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Title:

Cognitive stimulation for people with dementia in nursing homes: A protocol for a feasibility study examining a new 24/7 approach (CogStim24)

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ABSTRACT

Introduction: Based on the available evidence, cognitive stimulation is recommended as an intervention for people with mild to moderate dementia (PwD). Currently, cognitive stimulation is regularly offered as a group program in care facilities. However, some residents, such as those who are bedridden, cannot participate. Furthermore, group programs were not feasible during the pandemic. A concept that accompanies everyday life and enables cognitive stimulation in everyday communication (i.e., "24/7") has been missing. Therefore, this feasibility study aims to (i) assess the feasibility of a new continuous 24/7 cognitive stimulation program (CogStim24) based on a process evaluation and (ii) examine the possible effects of CogStim24 on the primary outcome of global cognition in PwD and further PwD- and staff-related outcomes.

Methods and Analysis: The complex CogStim24 program is developed to be conducted as an everyday intervention during routine care including cognitively stimulating techniques, such as reminiscence therapy, multisensory stimulation, and physical activity. In this unblinded single-arm study with pre- and post-assessments, four nursing homes with a total of N=20 nursing and care staff will participate in an 11-week CogStim24 training program. The intervention will be conducted to N=60 PwD. Neuropsychological assessments will be conducted pre- and post-staff training, as well as after a 6-week implementation phase. A process evaluation will be performed.

Ethics and dissemination: Although cognitive stimulation is known to be effective for enhancing global cognition and quality of life in PwD, it is currently undersupplied to PwD. Therefore, CogStim24 has the potential to reach many more PwD. This study has the potential to serve as a basis for a large multicenter cluster randomized controlled trial. An interdisciplinarity team and mixed-methods approach will help generate information on the practicality and mechanisms of impact of CogStim24. This is important for the further development of the intervention and for facilitating its implementation.

Trial registration: German Clinical Trials Register (ID: DRKS00024381).

Strengths and limitations of this study:

- CogStim24 has been developed as a complex cognitive stimulation approach for the everyday use during routine care of people with dementia (PwD); it includes a 11-week training program for nursing and care staff.
- The development was based on a systematic review of cognitive stimulation techniques for PwD and a participatory approach including a survey on the current practice of cognitive stimulation in German nursing homes, and focus group discussions with nursing and care staff on their experiences, barriers, and needs regarding cognitive stimulation intervention implementation.
- The pilot study aims to evaluate the implementation fidelity, to assess the feasibility of the study design, and to examine possible effects of CogStim 24 on the primary outcome global cognition in PwD and further PwD- and staff-related outcomes.
- The trial is limited to a unblinded single-arm study with pre- and post-assessments; large multicenter cluster randomized controlled trial will have to follow.

Keywords:

Dementia, Alzheimer's disease, cognitive stimulation, non-pharmacological therapy, nursing home, mixed-methods, study protocol, process evaluation, logic model, complex intervention

INTRODUCTION

Over 55 million people currently live with dementia globally; it is estimated this number will reach 78 million by 2030. With dementia being the 7th leading cause of global mortality and its high cost of treatment and care, it constitutes a major challenge not only for those affected but for society as a whole (1). Cognitive dysfunctions are the primary symptoms of dementia; however, people with dementia (PwD) also suffer from psychiatric and behavioral symptoms, leading to high caregiver burden (1). PwD typically require care throughout the course of the disease. Although many PwD receive long-term formal and informal care at home, there is a high risk of institutionalization in later disease stages (2).

Symptomatic pharmacological treatment includes acetylcholinesterase inhibitors and memantine to stabilize cognition for a short time; however, the efficacy is limited, and disease-modifying therapy is not yet available (3). Non-pharmacological treatment has attracted increased research and clinical practice interest. These treatments include cognitive interventions, physical exercise, and occupational and music therapy (4). Cognitive interventions utilize different approaches. One approach is cognitive training, which involves standardized paper-and-pencil or computerized tasks provided in individual or group sessions targeting specific cognitive functions. Another is cognitive stimulation, which is the global activation of cognitive and social skills in a small group setting via stimulating exercises, games, and conversation rounds, often in combination with reality orientation and reminiscence therapy (5, 6).

The current literature gives a relatively homogeneous picture regarding the effectiveness of cognitive stimulation in PwD, which is reflected in the recommendations of the German S3 guidelines to diagnose and treat dementia (7) (recommendation grade B: “should be offered”). Randomized controlled trials (RCTs) and systematic reviews and meta-analyses have demonstrated a positive effect of cognitive stimulation on various cognitive and non-cognitive parameters, including significant effects on global cognition (5, 6, 8), quality of life (6, 8), psychological and behavioral symptoms (6, 8), and communication skills and social interaction (6). A Cochrane review concluded that the effects shown are equivalent to or even exceed those of pharmacological therapy (6).

However, investigations of the effectiveness of these approaches have only been carried out in the context of individual and/or small-group interventions with defined time periods, such as 6 or 8 weeks (6). In these studies, the approaches are seen as “add-ons” to the individual care of PwD. Programs such as cognitive stimulation therapy (9), the multicomponent program MAKS therapy (10), StaKogS (11), and NEUROvitalis Sinnreich (12) are designed for a period of several weeks or months and for settings in which groups and exercise leaders come together. Therefore, such intervention effects may lack sustainability as they might not last. Furthermore, many PwD cannot take part in such programs due to being bedridden or because the nursing home lacks resources to provide cognitive stimulation (e.g., lack of staff to conduct the interventions and/or take inpatients to the group or a lack of rooms). In outpatient settings, intervention groups may not be available at all (e.g., in rural areas). Additionally, during the SARS-CoV-19 pandemic, group activities, including cognitive stimulation and “memory training groups,” were paused in most settings (13).

On the basis of the considerations highlighted above, a 24/7 approach in which cognitive stimulation is used as an intervention accompanying daily routine care may enable sustainable stimulation for many PwD within existing care structures. To date, there is no concept of cognitive stimulation as a 24/7 approach to everyday contact between PwD and caregivers. This is supported by a recent scoping review on manual-based complex interventions in outpatient and inpatient care of PwD (14), where no study with a 24-hour cognitive stimulation concept was identified. The 24/7 cognitive stimulation program (CogStim24) project is the first step to filling this important gap in research and clinical practice.

Therefore, the present study aims to pilot the newly developed CogStim24 intervention as a 24/7 fixed component in everyday inpatient care for PwD. CogStim24 seeks to enable nurses and caregivers to provide cognitive stimulation at any time, such as during everyday personal hygiene activities or during meals, by anchoring the stimulation elements through conversation impulses, low-threshold available stimulating materials, and pocket exercises.

This feasibility study has several aims:

1. To evaluate the implementation fidelity, including the feasibility of the educational program for conducting CogStim24 and evaluating promoting and inhibiting factors of the intervention's implementation (i.e., process evaluation).
2. To assess the feasibility of the study design of CogStim24 in nursing homes as a basis for future cluster RCTs.
3. To examine the possible effects of CogStim24 (I = Intervention) on the primary outcome of global cognition (O = Outcome) in PwD (P = Population) and the secondary outcomes of quality of life, depression, and behavioral and psychiatric symptoms in dementia (BPSD), as well as the work-related quality of life and stress experiences of nursing and care staff using a pre-post design. As this is a non-controlled study, no comparators can be defined (C = Comparison).

This study is based on a logic model for the CogStim24 intervention (Figure 1). The logic model was created and discussed, with several iterations developed by the entire research team, using the current literature and authors' expertise. This process enabled the relevant theoretical assumptions, actors, and procedural outcomes for the evaluation to be considered. The logic model includes theoretical assumptions, the intervention, implementation, mechanism of impact, outcomes, and the micro-to-macro context (15, 16).

METHODS AND ANALYSIS

This report follows the SPIRIT guidelines for the minimum content of a clinical trial protocol (17). See Supplement 1 for the SPIRIT checklist.

Design/Methodology

Study design

This study was conceptualized as an uncontrolled, non-masked, single-arm study involving pre- and post-assessments using a mixed-methods approach. A process evaluation will be performed in conjunction with

the study (16, 18). Within this study, several project steps will be carried out (Figure 2). These include training nursing and care staff on how to conduct CogStim24, piloting the CogStim24 intervention in nursing homes, using quantitative pre- and post-intervention assessments and qualitative interviews with PwD, nursing and care staff, nursing home managers, and head nurses, and evaluating the process of the overall implementation phase (training plus intervention implementation phase).

As a first step, nursing and care staff will receive an 11-week training on how to conduct the CogStim24 intervention, including e-learning modules for self-administration and group training sessions delivered in person and digitally. During the training program, the staff will implement CogStim24 stimulation techniques step by step in their everyday work routine so that they are able to implement the full program at the end of the training period. To investigate whether the protocol for the quantitative pre- and post-intervention assessments is feasible and to gain evidence for effects as a basis for a future cluster RCT, neuro-psychological tests and questionnaires will be administered to the participants (PwD and nursing and care staff) two weeks before (T0), immediately after the 11-week training program (T1), and two weeks after the 6-week intervention period (T2).

The process evaluation will be conducted for the full study duration, including the 11-week staff training and 6-week intervention period. The degree of implementation, mechanisms of change, and acceptance of the complex intervention in the participating nursing home facilities will be investigated. In addition, factors conducive to and inhibiting implementation will be explored.

CogStim24 intervention

CogStim24 was developed as a cognitive stimulation program that can be conducted in everyday life for people with cognitive impairments or PwD, provided by staff in nursing homes or in day care facilities and by relatives at home.

The development of the CogStim24 program was based on several factors:

- The authors' expertise in developing cognitive intervention programs (12, 19) and training courses for such interventions, as well as in conducting clinical studies that examine the effects and mechanisms of cognitive interventions in various target groups, including PwD (8, 20). This expertise was brought together in several expert meetings, in which the CogStim24 concept was created.
- A systematic literature review of the characteristics of cognitive stimulation interventions for PwD (see review registration under https://www.crd.york.ac.uk/prospero/display_record.php?ID=CRD42021227904).
- A participatory approach during the entire development process and pilot study conduction, which included (i) a survey conducted in 64 nursing homes in North-Rhine Westphalia, Germany, on the current practice of cognitive stimulation (its challenges and barriers and current opinions and needs) and (ii) focus group discussions with nursing and care staff of inpatient long-term care facilities on their experiences, barriers, and needs regarding cognitive stimulation intervention implementation, as well as their opinions regarding the idea, possible structure, and content of a CogStim24 approach that included staff training (21).

The resulting concept of the CogStim24 intervention is expected to stabilize global cognition and improve the quality of life and mood of PwD. It is also expected to promote communication between PwD and nursing and care staff and improve the work-related quality of life and stress experiences of the staff.

The program consists of a large body of exercises that can be categorized under several cognitive stimulation techniques: reminiscence therapy, cognitive training, occupational exercises, multisensory stimulation, music therapy, physical intervention, and relaxation. In addition, patient-centered communication and reality orientation techniques are basic concepts of the program and are considered integral parts of all exercises. Each block of stimulation techniques contains ten exercises that are easy to conduct in daily routine care. Each exercise has two difficulty levels for PwD with cognitive impairments of different severity (Supplement 2). An "activity clock" was developed. This can be displayed in each resident's room and illustrates all the cognitive stimulation areas mentioned above. It can be used to make

choices regarding the stimulation area of focus. The use of this clock promotes reality orientation and contributes to cognitive stimulation by focusing on the decision-making process.

The CogStim24 intervention includes a detailed instruction manual for all exercises as well as material to be placed in each resident's room, including booklets with images and verbal exercises (e.g., for completing proverbs) and materials for physical exercises (e.g., a ball and a resistance band). Nurses and care staff are encouraged to collect autobiographical information and corresponding material, such as photos or belongings with personal value, for each resident and place it into the room for use within the CogStim24 program.

An overview of the program following the TIDieR guidelines (22) is displayed in Table 1.

Table 1. CogStim24 program overview based on the TIDieR guidelines.

What? ***Procedures, tailoring, and modifications***	**Why?** ***Rationale and theory***	**What?** ***Materials***	**How? Where?** ***Modes of delivery***	**Who?** ***Intervention provider***	**When & how much?**
Procedures Staff training Nursing and care staff receive an 11-week training program (max. 3h/week; cf. Supplement 3). CogStim24 Cognitive stimulation exercises that are easy to conduct in daily routine care based on the following techniques: • Reality orientation • Reminiscence therapy • Cognitive training • Occupational exercises • Multisensory stimulation • Music therapy • Physical intervention • Relaxation All interactions are based on the principles of patient-centered communication. *Tailoring* Nursing and care staff can choose from the ten exercises for each technique and from two difficulty levels, depending on residents' abilities. *Modifications* Based on the participatory approach, adjustments in intervention and implementation are possible.	Cognitive stimulation has been shown to have positive effects on global cognition and quality of life. However, many PwD living in nursing homes cannot participate in group-based cognitive stimulation programs.	• Manual for nursing and care staff. • An "activity clock" indicates all possible activity domains. • Material in each resident's room (e.g., booklets with images and resistance bands) • If possible, autobiographic information and material relating to the resident will be placed in their rooms (e.g., a short CV, pictures, and other meaningful items).	The intervention will be conducted during everyday care in nursing homes, both in resident rooms and other facility areas.	Nursing and care staff will be educated on the intervention during the 11-week staff training program	The intervention can be conducted in any interaction between PwD and nursing and care staff

Abbreviations: PwD*:* People with dementia.

Training program for nursing and care staff

Each participating nursing and care staff team member of the nursing homes involved in the study will receive an 11-week training program, which will be facilitated by members of the research team, including psychologists, gerontologists, and nursing scientists who hold a minimum of a bachelor's degree. The training consists of several components: e-learning modules for self-administration, group face-to-face sessions, and digital meetings. Overall, the training includes 12 hours of face-to-face and 12 hours of digital

meetings, as well as five 30-minute self-administered sessions supported by e-learning modules. As CogStim24 has too many modules to be implemented at once, the topics and techniques of the intervention are introduced step by step so that the staff are able to implement the full spectrum of the intervention components when the training course has been completed. Each module is introduced by an e-learning module in the form of an audio-backed PowerPoint presentation and a workbook with information and exercises to deepen the understanding of topic contents, both of which are sent to the participants one week in advance of the following session. In the group face-to-face sessions, the topic and cognitive stimulation exercises are extensively explained and discussed, and exercises are practiced interactively. This is followed by a one-week implementation phase, where the staff can trial the module in everyday care. In the middle of the implementation phase, an online "reflection" session is held, in which experiences with the exercises and materials and the successes, failures, and barriers in the implementation are discussed. Participants will be given a "CogStim24 diary" as an aid, which will contain a checklist of the relevant aspects for the purpose of self-reflection. This checklist includes several aspects related to participants' experiences during the implementation phase:

- The CogStim24 exercises and materials were used and why (free text).
- The experiences had in implementing the exercises (free text).
- The barriers faced when conducting the exercises (free text).
- An evaluation of the setting conditions as a basis for conducting the exercises (free text).
- How the implementation was for the staff in terms of difficulty level, time expenditure, satisfaction with the exercises, and motivation. Responses are rated on a 6-point Likert scale ranging from "very low" to "very high."
- How the exercise was for individuals with cognitive impairment (free text) in terms of difficulty level, time expenditure, satisfaction with the exercises, and motivation. Responses are rated on a 6-point Likert scale, ranging from "very low" to "very high."

The whole training is framed by an introductory and final reflection and exchange session. The structure of the training is displayed in Supplement 3. Based on the still uncertain pandemic situation, all face-to-face meetings are prepared so that they can easily be held digitally if necessary.

Setting, participants, and sample size

The study will be conducted in four nursing homes (a convenience sample) in Cologne, North-Rhine Westphalia, Germany. All facilities have a high proportion of residents with cognitive impairments and dementia. During study participation, usual treatment regimens will be followed, and changes are allowable at any time.

The following eligibility criteria for all participants including PwD, nursing and care staff, nursing home managers as well as head nurses have been defined.

Inclusion criteria

- PwD: Residents of the participating long-term care facilities who have a clinically confirmed dementia diagnosis or have undergone a third-party assessment by nursing or care staff using the Dementia Screening Scale (DSS) and received a score of ≥ 3 points (23). Must be able to be interviewed, provide written informed consent signed by themselves or a legal representative, have good or sufficiently corrected vision and hearing abilities, and good German language skills.
- Nursing and care staff: Nursing professionals who are willing to participate in the CogStim24 training and implement the intervention in their daily work. Nursing participants must be permanent employees who work in day and/or night care. Care staff participants should be professionally trained (e.g., social services employees, such as social pedagogues, social workers, gerontologists, or additional care staff members according to the long-term care insurance act; SGB XI). Must have good or sufficiently corrected vision and hearing abilities and good German language skills.

- Nursing home managers/head nurses: Management of a nursing home in which the study conducted; position as (deputy) head nurse or nursing home manager; good or sufficiently corrected vision and hearing abilities; good German language skills.

Exclusion criteria

- PwD: Residents who lack a dementia diagnosis, lack the ability to provide consent, do not have a legal representative, or have life-threatening illnesses or other diseases that make study participation impossible.

Sample size calculation and dropout management

Four nursing homes are planned for inclusion. These nursing homes have a large number of people with cognitive dysfunctions and PwD. For the pre- and post-intervention study, around 20 nursing and care staff members (*n* = 5 per nursing home), 4–8 nursing home managers and head nurses (*n* = 1–2 per nursing home), and N = 60 PwD (*n* = 15 per nursing home) will be enrolled. These sample sizes ensure sufficient saturation regarding the qualitative study objectives, as the essential characteristics, views, and opinions of participants with a prevalence of 5% will be detected with a probability of 64.2%, 26.5%, and 95.4%, respectively. A sample size of 44 PwD is sufficient to detect changes in quantitative outcomes over time with an effect size of 0.5 (mean differences and standard deviation of differences) and a power of 90% (paired *t*-test, 5% alpha two-sided).

Outcomes and measurement instruments for the quantitative pre-post study and data analysis

A neuropsychological test battery with different sets of instruments for nursing and care staff and PwD will be completed within two weeks before staff training begins (T0), immediately after staff training (T1), and within two weeks after the implementation period (T2). An overview of all instruments used for the effect

analysis and the schedule of enrolment and interventions is displayed in Table 2. The tests will be carried out by the project's research staff, including psychologists and nursing scientists who hold at least a bachelor's degree. Researchers will not be blinded for the time points of assessments.

Table 2. Schedule of enrolment, interventions, and data collection following the SPIRIT guidelines.

	STUDY PERIOD			
	Enrolment	Post-allocation		
TIMEPOINT	**Pre-study**	**Before staff training (T0)**	**After staff training (T1)**	**After the implementation phase (T3)**
ENROLMENT:				
Eligibility screen	X			
Informed consent	X			
INTERVENTION:				
CogStim24		←	—	→
ASSESSMENTS:				
Demographics & clinical data	X			
Global cognition (MMSE & ADAS-Cog)		X	X	X
Quality of Life (QoL-AD)		X	X	X
BPSD (NPI-NH)		X	X	X
Depression (GDS & CSDD)		X	X	X
Work-related Quality of life/ Stress experience (RCB-related Distress Index)		X	X	X

Abbreviations: ADAS-Cog: Alzheimer's Disease Assessment Cognitive Scale; BPSD: Behavioral and psychiatric symptoms in dementia; CSDD: Cornell Scale for Depression in Dementia; GDS: Geriatric Depression Scale; MMSE: Mini-Mental State Examination; NPI-NH: Neuropsychiatric Inventory Nursing Home Version; QoL-AD NH: Quality of Life in Alzheimer's Disease Nursing Home Version; RCB-Related Distress Index: Residents' challenging behavior Related Distress Index.

The primary outcome is global cognition of PwD, which will be operationalized with the Mini-Mental State Examination (MMSE) (24, 25). Secondary outcomes will be assessed using the Alzheimer's Disease Assessment Scale – Cognitive Subscale (ADAS-Cog) (26) to further evaluate cognition; the Quality of Life in Alzheimer's Disease Nursing Home Version (QoL-AD NH) (27, 28) questionnaire for self-assessment and proxy ratings to assess the quality of life of PwD; the Geriatric Depression Scale (GDS) (29) for self-

assessment and the Cornell Scale for Depression in Dementia (CSDD) (30) as a proxy rating to measure depression in PwD; the Neuropsychiatric Inventory Nursing Home Version (NPI-NH) (31, 32) for a BPSD proxy rating; and the Residents' challenging behavior (RCB)-related distress index (33) for self-assessment of work-related quality of life and stress experience among nursing and care staff. Cognitive stimulation is not known to be associated with any adverse events. Therefore, in this feasibility trial, adverse events will not be registered in a structured form.

