

BMJ Open Analgesic use, pain and daytime sedation in people with and without dementia in aged care facilities: a cross-sectional, multisite, epidemiological study protocol

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To cite: Tan ECK, Visvanathan R, Hilmer SN, *et al*. Analgesic use, pain and daytime sedation in people with and without dementia in aged care facilities: a cross-sectional, multisite, epidemiological study protocol. *BMJ Open* 2014;**4**:e005757. doi:10.1136/bmjopen-2014-005757

► Prepublication history for this paper is available online. To view these files please visit the journal online (<http://dx.doi.org/10.1136/bmjopen-2014-005757>).

Received 22 May 2014
Accepted 27 May 2014



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ABSTRACT

Introduction: People living with dementia may experience and express pain in different ways to people without dementia. People with dementia are typically prescribed fewer analgesics than people without dementia indicating a potential difference in how pain is identified and treated in these populations. The objectives of this study are to (1) investigate the prevalence of analgesic load, pain and daytime sedation in people with and without dementia in Australian residential aged care facilities (RACFs), and (2) investigate the clinical and diagnostic associations between analgesic load, pain and daytime sedation in people with and without dementia in Australian RACFs.

Methods/analysis: This will be a cross-sectional study of 300 permanent residents of up to 10 low-level and high-level RACFs in South Australia with and without dementia. Trained study nurses will administer validated and dementia-specific assessments of self-reported and clinician-observed pain, sedation and other clinical and humanistic outcomes. Medicine-use data will be extracted directly from each resident's medication administration chart. Binary and multinomial logistic regression will be used to compute unadjusted and adjusted ORs and 95% CIs for factors associated with pain, analgesic load and daytime sedation. These factors will include dementia severity, behavioural and psychological symptoms, quality of life, resident satisfaction, attitudes towards medicines, activities of daily living and nutritional status.

Ethics and dissemination: Institutional ethics approval has been granted. The findings will be disseminated through public lectures, professional and scientific conferences and in peer-reviewed journal articles. The findings of this study will allow for a better understanding of the prevalence and factors associated with analgesic use, pain and other outcomes in residential care. The findings of this study will be used to inform the development and implementation of strategies to improve the quality of life of people with dementia.

Strengths and limitations of this study

- A broad range of outcomes and risk factors will be assessed, thus allowing for the generation and exploration of a range of hypotheses. The additional prospective collection of hospitalisation and mortality data will enable an exploration of the effect of pain, analgesia and other covariates on the development of these outcomes.
- The findings of this research will enable a better understanding of the prescribing practices in aged care facilities and will assist in the development of targeted pain management services for people with dementia.
- The cross-sectional study design means it is difficult to make causal inferences about the data. Although the study will involve multiple aged care facilities, the generalisability may be limited. As with all observational studies, there will be the possibility of confounding.

BACKGROUND

A key objective when offering treatment to people with Alzheimer's disease (AD) and other dementias is to alleviate suffering and maintain quality of life. Pain is common among residents of residential aged care facilities (RACFs) with and without dementia.^{1 2} The way that people with dementia experience and express pain is a topic of ongoing research.³

People with AD may communicate pain non-verbally via facial expressions, body movements and behavioural disturbances. These pain signs may go unrecognised and therefore not prompt clinicians to prescribe analgesic medicines.^{1 3} Most previous studies have reported lower overall use of analgesics

in people with dementia compared with those without dementia and hypothesised that this may reflect untreated pain in these people.⁴⁻⁶ Untreated pain has been associated with increased use of healthcare and aggression.^{7,8} Use of analgesic medicines has been associated with higher quality of life in people with dementia.⁹ Pain-related behavioural disturbances may also be misinterpreted as behavioural and psychological symptoms of dementia leading to inappropriate prescription of psychotropic medicines which have been associated with impaired cognition, falls and fractures and increased risk of death.^{10,11}

Clinicians working in RACFs are faced with the need to alleviate pain while minimising daytime sedation and prescription of psychotropic medicines. Medicine selection is also challenging as older people have a high prevalence of multimorbidity, frailty, polypharmacy and increased susceptibility to adverse drug events (ADEs).¹²⁻¹⁴ The lower prevalence of analgesic use among people with dementia may be partly linked to fear of ADEs (eg, excess sedation, falls and fractures, delirium and respiratory depression) as well as non-recognition of pain.¹⁵⁻¹⁷ A cluster randomised controlled trial has demonstrated that a systematic approach to pain management, using a stepwise protocol for analgesic use, reduced agitation in aged care facility residents.¹⁸ This finding suggests that improved recognition and treatment of pain may be an effective strategy to reduce the unnecessary use of sedative and psychotropic medicines among residents of aged care facilities.

