ISRCTN11686133 https://doi.org/10.1186/ISRCTN11686133

Therapeutic rehabilitative care in a multi-professional team

Submission date 24/03/2023	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 27/03/2023	**Overall study status** Ongoing	
Last Edited 27/03/2023	**Condition category** Other	

Plain English summary of protocol

Background and study aims
Currently, around 2.4 million people in Germany depend on formal or informal care. By 2030, approximately 3.4 million people will be in need of long-term care. Especially after hospitalization, the risk of permanent inpatient care is high. Despite improvements in discharge and quality management, there is still a massive deficit regarding rehabilitative approaches for residents in inpatient care. Own preliminary analyses of a regional best-practice model of therapeutic-rehabilitative care (Haus Ruhrgarten, Mülheim, Germany) showed significantly lower values for treatment costs and the number and duration of hospital stays than in comparable nursing homes. Based on this best-practice model, this study aims to implement an innovative therapeutic-rehabilitative intervention in nursing homes to improve the residents' activities of daily living skills, cognitive performance and quality of life, as well as improve the job satisfaction of healthcare employees and the quality of life of residents' relatives. Furthermore, the intervention aims to reduce the use of inadequate pharmaceuticals and the re-hospitalization rate as well as to increase the number of people who can return to their own homes. The innovative program comprises an extended therapy offer as well as the structured integration of therapeutic elements into the daily care routine, thereby enhancing interdisciplinary cooperation and improving communication with relatives.

Who can participate?
Residents, aged 65+ years old, in 12 nursing homes in the federal states of North Rhine-Westphalia and Hamburg (Germany), 1 relative per participating resident, and employees in the facility

What does the study involve?
The study follows a stepped-wedge design with one 6-month control period followed by three 6-month periods where participating nursing homes successively begin with the intervention. The study includes quantitative assessments with residents, relatives and staff members, a health economics analysis, as well as a qualitative process and results evaluation.

Control group participants receive nursing and therapeutic treatment as usual. Participants involved in the intervention group receive additional care that includes therapeutic-rehabilitative and biography-related elements in all nursing activities. Furthermore, the

participants in the intervention group receive additional therapeutic treatments in the areas of physiotherapy, occupational therapy and music or art therapy. The nursing and therapeutic needs and the evaluation of the progress are regularly discussed in multi-professional team meetings with the participation of the nursing team, therapists, a general practitioner and/or a gerontological psychiatrist/neurologist, and a pharmacist. The aim is to ensure multi-professional and resident-oriented care with reduced polypharmacy and administration of psychotropic drugs. Relatives of participating residents in the intervention group receive improved communication with staff members. For the duration of the intervention therapeutic, nursing, and social care staff ratios will be raised. Staff members receive a training programme for therapeutic-rehabilitative nursing practice as well as team supervision.

What are the possible benefits and risks of participating?
Possible benefits include better staffing and higher work motivation, improved care and quality of life for residents in the intervention group and better communication and quality of life for their relatives. Furthermore, all participants (control and intervention group participants) can contribute to the improvement of the healthcare situation in general. For residents in the intervention group, minor risks are associated with participation due to increased therapy and possible medication changes. A possible reduction of medication is only considered in detailed medical examination by the general practitioner, psychiatrist/neurologist and pharmacist and in communication with residents. Residents' well-being is the main priority at all times.

Where is the study run from?
The University of Potsdam (Germany)

When is the study starting and how long is it expected to run?
July 2022 to June 2026

Who is funding the study?
German Innovation Fund (Gemeinsame Bundesausschuss; 01NVF21108) (Germany)

Who is the main contact?
Prof. Dr. Dr. M. Rapp, michael.rapp@uni-potsdam.de (Universität Potsdam) (Germany)

Contact information

Type(s)
Principal investigator

Contact name
Prof Michael Rapp

ORCID ID
https://orcid.org/0000-0003-0106-966X

Contact details
University of Potsdam
Campus Golm
Haus 62, Raum 2.07 (H-Lab)
Am Mühlenberg 9
Potsdam
Germany

14476
+49 (0) 331 977 4095
michael.rapp@uni-potsdam.de

Type(s)
Scientific

Contact name
Dr Andreas Ludwig Günter Häusler

ORCID ID
https://orcid.org/0000-0003-1963-8373

Contact details
University of Potsdam
Campus Golm
Haus 62 (H-Lab)
Am Mühlenberg 9
Potsdam
Germany
14476
+49 (0) 331 977 4185
andreas.haeusler@uni-potsdam.de

Type(s)
Public

Contact name
Ms Isabella Heller

Contact details
Press spokesperson AOK
AOK Rheinland/Hamburg – die Gesundheitskasse
Kasernenstraße 61
Düsseldorf
Germany
40213
+49 (0) 211 8791 28474
presse@rh.aok.de