Data collection will follow the German General Data Protection Regulation. Pseudonymized clinical data collected during the trial will be anonymized and made available upon request immediately following publication for a period of 10 years. Requests for data reuse will be approved by the coordinating investigator. To gain data access, data requestors will need to sign a data access agreement. Data entry will be double-checked, and range-checks for data will be provided. No data monitoring committee will be used for this feasibility trial. All data analyses will be conducted using the statistical program IBM SPSS Statistics (version 28). All data will be checked for normal distribution using the Kolmogorov-Smirnov test. Descriptive analyses of sociodemographic and clinical characteristics at baseline, including frequencies, means, and standard deviations or median and ranges (depending on the data distribution), will be reported. Intervention effects at T0, T1, and T2 data will be evaluated using linear mixed models for repeated measures (MMRM) with fixed effects of group, time, and group*time (ARH1-structured variance-covariance matrix over time). Missing data are implicitly handled by MMRM (assuming missingness-at-random [MAR]). Multiple imputation approaches will be used for sensitivity analysis, potentially considering not-missing-at-random (NMAR) scenarios. Per-protocol analysis for all PwD with complete data for all measurement time points will be performed and could be used for sensitivity analysis.

The study protocol and study results will be disseminated via presentations at scientific conferences and meetings for healthcare professionals and PwD and their relatives. The study results will be published in peer-reviewed journals.

Process evaluation, data collection, and analysis

In the evaluation of complex interventions, a process evaluation is required to enable a better understanding of the intervention implementation (16, 34). The process evaluation procedure was developed according to the models of Grant et al. (18) and Moore et al. (16) (see Figure 1). Several overarching elements will be addressed:

- Recruitment of nursing home facilities, nursing and care staff, and PwD (Reach).
- Context factors (micro, meso, and macro level).
- Implementation of the intervention components (Fidelity, Dose, Adaptation, and Reach).
- Change processes implemented in the facilities based on the intervention and logical model (participants' reactions to and interactions with the intervention, mediators, unexpected courses, and consequences).
- Inhibiting and promoting factors and contextual conditions.

Qualitative and quantitative methods will be used for data collection (Table 3).

The process data analyses will be blinded to the results of the effect study. Quantitative data will be descriptively analyzed. Qualitative data (interviews and focus groups) will be analyzed based on qualitative content analysis (35). Qualitative analysis of the documents and structured interviews will be conducted by one researcher, and 10% of the data will be independently analyzed by a second researcher. All further analyses will be conducted by one researcher. If needed, a peer group will be available to discuss uncertainties. The interim results of the qualitative analyses will be regularly presented to the research team and critically discussed. All results of the process evaluation will be narratively described and summarized.

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Table 3. Process evaluation: An overview of data collection methods.

Parameter	Material	Measurement time points	Process evaluation elements
Recruitment description	Recruitment protocol: documentation of the recruitment process, collection of reasons for participation or withdrawal of the facilities, collection of reasons for participation or withdrawal of staff members.	T0, T1, T2	Reach
Description of the context factors of the nursing homes	Structured questionnaire for nursing home managers and head nurses to assess the existence of concepts or standards for cognitive stimulation of PwD	T0	Context
	▪ *Organizational Readiness for Implementing Change* (ORIC) questionnaire (36) to provide a description of cluster facility culture. ▪ *Person-centered climate* (PCQ-S; staff version) questionnaire (37). ▪ *Assessment of Interprofessional Team Collaboration Scale* (AITCS) questionnaire (38). ▪ *Index for the stress of staff in inpatient geriatric care facilities due to changes in the behavior of residents RCB-related distress index* (33) questionnaire. *Sample: All nursing and care staff and management staff of the participating residential facilities.*	T0, T2	
Implementation of the intervention components	▪ Staff training protocol: number of training sessions offered and received per cluster, including the duration, number, and function of participants, topics, and adaptations (type and reasons). ▪ Staff training protocol: number of reflection sessions offered and received per cluster, including the duration, number, and function of participants, topics, and adaptations (type and reasons). ▪ Staff training protocol: number of additional components offered and received.	T1, T2	Fidelity, Dose, Adaptation, Reach, and inhibiting and promoting factors
	▪ Reflection questionnaire and training evaluation for the staff members: Perceived content of training and reflection. ▪ Reflection sessions after each introduction and implementation of a new program module during staff training.	T1, T2	
Implementation of the intervention components in daily care and reactions of study participants	▪ Focus group interviews with N = 4 staff members: Process adaptations within the context of the intervention (e.g., cooperation between social services and nursing services, and facility staff); Total: N = 4	T2	
	▪ Focus group interviews with N = 4 staff members to assess acceptance and satisfaction with the content of the staff training, reflection units, and the process. n = 1 per institution; Total: N = 4.; Total: N = 4 ▪ Individual interviews with 3 PwD per facility on their representatives to assess their acceptance and satisfaction with the program content, reflection units, and the process. n = 3 per facility; Total: N = 12	T2	Mechanism of impact
Nursing home changes	▪ Qualitative interviews to assess the perceptions of PwD or their representatives regarding cognitive stimulation changes. PwD or their representatives (N = 3 per facility); Total: N = 12	T2	
Target group perspectives	▪ Qualitative interviews to assess the perspectives of the target groups (head nurses, head of social services, staff members actively involved in the intervention, head of nursing, and head of social services as well as N = focus group interview with N = 4 staff members per facility); Total: N = 4 focus group interviews with staff members, N = 8 interviews	T2	Inhibiting and promoting factors and contextual conditions

Abbreviations: PwD: people with dementia.

ETHICS AND DISSEMINATION

Ethics approval was obtained from the ethics committee of the Faculty of Medicine of the University of Cologne, Cologne, Germany (21-1287). All participants will receive oral and written study information. The authors were guided by their local ethics committee to provide easy-to-understand study information l for PwD. All participants will provide written informed consent before taking part in the study. The consent form is available by request to the corresponding author. In cases where participants are unable to provide consent due to advanced cognitive dysfunctions, a legal representative will be involved in the consent process. All study participants will have the opportunity to cease study participation at any time without reason. Any changes to the study protocol will be directly updated in the trial registry entry by the research team.

The participatory research approach during all phases of the study, including the development of the CogStim24 intervention, the training program, and the conduct of the study, provides adequate representation for all relevant target groups. Furthermore, this approach guarantees the development of an intervention that is suitable for the target groups both conducting and receiving the program. Ultimately, the final implementation of the intervention will involve its inclusion in daily routine care to ensure its sustainability.

PwD participating in the study may receive a direct benefit from the cognitive stimulation program in terms of global cognition, quality of life, and other outcomes. Likewise, participating nursing and care staff members may benefit from improved work-related quality of life and stress experience. Employees of the inpatient long-term care facilities are expected to become more aware of cognitive stimulation application, which may benefit other PwD not directly involved in the study.

DISCUSSION

To the best of the authors' knowledge, this is the first study to develop and evaluate a cognitive stimulation program as a 24-hour everyday approach in nursing homes. If the implementation of the CogStim24 staff training and program and study protocol is successful, this study has the potential to serve as a basis for a large multicenter cluster RCT and, ultimately, act as the starting point for delivering cognitive stimulation to a greater number of PwD in nursing homes, including those who are bedridden. There is the potential to adapt the intervention to outpatients and their relatives, as this population has historically been massively undersupplied in terms of cognitive interventions.

There are several possible challenges and limitations associated with conducting the study. The first is that the recruitment of staff and PwD constitutes a challenge in this study and for future implementation due to the time, room, and other resource restrictions present in nursing homes and the health issues of PwD. The SARS-CoV-19 pandemic has exacerbated this challenge. Secondly, there are several methodological limitations, including a lack of non-blinded outcome assessors for the pre-post assessments, a lack of a control group, and a small sample size. However, the primary aim of this study is to demonstrate feasibility.

A particular strength of the project is the interdisciplinarity of the research team, which includes neuropsychologists, gerontologists, nursing scientists, and sports scientists. Furthermore, the participatory approach includes all relevant target groups (nursing home managers, head nurses, nursing and care staff, and PwD) in all steps of the development of the program and study. Only through this interdisciplinarity and mixed-methods approach, in combination with the quantitative and qualitative research methods, process evaluation, and feedback "development loops," can the unique needs of these target groups and the unique setting of nursing homes be adequately considered. This impacts the feasibility of a wider implementation of the intervention in everyday care.

LIST OF ABBREVIATIONS

ADAS-Cog: Alzheimer's Disease Assessment Cognitive Scale; BPSD: Behavioral and psychiatric symptoms in dementia; CSDD: Cornell Scale for Depression in Dementia; DSS: Dementia Screening Scale; GDS: Geriatric Depression Scale; MAR: Missingness-at-random; MMRM: Mixed models for repeated measures; MMSE: Mini-Mental State Examination; NMAR: Not-missing-at-random; NPI-NH: Neuropsychiatric Inventory Nursing Home Version; PwD: People with dementia; QoL-AD NH: Quality of Life in Alzheimer's Disease Nursing Home Version; RCB-Related Distress Index: Residents' challenging behavior Related Distress Index; RCT: Randomized Controlled Trial.

DECLARATIONS

Acknowledgments

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Author Contributions

Conception and design: AKF, ÜSS, JG, MND, MH, SK, and EK; manuscript drafting: AKF, ÜSS, MND, and EK; manuscript revisions: JG, MH, and SK; final manuscript approval: AKF, ÜSS, JG, MND, MH, SK, and EK; agreed to be accountable for all aspects of the work: AKF, ÜSS, JG, MND, MH, SK, and EK.

Funding

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Competing interests

AKF and EK are authors of the cognitive intervention series NEUROvitalis (ProLog, Cologne); however, they receive no corresponding honoraria for this. ÜSS, JG, MND, MH, and SK have no conflicts of interest to declare.

Ethics approval and patient consent

This study was conducted in accordance with the Declaration of Helsinki (as revised in 2013) and was approved by the ethics committee of the Faculty of Medicine of the University of Cologne, Cologne, Germany (21-1287). All participants and the legal representatives of PwD will provide written informed consent before taking part in the study.

Consent for publication

The authors have informed consent from all subjects for the publication of identifying information and images in an online open-access publication (Supplement 2; the subjects are members of our research team).

Availability of data and materials

The datasets used and/or analyzed during the current study will be available from the corresponding author upon reasonable request after study completion.

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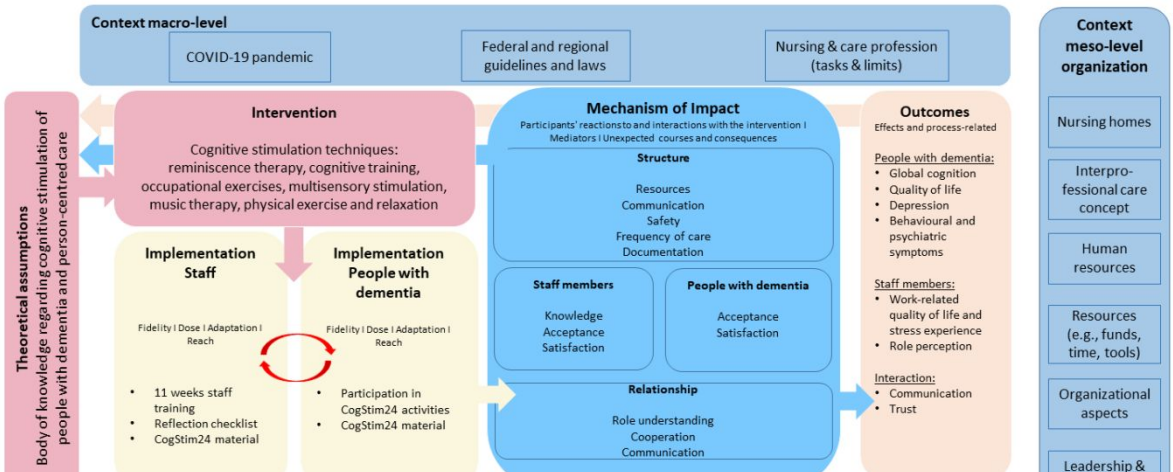


Figure 1. Logic model for CogStim24.

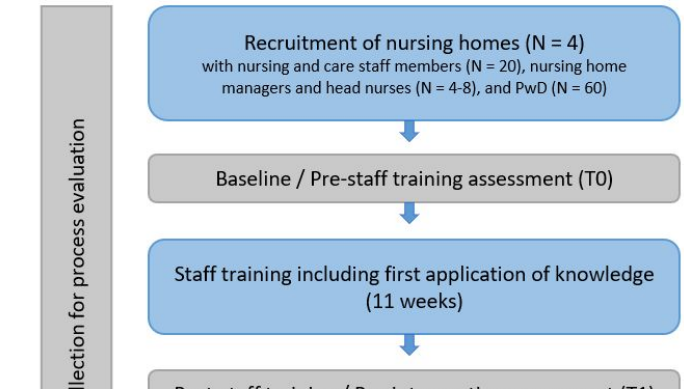


Figure 2. Overview of the study process (PwD: people with dementia).

Supplement 1. SPIRIT 2013 checklist.

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	3
	2b	All items from the World Health Organization Trial Registration Data Set	N/A (all information listed in DRKS registration)
Protocol version	3	Date and version identifier	1
Funding	4	Sources and types of financial, material, and other support	21f.
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1, 21
	5b	Name and contact information for the trial sponsor	1, 21f.
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	21f.
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	N/A
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4ff.
	6b	Explanation for choice of comparators	N/A
Objectives	7	Specific objectives or hypotheses	5f.
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	6f.

Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	12
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	13
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	7ff.
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	N/A (non-pharmacological approach)
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	7ff.
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	N/A
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	14ff.
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	14ff.
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	13f.
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	12f.
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	N/A
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	N/A
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	N/A

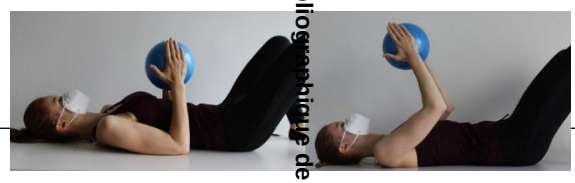
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	N/A
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	14ff.
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	14ff.
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	14ff.
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	14ff.
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	14ff.
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	14ff.
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	14ff.
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	N/A
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	16
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	N/A
Ethics and dissemination			

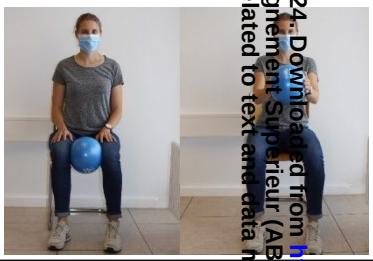
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	19
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	N/A
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	19
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	14ff.
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	22
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	14ff.
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	16
	31b	Authorship eligibility guidelines and any intended use of professional writers	21
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	N/A
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	19
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A

Supplement 2. CogStim24 modules accompanying everyday care with exercises and materials.

Module	Exercises	Materials	Examples
Communication	*General principles:* • Person-centered approach.[1] • Humanistic attitude and behavioral strategies.[2] • Communication rules are based on the validation approach.[3]	-	• Face the person with dementia directly, make eye contact, and draw their attention. • Speak in "I" phrases, stating everything you intend to do. • Use few words and short and clear statements, and patiently repeat what you have said. • Avoid negations. • Ask questions that are more precise (e.g., how? what? when? where?) rather than asking for causes (why?). • Verbalize the affect of the person's feelings. • Speak calmly and slowly and avoid using a high-pitched voice. • Use simple language and jargon, use a moderate speech pace, and use short sentences. • Allow sufficient time for the person to think and respond. • Accompany actions with words that describe what is being done.
Reality orientation	*This module constitutes a general CogStim24 approach:* • Presentation of and reference to personal and/or biographical details, as well as other information such as the time, date, location, weather, season, and holidays, in everyday interactions. • Use of the CogStim24 "Activity clock." • Use of the CogStim24 "Mood barometer." • It is recommended to place items supporting reality orientation in the residents' rooms, such as individual calendars, large clocks, and labels on doors and other items in the room. • It is recommended to place brief information about the resident in the room, such as a fact sheet or labeling pictures with the names of the person/s depicted. Furthermore, residents should be encouraged to use a mirror in daily personal hygiene activities (e.g., combing hair and brushing teeth).	• CogStim24 "Activity clock." • CogStim24 "Mood barometer." • Recommended: calendar, clock, labels on items and pictures in the room, and a personal fact sheet.	-
Reminiscence therapy	*This module involves ten exercises, each with two difficulty levels:* 1. Shopping list. 2. Planning a celebration. 3. "I've never..." 4. Meaningful pictures. 5. Personal memories with knowledge connection.	• A booklet with pictures supporting references to biographical information. • Personal photos.	**2. Planning a celebration** ***Lower difficulty level*** *The task is to plan a celebration. The caregiver asks:* • Have you ever planned a celebration before, for example, a birthday or a wedding? • Whose birthday/wedding/celebration was it?

	6. Remembering everyday activities/addressing one's own needs. 7. Individual biography and photo box. 8. Everyday situation pictures with biographical references. 9. Associating words. 10. "My people" in the life cycle.		• What needed to be prepared? • Another option: Ask the person to plan a party for an upcoming holiday in mind. ***Higher difficulty level*** *The task is to plan a celebration. The caregiver asks:* • Have you ever planned a celebration before, for example, a birthday or wedding? • Whose birthday/wedding/celebration was it? • What preparations did you make to plan the celebration, and what tasks did you complete? • What was the schedule? When did you start preparing the celebration, and what time did the guests arrive? • Do you have any special memories of the day? What did you particularly like about
Cognitive exercises	*This module involves ten exercises, each with two difficulty levels:* 1. Orientation. 2. Language: finding opposites. 3. Language: taboo. 4. Perception: following perception. 5. Perception: visual search. 6. Memory: remembering proverbs and grasping their meaning. 7. Memory: remembering packing a suitcase: What belongs in a suitcase? 8. Executive function: decision-making. 9. Executive function: findings words of specific semantic or phonematic categories. 10. Executive functions: identifying connections.	• Pocket booklets with pictures and verbal material.	**5. Perception: visual search** ***Lower difficulty level*** *The caregiver asks:* • Look around the room here. What things are useful to you? • Which things are bigger than a book? • Which things are smaller than a book? • What things can you carry with your hands? • Which things feel smooth/soft/firm/rough? ***Higher difficulty level*** *The caregiver asks:* • Look around the room. What things do you use every day? • What things are bigger than this pillow (point to the pillow)? • What things are smaller than this pillow? • What things are red/blue/green/etc.? • Which things feel soft to the touch?
Occupational exercises	*This module involves ten exercises, each with two difficulty levels:* 1. Relax hand muscles. 2. Independence: self-care 3. Independence: room care (own room, common room) 4. Calendar management. 5. Encourage contact: write postcards/letters. 6. Creativity: prayer 7. Creativity: diary management 8. Creativity: creative leisure 9. Creativity: geometric shapes 10. Creativity: painting (creative vs. supplemented by	• Balls. • Everyday objects. • Postcards. • Writing materials. • Diary. • Creativity materials.	**2. Independence: self-care** ***Lower difficulty level*** Care: Give the resident a wash cloth to clean areas, such as their arms, by themself. Alternatively, put some body lotion on their arms and have the resident rub the cream in. Eating: Pick up food with a fork or spoon and put it in the resident's hand so that they can bring the food to their mouth independently. ***Higher difficulty level*** Care: Have the resident brush their teeth. Alternatively, have the resident put on an item of clothing (e.g., pants or a top) themselves. Let the resident choose their outfit. Ask for a suitable color combination (in relation to the season). If needed, put a few matching outfit combinations

	tasks).		together on a suitable surface. Eating: Allow the resident to eat independently as much as possible. Offer assistance if needed. After the meal, have the resident put their tray in the trolley.
Multisensory stimulation	*This module involves ten exercises, each with two difficulty levels:* 1. Recognizing everyday objects. 2. Touching surfaces. 3. Touch exercise. 4. Tea smell exercise. 5. Scent exercise. 6. Auditory exercise animals. 7. Relaxation exercise. 8. Visual exercise. 9. Mindfulness practice I. 10. Mindfulness practice II.	• Everyday items. • Tote bag and items for exercise recognizing items via touch. • Olfactory material (e.g., tea bags, spices, etc.). • Music player and audio recordings (e.g., of animal sounds or from the internet).	**1. Recognizing everyday objects** ***Lower difficulty level*** Everyday objects that are already in the room are to be felt. For example, pens, cutlery, glasses, paper, and clothes hangers. The residents' task is to touch the objects and express their thoughts about them. Caregivers can ask questions like "do you know this object?", "do you know what it is?" and "how does it feel?" ***Higher difficulty level*** Everyday objects that are already in the room are to be felt. For example, pens, cutlery, glasses, paper, and clothes hangers. The residents' task is to feel and name the objects. Following this, a biographical reference can be made. Caregivers can ask questions like "what do you associate with this object?" and "did you use this object frequently in the past?"
Music therapy	*This module involves ten exercises, each with two difficulty levels:* 1. Active music making: singing folk songs. 2. Active music making: making music without instruments. 3. Active music making: making music with instruments. 4. Rhythm exercise: clapping exercise. 5. Rhythm exercise: sway exercise. 6. Active and passive listening: music memory training. 7. Active and passive listening: listening to music and reminiscing. 8. Active and passive listening: auditory memory exercise. 9. Active and passive listening: recognizing instruments. 10. Active and passive listening: passive music exercise.	• Music player. • Printed lyrics. • Everyday items. • Easy-to-use musical instruments (e.g., tone woods and rattles)	**7. Active and passive listening: listening to music and reminiscing** ***Higher difficulty level*** Well-known music/songs from different decades are played, and then thoughts, memories, and emotions about the music are shared. The caregiver will say, "I will now play a few songs. Afterward, I will ask you some questions about these songs." These questions will include "did you know this song?", "when was the last time you heard it?" and "do you associate certain memories or feelings with this music?" ***Lower difficulty level*** Well-known music/songs from different decades are played, and then the participants are asked whether they know the music. The caregiver will say, "I will now play a few songs. Afterward, I will ask you if you know these songs and if you like this music."
Physical activity	*This module involves ten exercises, each with two difficulty levels:* 1. Pressing a Pilates ball. 2. Strengthening with the loop band. 3. Holding up a balloon. 4. Balancing a rice bag. 5. Figure driving with a hedgehog ball. 6. Support and press. 7. Hedgehog ball massage. 8. Stork walk. 9. Mobilization with a Pilates ball.	• Balls. • Pilates balls. • Thera-Band. • Balloons. • Small bean bag. • Spiky massage ball. • Weights.	**10. Pressing a Pilates ball** ***Lower difficulty level*** Starting in the back position, the Pilates ball is taken between the knees and slowly squeezed. After approximately one second, the ball is released without letting it fall. The whole exercise is repeated 15 times. The exercise is then repeated with the ball between the hands. 

