ISRCTN15722923 https://doi.org/10.1186/ISRCTN15722923

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

Registration date
07/08/2019

Overall study status
Completed

Last Edited
29/12/2022

Condition category
Nervous System Diseases

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] 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
Erlangen
Germany
91054

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Cluster randomised trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

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).

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, 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 facilitate body perception and contracture prophylaxis than to complex movement sequences and coordination. In the

cognitive module (K), due to the advanced reduction of 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 a 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.

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).

Intervention Type
Behavioural

Primary outcome measure
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)

Secondary outcome measures
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)

Overall study start date
01/07/2019

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

Age group
Mixed

Sex
Both

Target number of participants
144 people with severe dementia (participants) in 24 nursing homes (clusters)

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)

Sponsor details
Reinhardtstraße 28
Berlin
Germany
10117

Sponsor type
Other

Website
https://gkv-spitzenverband.de

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

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
31/12/2022

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?
Protocol article	protocol	15/10/2020	22/10/2020	Yes	No
Results article		28/12/2022	29/12/2022	Yes	No