

Risk reduction of hospital admissions for people with dementia in German shared-housing arrangements with outpatient care

Submission date 05/06/2019	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 16/07/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 07/05/2025	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

The risk for hospital admissions is higher for people with dementia compared to those free of dementia. Unfortunately, the literature shows that hospitalization has negative effects on the people with dementia, their family and the healthcare system. Hence, the DemWG project aims at reducing hospital admissions, stabilizing cognition and quality of life, and reducing agitation as well as the risk of falling in people with dementia in German shared-housing arrangements with outpatient care. For this purpose, a complex intervention will be conducted with:

1. Education of the nursing staff and other people working in the shared-housing arrangement.
2. Sensitization for hospitalization risks and fostering the involvement of the involved general practitioners.
3. Motor and cognitive training for the people with dementia in the shared-housing arrangement.

Who can participate?

People with mild cognitive impairment or mild to moderate dementia who live in a shared-housing arrangement with outpatient care in Germany can participate. There is no restriction regarding age or gender. People with the following conditions cannot participate in the study: severe dementia, severe hearing and/or visual impairment, cognitive decline due to diseases other than dementia (e.g. schizophrenia or Korsakov), permanently immobile, no verbal communication in German possible, history of severe major depression and/or more than one stroke.

What does the study involve?

The multimodal motor and cognitive training MAKS-mk+ is based on the central elements "cognition" (K) and "motor stimulation" (M) of the evidence-based MAKS therapy (www.maks-therapie.de). These elements have been extended by evidence based exercises to increase muscle strength and balance (+), derived from the evidence-based OTAGO exercise program for fall prevention, and adapted to the situation in shared-housing arrangements when developing the intervention MAKS-mk+. MAKS therapy has been shown to stabilize cognition and abilities of daily living in nursing homes and day care. In the DemWG project, MAKS-mk+ will be performed for 60 minutes five days a week in groups of maximum 12 persons for six months.

Education for nursing staff and other people working in shared-housing arrangements focuses on detecting health risk situations and informing about possible action strategies. General practitioners get also involved through further education about risks and consequences of hospital admissions and awareness raising interventions.

Participants will be examined with regard to the main and secondary outcomes before and after the therapy. The main outcome is hospital admissions in the last 6 months and secondary outcomes are quality of life, behavioural and psychological symptoms of dementia (including e.g. agitation), risk of falling and cognition. Additionally, focus groups and expert interviews are planned to be performed.

Of the 180 shared-housing arrangements in Germany collaborating in the study, 90 will perform the complex intervention immediately (intervention group); the others 12 months later optionally (waiting control group).

Additionally, an analysis of health insurance data will be performed to calculate the costs of health service utilization.

What are the possible benefits and risks of participating?

The possible benefits of participating in the study are stabilized cognition and quality of life, and reduced agitation as well as reduced risk of falling in people with dementia in German shared-housing arrangements with outpatient care. On the basis of previous studies, no side effects of the treatments are expected, neither for the evidence-based MAKs therapy (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>) nor for the evidence-based OTAGO exercise program for fall prevention (see <https://academic.oup.com/ageing/article/39/6/681/9467>).

Where is the study run from?

The study is run from the Institute for Public Health and Nursing Research (IPP) of the University of Bremen and 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 DemWG project starts in April 2019 and will start with participant recruitment in January 2020. The end of the trial is 31/12/2022.

Who is funding the study?

The main sponsor is the Innovationsausschuss beim Gemeinsamen Bundesausschuss (Innovation Committee at the Federal Joint Committee [G-BA]).

Who is the main contact?

For further information, please contact the study supervisors: Prof. Dr. Karin Wolf-Ostermann (Mail: wolf-ostermann@uni-bremen.de) and Dr. Carolin Donath (Mail: carolin.donath@uk-erlangen.de).

Contact information

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

01VSF18054

Study information

Scientific Title

Risk reduction of hospital admissions for people with dementia in German shared-housing arrangements with outpatient care by a complex intervention: a cluster-randomized controlled trial

Acronym

Study objectives

Primary Hypothesis:

1. Compared to the control group (treatment as usual), the intervention will lead to a reduction in hospital admissions and related consequences in the intervention group.

Secondary Hypotheses:

1. Compared to the control group (treatment as usual), the intervention will stabilize the quality of life for people with dementia in the intervention group.
2. Compared to the control group (treatment as usual), the intervention will reduce agitation and behavioral psychological symptoms of dementia in the intervention group.
3. Compared to the control group (treatment as usual), the intervention will reduce the risk of falling for people with dementia in the intervention group.
4. Compared to the control group (treatment as usual), the intervention will stabilize cognition for people with dementia in the intervention group.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 24/09/2019, the Ethics Committee of the University of Bremen (Mrs Strehmel-Fischer, Universität Bremen, Rechtsstelle – Referat 06, Postfach 330440, 28334 Bremen; tstrehm@uni-bremen.de; +49421 218 60220), ref: 2019-18 06-3

Study design

Two-armed study:

1. Cluster-randomized controlled multi-center intervention study, complex intervention, waiting control group. Longitudinal data acquisition. Additional, focus groups and expert interviews are planned to be performed.
2. Panel study: analysis of health insurance data to calculate costs of health service utilization.

Primary study design

Interventional

Study type(s)

Quality of life

Health condition(s) or problem(s) studied

Mild cognitive impairment, mild or moderate dementia (degenerative type, not solely vascular).