	10. Dribbling a Pilates ball.		***Higher difficulty level*** Starting in the seated position, the Pilates ball is taken between the knees and slowly squeezed. After approximately one second, the ball is released without letting it fall. The whole exercise is repeated 15 times. The exercise is then repeated with the ball between the hands and arms extended. 
Relaxation	*This module involves ten exercises, each with two difficulty levels:* 1. Journey through the upper body. 2. Journey through the lower body. 3. Journey through the trunk and head. 4. Pelvic clock. 5. Breath control. 6. Feeling heaviness. 7. Feeling warmth. 8. Progressive arm muscle relaxation. 9. Progressive leg muscle relaxation. 10. Straightening and breathing.	• Music player and relaxation music (e.g., from the internet). • Small bean bag, • Cherry pit pillow.	**8. Progressive arm muscle relaxation** ***Lower difficulty level*** Starting in the back position with the arms resting beside the body, the writing hand is clenched into a fist, and the tension is held for 5–10 seconds. The fist is opened, and the arms are rested for 30 seconds. The difference between tightening and relaxing is noted. The exercise is then repeated with the other hand. ***Higher difficulty level*** Starting in the seated position with hands resting on the thighs, the writing hand is clenched into a fist, and the tension is held for 5–10 seconds. The fist is opened, and the arms are rested for 30 seconds. The difference between tightening and relaxing is noted. The exercise is then repeated with the other hand and other muscle groups.

Note. All pictures belong to the Department of Medical Psychology | Neuropsychology and Gender Studies, Faculty of Medicine and University Hospital Cologne, University of Cologne. The authors gained informed consent from all subjects to publish identifying information/images in an online open-access publication.

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Supplement 3. Structure and content of the CogStim24 training program for the nursing and care staff.

Session	Topic	Duration	Type of session

number			
0	Introductory session to introduce cognitive stimulation in PwD aims and content of the CogStim24 intervention, and structure of the training program,	90 min	Online
	1-week break & audio-recorded PowerPoint presentation: Topic 1a		
1a	Communication with PwD,	180 min	Online, interactive exercises
	1-week implementation phase: Topic 1a		
1b	Reflection.	90 min	Online
	1-week implementation phase: Topic 1a. Audio-recorded PowerPoint presentation: Topic 2a		
2a	Reality orientation and reminiscence therapy on "my life."	180 min	Face-to-face, interactive exercises
	1-week implementation phase: Topic 2a		
2b	Reflection.	90 min	Online
	1-week implementation phase: Topic 2a. Audio-recorded PowerPoint presentation: Topic 3a		
3a	Cognitive exercises ("brain training") and occupational exercises,	180 min	Face-to-face, interactive exercises
	1-week implementation phase: Topic 3a		
3b	Reflection.	90 min	Online
	1-week implementation phase: Topic 3a. Audio-recorded PowerPoint presentation: Topic 4a		
4a	Multisensory stimulation and music therapy.	180 min	Face-to-face, interactive exercises
	1-week implementation phase: Topic 4a		
4b	Reflection.	90 min	Online
	1-week implementation phase: Topic 4a. Audio-recorded PowerPoint presentation: Topic 5a		
5a	Physical activity & relaxation.	180 min	Face-to-face, interactive exercises
	1-week implementation phase: Topic 5a		
5b	Reflection. & final exchange session.	90 min	Online
			11 weeks in total

Abbreviations: PwD: people with dementia.

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Title:

Cognitive stimulation for people with dementia in nursing homes: A protocol for a feasibility study examining a new 24/7 approach (CogStim24)

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ABSTRACT

Introduction: Based on the available evidence, cognitive stimulation is recommended as an intervention for people with mild to moderate dementia (PwD). Currently, cognitive stimulation is regularly offered as a group program in care facilities. However, some residents, such as those who are bedridden, cannot participate. Furthermore, group programs were not feasible during the pandemic. A concept that accompanies everyday life and enables cognitive stimulation in everyday communication (i.e., "24/7") has been missing. Therefore, this feasibility study aims to (i) assess the feasibility of a new continuous 24/7 cognitive stimulation program (CogStim24) based on a process evaluation and (ii) examine the possible effects of CogStim24 on the primary outcome of global cognition in PwD and further PwD- and staff-related outcomes.

Methods and Analysis: The complex CogStim24 program is developed to be conducted as an everyday intervention during routine care including cognitively stimulating techniques, such as reminiscence therapy, multisensory stimulation, and physical activity. In this unblinded single-arm study with pre- and post-assessments, four nursing homes with a total of N=20 nursing and care staff will participate in an 11-week CogStim24 training program. The intervention will be conducted to N=60 PwD. Neuropsychological assessments will be conducted pre- and post-staff training, as well as after a 6-week implementation phase. A process evaluation will be performed.

Ethics and dissemination: Although cognitive stimulation is known to be effective for enhancing global cognition and quality of life in PwD, it is currently undersupplied to PwD. Therefore, CogStim24 has the potential to reach many more PwD. This study has the potential to serve as a basis for a large multicenter cluster randomized controlled trial. An interdisciplinarity team and mixed-methods approach will help generate information on the practicality and mechanisms of impact of CogStim24. This is important for the further development of the intervention and for facilitating its implementation.

Trial registration: German Clinical Trials Register (ID: DRKS00024381).

Strengths and limitations of this study:

- CogStim24 has been developed as a complex cognitive stimulation approach for the everyday use during routine care of people with dementia (PwD); it includes a 11-week training program for nursing and care staff.
- The development was based on a systematic review of cognitive stimulation techniques for PwD and a participatory approach including a survey on the current practice of cognitive stimulation in German nursing homes, and focus group discussions with nursing and care staff on their experiences, barriers, and needs regarding cognitive stimulation intervention implementation.
- The pilot study aims to evaluate the implementation fidelity, to assess the feasibility of the study design, and to examine possible effects of CogStim 24 on the primary outcome global cognition in PwD and further PwD- and staff-related outcomes.
- The trial is limited to a unblinded single-arm study with pre- and post-assessments; large multicenter cluster randomized controlled trial will have to follow.

Keywords:

Dementia, Alzheimer's disease, cognitive stimulation, non-pharmacological therapy, nursing home, mixed-methods, study protocol, process evaluation, logic model, complex intervention

INTRODUCTION

Over 55 million people currently live with dementia globally; it is estimated this number will reach 78 million by 2030. With dementia being the 7th leading cause of global mortality and its high cost of treatment and care, it constitutes a major challenge not only for those affected but for society as a whole (1). Cognitive dysfunctions are the primary symptoms of dementia; however, people with dementia (PwD) also suffer from psychiatric and behavioral symptoms, leading to high caregiver burden (1). PwD typically require care throughout the course of the disease. Although many PwD receive long-term formal and informal care at home, there is a high risk of institutionalization in later disease stages (2).

Symptomatic pharmacological treatment includes acetylcholinesterase inhibitors and memantine to stabilize cognition for a short time; however, the efficacy is limited, and disease-modifying therapy is not yet available (3). Non-pharmacological treatment has attracted increased research and clinical practice interest. These treatments include cognitive interventions, physical exercise, and occupational and music therapy (4). Cognitive interventions utilize different approaches. One approach is cognitive training, which involves standardized paper-and-pencil or computerized tasks provided in individual or group sessions targeting specific cognitive functions. Another is cognitive stimulation, which is the global activation of cognitive and social skills in a small group setting via stimulating exercises, games, and conversation rounds, often in combination with reality orientation and reminiscence therapy (5, 6).

The current literature gives a relatively homogeneous picture regarding the effectiveness of cognitive stimulation in PwD, which is reflected in the recommendations of the German S3 guidelines to diagnose and treat dementia (7) (recommendation grade B: “should be offered”). Randomized controlled trials (RCTs) and systematic reviews and meta-analyses have demonstrated a positive effect of cognitive stimulation on various cognitive and non-cognitive parameters, including significant effects on global cognition (5, 6, 8), quality of life (6, 8), psychological and behavioral symptoms (6, 8), and communication skills and social interaction (6). A Cochrane review concluded that the effects shown are equivalent to or even exceed those of pharmacological therapy (6).

However, investigations of the effectiveness of these approaches have mainly been carried out in defined time periods, such as 6 or 8 weeks (6). For example, programs such as cognitive stimulation therapy (9), the multicomponent program MAKS therapy (10), StaKogS (11), and NEUROvitalis Sinnreich (12) are designed for a period of several weeks or months and for settings in which PwD and exercise leaders come together. These programs have mostly been conducted in small group settings, an aspect which itself may contribute to the effectiveness, as social activity is cognitively stimulating (13). However, it should be noted that these approaches can be seen as “add-ons” to the individual care of PwD. As these intervention programs are conceptualized with a low frequency, intervention effects may lack sustainability. Also, many PwD cannot take part in such programs due to being bedridden or because the nursing home lacks resources to provide cognitive stimulation (e.g., lack of staff to conduct the interventions in small group settings and/or take inpatients to the group or a lack of rooms). In outpatient settings, intervention groups may not be available at all (e.g., in rural areas). Additionally, during the SARS-CoV-19 pandemic, group activities, including cognitive stimulation and “memory training groups,” were paused in most settings (14).

On the basis of the considerations highlighted above, a 24/7 approach in which cognitive stimulation is used as an intervention accompanying daily routine care may enable sustainable stimulation for many PwD within existing care structures. To date, there is no concept of cognitive stimulation as a 24/7 approach to everyday contact between PwD and caregivers. This is supported by a recent scoping review on manual-based complex interventions in outpatient and inpatient care of PwD (15), where no study with a 24-hour cognitive stimulation concept was identified. The 24/7 cognitive stimulation program (CogStim24) project is the first step to filling this important gap in research and clinical practice.

Therefore, the present study aims to pilot the newly developed CogStim24 intervention as a 24/7 fixed component in everyday inpatient care for PwD. CogStim24 seeks to enable nurses and caregivers to provide cognitive stimulation at any time, such as during everyday personal hygiene activities or during meals, by anchoring the stimulation elements through conversation impulses, low-threshold available stimulating materials, and pocket exercises.

This feasibility study has several aims:

1. To evaluate the implementation fidelity, including the feasibility of the educational program for conducting CogStim24 and evaluating promoting and inhibiting factors of the intervention's implementation (i.e., process evaluation).
2. To assess the feasibility of the study design of CogStim24 in nursing homes as a basis for future cluster RCTs.
3. To examine the possible effects of CogStim24 (I = Intervention) on the primary outcome of global cognition (O = Outcome) in PwD (P = Population) and the secondary outcomes of quality of life, depression, and behavioral and psychiatric symptoms in dementia (BPSD), as well as the work-related quality of life and stress experiences of nursing and care staff using a pre-post design. As this is a non-controlled study, no comparators can be defined (C = Comparison).

This study is based on a logic model for the CogStim24 intervention (Figure 1). The logic model was created and discussed, with several iterations developed by the entire research team, using the current literature and authors' expertise. This process enabled the relevant theoretical assumptions, actors, and procedural outcomes for the evaluation to be considered. The logic model includes theoretical assumptions, the intervention, implementation, mechanism of impact, outcomes, and the micro-to-macro context (16, 17).

METHODS AND ANALYSIS

This report follows the SPIRIT guidelines for the minimum content of a clinical trial protocol (18). See Supplement 1 for the SPIRIT checklist.

Design/Methodology

Study design

This study was conceptualized as an uncontrolled, non-masked, single-arm study involving pre- and post-assessments using a mixed-methods approach. A process evaluation will be performed in conjunction with the study (17, 19). Within this study, several project steps will be carried out (Figure 2). These include training nursing and care staff on how to conduct CogStim24, piloting the CogStim24 intervention in nursing homes, using quantitative pre- and post-intervention assessments and qualitative interviews with PwD, nursing and care staff, nursing home managers, and head nurses, and evaluating the process of the overall implementation phase (training plus intervention implementation phase).

As a first step, nursing and care staff will receive an 11-week training on how to conduct the CogStim24 intervention, including e-learning modules for self-administration and group training sessions delivered in person and digitally. During the training program, the staff will implement CogStim24 stimulation techniques step by step in their everyday work routine so that they are able to implement the full program at the end of the training period. To investigate whether the protocol for the quantitative pre- and post-intervention assessments is feasible and to gain evidence for effects as a basis for a future cluster RCT, neuro-psychological tests and questionnaires will be administered to the participants (PwD and nursing and care staff) two weeks before (T0), immediately after the 11-week training program (T1), and two weeks after the 6-week intervention period (T2).

The process evaluation will be conducted for the full study duration, including the 11-week staff training and 6-week intervention period. The degree of implementation, mechanisms of change, and acceptance of the complex intervention in the participating nursing home facilities will be investigated. In addition, factors conducive to and inhibiting implementation will be explored. First patient-in was in May 2022.

CogStim24 intervention

CogStim24 was developed as a cognitive stimulation program that can be conducted in everyday life for people with cognitive impairments or PwD, provided by staff in nursing homes or in day care facilities and by relatives at home. The challenge to implement cognitively stimulating activities into everyday care which

is subject to limited resources in terms of times and personnel was considered in all developmental steps of the CogStim24 program.

The development of the CogStim24 program was based on several factors:

- The authors' expertise in developing cognitive intervention programs (12, 20) and training courses for such interventions, in conducting clinical studies that examine the effects and mechanisms of cognitive interventions in various target groups and settings, including PwD (8, 21) and nursing homes, as well as evaluating challenges and barriers that may be faced in nursing homes due to limitations in personnel and logistical resources. This expertise was brought together in several expert meetings and guided the selection of cognitive stimulation techniques and exercises as well as ideas for the staff training.
- A systematic literature review of the characteristics of cognitive stimulation interventions for PwD (see review registration under https://www.crd.york.ac.uk/prospero/display_record.php?ID=CRD42021227904) demonstrating the lack of a 24/7 approach. The included studies mostly used small group settings for the conduct of cognitive stimulation activities. Further, the literature showed a broad range of cognitive stimulation techniques included in the evaluated programs which also served as a basis for the development of our CogStim24 concept.
- A participatory approach during the entire development process and pilot study conduction, which included (i) a survey conducted in 64 nursing homes in North-Rhine Westphalia, Germany, on the current practice of cognitive stimulation (its challenges and barriers and current opinions and needs) and (ii) focus group discussions with nursing and care staff of inpatient long-term care facilities on their experiences, barriers, and needs regarding cognitive stimulation intervention implementation, as well as their opinions regarding the idea, possible structure, and content of a CogStim24 approach that included staff training (22).

The resulting concept of the CogStim24 intervention includes exercises and activities that have the potential to be conducted during everyday care with PwD including also those people that are bedridden. CogStim24 is expected to stabilize global cognition and improve the quality of life and mood of PwD. It is also expected to promote communication between PwD and nursing and care staff and improve the work-related quality of life and stress experiences of the staff.

The program consists of a large body of exercises that can be categorized under several cognitive stimulation techniques: reminiscence therapy, cognitive training, occupational exercises, multisensory stimulation, music therapy, physical exercise, and relaxation. In addition, patient-centered communication and reality orientation techniques are basic concepts of the program and are considered integral parts of all exercises. Each block of stimulation techniques contains ten exercises that are easy to conduct in daily routine care. Each exercise has two difficulty levels for PwD with cognitive impairments of different severity. The nursing and care staff can choose the difficulty level based on their own evaluation and experience with the PwD, or if he*she is uncertain, exercises with a lower difficulty level can be used, and if this works fine, the higher difficulty level can be chosen. An overview and examples for all exercise types are displayed in Supplement 2. An “activity clock” was developed. This can be displayed in each resident’s room and illustrates all the cognitive stimulation areas mentioned above. It can be used to make choices regarding the stimulation area of focus. The use of this clock promotes reality orientation and contributes to cognitive stimulation by focusing on the decision-making process.

The CogStim24 intervention includes a detailed instruction manual for all exercises as well as material to be placed in each resident’s room, including booklets with images and verbal exercises (e.g., for completing proverbs) and materials for physical exercises (e.g., a ball and a resistance band). Nurses and care staff are encouraged to collect autobiographical information and corresponding material, such as photos or belongings with personal value, for each resident and place it into the room for use within the CogStim24 program. All exercises can be conducted by nursing and care staff after participating in the staff training. No further training in, for example, physical exercise or music therapy is mandatory.

An overview of the program following the TIDieR guidelines (23) is displayed in Table 1.

Table 1. CogStim24 program overview based on the TIDieR guidelines.

What? ***Procedures, tailoring, and modifications***	**Why?** ***Rationale and theory***	**What?** ***Materials***	**How? Where?** ***Modes of delivery***	**Who?** ***Intervention provider***	**When & how much?**
Procedures Staff training Nursing and care staff receive an 11-week training program (max. 3h/week; cf. Supplement 3). CogStim24 Cognitive stimulation exercises that are easy to conduct in daily routine care based on the following techniques: • Reality orientation • Reminiscence therapy • Cognitive training • Occupational exercises • Multisensory stimulation • Music therapy • Physical intervention • Relaxation All interactions are based on the principles of patient-centered communication. *Tailoring* Nursing and care staff together with the PwD can choose from the ten exercises for each technique. Difficulty levels are chosen by staff, depending on residents' abilities. *Modifications* Based on the participatory approach, adjustments in intervention and implementation are possible.	Cognitive stimulation has been shown to have positive effects on global cognition and quality of life. However, many PwD living in nursing homes cannot participate in group-based cognitive stimulation programs. *Tailoring:* Cognitive interventions are most effective when under- and overextensions is avoided. That is why two difficulty levels are part of the CogStim24 program.	• Manual for nursing and care staff. • An "activity clock" indicates all possible activity domains. • Material in each resident's room (e.g., booklets with images and resistance bands) • If possible, autobiographic information and material relating to the resident will be placed in their rooms (e.g., a short CV, pictures, and other meaningful items). *Tailoring:* All CogStim24 exercises are available in two difficulty levels.	The intervention will be conducted during everyday care in nursing homes, both in resident rooms and other facility areas. *Tailoring:* The nursing and care staff can choose the difficulty level based on their own evaluation and experience with the PwD, or if he*she is uncertain, exercises with a lower difficulty level can be used, and if this works fine, the higher difficulty level can be chosen.	Nursing and care staff will be educated on the intervention during the 11-week staff training program. *Tailoring:* Choosing the difficulty level for the CogStim24 exercises will be performed by nursing and care staff.	The intervention is intended conducted in any interaction between PwD and nursing and care staff, if possible. *Tailoring:* CogStim24 is not conducted or paused if PwD seem too burdened or too exhausted.

