**Project Description**

Title:

Sustained Effective Oral Care to Significantly Reduce Aspiration Pneumonia Experienced by Adults with Dementia in Residential Care (H0016399; Version 2 – revision of application begun under NEAF)

Acronym: -

Project Team Roles & Responsibilities:

Principal researcher/Investigator 1:

Dr Lynette Goldberg

Senior Lecturer

Wicking Dementia Research and Education Centre

Private Bag 143

University of Tasmania

Hobart TAS 7001

Dr Goldberg, a speech pathologist and Senior Lecturer at the Wicking Dementia Research and Education Centre (University of Tasmania), will serve as Project Officer and will dedicate 60% of her time to the project. Dr Goldberg will work in collaboration with CIs Crocombe and Jones to guide the education and training of staff and facilitate the collection of pre- and post-project data on residents’ oral health and occurrences of aspiration pneumonia to achieve the research and evaluation aspects related to this project.

Principal researcher/Investigator 2:

Associate Professor Leonard Crocombe

Centre for Rural health

Private Bag 34

University of Tasmania

Hobart TAS 7001

Assoc. Prof Crocombe, a dentist and researcher in the Centre for Rural Health (University of Tasmania), will play a leading role in the screening of residents’ oral health, their referral for any needed off-site dental care, and the on-site supervision of dental/oral hygiene students as they assist direct care staff in residents’ oral care.

Principal researcher/Investigator 3:

Dr Ioan Jones

Oral Health Services Tasmania

2 Archer Street

New Town TAS 7008

Dr Jones, a qualified dentist at Oral Health Services Tasmania, will work at the two sites in Launceston. He will be responsible for the placement and on-site supervision of dental/oral hygiene students for the duration of the project.

Principal researcher/Investigator 4:

Professor Andrew Robinson (Aged Care Nursing)

Co-Director, Wicking Dementia Research and Education Centre

Private Bag 143

University of Tasmania

Hobart TAS 7001

Prof Robinson, a Professor of Aged Care Nursing, has been instrumental in obtaining a commitment from the two residential care centres in Launceston that are involved in this project. He will not be involved in on-site activities but will participate in data analysis and the development of manuscripts about the study.

Principal researcher/Investigator 5:

Dr Emma Lea

Research Fellow

Wicking Dementia Research and Education Centre

Private Bag 143

University of Tasmania

Hobart TAS 7001

Dr Lea is a Research Fellow at the Wicking Centre. She will not be involved in on-site activities and data collection but will participate in data analysis and the development of manuscripts about the study.

Principal researcher/Investigator 6:

Dr Juanita Westbury

Wicking Dementia Research and Education Centre

Private Bag 143

University of Tasmania

Hobart TAS 7001

Dr Westbury is a pharmacist at the Wicking Centre. She has just completed a national project to facilitate the appropriate reduction of psychotropic medications in 150 residential care centres. She will not be involved in on-site activities and data collection but will participate in data analysis and the development of manuscripts about the study.

Principal researcher/Investigator 7:

Professor Andrew Palmer

Menzies Institute for Medical Research

Private Bag 23

Hobart TAS 7001

Prof Palmer, a physician and health economist, will serve as the team’s health economist, documenting the costs of the integrated intervention, including staff and training costs. He will not be involved in on-site activities and data collection but will participate in data analysis and the development of manuscripts about the study.

Principal researcher/Investigator 8:

Professor Fran McInerney (Dementia Studies and Education)

Wicking Dementia Research and Education Centre

Private Bag 143

University of Tasmania

Hobart TAS 7001

Prof McInerney has a nursing and social science background. She will not be involved in on-site activities and data collection but will participate in data analysis and the development of manuscripts about the study.

Resources

We have received funding ($99,752) from the NHMRC/NNIDR – Dementia Collaborative Research Centres (DCRC). This funding will support the following activities:

Salaries

* Stipend for residential centre nurse-carer champions partners (2 people at each of the two residential care centres: $49,152
* Backfill for nurse-carer champions during education and training sessions ($2,000 x 2 centres): $4,000
* Stipend for the on-site Assessment Team: $38,400

Other

* Light food for meetings of investigators with residential centre staff members: $600
* Laptop computer for each residential care centre @ $800/centre: $1,600
* Electric timed toothbrushes ($50/toothbrush x 120 residents): $6,000

Additional in-kind support has been confirmed, as follows:

 Project Officer Goldberg $88,670

CI Crocombe $43,443

CI Jones $30,000

CI Robinson $10,647

CI Lea $6,775

CI Westbury $6,981

CI Palmer $10,647

CI McInerney $10,647

Background

**Literature review**

Principles of Care for people with dementia emphasise the need to eat well to maintain function, independence, and quality-of-life (QOL).1 However, eating relies on a pain-free and healthy mouth. With poor oral health, harmful oral bacteria colonise the mucosal lining of the mouth and pharynx. This proliferation of bacteria is particularly problematic for people with dementia and dysphagia (swallowing problems) in residential care.2,3 Residents with dementia frequently take many medications that reduce salivary flow or create xerostomia (dry mouth), which increase the pathogenic bacteria.4 These bacteria cause tooth decay, gum inflammation, gum disease, and painful disruption of the oral mucosa and supporting structures. Chronic inflammation of oral tissues results in bacteria entering the bloodstream with detrimental effects on the body and brain.5 Associated oral pain frequently necessitates a diet of modified foods, compounding the risk for malnutrition, with associated changes in behaviour, frailty, and a compromised immune system.6-8

