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Prevalence of delirium in German nursing homes: protocol for a cross-sectional study

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ABSTRACT

Introduction Delirium is a neuropathological syndrome that is associated with several negative outcomes. Nursing home residents are vulnerable to developing delirium. Valid prevalence data and associated factors are not yet available for Germany. Therefore, the aim of the prevalence study of the DeliA project (Delirium in Nursing Homes) is to assess the prevalence of delirium and its associated factors in 750 nursing home residents.

Methods and analysis Trained registered nurses from each participating nursing home will collect the data in a multicentre cross-sectional study. The inclusion criteria for residents are valid informed consent, age ≥65 years and sufficient language skills. The exclusion criteria are aphasia, coma, deafness or end-of-life status. The 4 'A's Test will be used as the primary measurement. Delirium motor subtypes will be determined using the Delirium Motor Subtype Scale. Covariables for associated factors, including functional impairments, pain, cognitive status and nutritional status, are assessed through standardised measurements. Moreover, data such as prescribed drugs or medical diagnosis, hearing impairment or falls will be assessed from the nursing records. Furthermore, the Drug Burden Index will be calculated, and associated factors will be determined using a logistic regression model. The period for data collection in participating nursing homes is planned for 2 consecutive weeks in April 2024.

Ethics and dissemination This study was approved by the Ethics Committee of Witten/Herdecke University (no. 82/2023). Findings will be published in peer-reviewed journals and presented at conferences.

Registration https://osf.io/xkfvh/ (DOI 10.17605/OSF.IO/XKFVH).

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The expected sample size will be one of the largest worldwide using primary research data compared with prevalence studies already conducted in nursing homes.
⇒ Planned data collection from 750 residents, including a maximum of 15 randomly selected residents in each participating nursing home.
⇒ Use of the 4 'A' Test, a well-validated tool for delirium screening, through trained nursing staff for each nursing home.
⇒ The gold standard, the Diagnostic and Statistical Manual of Mental Disorders (DSM-5-TR), will not be used to assess delirium in nursing home residents

INTRODUCTION

Delirium is a neuropathological syndrome that negatively affects perception, consciousness and cognitive performance. It derives within short time spans, and the course of the syndrome often fluctuates.[1] The genesis of delirium is multifactorial.[2–4] Predisposing and precipitating risk factors include advanced age, dementia, functional impairment, malnutrition, infections[5] or polypharmacy as well as a high anticholinergic and sedative load, as expressed in the Drug Burden Index.[6] The relationship between pain medication and pain management and delirium is unclear.[4] Delirium is associated with several negative outcomes, such as prolonged hospital stays, risk of institutional placement, incomplete functional recovery, dementia, morbidity and mortality.[7–9] Moreover, falls, pressure ulcers and dehydration are associated with negative events if delirium is present.[10 11] At the same time, delirium is a major cause of distress for patients, caregivers and healthcare providers.[12–15]

For persons at risk, it is recommended to observe them on a daily basis to recognise changes or fluctuations indicating delirium. Informants can be carers or relatives. If indicators of a delirium are recognised, appropriate tools should be used to assess the delirium.[16]

Nursing home residents in particular have a high risk of delirium because they have multiple risk factors.[17 18] At the same time, delirium and its symptoms are often underrecognised in nursing home residents.[19]

Literature reviews have demonstrated that, depending on different populations and study designs, there is high heterogeneity in the prevalence of delirium, ranging

from 1% to 70%, in nursing homes.[20 21] Studies with valid measurements to collect primary data for the estimation of delirium prevalence and associated factors in German nursing homes are not yet known. The aim of the proposed study is to assess the prevalence of delirium and its associated factors through a multicentre cross-sectional study. The following research questions are guiding the study:

1. What is the prevalence of delirium and its subtypes in residents of German nursing homes?
2. Which factors are associated with the occurrence of delirium in residents of German nursing homes?

METHODS AND ANALYSIS

Study design

The prevalence and associated factors are estimated within a multicentre cross-sectional observational study in nursing homes in the federal state of North Rhine-Westphalia in Germany. The study is part of the DeliA (Delirium in Nursing Homes) consortium project (https://delia.info).[22] The data collection takes place from 15 April to 28 April 2024.

Patient and public involvement

The residents of the nursing homes were not included in the design of the study. There are also no plans to involve residents in the further steps of the study.

Setting and participants

Cluster level

All nursing homes in the federal state of North Rhine-Westphalia in Germany according to paragraph 71, (2) SGB XI[23] that have at least 50 residents and do not exclusively care for specific groups of residents (eg, residents in a coma) can participate.