Abbreviations: PwD*:* People with dementia.

Training program for nursing and care staff

Nursing home managers have to agree to the study participation, and have to make their nursing and care staff available for taking part in the staff training. Each participating nursing and care staff team member of

the nursing homes involved in the study will receive an 11-week training program, which will be facilitated by members of the research team, including psychologists, gerontologists, and nursing scientists who hold a minimum of a bachelor's degree. The staff training was set up in a way that the main challenge, i.e., the implementation into everyday care, can be overcome in a best possible way. The training consists of several components: e-learning modules for self-administration, group face-to-face sessions, and digital meetings. Overall, the training includes 12 hours of face-to-face and 12 hours of digital meetings, as well as five 30-minute self-administered sessions supported by e-learning modules. As CogStim24 has too many modules to be implemented at once, the topics and techniques of the intervention are introduced step by step so that the staff are able to implement the full spectrum of the intervention components when the training course has been completed. Each module is introduced by an e-learning module in the form of an audio-backed PowerPoint presentation and a workbook with information and exercises to deepen the understanding of topic contents, both of which are sent to the participants one week in advance of the following session. In the group face-to-face sessions, the topic and cognitive stimulation exercises are extensively explained and discussed, and exercises are practiced interactively. This is followed by a one-week implementation phase, where the staff can trial the module in everyday care. In the middle of the implementation phase, an online "reflection" session is held, in which experiences with the exercises and materials and the successes, failures, and barriers in the implementation are discussed. Participants will be given a "CogStim24 diary" as an aid, which will contain a checklist of the relevant aspects for the purpose of self-reflection. This checklist includes several aspects related to participants' experiences during the implementation phase:

- The CogStim24 exercises and materials were used and why (free text).
- The experiences had in implementing the exercises (free text).
- The barriers faced when conducting the exercises (free text).
- An evaluation of the setting conditions as a basis for conducting the exercises (free text).

- How the implementation was for the staff in terms of difficulty level, time expenditure, satisfaction with the exercises, and motivation. Responses are rated on a 6-point Likert scale ranging from “very low” to “very high.”
- How the exercise was for individuals with cognitive impairment (free text) in terms of difficulty level, time expenditure, satisfaction with the exercises, and motivation. Responses are rated on a 6-point Likert scale, ranging from “very low” to “very high.”

The whole training is framed by an introductory and final reflection and exchange session. The structure of the training is displayed in Supplement 3. Based on the still uncertain pandemic situation, all face-to-face meetings are prepared so that they can easily be held digitally if necessary.

Setting, participants, and sample size

The study will be conducted in four nursing homes (a convenience sample) in Cologne, North-Rhine Westphalia, Germany. All facilities have a high proportion of residents with cognitive impairments and dementia. During study participation, usual treatment regimens will be followed, and changes are allowable at any time.

The following eligibility criteria for all participants including PwD, nursing and care staff, nursing home managers as well as head nurses have been defined.

Inclusion criteria

- PwD: To reflect nursing home reality, residents do not need to have a clinical dementia diagnosis. Thus, we include residents of the participating long-term care facilities who have a clinically confirmed dementia diagnosis, but also residents who have undergone a third-party assessment by nursing or care staff using the Dementia Screening Scale (DSS) and received a score of ≥ 3 points (24). Must be able to be interviewed, provide written informed consent signed by themselves or a legal

representative, have good or sufficiently corrected vision and hearing abilities, and good German language skills.

- Nursing and care staff: Nursing professionals who are willing to participate in the CogStim24 training and implement the intervention in their daily work. Nursing participants must be permanent employees who work in day and/or night care. Care staff participants should be professionally trained (e.g., social services employees, such as social pedagogues, social workers, gerontologists, or additional care staff members according to the long-term care insurance act; SGB XI). Must have good or sufficiently corrected vision and hearing abilities and good German language skills.
- Nursing home managers/head nurses: Management of a nursing home in which the study conducted; position as (deputy) head nurse or nursing home manager; good or sufficiently corrected vision and hearing abilities; good German language skills.

Exclusion criteria

- PwD: Residents who lack a dementia diagnosis, lack the ability to provide consent, do not have a legal representative, or have life-threatening illnesses or other diseases that make study participation impossible.

Sample size calculation and dropout management

Four nursing homes are planned for inclusion. All nursing homes are part of the researchers' network, and already participated in past studies. These nursing homes have a large number of people with cognitive dysfunctions and PwD. For the pre- and post-intervention study, around 20 nursing and care staff members (n = 5 per nursing home), 4–8 nursing home managers and head nurses (n = 1–2 per nursing home), and N = 60 PwD (n = 15 per nursing home) will be enrolled. These sample sizes ensure sufficient saturation regarding the qualitative study objectives, as the essential characteristics, views, and opinions of participants with a prevalence of 5% will be detected with a probability of 64.2%, 26.5%, and 95.4%,

respectively. A sample size of 44 PwD is sufficient to detect changes in quantitative outcomes over time with an effect size of 0.5 (mean differences and standard deviation of differences) and a power of 90% (paired *t*-test, 5% alpha two-sided).

Outcomes and measurement instruments for the quantitative pre-post study and data analysis

A neuropsychological test battery with different sets of instruments for nursing and care staff and PwD will be completed within two weeks before staff training begins (T0), immediately after staff training (T1), and within two weeks after the implementation period (T2). An overview of all instruments used for the effect analysis and the schedule of enrolment and interventions is displayed in Table 2. The tests will be carried out by the project's research staff, including psychologists and nursing scientists who hold at least a bachelor's degree. Researchers will not be blinded for the time points of assessments.

Table 2. Schedule of enrolment, interventions, and data collection following the SPIRIT guidelines.

	STUDY PERIOD			
	Enrolment	Post-allocation		
TIMEPOINT	**Pre-study**	**Before staff training (T0)**	**After staff training (T1)**	**After the implementation phase (T3)**
ENROLMENT:				
Eligibility screen	X			
Informed consent	X			
INTERVENTION:				
CogStim24		◆———	———	———◆
ASSESSMENTS:				
Demographics & clinical data	X			
Global cognition (MMSE & ADAS-Cog)		X	X	X
Quality of Life (QoL-AD)		X	X	X
BPSD (NPI-NH)		X	X	X
Depression (GDS & CSDD)		X	X	X
Work-related Quality of life/ Stress experience (RCB-related Distress Index)		X	X	X

Abbreviations: ADAS-Cog: Alzheimer's Disease Assessment Cognitive Scale; BPSD: Behavioral and psychiatric symptoms in dementia; CSDD: Cornell Scale for Depression in Dementia; GDS: Geriatric Depression Scale; MMSE: Mini-Mental State Examination; NPI-NH: Neuropsychiatric Inventory Nursing Home Version; QoL-AD NH: Quality of Life in Alzheimer's Disease Nursing Home Version; RCB-Related Distress Index: Residents' challenging behavior Related Distress Index.

We used established neuropsychological test instruments that have been widely used in dementia research including cognitive stimulation trials (6; 25). This refers both to the cognitive as well as to the non-cognitive outcomes. The primary outcome is global cognition of PwD, which will be operationalized with the Mini-Mental State Examination (MMSE) (26, 27). Secondary outcomes will be assessed using the Alzheimer's Disease Assessment Scale – Cognitive Subscale (ADAS-Cog) (28) to further evaluate cognition; the Quality of

Life in Alzheimer's Disease Nursing Home Version (QoL-AD NH) (29, 30) questionnaire for self-assessment and proxy ratings to assess the quality of life of PwD; the Geriatric Depression Scale (GDS) (31) for self-assessment and the Cornell Scale for Depression in Dementia (CSDD) (32) as a proxy rating to measure depression in PwD; the Neuropsychiatric Inventory Nursing Home Version (NPI-NH) (33, 34) for a BPSD proxy rating; and the Residents' challenging behavior (RCB)-related distress index (35) for self-assessment of work-related quality of life and stress experience among nursing and care staff. Cognitive stimulation is not known to be associated with any adverse events. Therefore, in this feasibility trial, adverse events will not be registered in a structured form.

Data collection will follow the German General Data Protection Regulation. Pseudonymized clinical data collected during the trial will be anonymized and made available upon request immediately following publication for a period of 10 years. Requests for data reuse will be approved by the coordinating investigator. To gain data access, data requestors will need to sign a data access agreement. Data entry will be double-checked, and range-checks for data will be provided. No data monitoring committee will be used for this feasibility trial. All data analyses will be conducted using the statistical program IBM SPSS Statistics (version 28). All data will be checked for normal distribution using the Kolmogorov-Smirnov test. Descriptive analyses of sociodemographic and clinical characteristics at baseline, including frequencies, means, and standard deviations or median and ranges (depending on the data distribution), will be reported. Intervention effects at T0, T1, and T2 data will be evaluated using linear mixed models for repeated measures (MMRM) with fixed effects of group, time, and group*time (ARH1-structured variance-covariance matrix over time). Missing data are implicitly handled by MMRM (assuming missingness-at-random [MAR]). Multiple imputation approaches will be used for sensitivity analysis, potentially considering not-missing-at-random (NMAR) scenarios. Per-protocol analysis for all PwD with complete data for all measurement time points will be performed and could be used for sensitivity analysis.

The study protocol and study results will be disseminated via presentations at scientific conferences and meetings for healthcare professionals and PwD and their relatives. The study results will be published in peer-reviewed journals.

Process evaluation, data collection, and analysis

In the evaluation of complex interventions, a process evaluation is required to enable a better understanding of the intervention implementation (17, 36). The process evaluation procedure was developed according to the models of Grant et al. (19) and Moore et al. (17) (see Figure 1). Several overarching elements will be addressed:

- Recruitment of nursing home facilities, nursing and care staff, and PwD (Reach).
- Context factors (micro, meso, and macro level).
- Implementation of the intervention components (Fidelity, Dose, Adaptation, and Reach).
- Change processes implemented in the facilities based on the intervention and logical model (participants' reactions to and interactions with the intervention, mediators, unexpected courses, and consequences).
- Inhibiting and promoting factors and contextual conditions.

Qualitative and quantitative methods will be used for data collection (Table 3).

The process data analyses will be blinded to the results of the effect study. Quantitative data will be descriptively analyzed. Qualitative data (interviews and focus groups) will be analyzed based on qualitative content analysis (37). Qualitative analysis of the documents and structured interviews will be conducted by one researcher, and 10% of the data will be independently analyzed by a second researcher. All further analyses will be conducted by one researcher. If needed, a peer group will be available to discuss uncertainties. The interim results of the qualitative analyses will be regularly presented to the research team and critically discussed. All results of the process evaluation will be narratively described and summarized.

Table 3. Process evaluation: An overview of data collection methods.

Parameter	Material	Measurement time points	Process evaluation elements
Recruitment description	Recruitment protocol: documentation of the recruitment process, collection of reasons for participation or withdrawal of the facilities, collection of reasons for participation or withdrawal of staff members.	T0, T1, T2	Reach
Description of the context factors of the nursing homes	Structured questionnaire for nursing home managers and head nurses to assess the existence of concepts or standards for cognitive stimulation of PwD	T0	Context
	▪ *Organizational Readiness for Implementing Change* (ORIC) questionnaire (38) to provide a description of cluster facility culture. ▪ *Person-centered climate* (PCQ-S; staff version) questionnaire (39). ▪ *Assessment of Interprofessional Team Collaboration Scale* (AITCS) questionnaire (40). ▪ *Index for the stress of staff in inpatient geriatric care facilities due to changes in the behavior of residents RCB-related distress index* (35) questionnaire. *Sample: All nursing and care staff and management staff of the participating residential facilities.*	T0, T2	
Implementation of the intervention components	▪ Staff training protocol: number of training sessions offered and received per cluster, including the duration, number, and function of participants, topics, and adaptations (type and reasons). ▪ Staff training protocol: number of reflection sessions offered and received per cluster, including the duration, number, and function of participants, topics, and adaptations (type and reasons). ▪ Staff training protocol: number of additional components offered and received.	T1, T2	Fidelity, Dose, Adaptation, Reach, and inhibiting and promoting factors
	▪ Reflection questionnaire and training evaluation for the staff members: Perceived content of training and reflection. ▪ Reflection sessions after each introduction and implementation of a new program module during staff training.	T1, T2	
Implementation of the intervention components in daily care and reactions of study participants	▪ Focus group interviews with N = 4 staff members: Process adaptations within the context of the intervention (e.g., cooperation between social services and nursing services, and facility staff); Total: N = 4	T2	
	▪ Focus group interviews with N = 4 staff members to assess acceptance and satisfaction with the content of the staff training, reflection units, and the process. n = 1 per institution; Total: N = 4.; Total: N = 4 ▪ Individual interviews with 3 PwD per facility on their representatives to assess their acceptance and satisfaction with the program content, reflection units, and the process. n = 3 per facility; Total: N = 12	T2	Mechanism of impact
Nursing home changes	▪ Qualitative interviews to assess the perceptions of PwD or their representatives regarding cognitive stimulation changes. PwD or their representatives (N = 3 per facility); Total: N = 12	T2	
Target group perspectives	▪ Qualitative interviews to assess the perspectives of the target groups (head nurses, head of social services, staff members actively involved in the intervention, head of nursing, and head of social services as well as N = focus group interview with N = 4 staff members per facility); Total: N = 4 focus group interviews with staff members, N = 8 interviews	T2	Inhibiting and promoting factors and contextual conditions

Abbreviations: PwD: people with dementia.

Patient and Public Involvement

For the development of the CogStim24 program, a participatory approach considering people who are conducting the intervention was used. This included a quantitative survey on the current practice of cognitive stimulation which addressed nursing home managers as well as focus group discussions with nursing and care staff of inpatient long-term care facilities on their experiences, barriers, and needs regarding cognitive stimulation intervention implementation. Further, the authors' experience in developing cognitive intervention materials specifically for PwD and conducting cognitive stimulation trials with PwD served as a further basis for the development of the CogStim24 activities and for the selection of the neuropsychological assessment instruments. Also, the project was presented and discussed at a multidisciplinary conference of the German Alzheimer's society, which is the largest self-help group organization for PwD and their relatives in Germany, at the beginning of the project and before finalizing the study protocol. The conference aims to bring together, among others, patient representatives, politicians, nursing and care staff as well as scientists. Further integration of the lived experience of PwD and their relatives was limited due to the SARS-CoV-2 pandemic. The German Alzheimer's Society will also support the dissemination of the study results to the target group.

ETHICS AND DISSEMINATION

Ethics approval was obtained from the ethics committee of the Faculty of Medicine of the University of Cologne, Cologne, Germany (21-1287). All participants will receive oral and written study information. The authors were guided by their local ethics committee to provide easy-to-understand study information l for PwD. All participants will provide written informed consent before taking part in the study. The consent form is available by request to the corresponding author. In cases where participants are unable to provide consent due to advanced cognitive dysfunctions, a legal representative will be involved in the consent

process. All study participants will have the opportunity to cease study participation at any time without reason. Any changes to the study protocol will be directly updated in the trial registry entry by the research team.

The participatory research approach during all phases of the study, including the development of the CogStim24 intervention, the training program, and the conduct of the study, provides adequate representation for all relevant target groups. Furthermore, this approach guarantees the development of an intervention that is suitable for the target groups both conducting and receiving the program. Ultimately, the final implementation of the intervention will involve its inclusion in daily routine care to ensure its sustainability.

PwD participating in the study may receive a direct benefit from the cognitive stimulation program in terms of global cognition, quality of life, and other outcomes. Notably, the CogStim24 activities might be tiring and exhausting for some PwD. However, nursing and care staff will be sensitized during the staff training regarding this topic, and are guided to make thoughtful decisions on when to pause the CogStim24 activities. Also, participating nursing and care staff members may benefit from improved work-related quality of life and stress experience. Employees of the inpatient long-term care facilities are expected to become more aware of cognitive stimulation application, which may benefit other PwD not directly involved in the study.

DISCUSSION

To the best of the authors' knowledge, this is the first study to develop and evaluate a cognitive stimulation program as a 24-hour everyday approach in nursing homes. If the implementation of the CogStim24 staff training and program and study protocol is successful, this study has the potential to serve as a basis for a large multicenter cluster RCT and, ultimately, act as the starting point for delivering cognitive stimulation to a greater number of PwD in nursing homes, including those who are bedridden. There is the potential to

adapt the intervention to outpatients and their relatives, as this population has historically been massively undersupplied in terms of cognitive interventions.

There are several possible challenges and limitations associated with conducting the study. One important issue is that the recruitment of staff and PwD constitutes a challenge in this study and for future implementation due to the time, room, and other resource restrictions present in nursing homes and the health issues of PwD. The SARS-CoV-19 pandemic has exacerbated this challenge. Furthermore, the successful conduct and implementation of the nursing and care staff training and the CogStim24 program itself is questionable due to the fact that everyday care is subject to limited resources in terms of times and personnel. That is why this feasibility trial can be regarded as a proof-of-concept. Aspects that might interfere with a successful program implementation might be, for example, that staff members only incompletely participate in the staff training or that PwD might be strained by the 24/7 approach and refuse to regularly take part in the exercises. Also, it cannot be guaranteed that nursing and care staff successfully implement the CogStim24 activities into everyday care and conducting different types of exercises in a balanced way. While feedback on the conduct of specific activities is considered in the reflection sessions during the staff training in this study protocol, no further ways of monitoring the actual CogStim24 implementation are planned. However, in future trials, monitoring, for example, by means of participant observation, could help to track whether CogStim24 has been used and, if so, on which factors its implementation depends. Furthermore, there are several methodological limitations that might lead to a risk of bias. First, due to staff resource limitations, blinded outcome assessments for the pre-post assessments cannot be guaranteed. Second, the study design of this feasibility trial does not include a control group. Third, for this feasibility trial a small sample size was selected. Fourth, the neuropsychological test battery might be too long and tiring for the PwD. Fifth, the conduct of the external assessments by nursing and care staff could be incomplete due to personnel restrictions. Sixth, adverse events are only addressed in the qualitative interviews with nursing and home staff. Future studies should record adverse effects in a structured manner. Finally, incomplete data sets and drop outs can be expected in our target group of PwD living in nursing homes.

A particular strength of the project is the interdisciplinarity of the research team, which includes neuropsychologists, gerontologists, nursing scientists, and sports scientists. Furthermore, the participatory approach includes all relevant target groups (nursing home managers, head nurses, nursing and care staff, and PwD) in all steps of the development of the program and study. Only through this interdisciplinarity and mixed-methods approach, in combination with the quantitative and qualitative research methods, process evaluation, and feedback "development loops," can the unique needs of these target groups and the unique setting of nursing homes be adequately considered. This impacts the feasibility of a wider implementation of the intervention in everyday care.

LIST OF ABBREVIATIONS

ADAS-Cog: Alzheimer's Disease Assessment Cognitive Scale; BPSD: Behavioral and psychiatric symptoms in dementia; CSDD: Cornell Scale for Depression in Dementia; DSS: Dementia Screening Scale; GDS: Geriatric Depression Scale; MAR: Missingness-at-random; MMRM: Mixed models for repeated measures; MMSE: Mini-Mental State Examination; NMAR: Not-missing-at-random; NPI-NH: Neuropsychiatric Inventory Nursing Home Version; PwD: People with dementia; QoL-AD NH: Quality of Life in Alzheimer's Disease Nursing Home Version; RCB-Related Distress Index: Residents' challenging behavior Related Distress Index; RCT: Randomized Controlled Trial.

DECLARATIONS

Acknowledgments

The authors would like to thank all the participants that have contributed to the study so far and in the future, including the PwD, nursing and care staff, head nurses, and nursing home managers as well as all patient representatives who discussed the project with us in the course of development phase. Further, the

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Author Contributions

Conception and design: AKF, ÜSS, JG, MND, MH, SK, and EK; manuscript drafting: AKF, ÜSS, MND, and EK; manuscript revisions: JG, MH, and SK; final manuscript approval: AKF, ÜSS, JG, MND, MH, SK, and EK; agreed to be accountable for all aspects of the work: AKF, ÜSS, JG, MND, MH, SK, and EK.

Funding

German Alzheimer's Society (grant number: NA).

Competing interests

AKF and EK are authors of the cognitive intervention series NEUROvitalis (ProLog, Cologne); however, they receive no corresponding honoraria for this. ÜSS, JG, MND, MH, and SK have no conflicts of interest to declare.

