well as an improvement in the quality of life in people with severe dementia by means of satisfaction of elementary basic needs. Furthermore, by attending the intervention MAKS-s a significantly better development of activities of daily living in people with dementia. As well a significant reduction in the caregiver burden of nursing and care staff should be achieved. A relevant reduction in the number of days of incapacity to work is also assumed.

Who can participate?

People with severe dementia who living in a nursing home within Germany can participate. There is no restriction regarding age or gender. People with the following conditions cannot participate in the study: mild to moderate dementia respectively no cognitive impairment, severe hearing and/or severe visual impairment, cognitive decline due to diseases other than dementia (e.g. schizophrenia or Korsakov), permanently immobile,

What does the study involve?

The intervention MAKS-s is a multimodal psychosocial group intervention for people with severe dementia. It is a further development of evidence-based MAKS therapy for people with mild to moderate dementia and mild cognitive impairment.

The intervention MAKS-s was developed based on scientific findings on the progression of degenerative dementia and the special physiological conditions of people with severe dementia. The concept takes the basic needs of people with severe dementia into account. It consists of the modules motor stimulation (M), activities of daily living (A) and cognition (K for the German word "Kognition") as well as social communicative attunement (S) aimed at people with severe (s) dementia. Compared to the original MAKS therapy, the modules of MAKS-s are clearly modified and adapted to the special requirements of people with severe dementia. For example, a MAKS-s unit lasts only one hour in order to take into account the lower attention span of

people with severe dementia. In the social module (S), in contrast to MAKs therapy, biographical conversations are removed due to the severe limitations of autobiographical memory. In the motor stimulation module (M), more attention is paid to the promotion of body perception and contracture prophylaxis than to complex movement sequences and coordination. In the cognitive module (K), due to the advanced reduction in cortical performance in people with severe dementia, higher cognitive processes cannot be attained. Instead, multisensory stimulation is used to address and activate memory contents that are far in the past and mostly unconscious. Especially the cortex areas, which are little affected by Alzheimer's dementia, such as the somatosensory cortex, which processes sensory impressions of the sense of touch and the depth sensitivity. In the activities of daily living module (A), instead of complex everyday actions, basal processes, such as applying cream to hands or cut fruit, are used.

In the intervention group, MAKs-s is provided in each participating nursing home as a group offer on three days a week, for six months, with six people with severe dementia per institution. A standardized manual will be made available to the facilities, which will ensure a largely uniform implementation in all participating facilities. The implementation is controlled by monitoring visits. Participants will be examined with regard to the main and secondary outcomes before and after the intervention (6 months later) as well as 2 months after the intervention start. The main outcomes are behavioral and psychological symptoms and quality of life, secondary outcomes are activities of daily living, dementia-related caregiver burden of nursing and care staff, and days of incapacity for work of nursing and care staff. Of the 24 Nursing Homes in Germany collaborating in the study, 12 will perform the intervention MAKs-s immediately (intervention group); the others 6 months later (waiting control group).

What are the possible benefits and risks of participating?

The possible benefits of participating in the study are positive effects on behavioral and psychological symptoms, quality of life, and activities of daily living in people with severe dementia. Furthermore, reduced dementia-related caregiver burden of nursing and care staff, as well as fewer days of incapacity for work, are expected. No side effects are expected in the study.

Where is the study run from?

The study is run from the Center for Health Services Research in Medicine of the Department of Psychiatry and Psychotherapy of the Universitätsklinikum Erlangen (University Hospital Erlangen).

When is the study starting and how long is it expected to run for?

The study starts on the 01/07/2019 and will start with participant recruitment in 01/01/2020. The end of the trial is the 30/06/2021.

Who is funding the study?

German National Association of the Statutory Health Insurance and Long-Term Care Insurance Funds (GKV-Spitzenverband)

Who is the main contact?

For further information, please contact the study supervisor: Prof. Dr. Elmar Gräßel (Mail: elmar.graessel@uk-erlangen.de).

Contact information

Type(s)

Scientific

Contact name

Prof Elmar Gräßel

Contact details

Schwabachanlage 6
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91054

Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Protocol serial number

GKV-SV339

Study information

Scientific Title

MAKS-s – multimodal psychosocial intervention for people with severe dementia in inpatient care: a cluster-randomized controlled trial assessing the effects on behavioral and psychological symptoms, quality of life, and activities of daily living of people with severe dementia as well as caregiver burden

Acronym

MAKS-s

Study objectives

Primary hypothesis:

1. Compared to the control group (treatment as usual), the intervention MAKS-s will lead to a significantly better development of behavioral and psychological symptoms as well as quality of life in people with severe dementia in the intervention group.

Secondary hypotheses:

2. Compared to the control group (treatment as usual), the intervention MAKS-s will lead to a significantly better development of activities of daily living in people with severe dementia in the intervention group.

3. Compared to the control group (treatment as usual), the intervention MAKS-s will lead to a significantly better development of dementia-related caregiver burden of the nursing and care staff in the intervention group.

