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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]

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

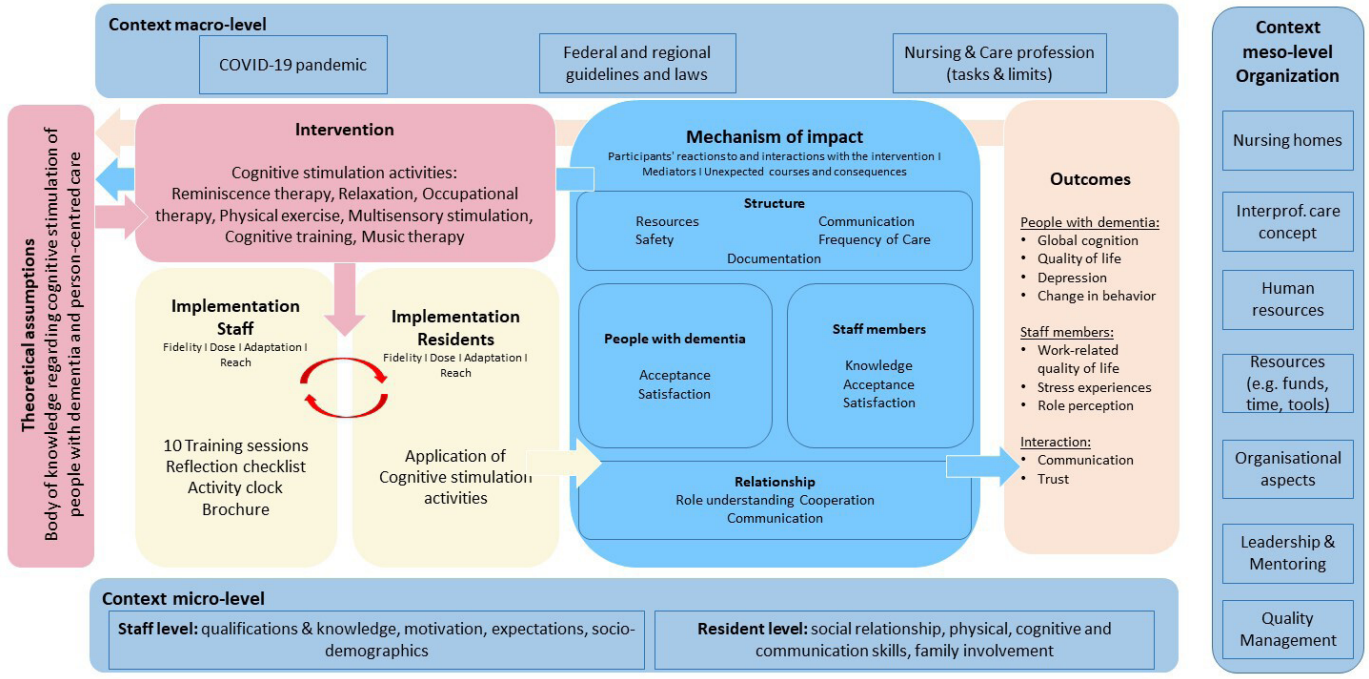

Figure 1 Logic model for CogStim24.

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).

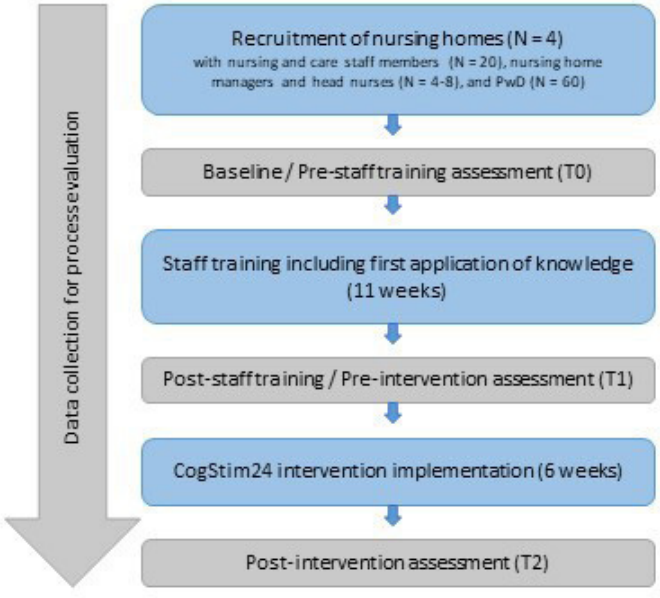

Figure 2 Overview of the study process. PwD, people with dementia.

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

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

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'.

- 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

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).

- 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.

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

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

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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