Ethics approval and patient consent

This study was conducted in accordance with the Declaration of Helsinki (as revised in 2013) and was approved by the ethics committee of the Faculty of Medicine of the University of Cologne, Cologne, Germany (21-1287). All participants and the legal representatives of PwD will provide written informed consent before taking part in the study.

Consent for publication

The authors have informed consent from all subjects for the publication of identifying information and images in an online open-access publication (Supplement 2; the subjects are members of our research team).

Availability of data and materials

The datasets used and/or analyzed during the current study will be available from the corresponding author upon reasonable request after study completion.

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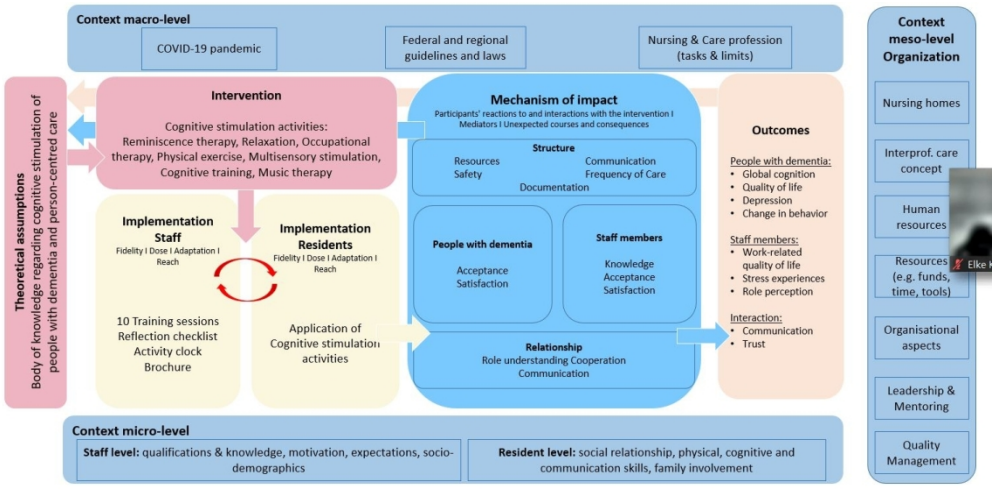

Figure 1

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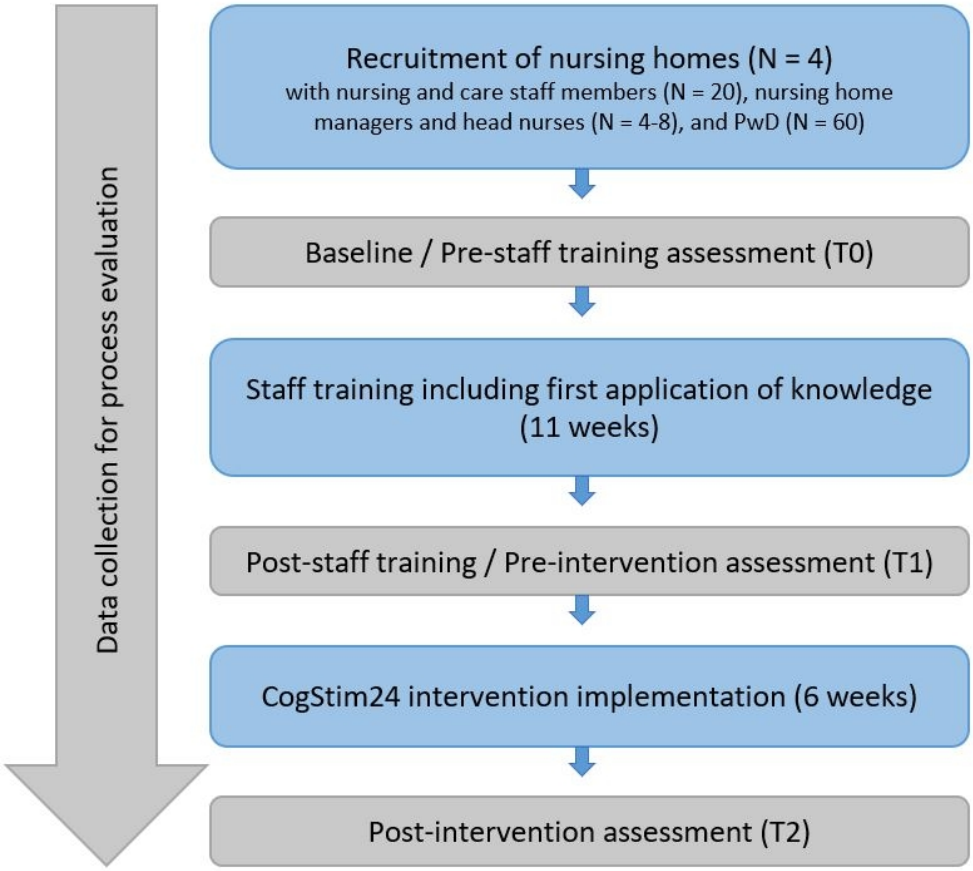


Figure 2

168x153mm (120 x 120 DPI)

Supplement 1. SPIRIT 2013 checklist. PAGE NUMBERS WILL BE UPDATED AS SOON AS THE FINAL PROOFS ARE AVAILABLE

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	3
	2b	All items from the World Health Organization Trial Registration Data Set	N/A (all information listed in DRKS registration)
Protocol version	3	Date and version identifier	1
Funding	4	Sources and types of financial, material, and other support	21f.
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1, 21
	5b	Name and contact information for the trial sponsor	1, 21f.
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	21f.
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	N/A
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4ff.
	6b	Explanation for choice of comparators	N/A
Objectives	7	Specific objectives or hypotheses	5f.
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	6f.

Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	12
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	13
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	7ff.
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	N/A (non-pharmacological approach)
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	7ff.
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	N/A
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	14ff.
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	14ff.
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	13f.
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	12f.
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	N/A
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	N/A
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	N/A

Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	N/A
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	14ff.
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	14ff.
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	14ff.
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	14ff.
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	14ff.
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	14ff.
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	14ff.
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	N/A
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	16
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	N/A
Ethics and dissemination			

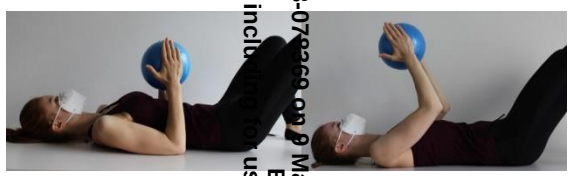
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	19
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	N/A
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	19
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	14ff.
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	22
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	14ff.
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	16
	31b	Authorship eligibility guidelines and any intended use of professional writers	21
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	N/A
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	19
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A

Supplement 2. CogStim24 modules accompanying everyday care with exercises and materials.

Module	Exercises	Materials	Examples
Communication	*General principles:* • Person-centered approach.[1] • Humanistic attitude and behavioral strategies.[2] • Communication rules are based on the validation approach.[3]	-	• Face the person with dementia directly, make eye contact, and draw their attention. • Speak in "I" phrases, narrating everything you intend to do. • Use few words and short and clear statements, and patiently repeat what you have said. • Avoid negations. • Ask questions that are more precise (e.g., how? what? when? where?) rather than looking for causes (why?). • Verbalize the affected person's feelings. • Speak calmly and slowly and avoid using a high-pitched voice. • Use simple language and jargon, use a moderate speech pace, and use short sentences. • Allow sufficient time for the person to think and respond. • Accompany actions with words that describe what is being done.
Reality orientation	*This module constitutes a general CogStim24 approach:* • Presentation of and reference to personal and/or biographical details, as well as other information such as the time, date, location, weather, season, and holidays, in everyday interactions. • Use of the CogStim24 "Activity clock." • Use of the CogStim24 "Mood barometer." • It is recommended to place items supporting reality orientation in the residents' rooms, such as individual calendars, large clocks, and labels on doors and other items in the room. • It is recommended to place brief information about the resident in the room, such as a fact sheet or labeling pictures with the names of the person/s depicted. Furthermore, residents should be encouraged to use a mirror in daily personal hygiene activities (e.g., combing hair and brushing teeth).	• CogStim24 "Activity clock." • CogStim24 "Mood barometer." • Recommended: calendar, clock, labels on items and pictures in the room, and a personal fact sheet.	-
Reminiscence therapy	*This module involves ten exercises, each with two difficulty levels:* 1. Shopping list. 2. Planning a celebration. 3. "I've never..." 4. Meaningful pictures. 5. Personal memories with knowledge connection.	• A booklet with pictures supporting references to biographical information. • Personal photos.	**2. Planning a celebration** ***Lower difficulty level*** *The task is to plan a celebration. The caregiver asks:* • Have you ever planned a celebration before, for example, a birthday or a wedding? • Whose birthday/wedding/celebration was it?

	6. Remembering everyday activities/addressing one's own needs. 7. Individual biography and photo box. 8. Everyday situation pictures with biographical references. 9. Associating words. 10. "My people" in the life cycle.		• What needed to be prepared? • Another option: Ask the person to plan a party for an upcoming holiday in mind. ***Higher difficulty level*** *The task is to plan a celebration. The caregiver asks:* • Have you ever planned a celebration before, for example, a birthday or wedding? • Whose birthday/wedding/celebration was it? • What preparations did you make to plan the celebration, and what tasks did you complete? • What was the schedule? When did you start preparing the celebration, and what time did the guests arrive? • Do you have any special memories of the day? What did you particularly like about
Cognitive exercises	*This module involves ten exercises, each with two difficulty levels:* 1. Orientation. 2. Language: finding opposites. 3. Language: taboo. 4. Perception: following perception. 5. Perception: visual search. 6. Memory: remembering proverbs and grasping their meaning. 7. Memory: remembering packing a suitcase: What belongs in a suitcase? 8. Executive function: decision-making. 9. Executive function: findings words of specific semantic or phonematic categories. 10. Executive functions: identifying connections.	• Pocket booklets with pictures and verbal material.	**5. Perception: visual search** ***Lower difficulty level*** *The caregiver asks:* • Look around the room here. What things are useful to you? • Which things are bigger than a book? • Which things are smaller than a book? • What things can you carry with your hands? • Which things feel smooth/soft/firm/rough? ***Higher difficulty level*** *The caregiver asks:* • Look around the room. What things do you use every day? • What things are bigger than this pillow (point to the pillow)? • What things are smaller than this pillow? • What things are red/blue/green/etc.? • Which things feel soft to the touch?
Occupational exercises	*This module involves ten exercises, each with two difficulty levels:* 1. Relax hand muscles. 2. Independence: self-care 3. Independence: room care (own room, common room) 4. Calendar management. 5. Encourage contact: write postcards/letters. 6. Creativity: prayer 7. Creativity: diary management 8. Creativity: creative leisure 9. Creativity: geometric shapes 10. Creativity: painting (creative vs. supplemented by	• Balls. • Everyday objects. • Postcards. • Writing materials. • Diary. • Creativity materials.	**2. Independence: self-care** ***Lower difficulty level*** Care: Give the resident a washcloth to clean areas, such as their arms, by themself. Alternatively, put some body lotion on their arms and have the resident rub the cream in. Eating: Pick up food with a fork or spoon and put it in the resident's hand so that they can bring the food to their mouth independently. ***Higher difficulty level*** Care: Have the resident brush their teeth. Alternatively, have the resident put on an item of clothing (e.g., pants or a top) themselves. Let the resident choose their outfit. Ask for a suitable color combination (in relation to the season). If needed, put a few matching outfit combinations

	tasks).		together on a suitable surface. Eating: Allow the resident to eat independently as much as possible. Offer assistance if needed. After the meal, have the resident put their tray in the trolley.
Multisensory stimulation	*This module involves ten exercises, each with two difficulty levels:* 1. Recognizing everyday objects. 2. Touching surfaces. 3. Touch exercise. 4. Tea smell exercise. 5. Scent exercise. 6. Auditory exercise animals. 7. Relaxation exercise. 8. Visual exercise. 9. Mindfulness practice I. 10. Mindfulness practice II.	• Everyday items. • Tote bag and items for exercise recognizing items via touch. • Olfactory material (e.g., tea bags, spices, etc.). • Music player and audio recordings (e.g., of animal sounds or from the internet).	**1. Recognizing everyday objects** ***Lower difficulty level*** Everyday objects that are already in the room are to be felt. For example, pens, cutlery, glasses, paper, and clothes hangers. The residents' task is to touch the objects and express their thoughts about them. Caregivers can ask questions like "do you know this object?", "do you know what it is?" and "how does it feel?" ***Higher difficulty level*** Everyday objects that are already in the room are to be felt. For example, pens, cutlery, glasses, paper, and clothes hangers. The residents' task is to feel and name the objects. Following this, a biographical reference can be made. Caregivers can ask questions like "what do you associate with this object?" and "did you use this object frequently in the past?"
Music therapy	*This module involves ten exercises, each with two difficulty levels:* 1. Active music making: singing folk songs. 2. Active music making: making music without instruments. 3. Active music making: making music with instruments. 4. Rhythm exercise: clapping exercise. 5. Rhythm exercise: sway exercise. 6. Active and passive listening: music memory training. 7. Active and passive listening: listening to music and reminiscing. 8. Active and passive listening: auditory memory exercise. 9. Active and passive listening: recognizing instruments. 10. Active and passive listening: passive music exercise.	• Music player. • Printed lyrics. • Everyday items. • Easy-to-use musical instruments (e.g., tone woods and rattles)	**7. Active and passive listening: listening to music and reminiscing** ***Higher difficulty level*** Well-known music/songs from different decades are played, and then thoughts, memories, and emotions about the music are shared. The caregiver will say, "I will now play a few songs. Afterward, I will ask you some questions about these songs." These questions will include "did you know this song?", "when was the last time you heard it?" and "do you associate certain memories or feelings with this music?" ***Lower difficulty level*** Well-known music/songs from different decades are played, and then the participants are asked whether they know the music. The caregiver will say, "I will now play a few songs. Afterward, I will ask you if you know these songs and if you like this music."
Physical activity	*This module involves ten exercises, each with two difficulty levels:* 1. Pressing a Pilates ball. 2. Strengthening with the loop band. 3. Holding up a balloon. 4. Balancing a rice bag. 5. Figure driving with a hedgehog ball. 6. Support and press. 7. Hedgehog ball massage. 8. Stork walk. 9. Mobilization with a Pilates ball.	• Balls. • Pilates balls. • Thera-Band. • Balloons. • Small bean bag. • Spiky massage ball. • Weights.	**10. Pressing a Pilates ball** ***Lower difficulty level*** Starting in the back position, the Pilates ball is taken between the knees and slowly squeezed. After approximately one second, the ball is released without letting it fall. The whole exercise is repeated 15 times. The exercise is then repeated with the ball between the hands.

	10. Dribbling a Pilates ball.		 ***Higher difficulty level*** Starting in the seated position, the Pilates ball is taken between the knees and slowly squeezed. After approximately one second, the ball is released without letting it fall. Then the exercise is repeated 15 times. The exercise is then repeated holding the ball between the hands and arms extended.
Relaxation	*This module involves ten exercises, each with two difficulty levels:* 1. Journey through the upper body. 2. Journey through the lower body. 3. Journey through the trunk and head. 4. Pelvic clock. 5. Breath control. 6. Feeling heaviness. 7. Feeling warmth. 8. Progressive arm muscle relaxation. 9. Progressive leg muscle relaxation. 10. Straightening and breathing.	• Music player and relaxation music (e.g., from the internet). • Small bean bag, • Cherry pit pillow.	 **8. Progressive arm muscle relaxation** ***Lower difficulty level*** Starting in the back position with the arms resting beside the body, the writing hand is clenched into a fist, and the tension is held for 5–10 seconds. The fist is opened, and the arms are rested for 30 seconds. The difference between tightening and relaxing is noted. The exercise is then repeated with the other hand. ***Higher difficulty level*** Starting in the seated position with hands resting on the thighs, the writing hand is clenched into a fist, and the tension is held for 5–10 seconds. The fist is opened, and the arms are rested for 30 seconds. The difference between tightening and relaxing is noted. The exercise is then repeated with the other hand and other muscle groups.

Note. All pictures belong to the Department of Medical Psychology | Neuropsychology and Gender Studies, Faculty of Medicine and University Hospital Cologne, University of Cologne. The authors gained informed consent from all subjects to publish identifying information/images in an online open-access publication.

References. [1] Kitwood T. *Demenz: Der personenzentrierte Ansatz im Umgang mit verwirrten Menschen. Deutschsprachige Ausgabe herausgegeben von Christian Müller-Hergl.* Huber, 2000. [2] Rogers CR. *Die nicht-direktive Beratung.* Kindler Verlag GmbH, München, 1972. [3] Feil N, de Klerk-Rubin. *Validation. Ein Weg zum Verständnis verwirrter alter Menschen (11. Auflage).* Ernst Reinhardt Verlag, 2007.

Supplement 3. Structure and content of the CogStim24 training program for the nursing and care staff.

Session number	Topic	Duration	Type of session
0	Introductory session to introduce cognitive stimulation in PwD aims and content of the CogStim24 intervention, and structure of the training program,	90 min	Online
	1-week break & audio-recorded PowerPoint presentation: Topic 1a		
1a	Communication with PwD,	180 min	Online, interactive exercises
	1-week implementation phase: Topic 1a		
1b	Reflection.	90 min	Online
	1-week implementation phase: Topic 1a. Audio-recorded PowerPoint presentation: Topic 2a		
2a	Reality orientation and reminiscence therapy on "my life."	180 min	Face-to-face, interactive exercises
	1-week implementation phase: Topic 2a		
2b	Reflection.	90 min	Online
	1-week implementation phase: Topic 2a. Audio-recorded PowerPoint presentation: Topic 3a		
3a	Cognitive exercises ("brain training") and occupational exercises,	180 min	Face-to-face, interactive exercises
	1-week implementation phase: Topic 3a		
3b	Reflection.	90 min	Online
	1-week implementation phase: Topic 3a. Audio-recorded PowerPoint presentation: Topic 4a		
4a	Multisensory stimulation and music therapy.	180 min	Face-to-face, interactive exercises
	1-week implementation phase: Topic 4a		
4b	Reflection.	90 min	Online
	1-week implementation phase: Topic 4a. Audio-recorded PowerPoint presentation: Topic 5a		
5a	Physical activity & relaxation.	180 min	Face-to-face, interactive exercises
	1-week implementation phase: Topic 5a		
5b	Reflection. & final exchange session.	90 min	Online
			11 weeks in total

Abbreviations: PwD: people with dementia.

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Title:

Cognitive stimulation for people with dementia in nursing homes: A protocol for a feasibility study examining a new 24/7 approach (CogStim24)

Authors:

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ABSTRACT

Introduction: Based on the available evidence, cognitive stimulation is recommended as an intervention for people with mild to moderate dementia (PwD). Currently, cognitive stimulation is regularly offered as a group program in care facilities. However, some residents, such as those who are bedridden, cannot participate. Furthermore, group programs were not feasible during the pandemic. A concept that accompanies everyday life and enables cognitive stimulation in everyday communication (i.e., "24/7") has been missing. Therefore, this feasibility study aims to (i) assess the feasibility of a new continuous 24/7 cognitive stimulation program (CogStim24) based on a process evaluation and (ii) examine the possible effects of CogStim24 on the primary outcome of global cognition in PwD and further PwD- and staff-related outcomes.

Methods and Analysis: The complex CogStim24 program is developed to be conducted as an everyday intervention during routine care including cognitively stimulating techniques, such as reminiscence therapy, multisensory stimulation, and physical activity. In this unblinded single-arm study with pre- and post-assessments, four nursing homes with a total of N=20 nursing and care staff will participate in an 11-week CogStim24 training program. The intervention will be conducted to N=60 PwD. Neuropsychological assessments will be conducted pre- and post-staff training, as well as after a 6-week implementation phase. A process evaluation will be performed.

Ethics and dissemination: Ethics approval was obtained from the ethics committee of the Faculty of Medicine of the University of Cologne, Cologne, Germany. Although cognitive stimulation is known to be effective for enhancing global cognition and quality of life in PwD, it is currently undersupplied to PwD. Therefore, CogStim24 has the potential to reach many more PwD. This study has the potential to serve as a basis for a large multicenter cluster randomized controlled trial. An interdisciplinarity team and mixed-methods approach will help generate information on the practicality and mechanisms of impact of

CogStim24. This is important for the further development of the intervention and for facilitating its implementation. The study results will be disseminated via presentations at scientific conferences and meetings for healthcare professionals and PwD and their relatives. Several manuscript presenting results of the different study parts will be published in peer-reviewed journals.

Trial registration: German Clinical Trials Register (ID: DRKS00024381).