Resident level

Residents ≥65 years who receive long-term care can participate if they understand German sufficiently to answer the questions of the rater. To participate in the study, residents or their legal representatives must sign an informed consent form. Residents with end-of-life status, in a coma, with deafness (despite aids) or aphasia will be excluded.

Nurse level

Registered nurses who participate as raters in the DeliA prevalence study need to have at least 3 years of professional education, which is standard in Germany. They are responsible for the recruitment of participants and data collection. Before the empirical phase starts, a 1-day education session is mandatory, with knowledge transfer related to delirium and study management.

Recruitment

The objective is to recruit 50 nursing homes. Potential facilities are recruited via e-mail, telephone and trade journals. The start of the recruitment phase of the nursing homes was September 2023. In each nursing home, the aim is to recruit 15 residents by random selection. The selection phase began in February 2024 and will continue until the start of the data collection period in April 2024. Each participating nursing home creates a fixed list, numbered in ascending order, of all long-term care residents living in the nursing home on a reference day. This forms the starting point for the selection procedure of potential participants within the study. The research team is informed only about the number of residents without identifiable information. At the research centre, these numbers will be randomly listed for each nursing home. Subsequently, the first 30 random numbers will then be added to a recruitment list and sent back to the nursing home. The rater then assigns the residents on the recruitment list according to their numbering and starts recruitment with the individual at the top of the list, proceeding to the individual at the bottom. If there are reasons for exclusion, a resident does not want to participate or is no longer available (eg, due to removal or hospitalisation), the next resident on the list is checked for eligibility and asked to participate until 15 eligible residents in each nursing home agree to participate. If the initial 30 random numbers are not sufficient for the recruitment process, an additional 10 numbers can be requested from the study team multiple times until all numbers from a nursing home have been sent. The raters of each participating nursing home are responsible for informing the residents or their legal representatives about the study and obtaining informed consent.

Data collection

For the data collection, registered nurses from participating nursing homes recruit residents and collect the data. The data collection starts when the signed informed consent of the participant is available.

Educational training

The DeliA study team developed a 1-day training for the raters. The training will be conducted in four different locations of the federal state of North Rhine-Westphalia. The training includes three modules: (1) study management (random selection procedure, handling of the computerised recruitment list, eligibility criteria, obtaining informed consent, handling of all measurements for data collection and especially for the primary measurement with case studies, carrying out the data collection, data security issues and transfer of collected data to the study team); (2) medical knowledge transfer regarding delirium (pathogenesis, symptoms, risk factors and differential diagnoses of dementia, depression and psychosis) and (3) pharmacotherapeutic knowledge (neurophysiological effect of drugs and groups of drugs with deliriogenic potential). If the raters are unable to participate in one of the planned training sessions, additional online training or in-house training will be offered through the study team. Furthermore, the raters will be given a training manual that describes the processes of the study and contains instructions on how to carry

out the measurements. In addition, the study team can be contacted via telephone or email for questions throughout the entire duration of the study. The training will be conducted by members of the research team, consisting of a general practitioner with several years of clinical experience in the treatment of nursing home residents, a pharmacist and a team of nursing scientists who also possess clinical expertise in managing delirium.

Process of data collection

The data will be collected using standardised forms via 'Paper & Pencil'; data on medication will be taken from the records of the nursing home residents (copies or printouts). The raters prepare themselves for the data collection in terms of analysing the nursing records and exchange with nurses who are most familiar with the participating residents to obtain all the necessary information for successful data collection. The data collection period is planned in two phases. The first phase begins with measurements based on the assessments of the 15 participating residents in each nursing home (primary measure delirium and delirium subtype, secondary measures functional impairments, pain, cognitive impairments, neuropsychiatric symptoms, malnutrition). During the first 5 days of the data collection period, the raters can carry out the measurements at any time. If the primary measure is assessed for a participant, all further assessments need to be carried out immediately afterwards. When measurements are assessed, the second phase of data collection takes place. The raters then collect data from the residents' nursing records. If medication plans cannot be copied or printed, the information is also collected using standardised forms ('Paper & Pencil'). Only data from the nursing records that were recorded up to the day on which the assessment was performed are considered.

To describe the characteristics of the raters, sociodemographic data will be assessed.

To describe the characteristics of the participating nursing homes, corresponding structural data such as sponsorship or number of living areas of the facilities will be collected.