The aims of this study are to (1) investigate the prevalence of analgesic load, pain and daytime sedation in people with and without dementia in Australian RACFs and (2) investigate the clinical and diagnostic correlates of analgesic load, pain and daytime sedation in people with and without dementia in Australian RACFs.

METHODS

Design and setting

This will be a cross-sectional study among permanent residents of up to 10 low-level or high-level RACFs in South Australia. These RACFs will be located in metropolitan Adelaide (population 1.2 million) and Mt Gambier (population 25 000). Adelaide is the state capital city and the fifth most populous city in Australia. Mt Gambier is a regional centre located approximately 450 km south of Adelaide. The aged care facilities will be approached to participate via one provider of aged care in South Australia.

Consumer involvement

The project will be conducted in accordance with Alzheimer's Australia guidelines for involving people living with dementia and their families in research (Alzheimer's Australia, 2013). The investigative team includes a member of the Alzheimer's Australia Consumer Dementia Research Network (TQ). The

member of the Consumer Dementia Research Network has reviewed all project proposals from a consumer perspective, will participate on the project advisory committee and will assist in dissemination of the findings.

Participants

Permanent residents of low-level or high-level care RACFs will be invited to participate by a trained study nurse. This will include residents with and without dementia. Inclusion criteria will be age 65 years or older and ability to participate in structured assessments in English. Residents may be excluded at the discretion of RACF staff and their treating clinicians. Residents deemed by facility staff to be medically unstable (eg, experiencing delirium) or estimated by facility staff to have less than 3 months to live will be excluded from participation.

Data collection

Data will be collected using a standard data extraction form comprising a series of validated and widely used scales. The choice of scales was consistent with those included in the Dementia Management Outcomes Suite of the Australian Government Dementia Collaborative Research Centres. Data will be collected by experienced nurses employed by the participating aged care provider. Where possible, data will be collected by the same nurses at each RACF. Study nurses will undergo training in a centralised location in the standard administration of the study assessment tools. All nurses involved in the data collection will have undergone the mandatory police clearances for working with older people. The concordance between assessments performed by different study nurses will be established for an initial subsample of residents at one RACF. If required, each resident's general medical practitioner or community pharmacist may be contacted to provide additional data relevant to the study outcomes. For scales requiring input of a staff informant, staff informants will be required to have known the resident for at least 2 weeks. If during the data collection process a study nurse identifies a sign or symptom requiring medical attention, this will be brought to the attention of the care coordinator or senior registered nurse at the respective aged care facility.

Primary outcomes

Pain

Two validated pain scales suitable for use among people with dementia will be used. This will include a dementia-specific, clinician-administered observational scale (Pain Assessment in Advanced Dementia (PAINAD) Scale) and a resident self-report scale (FACES Pain Scale Revised (FPS-R)). The resident self-report scale will be used in addition to the observational scale because observational scales may underestimate pain in people with dementia.^{6,19} The scales will be administered when each resident is at rest.