Strengths and limitations of this study:

- The CogStim24 approach was developed as a complex intervention considering the specific requirements of care facilities.
- The CogStim24 program development was based on a systematic review of cognitive stimulation techniques for PwD and a participatory approach including a survey on the current practice of cognitive stimulation in German nursing homes, and focus group discussions with nursing and care staff on their experiences, barriers, and needs regarding cognitive stimulation intervention implementation.
- The evaluation of the complex intervention CogStim24 includes a process evaluation that follows established frameworks.
- The trial is limited to an unblinded single-arm study with pre- and post-assessments; large multicenter cluster randomized controlled trial will have to follow.

Keywords:

Dementia, Alzheimer's disease, cognitive stimulation, non-pharmacological therapy, nursing home, mixed-methods, study protocol, process evaluation, logic model, complex intervention

INTRODUCTION

Over 55 million people currently live with dementia globally; it is estimated this number will reach 78 million by 2030. With dementia being the 7th leading cause of global mortality and its high cost of treatment and care, it constitutes a major challenge not only for those affected but for society as a whole (1). Cognitive dysfunctions are the primary symptoms of dementia; however, people with dementia (PwD) also suffer from psychiatric and behavioral symptoms, leading to high caregiver burden (1). PwD typically require care throughout the course of the disease. Although many PwD receive long-term formal and informal care at home, there is a high risk of institutionalization in later disease stages (2).

Symptomatic pharmacological treatment includes acetylcholinesterase inhibitors and memantine to stabilize cognition for a short time; however, the efficacy is limited, and disease-modifying therapy is not yet available (3). Non-pharmacological treatment has attracted increased research and clinical practice interest. These treatments include cognitive interventions, physical exercise, and occupational and music therapy (4). Cognitive interventions utilize different approaches. One approach is cognitive training, which involves standardized paper-and-pencil or computerized tasks provided in individual or group sessions targeting specific cognitive functions. Another is cognitive stimulation, which is the global activation of cognitive and social skills in a small group setting via stimulating exercises, games, and conversation rounds, often in combination with reality orientation and reminiscence therapy (5, 6).

The current literature gives a relatively homogeneous picture regarding the effectiveness of cognitive stimulation in PwD, which is reflected in the recommendations of the German S3 guidelines to diagnose and treat dementia (7) (recommendation grade B: “should be offered”). Randomized controlled trials (RCTs) and systematic reviews and meta-analyses have demonstrated a positive effect of cognitive stimulation on various cognitive and non-cognitive parameters, including significant effects on global cognition (5, 6, 8), quality of life (6, 8), psychological and behavioral symptoms (6, 8), and communication skills and social interaction (6). A Cochrane review concluded that the effects shown are equivalent to or even exceed those of pharmacological therapy (6).

However, investigations of the effectiveness of these approaches have mainly been carried out in defined time periods, such as 6 or 8 weeks (6). For example, programs such as cognitive stimulation therapy (9), the multicomponent program MAKS therapy (10), StaKogS (11), and NEUROvitalis Sinnreich (12) are designed for a period of several weeks or months and for settings in which PwD and exercise leaders come together. These programs have mostly been conducted in small group settings, an aspect which itself may contribute to the effectiveness, as social activity is cognitively stimulating (13). However, it should be noted that these approaches can be seen as “add-ons” to the individual care of PwD. As these intervention programs are conceptualized with a low frequency, intervention effects may lack sustainability. Also, many PwD cannot take part in such programs due to being bedridden or because the nursing home lacks resources to provide cognitive stimulation (e.g., lack of staff to conduct the interventions in small group settings and/or take inpatients to the group or a lack of rooms). In outpatient settings, intervention groups may not be available at all (e.g., in rural areas). Additionally, during the SARS-CoV-19 pandemic, group activities, including cognitive stimulation and “memory training groups,” were paused in most settings (14).

On the basis of the considerations highlighted above, a 24/7 approach in which cognitive stimulation is used as an intervention accompanying daily routine care may enable sustainable stimulation for many PwD within existing care structures. To date, there is no concept of cognitive stimulation as a 24/7 approach to everyday contact between PwD and caregivers. This is supported by a recent scoping review on manual-based complex interventions in outpatient and inpatient care of PwD (15), where no study with a 24-hour cognitive stimulation concept was identified. The 24/7 cognitive stimulation program (CogStim24) project is the first step to filling this important gap in research and clinical practice.

Therefore, the present study aims to pilot the newly developed CogStim24 intervention as a 24/7 fixed component in everyday inpatient care for PwD. CogStim24 seeks to enable nurses and caregivers to provide cognitive stimulation at any time, such as during everyday personal hygiene activities or during meals, by anchoring the stimulation elements through conversation impulses, low-threshold available stimulating materials, and pocket exercises.

This feasibility study has several aims:

1. To evaluate the implementation fidelity, including the feasibility of the educational program for conducting CogStim24 and evaluating promoting and inhibiting factors of the intervention's implementation (i.e., process evaluation).
2. To assess the feasibility of the study design of CogStim24 in nursing homes as a basis for future cluster RCTs.
3. To examine the possible effects of CogStim24 (I = Intervention) on the primary outcome of global cognition (O = Outcome) in PwD (P = Population) and the secondary outcomes of quality of life, depression, and behavioral and psychiatric symptoms in dementia (BPSD), as well as the work-related quality of life and stress experiences of nursing and care staff using a pre-post design. As this is a non-controlled study, no comparators can be defined (C = Comparison).

This study is based on a logic model for the CogStim24 intervention (Figure 1). The logic model was created and discussed, with several iterations developed by the entire research team, using the current literature and authors' expertise. This process enabled the relevant theoretical assumptions, actors, and procedural outcomes for the evaluation to be considered. The logic model includes theoretical assumptions, the intervention, implementation, mechanism of impact, outcomes, and the micro-to-macro context (16, 17).

METHODS AND ANALYSIS

This report follows the SPIRIT guidelines for the minimum content of a clinical trial protocol (18). See Supplement 1 for the SPIRIT checklist.

Design/Methodology

Study design

This study was conceptualized as an uncontrolled, non-masked, single-arm study involving pre- and post-assessments using a mixed-methods approach. A process evaluation will be performed in conjunction with the study (17, 19). Within this study, several project steps will be carried out (Figure 2). These include training nursing and care staff on how to conduct CogStim24, piloting the CogStim24 intervention in nursing homes, using quantitative pre- and post-intervention assessments and qualitative interviews with PwD, nursing and care staff, nursing home managers, and head nurses, and evaluating the process of the overall implementation phase (training plus intervention implementation phase).

As a first step, nursing and care staff will receive an 11-week training on how to conduct the CogStim24 intervention, including e-learning modules for self-administration and group training sessions delivered in person and digitally. During the training program, the staff will implement CogStim24 stimulation techniques step by step in their everyday work routine so that they are able to implement the full program at the end of the training period. To investigate whether the protocol for the quantitative pre- and post-intervention assessments is feasible and to gain evidence for effects as a basis for a future cluster RCT, neuro-psychological tests and questionnaires will be administered to the participants (PwD and nursing and care staff) two weeks before (T0), immediately after the 11-week training program (T1), and two weeks after the 6-week intervention period (T2).

The process evaluation will be conducted for the full study duration, including the 11-week staff training and 6-week intervention period. The degree of implementation, mechanisms of change, and acceptance of the complex intervention in the participating nursing home facilities will be investigated. In addition, factors conducive to and inhibiting implementation will be explored. First patient-in was in May 2022. Data collection was finished by end of 2023.

CogStim24 intervention

CogStim24 was developed as a cognitive stimulation program that can be conducted in everyday life for people with cognitive impairments or PwD, provided by staff in nursing homes or in day care facilities and

by relatives at home. The challenge to implement cognitively stimulating activities into everyday care which is subject to limited resources in terms of times and personnel was considered in all developmental steps of the CogStim24 program. The development of the CogStim24 program was based on several elements which all considered this main challenge:

- The authors' expertise in developing cognitive intervention programs (12, 20) and training courses for such interventions, in conducting clinical studies that examine the effects and mechanisms of cognitive interventions in various target groups and settings, including PwD (8, 21) and nursing homes. Especially challenges and barriers that may be faced in nursing homes due to limitations in personnel and logistical resources were considered. This expertise was brought together in several expert meetings and guided the selection of cognitive stimulation techniques and exercises as well as ideas for the staff training. Notably, experts also included nurses and nursing scientists who are well familiar with challenges and barriers in everyday care in nursing homes.
- A systematic literature review of the characteristics of cognitive stimulation interventions conducted in nursing homes with PwD (see review registration under https://www.crd.york.ac.uk/prospero/display_record.php?ID=CRD42021227904) demonstrating the lack of a 24/7 approach. The included studies mostly used small group settings for the conduct of cognitive stimulation activities. Further, the literature showed a broad range of cognitive stimulation techniques included in the evaluated programs which also served as a basis for the development of our CogStim24 concept.
- A participatory approach during the entire development process and pilot study conduction, which included (i) a survey conducted in 64 nursing homes in North-Rhine Westphalia, Germany, on the current practice of cognitive stimulation (its challenges and barriers and current opinions and needs) and (ii) focus group discussions with nursing and care staff of inpatient long-term care facilities on their experiences, barriers, and needs regarding cognitive stimulation intervention implementation, as well as their opinions regarding the idea, possible structure, and content of a CogStim24 approach that included staff training (22).

The resulting concept of the CogStim24 intervention includes exercises and activities that have the potential to be conducted during everyday care with PwD including also those people that are bedridden. CogStim24 is expected to stabilize global cognition and improve the quality of life and mood of PwD. It is also expected to promote communication between PwD and nursing and care staff and improve the work-related quality of life and stress experiences of the staff.

The program consists of a large body of exercises that can be categorized under several cognitive stimulation techniques: reminiscence therapy, cognitive training, occupational exercises, multisensory stimulation, music therapy, physical exercise, and relaxation. In addition, patient-centered communication and reality orientation techniques are basic concepts of the program and are considered integral parts of all exercises. Each block of stimulation techniques contains ten exercises that are easy to conduct in daily routine care. Each exercise has two difficulty levels for PwD with cognitive impairments of different severity. The nursing and care staff can choose the difficulty level based on their own evaluation and experience with the PwD, or if he*she is uncertain, exercises with a lower difficulty level can be used, and if this works fine, the higher difficulty level can be chosen. An overview and examples for all exercise types are displayed in Supplement 2. An “activity clock” was developed. This can be displayed in each resident’s room and illustrates all the cognitive stimulation areas mentioned above. It can be used to make choices regarding the stimulation area of focus. The use of this clock promotes reality orientation and contributes to cognitive stimulation by focusing on the decision-making process.

The CogStim24 intervention includes a detailed instruction manual for all exercises as well as material to be placed in each resident’s room, including booklets with images and verbal exercises (e.g., for completing proverbs) and materials for physical exercises (e.g., a ball and a resistance band). Nurses and care staff are encouraged to collect autobiographical information and corresponding material, such as photos or belongings with personal value, for each resident and place it into the room for use within the CogStim24 program. All exercises can be conducted by nursing and care staff after participating in the staff training. No further training in, for example, physical exercise or music therapy is mandatory.

An overview of the program following the TIDieR guidelines (23) is displayed in Table 1.

Table 1. CogStim24 program overview based on the TIDieR guidelines.

What? ***Procedures, tailoring, and modifications***	**Why?** ***Rationale and theory***	**What?** ***Materials***	**How? Where?** ***Modes of delivery***	**Who?** ***Intervention provider***	**When & how much?**
Procedures Staff training Nursing and care staff receive an 11-week training program (max. 3h/week; cf. Supplement 3). CogStim24 Cognitive stimulation exercises that are easy to conduct in daily routine care based on the following techniques: • Reality orientation • Reminiscence therapy • Cognitive training • Occupational exercises • Multisensory stimulation • Music therapy • Physical intervention • Relaxation All interactions are based on the principles of patient-centered communication. *Tailoring* Nursing and care staff together with the PwD can choose from the ten exercises for each technique. Difficulty levels are chosen by staff, depending on residents' abilities. *Modifications* Based on the participatory approach, adjustments in intervention and implementation are possible.	Cognitive stimulation has been shown to have positive effects on global cognition and quality of life. However, many PwD living in nursing homes cannot participate in group-based cognitive stimulation programs. *Tailoring:* Cognitive interventions are most effective when under- and overextensions is avoided. That is why two difficulty levels are part of the CogStim24 program.	• Manual for nursing and care staff. • An "activity clock" indicates all possible activity domains. • Material in each resident's room (e.g., booklets with images and resistance bands) • If possible, autobiographic information and material relating to the resident will be placed in their rooms (e.g., a short CV, pictures, and other meaningful items). *Tailoring:* All CogStim24 exercises are available in two difficulty levels.	The intervention will be conducted during everyday care in nursing homes, both in resident rooms and other facility areas. *Tailoring:* The nursing and care staff can choose the difficulty level based on their own evaluation and experience with the PwD, or if he*she is uncertain, exercises with a lower difficulty level can be used, and if this works fine, the higher difficulty level can be chosen.	Nursing and care staff will be educated on the intervention during the 11-week staff training program. *Tailoring:* Choosing the difficulty level for the CogStim24 exercises will be performed by nursing and care staff.	The intervention is intended conducted in any interaction between PwD and nursing and care staff, if possible. *Tailoring:* CogStim24 is not conducted or paused if PwD seem too burdened or too exhausted.

Abbreviations: PwD*:* People with dementia.

Training program for nursing and care staff

Nursing home managers have to agree to the study participation, and have to make their nursing and care staff available for taking part in the staff training. Each participating nursing and care staff team member of

the nursing homes involved in the study will receive an 11-week training program, which will be facilitated by members of the research team, including psychologists, gerontologists, and nursing scientists who hold a minimum of a bachelor's degree. The set up of the staff training was developed in a participatory approach, so that the main challenge, i.e., the implementation into everyday care, can be overcome in a best possible way. As described above, we gained information about the target group's perspectives, both from the survey and the focus group discussions. As a result, the training consists of several components: e-learning modules for self-administration, group face-to-face sessions, and digital meetings. Overall, the training includes 12 hours of face-to-face and 12 hours of digital meetings, as well as five 30-minute self-administered sessions supported by e-learning modules. As CogStim24 has too many modules to be implemented at once, the topics and techniques of the intervention are introduced step by step so that the staff are able to implement the full spectrum of the intervention components when the training course has been completed. Each module is introduced by an e-learning module in the form of an audio-backed PowerPoint presentation and a workbook with information and exercises to deepen the understanding of topic contents, both of which are sent to the participants one week in advance of the following session. In the group face-to-face sessions, the topic and cognitive stimulation exercises are extensively explained and discussed, and exercises are practiced interactively. This is followed by a one-week implementation phase, where the staff can trial the module in everyday care. In the middle of the implementation phase, an online "reflection" session is held, in which experiences with the exercises and materials and the successes, failures, and barriers in the implementation are discussed. Participants will be given a "CogStim24 diary" as an aid, which will contain a checklist of the relevant aspects for the purpose of self-reflection. This checklist includes several aspects related to participants' experiences during the implementation phase:

- The CogStim24 exercises and materials were used and why (free text).
- The experiences had in implementing the exercises (free text).
- The barriers faced when conducting the exercises (free text).
- An evaluation of the setting conditions as a basis for conducting the exercises (free text).

- How the implementation was for the staff in terms of difficulty level, time expenditure, satisfaction with the exercises, and motivation. Responses are rated on a 6-point Likert scale ranging from “very low” to “very high.”
- How the exercise was for individuals with cognitive impairment (free text) in terms of difficulty level, time expenditure, satisfaction with the exercises, and motivation. Responses are rated on a 6-point Likert scale, ranging from “very low” to “very high.”

The whole training is framed by an introductory and final reflection and exchange session. The structure of the training is displayed in Supplement 3. Based on the still uncertain pandemic situation, all face-to-face meetings are prepared so that they can easily be held digitally if necessary.

Setting, participants, and sample size

The study will be conducted in four nursing homes (a convenience sample) in Cologne, North-Rhine Westphalia, Germany. All facilities have a high proportion of residents with cognitive impairments and dementia. During study participation, usual treatment regimens will be followed, and changes are allowable at any time.

The following eligibility criteria for all participants including PwD, nursing and care staff, nursing home managers as well as head nurses have been defined.

Inclusion criteria

- PwD: To reflect nursing home reality, residents do not need to have a clinical dementia diagnosis. Thus, we include residents of the participating long-term care facilities who have a clinically confirmed dementia diagnosis, but also residents who have undergone a third-party assessment by nursing or care staff using the Dementia Screening Scale (DSS) and received a score of ≥ 3 points (24). Must be able to be interviewed, provide written informed consent signed by themselves or a legal

representative, have good or sufficiently corrected vision and hearing abilities, and good German language skills.

- Nursing and care staff: Nursing professionals who are willing to participate in the CogStim24 training and implement the intervention in their daily work. Nursing participants must be permanent employees who work in day and/or night care. Care staff participants should be professionally trained (e.g., social services employees, such as social pedagogues, social workers, gerontologists, or additional care staff members according to the long-term care insurance act; SGB XI). Must have good or sufficiently corrected vision and hearing abilities and good German language skills.
- Nursing home managers/head nurses: Management of a nursing home in which the study conducted; position as (deputy) head nurse or nursing home manager; good or sufficiently corrected vision and hearing abilities; good German language skills.

Exclusion criteria

- PwD: Residents who lack a dementia diagnosis, lack the ability to provide consent, do not have a legal representative, or have life-threatening illnesses or other diseases that make study participation impossible.
- Nursing and care staff: Nursing home staff without professional training as well as volunteers.
- Nursing home managers/head nurses: Management of outpatient and day-care facilities as well as facilities of disability assistance.

Sample size calculation and dropout management

Four nursing homes are planned for inclusion. All nursing homes are part of the researchers' network, and already participated in past studies. These nursing homes have a large number of people with cognitive dysfunctions and PwD. For the pre- and post-intervention study, around 20 nursing and care staff members (n = 5 per nursing home), 4–8 nursing home managers and head nurses (n = 1–2 per nursing home), and N =

60 PwD (*n* = 15 per nursing home) will be enrolled. These sample sizes ensure sufficient saturation regarding the qualitative study objectives, as the essential characteristics, views, and opinions of participants with a prevalence of 5% will be detected with a probability of 64.2%, 26.5%, and 95.4%, respectively. A sample size of 44 PwD is sufficient to detect changes in quantitative outcomes over time with an effect size of 0.5 (mean differences and standard deviation of differences) and a power of 90% (paired *t*-test, 5% alpha two-sided).

Outcomes and measurement instruments for the quantitative pre-post study and data analysis

A neuropsychological test battery with different sets of instruments for nursing and care staff and PwD will be completed within two weeks before staff training begins (T0), immediately after staff training (T1), and within two weeks after the implementation period (T2). An overview of all instruments used for the effect analysis and the schedule of enrolment and interventions is displayed in Table 2. The tests will be carried out by the project's research staff, including psychologists and nursing scientists who hold at least a bachelor's degree. Researchers will not be blinded for the time points of assessments.

Table 2. Schedule of enrolment, interventions, and data collection following the SPIRIT guidelines.

	STUDY PERIOD			
	Enrolment	Post-allocation		
TIMEPOINT	**Pre-study**	**Before staff training (T0)**	**After staff training (T1)**	**After the implementation phase (T3)**
ENROLMENT:				
Eligibility screen	X			
Informed consent	X			
INTERVENTION:				
CogStim24		←	—	→
ASSESSMENTS:				
Demographics & clinical data	X			
Global cognition (MMSE & ADAS-Cog)		X	X	X
Quality of Life (QoL-AD)		X	X	X
BPSD (NPI-NH)		X	X	X
Depression (GDS & CSDD)		X	X	X
Work-related Quality of life/ Stress experience (RCB-related Distress Index)		X	X	X

Abbreviations: ADAS-Cog: Alzheimer's Disease Assessment Cognitive Scale; BPSD: Behavioral and psychiatric symptoms in dementia; CSDD: Cornell Scale for Depression in Dementia; GDS: Geriatric Depression Scale; MMSE: Mini-Mental State Examination; NPI-NH: Neuropsychiatric Inventory Nursing Home Version; QoL-AD NH: Quality of Life in Alzheimer's Disease Nursing Home Version; RCB-Related Distress Index: Residents' challenging behavior Related Distress Index.