Primary measures

Delirium will be assessed using the 4-'A's Test (4AT).[24] The 4AT is proxy-rated and consists of four items—(*1) Alertness, (2) Abbreviated Mental Test-4,*[25] *(3) Attention (using Month Backwards Test)*[26] *and (4) Acute change or fluctuating course*—and creates a sum score of 0–12. A score of 0 indicates that delirium or cognitive impairment is unlikely (but still possible), a score of 1–3 points indicates possible moderate to severe cognitive impairment, and a score of 4 points or above indicates possible delirium.[24] The measurement showed good diagnostic results with a pooled specificity of 88% and a pooled sensitivity of 88%.[27]

If the 4AT screening is positive (≥4), the Delirium Motor Subtype Scale (DMSS) will be applied.[28] The DMSS is proxy rated and consists of 11 items: (*1) Increased quantity of motor activity, (2) Loss of control of activity, (3) Restlessness, (4) Wandering, (5) Decreased amount of activity, (6) Decreased speed of actions, (7) Reduced awareness of surroundings, (8) Decreased amount of speech, (9) Decreased speed of speech, (10) Listlessness and (11) Reduced alertness/withdrawal,* which are rated as present or absent. Items 1–4 are classified as hyperactive symptoms, and items 5–11 are classified as hypoactive symptoms. If at least two of the first four items are answered as positive, a hyperactive subtype can be identified. When items 5 or 6 are answered positively and there are at least one or more items from items 7 to 11, it is considered a hypoactive subtype. A mixed type can be identified if the criteria for the hyperactive and hypoactive subtypes are met. No subtype can be classified if the criteria for any subtype are not fulfilled.[28]

Secondary measures

To record residents' functional impairments, the Physical Self Maintenance Scale (PSMS), a proxy-rated measurement with items relating to activities of daily living (ADLs), will be used.[29] The items (*1) Toilet, (2) Feeding, (3) Dressing, (4) Grooming, (5) Physical ambulation and (6) Bathing* for the ADLs domain are rated on a scale ranging from not dependent to completely dependent.[29]

The Numerical Rating Scale for pain (NRS) is a self-rated measurement with a score ranging from 0 to 10. Higher ratings indicate greater pain. The measurement was validated in different settings.[30 31] The NRS is reported to be valid, reliable and appropriate in clinical practice.[32] In this study, only participants who are able to provide information from their perspective based on the judgement of the rater will be asked to rate their pain.

To assess pain from the proxy-rating perspective, the German Version[33] of the Pain Assessment in Advanced Dementia[34] will be used for all residents. The scale consists of five items: (*1) Breathing, (2) Negative vocalisation, (3) Facial expression, (4) Body language* and (*5) Consolability.* To rate the items, behaviour needs to be observed at rest or in a mobilisation process. A total score between 0 and 10 points can be determined.[34] A score of ≥2 indicates the presence of probable pain.[35] To compare the results between participants, in this study, we decided to rate the pain exclusively at rest.

The Dementia Screening Scale (DSS) will be applied to assess residents' cognitive impairments. The DSS was developed as a proxy-rated measurement for registered nurses.[36] The scale includes two domains of cognitive functioning (memory and orientation) and consists of seven items: (*1) Did he/she recognise friends/relatives/staff, (2) Did he/she know friends/relatives/staff by name, (3) Could he/she remember what happened in the past few days, (4) Does he/she confuse people, and does he/she not know where he/she is, (5) Could he/she orient himself/herself in his/her room, (6) Could he/she orient himself/herself in the home/living area and (7) Could he/she orient himself/herself in the neighbourhood of the home?* A total score between 0 and 14 points is possible. Higher scores indicate more severe cognitive impairment.

The cut-off that has proven to be most suitable for identifying people with dementia syndrome in nursing homes is≥3 points.[36]

Neuropsychiatric symptoms will be assessed using the Neuropsychiatric Inventory-Questionnaire (NPI-Q),[37] a short form of the Neuropsychiatric Inventory.[38] The survey with the NPI-Q is a proxy-rated measurement and consists of 12 items: (*1) Delusions, (2) Hallucinations, (3) Agitation/aggression, (4) Dysphoria/depression, (5) Anxiety, (6) Euphoria/elation, (7) Apathy/indifference, (8) Disinhibition, (9) Irritability/lability, (10) Aberrant motor behaviours, (11) Night-time behavioural disturbances and (12) Appetite/eating disturbances*. The rating refers to the presence of symptoms. The severity of the symptoms can be scored between 0 and 36 points (total score).[37]

