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of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention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)

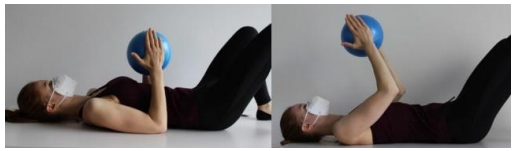
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality 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,

Folkerts A-K, *et al. BMJ Open* 2024; 14:e078369. doi: 10.1136/bmjopen-2023-078369

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.

Folkerts A-K, *et al. BMJ Open* 2024; 14:e078369. doi: 10.1136/bmjopen-2023-078369

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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