We used established neuropsychological test instruments that have been widely used in dementia research including cognitive stimulation trials (6; 25). This refers both to the cognitive as well as to the non-cognitive outcomes. The primary outcome of the pre-post-examination is global cognition of PwD, which will be operationalized with the Mini-Mental State Examination (MMSE) (26, 27) and the Alzheimer's Disease Assessment Scale – Cognitive Subscale (ADAS-Cog) (28). Secondary outcomes include PwD' quality of life

assessed with the Quality of Life in Alzheimer's Disease Nursing Home Version (QoL-AD NH) (29, 30) questionnaire for self-assessment and proxy ratings; depression in PwD measured with the Geriatric Depression Scale (GDS) (31) for self-assessment and the Cornell Scale for Depression in Dementia (CSDD) (32) as a proxy rating; BPSD operationalized with the Neuropsychiatric Inventory Nursing Home Version (NPI-NH) (33, 34) for a proxy rating; and the Residents' challenging behavior (RCB)-related distress index (35) for self-assessment of work-related quality of life and stress experience among nursing and care staff. Cognitive stimulation is not known to be associated with any adverse events. Therefore, in this feasibility trial, adverse events will not be registered in a structured form.

Data collection will follow the German General Data Protection Regulation. Pseudonymized clinical data collected during the trial will be anonymized and made available upon request immediately following publication for a period of 10 years. Requests for data reuse will be approved by the coordinating investigator. To gain data access, data requestors will need to sign a data access agreement. Data entry will be double-checked, and range-checks for data will be provided. No data monitoring committee will be used for this feasibility trial. All data analyses will be conducted using the statistical program IBM SPSS Statistics (version 28). All data will be checked for normal distribution using the Kolmogorov-Smirnov test. Descriptive analyses of sociodemographic and clinical characteristics at baseline, including frequencies, means, and standard deviations or median and ranges (depending on the data distribution), will be reported. Intervention effects at T0, T1, and T2 data will be evaluated using linear mixed models for repeated measures (MMRM) with fixed effects of group, time, and group*time (ARH1-structured variance-covariance matrix over time). Missing data are implicitly handled by MMRM (assuming missingness-at-random [MAR]). Multiple imputation approaches will be used for sensitivity analysis, potentially considering not-missing-at-random (NMAR) scenarios. Per-protocol analysis for all PwD with complete data for all measurement time points will be performed and could be used for sensitivity analysis.

The study protocol and study results will be disseminated via presentations at scientific conferences and meetings for healthcare professionals and PwD and their relatives. The study results will be published in peer-reviewed journals. Separate manuscripts will be provided for (i) the systematic review of the

characteristics of cognitive stimulation interventions, (ii) the survey on current practice of cognitive stimulation in nursing homes, (iii) the focus group discussions with nursing and care staff of inpatient long-term care facilities on their experiences, barriers, and needs regarding cognitive stimulation intervention implementation, (iv) the process evaluation of the CogStim24 implementation, and (v) the quantitative results of the pre-post-study.

Process evaluation, data collection, and analysis

In the evaluation of complex interventions, a process evaluation is required to enable a better understanding of the intervention implementation (17, 36). The process evaluation procedure was developed according to the models of Grant et al. (19) and Moore et al. (17) (see Figure 1). Several overarching elements will be addressed:

- Recruitment of nursing home facilities, nursing and care staff, and PwD (Reach).
- Context factors (micro, meso, and macro level).
- Implementation of the intervention components (Fidelity, Dose, Adaptation, and Reach).
- Change processes implemented in the facilities based on the intervention and logical model (participants' reactions to and interactions with the intervention, mediators, unexpected courses, and consequences).
- Inhibiting and promoting factors and contextual conditions.

Qualitative and quantitative methods will be used for data collection (Table 3).

The process data analyses will be blinded to the results of the effect study. Quantitative data will be descriptively analyzed. Qualitative data (interviews and focus groups) will be analyzed based on qualitative content analysis (37). Qualitative analysis of the documents and structured interviews will be conducted by one researcher, and 10% of the data will be independently analyzed by a second researcher. All further analyses will be conducted by one researcher. If needed, a peer group will be available to discuss

uncertainties. The interim results of the qualitative analyses will be regularly presented to the research team and critically discussed. All results of the process evaluation will be narratively described and summarized.

Table 3. Process evaluation: An overview of data collection methods.

Parameter	Material	Measurement time points	Process evaluation elements
Recruitment description	Recruitment protocol: documentation of the recruitment process, collection of reasons for participation or withdrawal of the facilities, collection of reasons for participation or withdrawal of staff members.	T0, T1, T2	Reach
Description of the context factors of the nursing homes	Structured questionnaire for nursing home managers and head nurses to assess the existence of concepts or standards for cognitive stimulation of PwD ▪ *Organizational Readiness for Implementing Change* (ORIC) questionnaire (38) to provide a description of cluster facility culture. ▪ *Person-centered climate* (PCQ-S; staff version) questionnaire (39). ▪ *Assessment of Interprofessional Team Collaboration Scale* (AITCS) questionnaire (40). ▪ *Index for the stress of staff in inpatient geriatric care facilities due to changes in the behavior of residents RCB-related distress index* (35) questionnaire. *Sample: All nursing and care staff and management staff of the participating residential facilities.*	T0 T0, T2	Context
Implementation of the intervention components	▪ Staff training protocol: number of training sessions offered and received per cluster, including the duration, number, and function of participants, topics, and adaptations (type and reasons). ▪ Staff training protocol: number of reflection sessions offered and received per cluster, including the duration, number, and function of participants, topics, and adaptations (type and reasons). ▪ Staff training protocol: number of additional components offered and received. ▪ Reflection questionnaire and training evaluation for the staff members: Perceived content of training and reflection. ▪ Reflection sessions after each introduction and implementation of a new program module during staff training.	T1, T2 T1, T2	Fidelity, Dose, Adaptation, Reach, and inhibiting and promoting factors
Implementation of the intervention components in daily care and reactions of study participants	▪ Focus group interviews with N = 4 staff members: Process adaptations within the context of the intervention (e.g., cooperation between social services and nursing services, and facility staff); Total: N = 4 ▪ Focus group interviews with N = 4 staff members to assess acceptance and satisfaction with the content of the staff training, reflection units, and the process. n = 1 per institution; Total: N = 4.; Total: N = 4 ▪ Individual interviews with 3 PwD per facility on their representatives to assess their acceptance and satisfaction with the program content, reflection units, and the process. n = 3 per facility; Total: N = 12	T2 T2	Mechanism of impact
Nursing home changes	▪ Qualitative interviews to assess the perceptions of PwD or their representatives regarding cognitive stimulation changes. PwD or their representatives (N = 3 per facility); Total: N = 12	T2	
Target group perspectives	▪ Qualitative interviews to assess the perspectives of the target groups (head nurses, head of social services, staff members actively involved in the intervention, head of nursing, and head of social services as well as N = focus group interview with N = 4 staff members per facility); Total: N = 4 focus group interviews with staff members, N = 8 interviews	T2	Inhibiting and promoting factors and contextual conditions

Abbreviations: PwD: people with dementia.

Patient and Public Involvement

For the development of the CogStim24 program, a participatory approach considering people who are conducting the intervention was used. This included a quantitative survey on the current practice of cognitive stimulation which addressed nursing home managers as well as focus group discussions with nursing and care staff of inpatient long-term care facilities on their experiences, barriers, and needs regarding cognitive stimulation intervention implementation. Further, the authors' experience in developing cognitive intervention materials specifically for PwD and conducting cognitive stimulation trials with PwD served as a further basis for the development of the CogStim24 activities and for the selection of the neuropsychological assessment instruments. Also, the project was presented and discussed at a multidisciplinary conference of the German Alzheimer's society, which is the largest self-help group organization for PwD and their relatives in Germany, at the beginning of the project and before finalizing the study protocol. The conference aims to bring together, among others, patient representatives, politicians, nursing and care staff as well as scientists. Further integration of the lived experience of PwD and their relatives was limited due to the SARS-CoV-2 pandemic. The German Alzheimer's Society will also support the dissemination of the study results to the target group.

ETHICS AND DISSEMINATION

Ethics approval was obtained from the ethics committee of the Faculty of Medicine of the University of Cologne, Cologne, Germany (21-1287). All participants will receive oral and written study information. The authors were guided by their local ethics committee to provide easy-to-understand study information l for PwD. All participants will provide written informed consent before taking part in the study. The consent forms are available by request to the corresponding author; the consent form for PwD is displayed in Supplement 4. In cases where participants are unable to provide consent due to advanced cognitive

dysfunctions, a legal representative will be involved in the consent process. All study participants will have the opportunity to cease study participation at any time without reason. Any changes to the study protocol will be directly updated in the trial registry entry by the research team.

The participatory research approach during all phases of the study, including the development of the CogStim24 intervention, the training program, and the conduct of the study, provides adequate representation for all relevant target groups. Furthermore, this approach guarantees the development of an intervention that is suitable for the target groups both conducting and receiving the program. Ultimately, the final implementation of the intervention will involve its inclusion in daily routine care to ensure its sustainability.

PwD participating in the study may receive a direct benefit from the cognitive stimulation program in terms of global cognition, quality of life, and other outcomes. Notably, the CogStim24 activities might be tiring and exhausting for some PwD. However, nursing and care staff will be sensitized during the staff training regarding this topic, and are guided to make thoughtful decisions on when to pause the CogStim24 activities. Also, participating nursing and care staff members may benefit from improved work-related quality of life and stress experience. Employees of the inpatient long-term care facilities are expected to become more aware of cognitive stimulation application, which may benefit other PwD not directly involved in the study.

DISCUSSION

To the best of the authors' knowledge, this is the first study to develop and evaluate a cognitive stimulation program as a 24-hour everyday approach in nursing homes. If the implementation of the CogStim24 staff training and program and study protocol is successful, this study has the potential to serve as a basis for a large multicenter cluster RCT and, ultimately, act as the starting point for delivering cognitive stimulation to a greater number of PwD in nursing homes, including those who are bedridden. There is the potential to

adapt the intervention to outpatients and their relatives, as this population has historically been massively undersupplied in terms of cognitive interventions.

There are several possible challenges and limitations associated with conducting the study. One important issue is that the recruitment of staff and PwD constitutes a challenge in this study and for future implementation due to the time, room, and other resource restrictions present in nursing homes and the health issues of PwD. The SARS-CoV-19 pandemic has exacerbated this challenge. Furthermore, the successful conduct and implementation of the nursing and care staff training and the CogStim24 program itself is questionable due to the fact that everyday care is subject to limited resources in terms of times and personnel. That is why this feasibility trial can be regarded as a proof-of-concept. Aspects that might interfere with a successful program implementation might be, for example, that staff members only incompletely participate in the staff training or that PwD might be strained by the 24/7 approach and refuse to regularly take part in the exercises. Also, it cannot be guaranteed that nursing and care staff successfully implement the CogStim24 activities into everyday care and conducting different types of exercises in a balanced way. While feedback on the conduct of specific activities is considered in the reflection sessions during the staff training in this study protocol, no further ways of monitoring the actual CogStim24 implementation are planned. However, in future trials, monitoring, for example, by means of participant observation, could help to track whether CogStim24 has been used and, if so, on which factors its implementation depends. Furthermore, there are several methodological limitations that might lead to a risk of bias. First, due to staff resource limitations, blinded outcome assessments for the pre-post assessments cannot be guaranteed. Second, the study design of this feasibility trial does not include a control group. Third, for this feasibility trial a small sample size was selected. Fourth, the neuropsychological test battery might be too long and tiring for the PwD. Fifth, the conduct of the external assessments by nursing and care staff could be incomplete due to personnel restrictions. Sixth, adverse events are only addressed in the qualitative interviews with nursing and home staff. Future studies should record adverse effects in a structured manner. Finally, incomplete data sets and drop outs can be expected in our target group of PwD living in nursing homes.

A particular strength of the project is the interdisciplinarity of the research team, which includes neuropsychologists, gerontologists, nursing scientists, and sports scientists. Furthermore, the participatory approach includes all relevant target groups (nursing home managers, head nurses, nursing and care staff, and PwD) in all steps of the development of the program and study. Only through this interdisciplinarity and mixed-methods approach, in combination with the quantitative and qualitative research methods, process evaluation, and feedback "development loops," can the unique needs of these target groups and the unique setting of nursing homes be adequately considered. This impacts the feasibility of a wider implementation of the intervention in everyday care.

LIST OF ABBREVIATIONS

ADAS-Cog: Alzheimer's Disease Assessment Cognitive Scale; BPSD: Behavioral and psychiatric symptoms in dementia; CSDD: Cornell Scale for Depression in Dementia; DSS: Dementia Screening Scale; GDS: Geriatric Depression Scale; MAR: Missingness-at-random; MMRM: Mixed models for repeated measures; MMSE: Mini-Mental State Examination; NMAR: Not-missing-at-random; NPI-NH: Neuropsychiatric Inventory Nursing Home Version; PwD: People with dementia; QoL-AD NH: Quality of Life in Alzheimer's Disease Nursing Home Version; RCB-Related Distress Index: Residents' challenging behavior Related Distress Index; RCT: Randomized Controlled Trial.

DECLARATIONS

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Author Contributions

Conception and design: AKF, ÜSS, JG, MND, MH, SK, and EK; manuscript drafting: AKF, ÜSS, MND, and EK; manuscript revisions: JG, MH, and SK; final manuscript approval: AKF, ÜSS, JG, MND, MH, SK, and EK; agreed to be accountable for all aspects of the work: AKF, ÜSS, JG, MND, MH, SK, and EK.

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Competing interests

AKF and EK are authors of the cognitive intervention series NEUROvitalis (ProLog, Cologne); however, they receive no corresponding honoraria for this. ÜSS, JG, MND, MH, and SK have no conflicts of interest to declare.

Ethics approval and patient consent

This study was conducted in accordance with the Declaration of Helsinki (as revised in 2013) and was approved by the ethics committee of the Faculty of Medicine of the University of Cologne, Cologne, Germany (21-1287). All participants and the legal representatives of PwD will provide written informed consent before taking part in the study.

Consent for publication

The authors have informed consent from all subjects for the publication of identifying information and images in an online open-access publication (Supplement 2; the subjects are members of our research team).

Availability of data and materials

The datasets used and/or analyzed during the current study will be available from the corresponding author upon reasonable request after study completion.

Figure captions

Figure 1. Logic model for CogStim24.

Figure 2. Overview of the study process (PwD: people with dementia).

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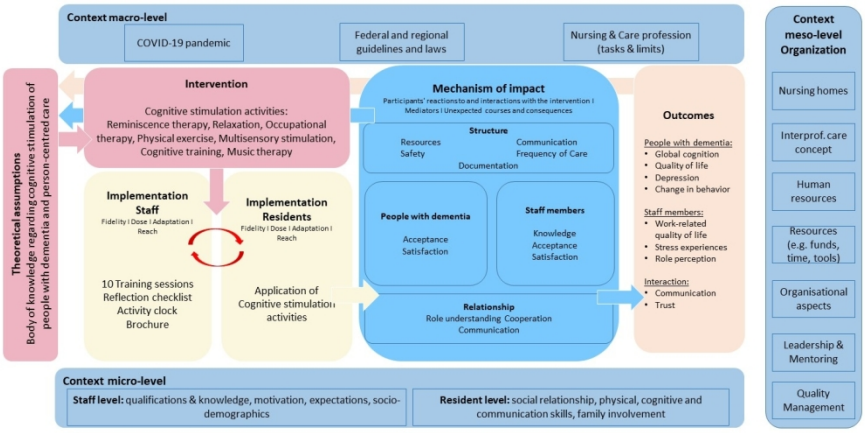

Figure 1. Logic model for CogStim24.

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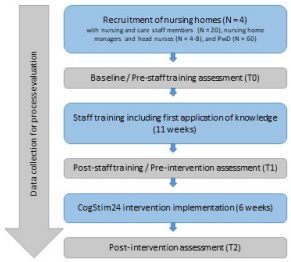


Figure 2. Overview of the study process (PwD: people with dementia).

338x190mm (96 x 96 DPI)

Supplement 1. SPIRIT 2013 checklist.

PAGE NUMBERS WILL BE UPDATED AS SOON AS THE FINAL PROOFS ARE AVAILABLE

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	3
	2b	All items from the World Health Organization Trial Registration Data Set	N/A (all information listed in DRKS registration)
Protocol version	3	Date and version identifier	1
Funding	4	Sources and types of financial, material, and other support	21f.
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1, 21
	5b	Name and contact information for the trial sponsor	1, 21f.
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	21f.
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	N/A
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4ff.
	6b	Explanation for choice of comparators	N/A
Objectives	7	Specific objectives or hypotheses	5f.
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	6f.

Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	12
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	13
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	7ff.
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	N/A (non-pharmacological approach)
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	7ff.
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	N/A
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	14ff.
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	14ff.
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	13f.
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	12f.
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	N/A
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	N/A
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	N/A

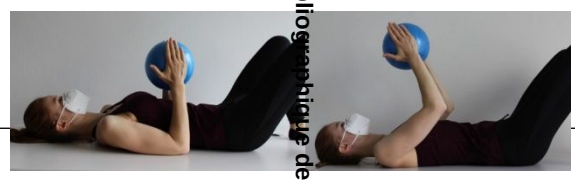
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	N/A
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	14ff.
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	14ff.
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	14ff.
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	14ff.
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	14ff.
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	14ff.
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	14ff.
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	N/A
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	16
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	N/A
Ethics and dissemination			

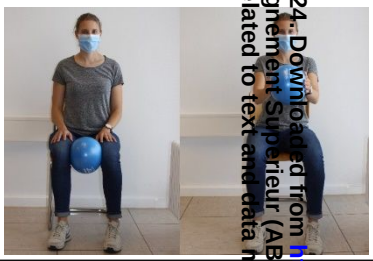
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	19
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	N/A
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	19
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	14ff.
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	22
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	14ff.
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	16
	31b	Authorship eligibility guidelines and any intended use of professional writers	21
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	N/A
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	19
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A

Supplement 2. CogStim24 modules accompanying everyday care with exercises and materials.

Module	Exercises	Materials	Examples
Communication	*General principles:* • Person-centered approach.[1] • Humanistic attitude and behavioral strategies.[2] • Communication rules are based on the validation approach.[3]	-	• Face the person with dementia directly, make eye contact, and draw their attention. • Speak in "I" phrases, stating everything you intend to do. • Use few words and short and clear statements, and patiently repeat what you have said. • Avoid negations. • Ask questions that are more precise (e.g., how? what? when? where?) rather than asking for causes (why?). • Verbalize the affect of the person's feelings. • Speak calmly and slowly and avoid using a high-pitched voice. • Use simple language and jargon, use a moderate speech pace, and use short sentences. • Allow sufficient time for the person to think and respond. • Accompany actions with words that describe what is being done.
Reality orientation	*This module constitutes a general CogStim24 approach:* • Presentation of and reference to personal and/or biographical details, as well as other information such as the time, date, location, weather, season, and holidays, in everyday interactions. • Use of the CogStim24 "Activity clock." • Use of the CogStim24 "Mood barometer." • It is recommended to place items supporting reality orientation in the residents' rooms, such as individual calendars, large clocks, and labels on doors and other items in the room. • It is recommended to place brief information about the resident in the room, such as a fact sheet or labeling pictures with the names of the person/s depicted. Furthermore, residents should be encouraged to use a mirror in daily personal hygiene activities (e.g., combing hair and brushing teeth).	• CogStim24 "Activity clock." • CogStim24 "Mood barometer." • Recommended: calendar, clock, labels on items and pictures in the room, and a personal fact sheet.	-
Reminiscence therapy	*This module involves ten exercises, each with two difficulty levels:* 1. Shopping list. 2. Planning a celebration. 3. "I've never..." 4. Meaningful pictures. 5. Personal memories with knowledge connection.	• A booklet with pictures supporting references to biographical information. • Personal photos.	**2. Planning a celebration** ***Lower difficulty level*** *The task is to plan a celebration. The caregiver asks:* • Have you ever planned a celebration before, for example, a birthday or a wedding? • Whose birthday/wedding/celebration was it?