The nutritional status of participants will be assessed using the revised short form of the validated Mini Nutritional Assessment (MNA)[39]—the MNA short form (MNA-SF).[40] The revised short form has seven items: (*1) Has food intake declined over the past 3 months due to loss of appetite, digestive problems, chewing or swallowing difficulties? (2) Weight loss during the last 3 months, (3) Mobility, (4) Have you suffered psychological stress or acute disease in the past 3 months? (5) Neuropsychological problems, (6) Body Mass Index (BMI) (weight in kg)/(height in m²) and (7) Calf circumference (CC) in cm*. The MNA-SF scale ranges from 0 to 14 points (12–14 points: normal nutritional status, 8–11 points: risk of malnutrition, 0–7 points: malnutrition).[40] To compare the results across all nursing homes more accurately, we decided to assess only CC rather than BMI.

The raters will be collecting further information, such as age, sex or medical diagnoses, based on the available nursing records of the participating residents (table 1).

In addition, data on each prescribed medication will be recorded based on the items of the German Federal Standardised Medication Plan[41] (table 2).

Bias

Residents in the facilities will be recruited on the basis of a random sample, which avoids a greater selection bias. However, bias may arise during the recruitment phase in connection with the recruitment list, for example, due to incorrect allocation of residents to the recruitment list or a non-chronological selection process of residents. To minimise this bias, the raters were trained in the use of the list (*see educational training*). Furthermore, the research team will provide the recruitment list with the random numbers, and only the first 30 numbers on each list will be sent back to each nursing home. The risk of bias is, therefore, considered low. Further bias can arise through the assessment of the residents by the raters themselves. The evaluation of very well-known residents in nursing homes may lead raters to make subjective judgements during data collection. However, training for the rater in the correct use of the assessments will also help to reduce the scope for discretion and thus minimise potential observer bias.

Sample size calculation

The sample size calculation was conducted in accordance with Bujang *et al*,[42] who proposed estimating the prevalence with logistic regression models including covariables. The calculation was undertaken for a final regression model with up to 11 relevant covariables. This leads to a necessary sample size of n=650 residents for the present study. To compensate for potential drop-out,

Table 1 Nursing records data

Definition of items	Number of items	Empirical measure
Sex of resident	1	Female/male or non-binary
Year of birth	1	Date (year)
Move-in date in actual nursing home	1	Date (month/day/year)
Family status of resident	1	Single/married/divorced/widowed or other (free-text)
Care level according to Long Term Care Insurance SGB XI	1	No degree of care/degree of care: 1, 2, 3, 4 or 5
Stationary hospital stay(s) of resident in the past 3 months	1	Yes*/no *Period of each hospital stay (free-text)
Vision impairment and hearing impairment (with hearing aid)	2	Yes/no
Fall(s) in the past 3 months in nursing home	1	Yes/no/unable to specify
Measures to deprive of freedom in the past 4 weeks in nursing home (multiple selections possible)	1	Bed rails/belt restraint/other (free-text)/none/unable to specify
Presence of feeding tube	1	PEG/PEJ/other (free-text)/none
Presence of urinary catheter	1	Suprapubic/transurethral/none
Infectious disease(s) with date of onset	1	Free text
Selected medical diagnoses (multiple selection possible)	1	Dementia/depression/Parkinson and/or hypertension
All medical diagnoses with ICD code (if available)	1	Free-text

ICD, International Classification of Diseases; PEG, percutaneous endoscopic gastrostomy; PEJ, percutaneous endoscopic jejunostomy; SGB XI, Sozialgesetzbuch XI - Pflegeversicherung.

Table 2 Medication data based on nursing records

Data for each prescribed medication	Number of items	Empirical measure
Drug and trade name	2	Free-text
Strength and unit	1	Strength (free-text) and µg/mg/g/mL/dL or I.E.
Form	1	Tablet/Sachet/Capsule/Spray/Powder/Paste/Ointment/Cream/Gel/Juice/Suppository/Drops/Solution/Liquid/Chewable tablet/Effervescent tablet/Plaster/Probe or Injection
Interval of intake (multiple selection possible)	1	Morning/midday/evening and/or night
Other interval of intake	1	Before eating/after eating/hourly/daily/weekly/monthly/when required/one time/two times/three times/four times/every 2 weeks/every 3 weeks/one time a week/two times a week/three times a week /every 2 days/every 3 days/every 4 days/every 2 hours/every 4 hours/every 6 hours/every 8 hours/every 12 hours/two times a day/three times a day or four times a day
Start of medication	1	Date (free-text)
On-demand medication	1	Yes/no

an additional 100 residents will be recruited. To reduce possible cluster effects, data from a maximum of 15 residents per participating nursing home will be collected. This means that participation is needed from at least 50 nursing homes for the prevalence study.