The PAINAD Scale is a five-item clinician-administered observational scale with domains related to breathing, negative vocalisation, facial expressions, body language and consolability.²⁰ Possible scores range from 0 to 10, with higher scores indicating more severe pain. The scale will be administered after observing the resident for 5 min. The FPS-R is designed for people who are able to self-report but may be unable to use a traditional numeric rating scale.²¹ The scale consists of six faces that show how much pain or discomfort someone is feeling. The face on the left shows no pain whereas the face on the right shows the worst pain possible. The scale is scored from 0 'no pain' to 10 'worst pain possible'. Using the FPS has been demonstrated to be feasible and more easily understood than a traditional horizontal Visual Analogue Scale in people with a Mini-Mental State Examination (MMSE) score less than 11 and a Clinical Dementia Rating score of 3.¹⁹

Medicine use and analgesic load

Medicine-use data from the previous 24 h will be extracted directly from each resident's medication administration chart by a study nurse. This will include prescription medicines, non-prescription medicines, vitamins and minerals and complementary and alternative medicines administered regularly and as required. The medicine name, strength, number of doses and whether it was administered will be recorded. This means that medicine-use data will represent each resident's actual use rather than their prescribed or intended pattern of use. Prescription and non-prescription medicines taken by the residents will be classified using the Anatomical Therapeutic Chemical (ATC) classification system recommended by the WHO.²²

Analgesics will be defined as paracetamol (N02BE), non-steroidal anti-inflammatory drugs (ATC codes M01AB-H, M01AX01, M02AA, M02AC, N02BA) and opioids (N02A). Opioids will be subclassified as strong and weak opioids. Low-dose (≤ 250 mg/day) aspirin will not be classified as an analgesic because it is primarily used as an antiplatelet. Analgesic load will be calculated according to a previously published model developed in the USA.²³ To calculate each resident's analgesic load, analgesic ratings will be assigned to each medicine taken by each resident on a regular or as-needed basis.

- ▶ Opioids for the treatment of moderate-to-severe pain (analgesic rating 9, eg, morphine, fentanyl).
- ▶ Opioids for the treatment of mild-to-moderate pain (analgesic rating 6, eg, tramadol).
- ▶ Non-opioid analgesics (analgesic rating 3, eg, ibuprofen, celecoxib).
- ▶ Adjuvant medicines (analgesic rating 1, eg, valproate, sertraline).
- ▶ Non-analgesic medicines (analgesic rating 0).

For each analgesic, a score will be derived by multiplying the daily dose by the analgesic rating and dividing by the average daily maintenance dose. The scores for

each analgesic will be summed to compute each resident's analgesic load.

Sedative load resulting from each resident's exposure to medicines with sedative properties will be computed using a published model.²⁴ This model considers medicines prescribed for sedation, medicines with sedation as a prominent side-effect and medicines with a sedating component.

Daytime sedation

Daytime sedation will be assessed using a clinician-administered observational scale (Pasero Opioid-induced Sedation Scale (POSS)) and a resident self-report scale (Epworth Sleepiness Scale (ESS)). The POSS is a five-item clinician-rated scale.²⁵ The reliability and validity of the POSS has been demonstrated for measuring sedation during administration of opioids.²⁶ The ESS is a widely used eight-item resident self-report scale. Respondents are asked to rate their chance of falling asleep in eight different situations on a four-point scale. The ESS has been used among people with AD,²⁷ and to assess the contribution of medicines to daytime sedation.²⁸ The scale has also been successfully used previously in the hostel setting.²⁹ Sleep quality will also be assessed using a previously validated six-item questionnaire. Three questions pertain to night-time sleep behaviour, including overall sleep quality, sleeping duration and restfulness. Other questions address alertness in the mornings and the frequency and duration of daytime napping.³⁰

Covariates and secondary outcomes

Dementia severity

The Dementia Severity Rating Scale (DSRS) will be used to assess the severity of each resident's dementia. This is a 12-item scale designed to be completed in consultation with a staff informant.³¹ It has been demonstrated to be a valid, reliable and sensitive measure of impairment associated with AD.³¹ Enrolled or registered nurses will complete the scale.

Behavioural and psychological symptoms

Behavioural and psychological symptoms common in dementia will be assessed using the Neuropsychiatric Inventory Nursing Home version (NPI-NH).³² The NPI-NH contains the same 12 domains as the original NPI,³³ but has been reworded to allow for completion in consultation with staff informants who did not know the resident prior to the onset of illness. The NPI-NH has domains related to delusions, hallucinations, aggression/agitation, depression/dysphoria, anxiety, elation/euphoria, apathy/indifference, disinhibition, irritability/lability and aberrant motor behaviour, sleep and night-time behaviour disorders and appetite and eating disorders.