Interventions

Treatment (the complex intervention) consists of three parts:

1. Education of nursing staff and other people working in shared-housing arrangements in detecting health risk situations and possible action strategies. education contents are risk factors for hospitalization, prevention options for falls, for dehydration and serious infections. The control group receives the education optionally one year after the intervention was implemented in the intervention group (ethical reasons).

2. Sensitization for hospitalization risks and fostering the involvement of general practitioners through further education about risks and consequences of hospital admissions and awareness

raising interventions. The control group receives this intervention component optionally one year after the intervention was implemented in the intervention group (ethical reasons).

3. The intervention MAKs-mk+: The evidence-based MAKs therapy (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>) will be adapted to the shared-housing arrangement setting (MAKS-mk+). MAKs-mk+ is a multicomponent group intervention. During the intervention time of six months, the modules "motor stimulation" (M) and "cognition" (K) of the MAKs therapy, extended by evidence-based exercises to increase muscle strength and balance (+), will be performed five days a week in the shared-house arrangements in groups of a minimum of three and a maximum of 12 persons. Each daily session will begin with approximately 30 minutes of motor exercises: exercises for upper limbs, derived from the module "motor stimulation" (M) of the MAKs therapy, on two days a week and evidence-based exercises to increase muscle strength and balance (+), derived from the evidence-based OTAGO exercise program for fall prevention (see <https://onlinelibrary.wiley.com/doi/full/10.1046/j.1532-5415.2002.50218.x?sid=nlm%3Apubmed> and <https://academic.oup.com/ageing/article/39/6/681/9467>), on three days a week. This is followed by about 30 minutes completing a variety of cognitive tasks from the module "cognition" (K) of the MAKs therapy projected digitally onto a large screen to be solved by the group five days a week. MAKs-mk+ was designed to promote activities that take place at an individual's performance limit. Therefore, therapists can choose cognitive tasks in various difficulty levels according to the cognitive impairment in the group. The control group receives the usual care offered in each shared-housing arrangement (treatment as usual). After a waiting time of one year, the control group receives training in MAKs-mk+ and the intervention manual optionally (ethical reasons).

Intervention Type

Mixed

Primary outcome(s)

Hospital admissions in the preceding 6 months are measured by nursing documentation of frequency, reasons and dates of hospital admissions at baseline, 6 months, 12 months and 18 months.

Key secondary outcome(s)

1. Quality of life is measured by QUALIDEM at baseline, 6 months, 12 months and 18 months.
2. Behavioural and psychological symptoms of dementia and agitation are measured by Neuropsychiatric Inventory (NPI) and Cohen-Mansfield Agitation Inventory (CMAI) at baseline, 6 months, 12 months and 18 months.
3. Falls are measured by a self-developed questionnaire at baseline, 6 months, 12 months and 18 months.
4. Cognition is measured using the Mini-Mental State Examination (MMSE) at baseline, 6 months, 12 months and 18 months.

Completion date

31/12/2022

Eligibility

Key inclusion criteria

Current inclusion criteria as of 25/11/2019:

1. Resident of shared-housing arrangements (with outpatient care).
2. Mild cognitive impairment or mild to moderate dementia.
3. Shared-housing arrangement is located in Bavaria, Bremen, Hamburg or Berlin. In order to reach the target number of participants we opened up the recruitment regions for the shared housing-arrangements to the remaining federal states of Germany.

Previous inclusion criteria:

1. Resident of shared-housing arrangements (with outpatient care).
2. Mild cognitive impairment or mild to moderate dementia.
3. Shared-housing arrangement is located in Bavaria, Bremen, Hamburg or Berlin.

Participant type(s)

Mixed

Healthy volunteers allowed

No

Age group

Senior

Sex

All

Total final enrolment

363

Key exclusion criteria

1. Severe hearing impairment.
2. Severe visual impairment.
3. Severe dementia.
4. Cognitive decline due to diseases other than dementia (e.g. schizophrenia or Korsakov).
5. Permanently immobile.
6. No verbal communication in German possible.
7. History of more than one stroke.
8. History of severe major depression.

Date of first enrolment

01/01/2020

Date of final enrolment

31/12/2020

Locations

Countries of recruitment

Germany

Study participating centre

University of Bremen, Institute for Public Health and Nursing Research (IPP)

Grazer Straße 4
Bremen
Germany
28359

Study participating centre

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

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91054

Sponsor information

Organisation

Innovation Committee at the Federal Joint Committee (Innovationsausschuss beim Gemeinsamen Bundesausschuss), general project administration: DLR Project Management Agency (DLR Projektträger)

Funder(s)

Funder type

Government

Funder Name

Innovation Committee at the Federal Joint Committee (Innovationsausschuss beim Gemeinsamen Bundesausschuss), general project administration: DLR Project Management Agency (DLR Projektträger)

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 Stephan Kloep (kloep@uni-bremen.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 through the data warehouse of the University Bremen 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	Primary data	06/05/2025	07/05/2025	Yes	No
Protocol article		02/12/2020	13/04/2021	Yes	No
Other publications	Validation of Cohen-Mansfield Agitation Inventory-Short Form (CMAI-SF) in German	29/05/2023	30/05/2023	Yes	No
Other publications	Urban versus rural locations	13/03/2025	18/03/2025	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes