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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 dementia (PwD). Currently, cognitive stimulation is regularly offered as a group programme in care facilities. However, some residents, such as those who are bedridden, cannot participate. Furthermore, group programmes were not feasible during the pandemic. A concept that accompanies everyday life and enables cognitive stimulation in everyday communication (ie, '24/7') has been missing. Therefore, this feasibility study aims to (1) assess the feasibility of a new continuous 24/7 cognitive stimulation programme (CogStim24) based on a process evaluation and (2) examine the possible effects of CogStim24 on the primary outcome of global cognition in PwD and further PwD-related and staff-related outcomes.

Methods and analysis The complex CogStim24 programme 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-assessments and post-assessments, four nursing homes with a total of N=20 nursing and care staff will participate in an 11-week CogStim24 training programme. The intervention will be conducted to N=60 PwD. Neuropsychological assessments will be conducted pre-staff 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 multicentre cluster randomised 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 manuscripts presenting results of the different study parts will be published in peer-reviewed journals.

Trial registration number 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 programme development was based on a systematic review of cognitive stimulation techniques for people with dementia 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-assessments- and post-assessments; a large multicentre cluster randomised controlled trial will have to follow.

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 seventh-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 behavioural symptoms, leading to a 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 institutionalisation in later disease stages.[2]

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Symptomatic pharmacological treatment includes acetylcholinesterase inhibitors and memantine to stabilise 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 use different approaches. One approach is cognitive training, which involves standardised paper-and-pencil or computerised 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'). Randomised 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 behavioural symptoms,[6 8] and communication skills and social interaction.[6 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, programmes, such as cognitive stimulation therapy,[9] the multicomponent programme 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 programmes 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 programmes are conceptualised with a low frequency, intervention effects may lack sustainability. Also, many PwD cannot take part in such programmes due to being bedridden or because the nursing home lacks resources to provide cognitive stimulation (eg, 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 (eg, 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 programme (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 programme for conducting CogStim24 and evaluating promoting and inhibiting factors of the intervention's implementation (ie, 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 behavioural 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 (Standard Protocol Items: Recommendations for Interventional Trials) guidelines for the minimum content of a clinical trial protocol.[18] See online supplemental file 1 for the SPIRIT checklist.

Design/methodology

Study design

This study was conceptualised as an uncontrolled, non-masked, single-arm study involving pre-assessments and

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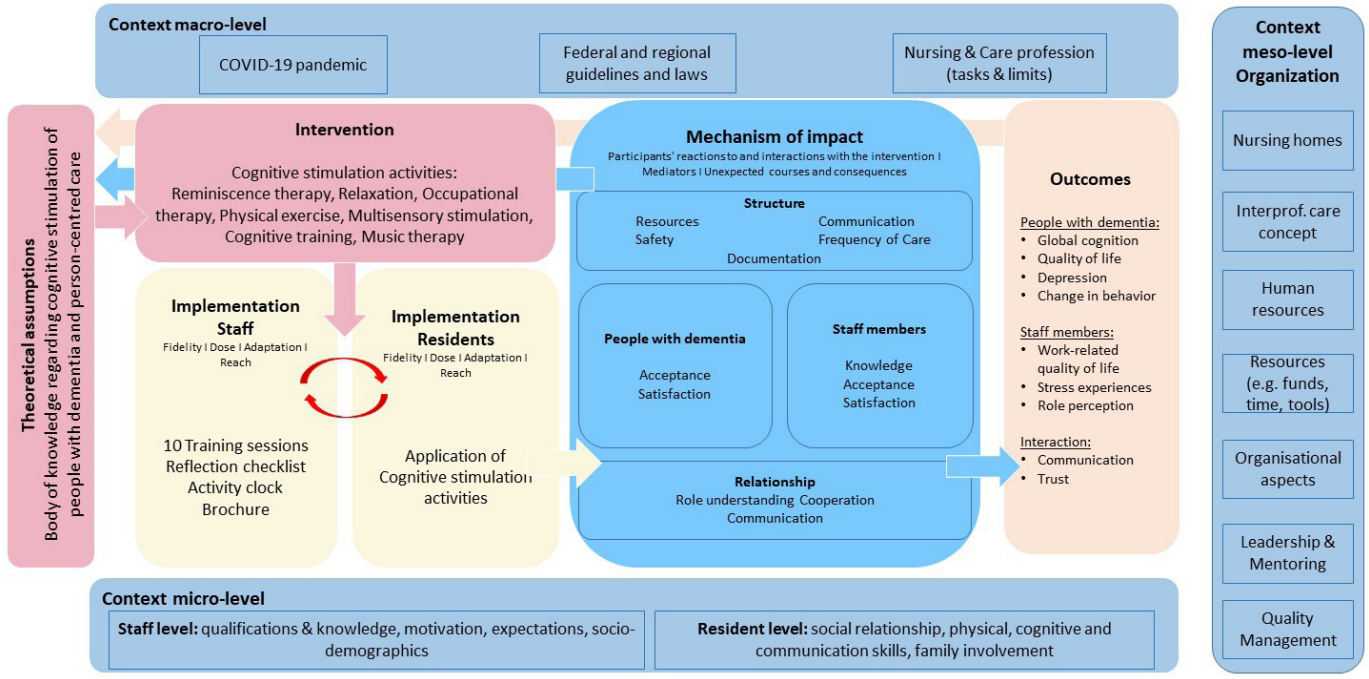


Figure 1 Logic model for CogStim24.

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 preintervention and postintervention 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).

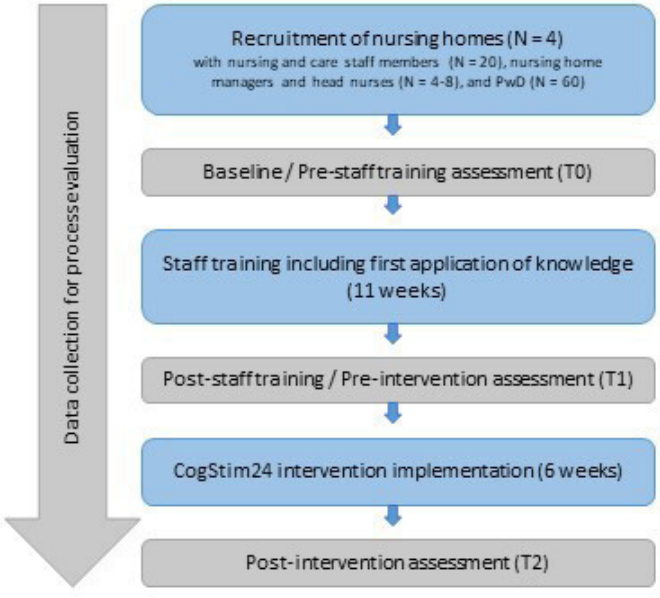


Figure 2 Overview of the study process. PwD, people with dementia.

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 programme, the staff will implement CogStim24 stimulation techniques step by step in their everyday work routine so that they are able to implement the full programme at the end of the training period. To investigate whether the protocol for the quantitative preintervention and postintervention assessments is feasible and to gain evidence for effects as a basis for a future cluster RCT, neuropsychological tests and questionnaires will be administered to the participants (PwD and nursing and care staff) 2 weeks before (T0), immediately after the 11-week training programme (T1) and 2 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. The first patient-in was in May 2022. Data collection was finished by the end of 2023.

CogStim24 intervention

CogStim24 was developed as a cognitive stimulation programme 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

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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 programme. The development of the CogStim24 programme was based on several elements which all considered this main challenge:

- The authors' expertise in developing cognitive intervention programmes[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 programmes, 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 (1) 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 (2) 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 who are bedridden. CogStim24 is expected to stabilise 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 programme consists of a large body of exercises that can be categorised under several cognitive stimulation techniques: reminiscence therapy, cognitive training, occupational exercises, multisensory stimulation, music therapy, physical exercise and relaxation. In addition, patient-centred communication and reality orientation techniques are basic concepts of the programme and are considered integral parts of all exercises. Each block of stimulation techniques contains 10 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 online supplemental file 1. 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 (eg, for completing proverbs) and materials for physical exercises (eg, a ball and a resistance band). Nurses and care staff are encouraged to collect autobiographical information and the corresponding material, such as photos or belongings with personal value, for each resident and place it into the room for use within the CogStim24 programme. 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 programme following the TIDieR (Template for Intervention Description and Replication) guidelines[23] is displayed in table 1.

Training programme 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 programme, 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, that is, the implementation into everyday care, can be overcome in the 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

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Table 1 CogStim24 programme overview based on the TIDieR guidelines

What? Procedures, tailoring and modifications	Why? Rationale and theory	What? Materials	How? Where? Modes ofdelivery	Who? Intervention provider	When and how much?
Procedures Staff training: Nursing and care staff receive an 11-week training programme (max. 3 hours/week; cf. (online 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-centred 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 programmes. Tailoring: Cognitive interventions are most effective when underextensions and overextensions are avoided. That is why two difficulty levels are part of the CogStim24 programme.	► Manual for nursing and care staff. ► An 'activity clock' indicates all possible activity domains. ► Material in each resident's room (eg, booklets with images and resistance bands). ► If possible, autobiographic information and material relating to the resident will be placed in their rooms (eg, 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 programme. *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.

.PwD, people with dementia; TIDieR, Template for Intervention Description and Replication.

meetings, as well as five 30 min 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 1 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 practised interactively. This is followed by a 1-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 they 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'.

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- 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 online supplemental file 1. Based on the still uncertain pandemic situation, all face-to-face meetings are prepared in a way 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 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 (eg, 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 was 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 drop-out 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 preintervention and postintervention 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 SD 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 2 weeks before staff training begins (T0), immediately after staff training (T1) and within 2 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 by the time points of assessments.