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
01

Study information

Scientific Title
Cross-sectoral gerontopsychiatric treatment and rehabilitation in nursing homes (Sektorenübergreifende gerontopsychiatrische Behandlung und Rehabilitation in Pflegeheimen)

Acronym
SGB Reha

Study objectives
The implementation of the rehabilitation concept will lead to:
1. An improvement of residents' activities of daily living skills
2. An increase in job satisfaction among the nursing staff and increase in quality of life among residents and their relatives
3. A reduction of hospitalizations and treatment costs
4. A reduction of pharmaceuticals
5. A higher number of residents returning to their own homes

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 19/12/2022, Ethics committee of the Brandenburg Medical School Theodor Fontane (Ethikkommission Medizinische Hochschule Brandenburg Theodor Fontane [Ethics Committee of the Brandenburg Medical School Theodor Fontane] Haus O, DG, Raum 311, Fehrbelliner Str. 38, 16816 Neuruppin, Germany; +49 (0) 3391 39-14663; ethikkommission@mhb-fontane.de), ref: E-02-20220930

Study design
A multicenter stepped wedge cluster randomized interventional study with embedded qualitative evaluation

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Elderly, multimorbid long-term residents of nursing homes, independently living relatives, nursing home staff working with nursing homes residents

Interventions
The intervention includes a complex of multimodal cross-sectoral rehabilitative measures for nursing home residents. The intervention involves residents older than 65 years, (re-)admitted in the last 12 months, publicly health insured and without major cognitive impairment (MMSE >11 or comparable instrument) in nursing homes.

The intervention includes the following components:
1. Interprofessional extended team meetings for individualized resident-centered care and rehabilitation planning
2. Training on therapeutic-rehabilitative care concepts and practice for facility staff including therapists, nurses, housekeeping, and social workers

3. Extended therapy offers (physio-, occupational, music/art)
4. Individual advice for nurses provided by therapists, to include therapeutic elements into daily nursing practice,
5. Implementation of the person-centered multi-professional rehabilitation concept as well as the continuation of therapeutic-rehabilitative measures by nursing and caregivers, under the direction of residents' respective primary nurses
6. Strengthening of social and day-structuring activities through social assistance
7. Team supervision
8. Increased communication between staff and residents' relatives

Prior to the start of the intervention, the employees from the areas of nursing, social care, therapy and, if necessary, housekeeping of each nursing home will be individually trained in two-day training sessions regarding therapeutic-rehabilitative care, resident orientation, activation and social integration, as well as multi-medication and psychotropic drugs.

The study follows a stepped-wedge design: After a control phase of 6 months without intervention in all nursing homes, 4 randomly selected facilities (3 urban and 1 rural) will proceed with the intervention consisting of 3 stages at 6-month intervals. After another 6 months, the next 4 randomly selected facilities will begin with the intervention consisting of 2 stages at 6-month intervals. After another 6 months, the last 4 facilities will join the intervention phase for one 6-month period.

The inclusion of the residents takes place during the first four weeks of each period.

Secondary outcome measures include the Tilburg Frailty Indicator (TFI), the Montreal-Cognitive-Assessment-Test (MOCA), 20 Coins Test (20-C-T), Short Form Health Survey (SF-12), WHO Quality of Life (WHOQOL-OLD), Mini Nutritional Assessment (MNA-SF), Charleston Comorbidity Index (CCI), Copenhagen Psychosocial Questionnaire (COPSOQ) (for staff) and the WHOQOL-BREF (for relatives). The number of hospitalisations, psychopharmacological medication in defined daily dosage, polypharmacy and proportion of patients discharged to their own are measured as well. In addition, health economic data (e.g. hospital stays, medical aids, travel costs) are assessed at the resident and nursing home level. For the subgroup of AOK insured, costs at the resident level and cost-effectiveness are assessed. The study includes a qualitative process evaluation as well as a qualitative evaluation of intervention effects. The goal of both qualitative evaluations is to refine a preliminary theory of change model developed for the SGB Reha intervention and to contextualize the results of the quantitative and health economics analyses. The process evaluation involves 4 phases of participant observation (1 before implementation in all 12 nursing homes, 3 after implementation in the respective intervention nursing homes in accordance with the stepped-wedge design). In each observation phase, the respective nursing home will be visited for one week and intervention-related practices will be observed (team meetings, nursing, therapy, and social activities). Each observation week includes subsequent semi-structured telephone or online interviews with 5-10 staff members per nursing home and the Organizational Readiness for Implementing Change (ORIC) questionnaire. The process evaluation's aim is to analyse infrastructure, motivation for change, organizational culture, and barriers to intervention implementation in order to develop strategies for optimal implementation.
The qualitative evaluation of intervention effects involves 3 phases of participant observation (at the end of each 6-month intervention period in the respective nursing homes). Each observation phase includes one-week visits in the same manner as the process evaluation. Semi-structured interviews with intervention residents, their relatives, and staff members (3-5 each) will be conducted on-site or via telephone or video call after each observation week for each nursing home. The qualitative evaluation of intervention results aims to analyse the effects of

the intervention components from residents', relatives' and staff members' subjective perspectives.