Quality of life

Each resident's quality of life will be assessed by a registered or enrolled nurse using the staff informant version of the 15-item Quality of Life in Alzheimer's Disease

Scale (QoL-AD). The 15-item version for use in RACFs is an adaptation of the original 13-item version for use among community-dwelling people with dementia.³⁴ Previous research suggests the QoL-AD scale has good validity and reliability when used for people with dementia with MMSE scores greater than 10.³⁵ In a recent study, the 15-item QoL-AD scale was successfully completed by 64% of residents with dementia in West Australian RACFs.³⁶

Attitudes towards medicine regimen

Residents' attitudes towards medicines will be assessed using the 10-item Patients' Attitudes Towards Deprescribing (PATD) questionnaire.³⁷ The PATD has satisfactory criterion validity and test-retest reliability when used in general adult samples. The PATD will be interviewer administered by the study nurse. The face validity of the PATD in people with dementia will be assessed prior to use.

Resident satisfaction

Resident satisfaction will be assessed using Hawthorne's revised 7-item Short Assessment of Patient Satisfaction (SAPS).³⁸ Residents will be asked questions in relation to their overall care at the facilities, with an emphasis on interactions with nursing staff and carers.

Other clinical factors

Each resident's nutritional status will be assessed using the Mini Nutritional Assessment Short Form (MNA-SF).³⁹ The MNA-SF has been validated as an assessment tool for evaluating malnutrition in elderly people.^{39 40} Nutritional status has been associated with polypharmacy and is strongly predictive of poor prognosis in residents of aged care facilities.⁴¹ Activities of daily living will be assessed using the Katz Activities of Daily Living (ADL) scale.⁴² This six-item scale includes domains related to bathing, dressing, toileting, transferring, continence and feeding. Diagnostic data will be extracted directly from each resident's electronic case notes and be used to compute a range of comorbidity indices including the Functional Comorbidity Index (FCI).⁴³

Hospitalisation and mortality

RACF records will be used to determine the number, reasons for and duration of days in hospital over a 36-month period following the cross-sectional data collection. Data on deaths that occur over a 36-month period following the cross-sectional data collection will be obtained from the Consumer and Business Services: Births, Deaths and Marriages, South Australia. Hospitalisation and mortality data will be investigated because a previous study has suggested that potentially inappropriate medicine use defined using Beers criteria is associated with increased hospitalisation and mortality among residents of aged care facilities.⁴⁴

Sample size and statistical analyses

Assuming a power of 80%, a two-sided level of significance of 0.05, dementia prevalence of 50%^{45 46} and an analgesic prevalence of 60%,⁴⁶ a sample size of 258 participants would be required to detect a significant prevalence ratio (PR) of 0.7 in our primary outcome of analgesic use (OpenEpi V.2.3.1). To maintain adequate power in multivariate analyses, an approximate sample size of 5–20 cases is required per adjustment variable. For this reason, we will aim to recruit up to 300 residents with and without dementia to allow our analyses to be adjusted for a range of clinically important covariates. This sample size is consistent with similar cohort studies investigating quality of life and neuropsychiatric symptoms in people with dementia in Australia and internationally.^{36 47}

Regression analyses will be performed to compute unadjusted and adjusted ORs and 95% CIs for the association between pain, analgesic load and daytime sedation in people with AD and other dementias. The ORs will be transformed to PRs when outcomes are more common than 10%.⁴⁸ Multiple imputation will be used to impute missing covariate values where applicable. This has been demonstrated to be superior complete case analyses when data are missing at random.⁴⁹ Analyses will be adjusted for age, sex, medicine use (eg, sedative load), diagnoses and other clinically relevant covariates. In addition to standard reporting in tables and figures, results will also be presented as three-dimensional, geometric frameworks to provide a visual representation.⁵⁰ Analyses will be undertaken using the Statistical Package for the Social Sciences (SPSS, V.17.0, Chicago, Illinois, USA).