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 operationalised with the Mini-Mental State Examination[26 27] and the Alzheimer's Disease Assessment Scale–Cognitive Subscale.[28] Secondary outcomes include PwD' quality of life assessed with the Quality of Life in Alzheimer's Disease Nursing Home Version[29 30] questionnaire for self-assessment and proxy ratings; depression in PwD measured with the Geriatric Depression Scale[31] for self-assessment and the Cornell Scale for Depression in Dementia[32] as a proxy rating; BPSD operationalised with the Neuropsychiatric Inventory Nursing Home Version[33 34] for a proxy rating; and the residents' challenging behaviour-related distress

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

	Study period			
	Enrolment	Postallocation		
Time point	Prestudy	Before staff training (T0)	After staff training (T1)	After the implementation phase (T3)
Enrolment:				
Eligibility screen	X			
Informed consent	X			
Intervention:				
CogStim24		◆———	———	———◆
Assessments:				
Demographics and clinical data	X			
Global cognition (MMSE and ADAS-Cog)		X	X	X
Quality of Life (QoL-AD)		X	X	X
BPSD (NPI-NH)		X	X	X
Depression (GDS and CSDD)		X	X	X
Work-related Quality of life/ Stress experience (RCB-related Distress Index)		X	X	X

ADAS-Cog, Alzheimer's Disease Assessment Cognitive Scale; BPSD, behavioural and psychiatric symptoms in dementia; CSDD, Cornell Scale for Depression in Dementia; GDS, Geriatric Depression Scale; RCB-Related Distress Index, Residents' challenging behaviour Related Distress Index; MMSE, Mini-Mental State Examination; NPI-NH, Neuropsychiatric Inventory Nursing Home Version; QoL-AD, Quality of Life in Alzheimer's Disease; SPIRIT, Standard Protocol Items: Recommendations for Interventional Trials.

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. Pseudonymised clinical data collected during the trial will be anonymised and made available on 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 (V.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 SDs 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). Multiple imputation approaches will be used for sensitivity analysis, potentially considering not-missing-at-random 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 (1) the systematic review of the characteristics of cognitive stimulation interventions, (2) the survey on current practice of cognitive stimulation in nursing homes, (3) 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, (4) the process evaluation of the CogStim24 implementation and (5) 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).

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- Context factors (microlevel, mesolevel and macrolevel).
- 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 analysed. Qualitative data (interviews and focus groups) will be analysed 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 analysed 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 summarised.

Patient and public involvement

For the development of the CogStim24 programme, 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 organisation for PwD and their relatives in Germany, at the beginning of the project and before finalising 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 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 online supplemental file 1. 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 programme 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 programme. 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 programme 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 sensitised 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 programme as a 24-hour everyday approach in nursing homes. If the implementation of the CogStim24 staff training and programme and study protocol is successful, this study has the potential to serve as a basis for a large multicentre 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.

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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
	► *Organisational Readiness for Implementing Change questionnaire*[38] *to provide a description of cluster facility culture.* ► *Person-centred climate (staff version) questionnaire.*[39] ► *Assessment of Interprofessional Team Collaboration Scale questionnaire.*[40] ► *Index for the stress of staff in inpatient geriatric care facilities due to changes in the behaviour 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 programme module during staff training.	T1, T2	
Implementation of the intervention components in daily care and reactions of the study participants	► Focus group interviews with N=4 staff members: Process adaptations within the context of the intervention (eg, cooperation between social services and nursing services, and facility staff); Total: N=4	T2	

Continued

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Table 3 Continued

Parameter	Material	Measurement time points	Process evaluation elements
Reactions of study participants	► 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 programme 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

.PwD, people with dementia; RCB, residents' challenging behaviour.

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 programme itself are 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 programme 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

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the programme 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.

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

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Competing interests A-KF 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.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

Provenance and peer review Not commissioned; externally peer reviewed.

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Supplement 1. SPIRIT 2013 checklist.

Section/item	Item No	Description
Administrative information		
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry
	2b	All items from the World Health Organization Trial Registration Data Set
Protocol version	3	Date and version identifier
Funding	4	Sources and types of financial, material, and other support
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors
	5b	Name and contact information for the trial sponsor
	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
	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)
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
	6b	Explanation for choice of comparators
Objectives	7	Specific objectives or hypotheses
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)
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
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)
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered
	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)
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial
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
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)
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
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size
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
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
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial

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
	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
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
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
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)
	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)
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
	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
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
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor
Ethics and dissemination		
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval
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)
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)

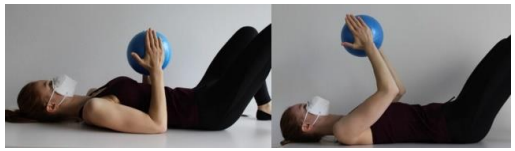
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site
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
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
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
	31b	Authorship eligibility guidelines and any intended use of professional writers
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code
Appendices		
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates
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

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 regarding 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, avoid 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 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, pens, 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 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,

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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.

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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]

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