Intervention Type
Mixed

Primary outcome(s)
Basal and instrumental daily living skills with the Scores of Independence for Neurologic and Geriatric Rehabilitation (SINGER) at baseline, 3 and 6 months

Key secondary outcome(s))
The following secondary outcome measures for nursing home residents are assessed at baseline, and after 3 and 6 months:
1. Frailty measured using the Tilburg Frailty Indicator (TFI)
2. Cognitive Function measured using the Montreal-Cognitive-Assessment-Test (MOCA)
3. Hand mobility measured using the 20 Coins Test (20-C-T)
4. Overall health status and quality of life measured using the Short Form Health Survey (SF-12)
5. Quality of Life for elderly individuals measured using the WHO Quality of Life (WHOQOL-OLD)
6. Nutritional Status of older individuals measured using the Mini Nutritional Assessment (MNA-SF)
7. Comorbidity burden measured using the Charleston Comorbidity Index (CCI) (at baseline only)

8. The number of hospitalisations (during 6 months), psychopharmacological medication defined daily dosage (at baseline, 3 and 6 months), polypharmacy (at baseline, 3 and 6 months) and proportion of patients discharged to their own home (during 6 months) measured using information from the nursing home residents´ file

9. Health economic data (e.g. hospital stays, medical aids, travel costs) measured at the resident and nursing home levels. For the subgroup of AOK insured, costs at the resident level and cost-effectiveness are assessed.

Other secondary measures for different participant groups comprise the following methods:
10. Job Satisfaction of nursing home staff with the Copenhagen Psychosocial Questionnaire (COPSOQ) at baseline, and after 6, 12, 18 and 24 months.
11. Quality of life of residents´ relatives with the WHOQOL-BREF at baseline and after 6 months.

Completion date
30/06/2026

Eligibility

Key inclusion criteria
Residents:
1. Residents of the participating nursing homes aged over 65 years old
2. Newly admitted in the nursing home after recent hospitalisation within the last 12 months or
3. Not longer than 12 months resident of the nursing home
4. At least level 2 of care (by § 15 SGB XI)
5. Declaration of consent

Relatives:
1. Being a participating resident’s relative (defined as a person with at least weekly contact)
2. Provide informed consent

Employees of nursing homes:
1. Working on wards that are part of the intervention
2. Provide informed consent

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
65 years

Sex
All

Key exclusion criteria
Residents:
1. Severe dementia (MMSE <=11)
2. Lack of capacity to consent / not providing consent
3. Residents with legal care
4. Residents with private health insurance (funder requirement)

Relatives:
1. Relatives of excluded residents
2. Not providing consent

Employees:
1. Working on wards that are not part of the intervention
2. Not providing consent

Date of first enrolment
01/04/2023

Date of final enrolment
01/12/2024

Locations

Countries of recruitment
Germany

Study participating centre
Residenz am Wiesenkamp
Wiesenkamp 16
Hamburg
Germany
22359

Study participating centre
Hospital zum heiligen Geist
Hinsbleek 11
Hamburg
Germany
22391

Study participating centre
Seniorenzentrum Erikaweg
Erikaweg 9
Hilden
Germany
40723

Study participating centre
Albertinen Haus
Sellhopsweg 18-22
Hamburg
Germany
22459

Study participating centre
Alten und Pflegeheim Wöllner-Stift gGmbH
Bahnhofstraße 26
Rösrath
Germany
51503

Study participating centre
Haus St. Raphael
Strüverweg 3
Aachen
Germany
52070

Study participating centre
Seniorenhaus Maria Einsiedeln
Haager Weg 32
Bonn
Germany
53127

Study participating centre
St. Ritastift Seniorenhaus
Rütger-von-Scheven-Str. 81
Düren
Germany
52349

Study participating centre
Martineum Essen
Augenerstraße 36
Essen
Germany
45276

Study participating centre
Seniorenheim Haus Maria Regina
Lange Str. 16
Wadersloh
Germany
59329

Study participating centre
Seniorenheim Linn
Quartelkämpchen 52
Krefeld
Germany
47809

Study participating centre
Seniorenheim Bischofstraße
Bischofstraße 10

Krefeld
Germany
47809

Sponsor information

Organisation
AOK

ROR
https://ror.org/004cmqw89

Funder(s)

Funder type
Government

Funder Name
Gemeinsame Bundesausschuss

Alternative Name(s)
Federal Joint Committee, G-BA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Germany

Results and Publications

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date