4. Compared to the control group (treatment as usual), the intervention MAKS-s will lead to a relevant reduction in days of incapacity for work of nursing and care staff in the intervention group due to better development of dementia-related caregiver burden, expected in hypothesis 3.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 08/10/2019, Ethics Committee of the Medical Faculty of Friedrich-Alexander University Erlangen-Nürnberg (Geschäftsstelle der Ethikkommission, Krankenhausstr. 12, 91054 Erlangen; ethikkommission@fau.de; +49 (0)91318522270), ref. 295_19 B

Study design

Cluster-randomized controlled multi-center intervention study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Severe dementia (degenerative type, not solely vascular)

Interventions

The intervention MAKS-s is a multimodal psychosocial group intervention for people with severe dementia. It is a further development of the evidence-based MAKS therapy for people with mild to moderate dementia and mild cognitive impairment (see <http://www.biomedcentral.com/1741-7015/9/129> and <https://www.aerzteblatt.de/int/archive/article/195559/Non-pharmacological-treatment-in-people-with-cognitive-impairment-results-from-the-randomized-controlled-German-Day-Care-Study>).

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In the intervention group, MAKS-s is provided in each participating nursing home as a group offer on three days a week, for six months, with six people with severe dementia per institution. A standardized manual will be made available to the facilities, which will ensure a largely uniform implementation in all participating facilities. The implementation is controlled by monitoring visits.

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Intervention Type

Behavioural

Primary outcome(s)

1. Quality of life measured by QUALIDEM
2. Behavioural and psychological symptoms of dementia measured by Neuropsychiatric Inventory – Nursing Home Version (NPI-NH)
Measured at t0 (baseline), t2 (2 months after baseline), t6 (6 months after baseline)

Updated 15/01/2020:

Measured at t0 (baseline), t2 (2 months after baseline), t6 (6 months after baseline), t12 (12 months after baseline)

Key secondary outcome(s)

Current secondary outcome measures as of 27/05/2020:

1. Activities of daily living measured by ADCS-ADL-severe at t0 (baseline), t2 (2 months after baseline), t6 (6 months after baseline)
2. Dementia-related caregiver burden of the nursing and care staff, measured by Professional Care Team Burden Scale (PTCB) at t0 (baseline), t6 (6 months after baseline)
3. Days of incapacity for work of nursing and care staff, measured by documentation of the employer for the entire study period
4. Extent of implementation and voluntary continuation of the intervention in follow-up period, measured by a self-developed questionnaire at t12 (12 months after baseline)

Previous secondary outcome measures:

1. Activities of daily living measured by Erlangen Test of Activities of Daily Living (E-ADL) at t0 (baseline), t2 (2 months after baseline), t6 (6 months after baseline)
 2. Dementia-related caregiver burden of the nursing and care staff, measured by Professional Care Team Burden Scale (PTCB) at t0 (baseline), t6 (6 months after baseline)
 3. Days of incapacity for work of nursing and care staff, measured by documentation of the employer for the entire study period
- Added 15/01/2020: 4. Extent of implementation and voluntary continuation of the intervention in follow-up period, measured by a self-developed questionnaire at t12 (12 months after baseline)

Completion date

30/06/2021

Eligibility

Key inclusion criteria

1. Psychometric verification of severe dementia syndrome: Mini Mental State Examination (MMSE) Score between 0 and 9
2. Informed consent for study participation

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Mixed

Sex

All

Total final enrolment

145

Key exclusion criteria

1. Mild to moderate dementia respectively no cognitive impairment (MMSE > 9)
2. Cognitive decline due to diseases other than dementia (e.g. schizophrenia or Korsakoff)
3. Severe hearing impairment
4. Severe visual impairment
5. Permanently bedridden persons
6. History of severe major depression
7. History of more than one stroke
8. No verbal communication in German possible

Date of first enrolment

01/12/2019

Date of final enrolment

10/07/2020

Locations

Countries of recruitment

Germany

Study participating centre

Universitätsklinikum Erlangen, Department of Psychiatry and Psychotherapy, Center for Health Services Research in Medicine

Schwabachanlage 6

Erlangen

Germany

91054

Sponsor information

Organisation

German National Association of the Statutory Health Insurance and Long-Term Care Insurance Funds (GKV-Spitzenverband)

ROR

<https://ror.org/03psr2094>

Funder(s)

Funder type

Government

Funder Name

German National Association of the Statutory Health Insurance and Long-Term Care Insurance Funds (GKV-Spitzenverband)

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Elmar Gräßel (elmar.graessel@uk-erlangen.de). Data will be available in the time interval from 12 months until 36 months after publication of the article. The data will be provided for non-commercial research purposes only to researchers with a proposal that was peer-reviewed and approved by an independent review committee. The inquiring researchers have to present an analysis plan and state the research purpose for which the data are needed, e. g. meta-analysis. Data will be available without any additional investigator support. The data that can be provided refer solely to the data underlying the presented results of the manuscript. They will be completely anonymized, linkage to the stored data with personal information will not be possible, thus case-specific additional information/clarification cannot be provided anymore. Generally, informed consent of patients was obtained concerning participation of the study and data acquisition. Patients were informed according to the EU data protection legislation and the corresponding German equivalent (DSGVO). For further interest see the study protocol.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		28/12/2022	29/12/2022	Yes	No
Protocol article	protocol	15/10/2020	22/10/2020	Yes	No