Poor oral health significantly worsens dementia-related health problems, including Type 2 diabetes, heart disease, chronic lung disease, dysphagia (swallowing difficulties) and aspiration pneumonia, particularly for people in residential care.7,9-14 Aspiration pneumonia is a frequent cause of hospitalisation, and re-hospitalisation for people with dementia, resulting in increased health care costs and death. 7,11,12,14

Aspiration pneumonia is characterised by sporadic fever and functional decline. It occurs when food, liquid, and/or saliva containing harmful oral bacteria is misdirected (aspirated) into the trachea (airway), rather than the oesophagus, and then into the lungs, and the lungs cannot clear the aspirated material. The aspirated material also may have refluxed from the stomach or oesophagus back into the airway. Chronic aspiration results in chronic lung inflammation.7 This inflammation increases vulnerability to sarcopenia, a decrease in muscle mass and strength, particularly of the swallowing muscles. The consequent dysphagia heightens the risk of aspiration, including silent aspiration where the individual does not cough, leading to a vicious cycle of aspiration-dysphagia-aspiration.2,7,8 Even when teeth are removed, oral pathogens remain a risk indicator for aspiration pneumonia as they line the mucosal surface of the oral and pharyngeal cavities, including the tongue.12,13 The current treatment approach for aspiration pneumonia solely with antibiotics is reactive and ineffective.3 Evidence-based and sustainable oral care needs to be an integral aspect of a paradigm shift to actively promote function, maintain health, and significantly reduce costs associated with ill health and hospitalisation for people in residential aged care, especially those with dementia.7 This evidence-base centres on 2-minutes of teeth cleaning after each meal or daily cleaning of dentures with removal for sleep.3,7,11-14

Australian guidelines for effective oral care exist.15 However, since publication of the Better Oral Health in Residential Care report, there has been limited evidence of their implementation. Of concern, literature documents the continuing fragmented and unequal provision of oral health care to Australian adults who live in residential communities.15-18 Barriers include organisational concern for anticipated high costs of dental services, lack of support, and inadequate time for care.16,19 A recent analysis of the time, frequency, and duration of the direct care provided to adults with dementia over an 8-hour shift showed that an average of 20 seconds was devoted to oral care18 – in striking contrast to the recommended 2 minutes of teeth brushing following each meal or daily denture cleaning.3,7,11-14

The purpose of this project is to document the effects of increased time for oral care for adults, including those with dementia, living in two residential aged care settings in Launceston, Tasmania. The hypothesis is that the effects of increased time for oral care will be positive, reduce the clinical signs of aspiration pneumonia related to poor oral health, and illustrate to care staff the importance of regular and sustained oral care.20