Statistical analysis

Descriptive analysis for continuous variables will be based on the calculation of the mean (±) and SD for normally distributed data or the median and IQR for non-parametrically distributed data. Categorical variables will be calculated as absolute numbers (n) and percentages (%). For the respective variables, appropriate parametric comparisons will be made between the residents with delirium and residents without delirium to determine significant differences. If the data are not normally distributed, non-parametric tests will be used.

For continuous variables such as the PSMS score and NRS score, the independent t-test or the Mann-Whitney U test will be used. Categorical variables, such as vision and hearing impairment, will be compared between the two groups using the χ^2 test or Fisher's exact test, depending on how many observations were made in each category.

Univariate regression analysis will be used to evaluate the associations between the variables and delirium.

Variables identified as significant will be included in a multivariable regression analysis to determine whether there is an independent association between delirium and these variables. If suitable, additional variables will be selected based on research results from similar studies. The significance level for the results will be set at 95% ($p<0.05$).

Further variables will be determined based on the medication data. The German Drug Burden Index will be calculated according to the Drug Burden Index developed by Hilmer *et al*,[43] taking drug dosages into account and applying the list of Kiesel *et al*[44] for the German drug market as described recently.[45] In addition, use of potentially inappropriate medications according to the PRISCUS (PIM) list version V.2.0[46] will be assessed. To record polypharmacy (≥5 pharmaceuticals), the number of medications for each resident will be computed. For this calculation, regular medication as well as medication as needed will be considered.

DISCUSSION

This will be the first study to present valid prevalence data regarding delirium and associated factors in German nursing homes. Moreover, the expected sample size will be one of the largest worldwide compared with prevalence studies already conducted in nursing homes.[47–50] A major strength of this study is that a maximum of 15 residents in each nursing home will be randomly selected. This may reduce the influence of organisational-specific and population-specific variables. Furthermore, a strength is the use of validated assessments as primary measures and the comprehensive training of registered nurses as raters in the participating nursing homes. This ensures that the data collection will be conducted by rater who are familiar with the environment, residents and colleagues. This can support the data collection.

To our knowledge, this will be the first study to analyse the association between DBI scores and delirium in German nursing home residents. Previous studies across different settings revealed polypharmacy as a relevant factor.[6 43 51] As the DBI reflects the anticholinergic and sedative properties of drugs, this measure should be more specific than simply counting the number of drugs used. Katipoglu *et al*[6] recently demonstrated an association between DBI and delirium in ambulatory patients with dementia.

As a limitation, the Diagnostic and Statistical Manual of Mental Disorders V (DSM-V),[1] the gold standard for delirium diagnosis, will not be used. Instead, the 4AT was chosen because of the good psychometric properties[27] and fast and easy administration. However, the 4AT may

overestimate delirium in people with dementia because of overlapping symptoms.[50] But currently, there is no instrument that is superior to the 4AT in terms of practicability and validity in this cohort. Furthermore, fluctuating symptoms are common for delirium; therefore there is a risk that delirium patients will not be identified.[52] In addition, the selected study design involved only a single delirium assessment for each participant at a specific time, which makes identification even more difficult. However, the 4AT allows measurement of fluctuating symptoms using evidence from anamnesis. In addition, the nursing home setting promotes an existing information history from residents. Another limitation is, that with the design of a prevalence study, delirium episodes that do not occur at the time point of assessment, are not detected. This is why prevalence studies may under-report delirium.

With our results, we expect to provide new evidence on delirium for the development of interventions for the nursing home setting and for the improvement of professional care.

Ethics approval and dissemination

The Ethics Committee of Witten/Herdecke University approved this study (no. 82/2023). Participants will receive written and oral information about the study from the nurses in the nursing homes. To participate in the study, written informed consent is necessary for residents. From residents with a legal representative, a written informed consent of them is needed to participate. Nurses who serve as raters also have to sign the informed consent. Information about the option to withdraw consent at any time will be given. The authors confirm that all steps in the study will be performed in accordance with the regulations of the Declaration of Helsinki.

The findings of the study will be disseminated in peer-reviewed publications in journals and will be presented at conferences.

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