	6. Remembering everyday activities/addressing one's own needs. 7. Individual biography and photo box. 8. Everyday situation pictures with biographical references. 9. Associating words. 10. "My people" in the life cycle.		• What needed to be prepared? • Another option: Ask the person to plan a party for an upcoming holiday in mind. ***Higher difficulty level*** *The task is to plan a celebration. The caregiver asks:* • Have you ever planned a celebration before, for example, a birthday or wedding? • Whose birthday/wedding/celebration was it? • What preparations did you make to plan the celebration, and what tasks did you complete? • What was the schedule? When did you start preparing the celebration, and what time did the guests arrive? • Do you have any special memories of the day? What did you particularly like about it?
Cognitive exercises	*This module involves ten exercises, each with two difficulty levels:* 1. Orientation. 2. Language: finding opposites. 3. Language: taboo. 4. Perception: following perception. 5. Perception: visual search. 6. Memory: remembering proverbs and grasping their meaning. 7. Memory: remembering packing a suitcase: What belongs in a suitcase? 8. Executive function: decision-making. 9. Executive function: findings words of specific semantic or phonematic categories. 10. Executive functions: identifying connections.	• Pocket booklets with pictures and verbal material.	**5. Perception: visual search** ***Lower difficulty level*** *The caregiver asks:* • Look around the room here. What things are useful to you? • Which things are bigger than a book? • Which things are smaller than a book? • What things can you carry with your hands? • Which things feel smooth/soft/firm/rough? ***Higher difficulty level*** *The caregiver asks:* • Look around the room. What things do you use every day? • What things are bigger than this pillow (point to the pillow)? • What things are smaller than this pillow? • What things are red/blue/green/etc.? • Which things feel soft to the touch?
Occupational exercises	*This module involves ten exercises, each with two difficulty levels:* 1. Relax hand muscles. 2. Independence: self-care 3. Independence: room care (own room, common room) 4. Calendar management. 5. Encourage contact: write postcards/letters. 6. Creativity: prayer 7. Creativity: diary management 8. Creativity: creative leisure 9. Creativity: geometric shapes 10. Creativity: painting (creative vs. supplemented by	• Balls. • Everyday objects. • Postcards. • Writing materials. • Diary. • Creativity materials.	**2. Independence: self-care** ***Lower difficulty level*** Care: Give the resident a wash cloth to clean areas, such as their arms, by themself. Alternatively, put some body lotion on their arms and have the resident rub the cream in. Eating: Pick up food with a fork or spoon and put it in the resident's hand so that they can bring the food to their mouth independently. ***Higher difficulty level*** Care: Have the resident brush their teeth. Alternatively, have the resident put on an item of clothing (e.g., pants or a top) themselves. Let the resident choose their outfit. Ask for a suitable color combination (in relation to the season). If needed, put a few matching outfit combinations

	tasks).		together on a suitable surface. Eating: Allow the resident to eat independently as much as possible. Offer assistance if needed. After the meal, have the resident put their tray in the trolley.
Multisensory stimulation	*This module involves ten exercises, each with two difficulty levels:* 1. Recognizing everyday objects. 2. Touching surfaces. 3. Touch exercise. 4. Tea smell exercise. 5. Scent exercise. 6. Auditory exercise animals. 7. Relaxation exercise. 8. Visual exercise. 9. Mindfulness practice I. 10. Mindfulness practice II.	• Everyday items. • Tote bag and items for exercise recognizing items via touch. • Olfactory material (e.g., tea bags, spices, etc.). • Music player and audio recordings (e.g., of animal sounds or from the internet).	**1. Recognizing everyday objects** ***Lower difficulty level*** Everyday objects that are already in the room are to be felt. For example, pens, cutlery, glasses, paper, and clothes hangers. The residents' task is to touch the objects and express their thoughts about them. Caregivers can ask questions like "do you know this object?", "do you know what it is?" and "how does it feel?" ***Higher difficulty level*** Everyday objects that are already in the room are to be felt. For example, pens, cutlery, glasses, paper, and clothes hangers. The residents' task is to feel and name the objects. Following this, a biographical reference can be made. Caregivers can ask questions like "what do you associate with this object?" and "did you use this object frequently in the past?"
Music therapy	*This module involves ten exercises, each with two difficulty levels:* 1. Active music making: singing folk songs. 2. Active music making: making music without instruments. 3. Active music making: making music with instruments. 4. Rhythm exercise: clapping exercise. 5. Rhythm exercise: sway exercise. 6. Active and passive listening: music memory training. 7. Active and passive listening: listening to music and reminiscing. 8. Active and passive listening: auditory memory exercise. 9. Active and passive listening: recognizing instruments. 10. Active and passive listening: passive music exercise.	• Music player. • Printed lyrics. • Everyday items. • Easy-to-use musical instruments (e.g., tone woods and rattles)	**7. Active and passive listening: listening to music and reminiscing** ***Higher difficulty level*** Well-known music/songs from different decades are played, and then thoughts, memories, and emotions about the music are shared. The caregiver will say, "I will now play a few songs. Afterward, I will ask you some questions about these songs." These questions will include "did you know this song?", "When was the last time you heard it?" and "do you associate certain memories or feelings with this music?" ***Lower difficulty level*** Well-known music/songs from different decades are played, and then the participants are asked whether they know the music. The caregiver will say, "I will now play a few songs. Afterward, I will ask you if you know these songs and if you like this music."
Physical activity	*This module involves ten exercises, each with two difficulty levels:* 1. Pressing a Pilates ball. 2. Strengthening with the loop band. 3. Holding up a balloon. 4. Balancing a rice bag. 5. Figure driving with a hedgehog ball. 6. Support and press. 7. Hedgehog ball massage. 8. Stork walk. 9. Mobilization with a Pilates ball.	• Balls. • Pilates balls. • Thera-Band. • Balloons. • Small bean bag. • Spiky massage ball. • Weights.	**10. Pressing a Pilates ball** ***Lower difficulty level*** Starting in the back position, the Pilates ball is taken between the knees and slowly squeezed. After approximately one second, the ball is released without letting it fall. The whole exercise is repeated 15 times. The exercise is then repeated with the ball between the hands. 

	10. Dribbling a Pilates ball.		***Higher difficulty level*** Starting in the seated position, the Pilates ball is taken between the knees and slowly squeezed. After approximately one second, the ball is released without letting it fall. This whole exercise is repeated 15 times. The exercise is then repeated with the ball between the hands and arms extended. 
Relaxation	*This module involves ten exercises, each with two difficulty levels:* 1. Journey through the upper body. 2. Journey through the lower body. 3. Journey through the trunk and head. 4. Pelvic clock. 5. Breath control. 6. Feeling heaviness. 7. Feeling warmth. 8. Progressive arm muscle relaxation. 9. Progressive leg muscle relaxation. 10. Straightening and breathing.	• Music player and relaxation music (e.g., from the internet). • Small bean bag, • Cherry pit pillow.	**8. Progressive arm muscle relaxation** ***Lower difficulty level*** Starting in the back position with the arms resting beside the body, the writing hand is clenched into a fist, and the tension is held for 5–10 seconds. The fist is opened, and the arms are rested for 30 seconds. The difference between tightening and relaxing is noted. The exercise is then repeated with the other hand. ***Higher difficulty level*** Starting in the seated position with hands resting on the thighs, the writing hand is clenched into a fist, and the tension is held for 5–10 seconds. The fist is opened, and the arms are rested for 30 seconds. The difference between tightening and relaxing is noted. The exercise is then repeated with the other hand and other muscle groups.

Note. All pictures show members of the working group and belong to the Department of Medical Psychology | Neuropsychology and Gender Studies, Faculty of Medicine and University Hospital Cologne, University of Cologne. The authors gained informed consent from all subjects to publish identifying information/images in an online open-access publication.

References. [1] Kitwood T. *Demenz: Der personenzentrierte Ansatz im Umgang mit verwirrten Menschen. Deutschsprachige Ausgabe herausgegeben von Christian Müller-Hergl.* Huber, 2000. [2] Rogers CR. *Die nicht-direktive Beratung.* Kindler Verlag GmbH, München, 1972. [3] Feil N, de Klerk-Rubin. *Validation. Ein Weg zum Verständnis verwirrter alter Menschen (11. Auflage).* Ernst Reinhardt Verlag, 2007.

Supplement 3. Structure and content of the CogStim24 training program for the nursing and care staff.

Session number	Topic	Duration	Type of session
0	Introductory session to introduce cognitive stimulation in PwD aims and content of the CogStim24 intervention, and structure of the training program,	90 min	Online
	1-week break & audio-recorded PowerPoint presentation: Topic 1a		
1a	Communication with PwD,	180 min	Online, interactive exercises
	1-week implementation phase: Topic 1a		
1b	Reflection.	90 min	Online
	1-week implementation phase: Topic 1a. Audio-recorded PowerPoint presentation: Topic 2a		
2a	Reality orientation and reminiscence therapy on "my life."	180 min	Face-to-face, interactive exercises
	1-week implementation phase: Topic 2a		
2b	Reflection.	90 min	Online
	1-week implementation phase: Topic 2a. Audio-recorded PowerPoint presentation: Topic 3a		
3a	Cognitive exercises ("brain training") and occupational exercises,	180 min	Face-to-face, interactive exercises
	1-week implementation phase: Topic 3a		
3b	Reflection.	90 min	Online
	1-week implementation phase: Topic 3a. Audio-recorded PowerPoint presentation: Topic 4a		
4a	Multisensory stimulation and music therapy.	180 min	Face-to-face, interactive exercises
	1-week implementation phase: Topic 4a		
4b	Reflection.	90 min	Online
	1-week implementation phase: Topic 4a. Audio-recorded PowerPoint presentation: Topic 5a		
5a	Physical activity & relaxation.	180 min	Face-to-face, interactive exercises
	1-week implementation phase: Topic 5a		
5b	Reflection. & final exchange session.	90 min	Online
			11 weeks in total

Abbreviations: PwD: people with dementia.

Supplement 4. Model consent form for people with dementia taking part in the pre-post-study (neuropsychological assessment only)

Part I: Information on participation in the study "Cognitive Stimulation in nursing homes"

Dear sir or madam,

we are delighted that you are interested in our study entitled "Cognitive stimulation in nursing homes" and would like to support us by taking part. In the following, we would like to inform you about the aims and the course of the study. We would like to explain why your participation is important. The study is being conducted for research purposes and is funded by the German Alzheimer Society.

We ask you to read this information carefully. You can then decide whether or not you wish to take part in this study.

Your participation in this study is voluntary. In order for you to participate in this study, we need your written informed consent. If you do not wish to participate or withdraw your consent later, you will not suffer any disadvantages.

The project staff have already provided you with information about the planned study. The following text is intended to inform you about the important aspects of the study. Please read the information letter carefully. Please do not hesitate to address any points that are unclear to you. You will be given sufficient time to think about your participation.

Study aim

The aim of this study is to develop and analyze a cognitive stimulation concept. Cognitive stimulation is often referred to "memory training". This concept should be able to be used at any time and includes, for example, conversation stimuli, stimulating materials, or exercises. This should enable nursing and care staff to carry out stimulating exercises with you at any time point in your everyday life. Cognitive stimulation is a collection of different exercises from different areas. Some examples are given below:

- Your personal life story is an important basis for discussions between you and nursing and care staff (biography work).
- Your senses (smell, touch, see, hear, feel) are stimulated using various methods and materials (multi-sensory stimulation).
- To improve your cognitive performance, e.g. to train your memory, proverbs and pictures are used (cognitive training).
- If possible, you will be involved in everyday tasks of the nursing home (everyday training).
- You will also be stimulated through musical activities such as singing or making music (music therapy).
- Relaxing exercises, breathing exercises, or fantasy journeys are used for relaxation (relaxation).
- Physical activity, i.e. sport, should promote your mobility and physical well-being (movement).

In addition, discussions should be held about your surroundings and everyday events in the nursing home or outside (reality orientation). Very importantly, in all the areas listed above, discussions between you and the nursing and care staff play a major role in the implementation of this new cognitive stimulation concept.

In the long term, the use of cognitive stimulation should lead to a stabilization of your cognitive abilities. It should also contribute to your quality of life. In order to be able to implement this concept in facilities,

we start with an 11-week training of the nursing and care staff, so that they are enabled to carry out the cognitive stimulation exercises with you and other residents.

In order to assess your overall mental abilities and well-being, you will be tested and interviewed at three different times. These three points at which you will be tested and/or interviewed are before the start of the study, during the study (at the end of the training, i.e. after 11 weeks) and after the end of the study (6 weeks after the end of the training).

The aim is to make this program accessible to as many nursing and care staff and residents in nursing homes as possible.

Nature of the study

We would like to use tests and questionnaires, which we will administer to you at three different time points, to find out whether the new cognitive stimulation program leads to individual changes. For example, we will analyze your cognitive performance (including memory and attention) and the quality of life you experience, as well as other aspects. We use various questionnaires and tests for this purpose, which we carry out with you using only paper and pencil. Completing the questionnaires and carrying out the tests takes about 60 minutes.

The Ethics Committee of the Medical Faculty of Cologne discussed and approved this study on November 16th, 2021.

Who can take part in this study?

People with mild cognitive impairment as well as people with mild or moderate dementia who are able to participate in the tests and questionnaires can take part in this scientific study. A total of four nursing homes will participate in the study, from which a total of 60 residents will be recruited to take part in the study. Subjects with more severe (physical and/or cognitive) disorders will be excluded, as this could distort the test results.

A written informed consent to participate in the study is required.

Possible risks/exposures/side effects associated with study participation

Study participation in the study is not associated with any medical risks for you. The only possible burden for you is the short-term stress caused by the tests and questionnaires. You may feel impatient or bored during the interview, and you may also experience symptoms of fatigue. In any case, you have the option of cancelling the interview at any time without giving a reason.

Possible benefits of study participation

To date, we are not aware of any cognitive stimulation programs that are applied 24 hours a day, 7 days a week. As there are currently many elderly people in Germany and the number continues to rise and more and more people are suffering from dementia, long-term inpatient care is playing an increasingly important role. The aim here is to offer residents a sufficient and varied supply of cognitively stimulating exercises.

Course of study participation

Socio-demographic and (neuro-) psychological aspects are analyzed as part of this study. We use various tests and questionnaires, which we carry out with you using only paper and pencil.

Before starting with the tests and questionnaires, we need your written informed consent. After that, we will start with some questions about yourself, such as your age, marital status, education, and occupation, and how long you have been living in the nursing home. We then start with a short neuropsychological test to of your cognitive abilities (e.g., your memory and attention performance). A questionnaire is then used to find out how you rate your quality of life. Finally, there is a short questionnaire to assess your mood.

Completing the tests and questionnaires takes about 60 minutes. We carry out this examination in a quiet, undisturbed environment of your nursing home. You can take breaks at any time if you wish.

In addition to your details and test results, we will ask nursing and care staff who knows you very well and is in daily contact with you to complete two further questionnaires about you. These are a questionnaire in which your mood is assessed from the point of view of the nursing and care staff, and another questionnaire in which your behaviour is assessed.

The data collected can later be used to record possible changes that the new cognitively stimulating exercises and conversations that accompany everyday life may have brought about. On completion of the examination, you can receive an overview of your results on request.

Data processing and data protection

The overall responsibility for this study lies with:

Medical Psychology | Neuropsychology and Gender Studies

Faculty of Medicine and University Hospital Cologne, University of Cologne

Univ.-Prof. Dr. Elke Kalbe

Kerpener Straße 62 · 50937 Cologne · Germany

☎ +49 221 478-6669 · ✉ elke.kalbe@uk-koeln.de

The data is analysed using statistical software once the data collection is complete. As part of the study, personal information about you will be collected and recorded in paper form and on electronic data carriers. After the interview, all study data will be processed exclusively in pseudonymised form (i.e., without mentioning your name or identifying data) within the participating study centres of the University Hospital of Cologne. Your identifying data (e.g., name, address, date of birth) will be stored separately from the study data and will remain at the respective study centre.

All information that we collect about you as part of the project is subject to the strictest confidentiality. It is stored securely in accordance with data protection regulations. The data is protected against unauthorised access. All data is stored securely in accordance with data protection regulations and will only be used for research purposes. You will not be recognisable as a participant in publications. Use in further scientific studies (secondary data analyses) and qualification work (e.g. doctoral theses) is planned.

The test documents are stored in pseudonymised form in a lockable cabinet on the premises of the Medical Psychology | Neuropsychology and Gender Study of the Faculty of Medicine and University Hospital Cologne of the University of Cologne. The test forms are labelled with abbreviations. The abbreviation consists of a random combination of numbers and letters (e.g. SH-369). The abbreviations are created automatically using a computer programme (Random ID Generator; http://www.brenz.net/)

and do not contain any personal information. For example, the initial letters of your first and last name are not used. The abbreviation is assigned to your name with the help of a so-called key list. This key list is stored independently of your study data in a lockable cabinet on the premises of the department of the Medical Psychology, University Hospital of Cologne. As soon as the data collection is completed, the key list will be destroyed. It will then no longer be possible to identify you personally.

The collected data will be destroyed after ten years in accordance with good scientific practice. The material will not be passed on to third parties. No documents containing personal or health-related information will be stored in online data backup systems (e.g. Dropbox, Google Drive, iCloud).

All persons - scientific project staff and contact persons in the cooperating care facilities - who have contact with you as a study participant as part of the study are obliged to maintain confidentiality. Compliance with the General Data Protection Regulation (GDPR) and the NRW State Data Protection Act is fully ensured. The collected and stored data of all participants will be kept confidential. This is also ensured in the event of scientific publication.

Are there any risks associated with data processing?

Any collection, storage, utilisation, and transmission of data involves confidentiality risks (e.g., the possibility of identifying the person concerned). These risks cannot be completely ruled out and increase the more data can be linked together. The study director/principal investigator assures you that he*she will do everything possible to protect your privacy in accordance with the state of the art and will only pass on data to organisations that can demonstrate a suitable data protection concept. You have the right at any time to receive information (including a copy free of charge) about the data concerning you and to request that data will be corrected or deleted.

Can I withdraw my written informed consent?

You can withdraw your written informed consent in writing or verbally at any time without giving reasons and without any disadvantage to you. If you withdraw your consent, no further data will be collected. However, the data processing carried out up to the point of withdrawal remains lawful.

In the event of withdrawal, all data will be deleted immediately or completely anonymised. However, this is only possible for as long as the key list still exists.

What other rights do I have in relation to data protection?

If you have any concerns regarding data processing and compliance with data protection requirements, you should primarily contact the study director/principal investigator of the study. You can also contact the following data protection officers:

Data Protection Officer of the University Hospital Cologne

Kerpener Straße 62 · 50937 Cologne · Germany

☎ +49 221 478-88008 · ✉ datenschutz@uk-koeln.de

Data Protection Officer of the University of Cologne

☎ +49 221 470-6370 · ✉ dsb@verw.uni-koeln.de

You also have the right to lodge a complaint with any supervisory authority for data protection. You can find a list of the supervisory authorities in Germany at https://www.bfdi.bund.de/DE/Infothek/Anschriften_Links/anschriften_links-node.html

The data protection supervisory authority responsible for this study is:

State Commissioner for Data Protection and Freedom of Information North Rhine-Westphalia

Postfach 20 04 44 · 40102 Düsseldorf · Germany

☎ +49 211 38424-0 · ✉ poststelle@ldi.nrw.de

Insurance for study participants

As a resident, you are insured through your nursing home. No further insurance cover is required.

Possible reasons for premature termination of the study

For the study participants (i.e. residents, nursing and care staff, nursing home management): Participants have the option to withdraw from the study at any time during the study, without giving reasons and without any disadvantage to them, if they personally wish to do so. No written statement is required. A verbal statement is sufficient.

Compensation for expenses and reimbursement of costs

Your study participation is not connected to any costs for you. You will be paid an expense allowance of €25 for your participation in the study.

Information about new findings

The project staff will also inform you within a reasonable period of time about any changes and other important information that becomes known during the study that could influence your consent to further participate in this study.

Do you have any further questions?

If you have any further questions about the course of the study, data protection, your rights, etc., please contact the study staff.

Part II: Consent form

General aspects

- I have received the information and have been informed about the nature, significance, scope and risks of the planned project. I have been given sufficient opportunity to clarify all open questions. I have the right to request further information about the study at any time.
- I voluntarily agree to participate in the study.
- I have the right to withdraw from the study at any time without giving reasons and without any disadvantages for me.

Data protection

In this scientific study, personal data about yourself will be collected. The storage, forwarding and evaluation of this data is carried out in accordance with legal regulations and requires the following voluntary consent before participation in the study:

1. I agree that data from neuropsychological tests and questionnaires, that have been collected during the study, may be recorded and forwarded to the sponsor of this study and/or the study director/principle investigator responsible for this study: Medical Psychology | Neuropsychology and Gender Studies, Faculty of Medicine and University Hospital Cologne, University of Cologne, Cologne, Germany.
2. I agree that my data will be stored in accordance with scientific standards for up to 10 years after completion or cancellation of the study. After that, my personal data will be deleted.
3. I have been informed that I can terminate my participation in the study at any time. In this case, any data already collected will be deleted or completely anonymized.
4. I have read the information on data protection and consent to the processing of my data.
   ☐ YES ☐ No

I have received the complete subject information for the study and a signed copy of this consent form.

[Location, date, name, and signature of the study participant]

I have conducted the informed consent discussion and obtained the consent of the study participant.

[Location, date, name, and signature of the project staff who conducted the informed consent discussion]