Ethical considerations

A study nurse employed by the aged care provider will be responsible for inviting each resident to participate in the project. All potential resident participants will be provided with verbal and written information about the study. This will be carried out in accordance with the ethical principles for involving people with cognitive impairment in research studies that are outlined in the Australian National Statement for Ethical Conduct in Human Research.⁵¹ Consent to participate will be obtained from the residents if they have the capacity to consent. In cases where residents are unable to provide written informed consent themselves, consent to participate will be sought from their guardian, next of kin or significant other. Residents with an enduring power of guardianship will be identified by the participating aged care provider. In these cases, the study nurse will still explain to the resident, as much as possible, what participation will involve and consent will be sought from the guardian. All data will be treated confidentially and in accordance with Australian regulations. Data will be stored in a locked cabinet at the Centre for Medicine Use and Safety, Faculty of Pharmacy and Pharmaceutical Sciences, Monash University for a minimum of 5 years.

The study will be conducted in accordance with the World Medical Association (WMA) Declaration of Helsinki.

Dissemination of research findings

The findings will be communicated to consumers and carers at one or more public lectures, with consumers and carers involved in the preparation and delivery of the lecture. The results will be presented at professional and scientific conferences. The results will also be disseminated in peer-reviewed scientific journal articles. All clinicians and RACFs that participate in the research will be provided with a copy of the final report, which will include a lay summary of the findings.

DISCUSSION

This study aims to improve pain management and, in turn, the quality of life of residents of RACFs with dementia. It will investigate outcomes that are important to consumers, and will involve close liaison with consumers, carers and clinicians throughout the study. The cross-sectional study design will enable the investigation of the prevalence of analgesic use, pain, sedation and other outcomes and the factors associated with these outcomes in residents of RACFs. Several different outcomes and risk factors will be assessed, thus allowing for the generation and exploration of a range of hypotheses. The additional prospective collection of hospitalisation and mortality data will enable an exploration of the effect of pain, analgesia and other covariates on the development of these outcomes. The findings of this research will enable a better understanding of the prescribing practices in RACFs and will assist in the development of targeted pain management services for people with dementia.

Limitations

The cross-sectional study design means it is difficult to make causal inferences about the data. Generalisability may be limited to the sampled population, and findings may not be applicable to all older people or other settings. Selection bias may occur, with volunteer bias being a potential limitation. Residents and families choosing to participate in the study may tend to be those who are healthier, have less cognitive impairment or are more involved in their pain management. These issues will be minimised by ensuring a census sample of eligible residents is recruited from each facility where possible. Additionally, demographics of the participants will be compared with all residents of the RACF to assess representativeness of the sample. Close engagement and monitoring by the research team will ensure that recruitment and data collection protocols are implemented consistently.

CONCLUSION

This study will investigate the association between medication use and clinical characteristics in residents with and without dementia in RACFs. The findings of this study will allow for a better understanding of the prevalence and risk factors associated with analgesic use, pain, sedation and other outcomes in aged care settings. This will help guide the development and implementation of strategies to improve the quality of life of people with dementia.

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Acknowledgements The authors would like to thank the Resthaven management team, research nurses, facility staff and participants for their valuable support and cooperation.

Contributors JSB, RV, SNH and AIV conceived the study and obtained grant funding. JSB, ECKT, RV, SNH, AIV and TQ participated in the design of the study protocol. All authors critically reviewed the study protocol. TE, LR, TS, SS, SL and RC assisted in the development and implementation of the study. Data will be collated and analysed by JSB, ECKT, RV, ER, DG and JI. JSB and ECKT drafted the manuscript. All authors read and approved the final manuscript.

Funding This work is supported by the Alzheimer's Australia Dementia Research Foundation via the Resthaven Incorporated Dementia Research Award, with additional funding provided by Resthaven Incorporated.

Competing interests DG is supported by a National Health and Medical Research Council Early Career Fellowship.

Patient consent Obtained.

Ethics approval The Royal Australian College of General Practitioners National Research and Evaluation Ethics Committee and the Monash University Human Research Ethics Committee.

Provenance and peer review Not commissioned; internally peer reviewed.

Data sharing statement The majority of data collected will be published. Any unpublished, de-identified data will be made available to interested persons on request.

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