References

1. Guideline Adaptation Committee (2016). Clinical Practice Guidelines and Principles of Care for People with Dementia. Sydney. Guideline Adaptation Committee.
2. Komiya, K., Ishii, H., & Kadota, J. (2015). Healthcare-associated pneumonia and aspiration pneumonia. *Aging and Disease*, *6*(1), 27-37.
3. Kaneoka, A., Pisegna, J.M., Miloro, K.V., ... & Langmore, S.E. (2015). Prevention of healthcare-associated pneumonia with oral care in individuals without mechanical ventilation: A systematic review and meta-analysis of randomized controlled trials. *Infection Control & Hospital Epidemiology, 36*(8), 899-906.
4. Westbury, J.L., Bindoff, I.K., & Peterson, G.M. (2015). Expansion of the reducing use of sedatives (RedUSe) project to Australian nursing homes. *American Journal of Geriatric Psychiatry*, *23*(3), S155. ISSN 1064-7481.
5. Vickers, J.C., Mitew, S., Woodhouse, A., … & King, A.E. (2016) Defining the earliest pathological changes of Alzheimer's disease. *Current Alzheimer Research*, *13*, 281-287.
6. Roque, M., Salva, A., & Vellas, B. (2013). Malnutrition in community-dwelling adults with dementia (NUTRIALZ Trial). *The Journal of Nutrition, Health, and Aging*, *17*(4), 295-299.
7. Ebihara, S., Sekiya, H., Miyagi, M. et al. (2016). Dysphagia, dystussia, and aspiration pneumonia in elderly people. *Journal of Thoracic Disease*, *8*(3), 632-639.
8. Charlton, K.E., Batterham, M., Bowden, S., Gosh, A., Caldwell (Kent), K., et al. (2013). A high prevalence of malnutrition in acute geriatric patients predicts adverse clinical outcomes and mortality within 12 months. *ESPEN Clinical Nutrition*, *8*(3), e120-e125.
9. Bauer, K., Schwarzkopf, L., Graessel, E., & Holleet, R. (2014). A claims data-based comparison of comorbidity in individuals with and without dementia. *BMC Geriatrics*, *14*, 10.
10. Foley, N.C., Afoo, R.H., & Martin, R.E. (2015). A systematic review and meta-analysis examining pneumonia-associated mortality in dementia. *Dementia Geriatrics and Cognitive Disorders*, *39*, 52-67.
11. Yoneyama, T., Yoshida, M., Ohrui, T., et al. (2002). Oral care reduces pneumonia in older patients in nursing homes. *Journal of the American Geriatric Society*, *50*(3), 430-433.
12. Wirth, R., Dziewas, R., Beck, A.M., Heppner, H.J., Langmore, S.E., et al. (2016). Oropharyngeal dysphagia in older persons – from pathophysiology to adequate intervention: A review and summary of an international expert meeting. *Clinical Interventions in Aging*, *11*, 189-208.
13. Ferozali, F., Johnson, G., & Cavagnaro, A. (2007). Health benefits and reductions in bacteria from enhanced oral care. *Special Care Dentistry*, *27*(5), 168-176.
14. Langmore, S.E., Skarupski, K.A., Park, P.S., et al. (2002). Predictors of aspiration pneumonia in nursing home residents. *Dysphagia*, *17*, 298-307.
15. Fricker, A., & Lewis, A. (2009). Better oral health in residential care: Final report. Australian Government Department of Health and Ageing.
16. Hearn, L., & Slack-Smith, L. (2015). Oral health care in residential aged care services: Barriers to engaging healthcare providers. *Australian Journal of Primary Health*, *21*, 148-156.
17. Bell, E., Crocombe, L.A., Campbell, S., Goldberg, L.R., et al. (2014). Understanding the research-policy divide for oral health inequality. *Healthcare Policy*, *10*(1), 64-78.
18. Qian, S., Yu, P., Hailey, D., et al. (2014). Time spent on daytime direct care activities by personal carers in two Australian residential aged care facilities: A time-motion study. *Australian Health Review*, *38*, 230-237.
19. Paley, G., & Slack-Smith, L. (2009). Oral health care issues in aged care facilities in Western Australia: Resident and family caregiver views. *Gerodontology*, *26*(2), 97-104.
20. Zenthöfer, A., Meyer-Kühling, Hufeland, A-L., et al. (2016). Carers’ education improves oral health of older people suffering from dementia – results of an intervention study. *Clinical Interventions in Aging*, *11*, 1755-1762.

**Rationale/Justification**

Accreditation standards for residential aged care communities require a commitment that each community will provide residents with oral care and maintain staff education about effective oral care. The problem is that routine oral care, or standard practice, can vary greatly from one residential community to another. Australian guidelines for effective oral care exist in the form of the published “Better Oral Health in Residential Care” report. However, since its publication in 2009, there has been limited evidence of its implementation to improve the oral health of people living in residential aged care, including those with dementia. Of concern, literature documents the continuing fragmented and unequal provision of oral health care to Australian adults with dementia who live in residential communities. Care frequently falls far short of the time needed to maintain residents’ oral health and thus their nutritional and general health, and the rate of residents’ hospitalisation for, and death from, aspiration pneumonia remains high.

Current evidence shows the best ways to promote oral and general health, and decrease risk for aspiration pneumonia for adults in residential aged care are (a) oral health screening when admitted to care, (b) brushing teeth for at least 2 minutes after each meal or cleaning dentures daily and removing them for sleep, and (c) providing timely access to off-site dental treatment when needed.

In Australian residential aged care communities, oral care generally is delegated to extended care assistants or personal care workers. Many view oral care as onerous and are reluctant to perform it; many have limited training to respond to changes in behaviour that may indicate residents’ distress; many do not understand how oral care is integral to the work of dentists, speech pathologists, dietitians, physiotherapists, and nurses, to promote residents’ function, overall health, and quality of life.

Our project will contribute to improved practice. The intent is to involve staff in (a) practical and time efficient oral screening of residents, including those with dementia, and (b) providing residents with 2-minutes of teeth cleaning after each meal, or daily cleaning of dentures and removal for sleep. Staff will be assisted in daily oral care by on-site supervised dental and oral hygiene students, particularly after the midday meal as staff currently feel they are too busy to help residents with oral care at this time. Regular conversations with the investigators during the project will facilitate problem-solving and a focus on oral health-related outcomes for residents, including people with dementia, such as improved eating and decreased behavioural difficulties, and reinforce the positive effects of regular and sustained oral care. Using a train-the trainer approach, staff involved in the project will be able to contribute to ongoing staff education about oral health and be recognised for this.

 **Exclusion criteria** for residents in this study:

* Inability to remain alert or to follow simple, 1-step directions
* Pre-existing dysphagia (swallowing problems) that prevents intake of thin liquids
* Head-of-bed is restricted to < 30°
* Presence of tracheotomy tube (a breathing tube inserted into the throat above the collar bones)
* Doctor has ordered nothing by mouth (nil-per-os; NPO) for medical or surgical reasons
* Presence of a feeding tube inserted directly into the stomach.

**Research Questions/Aims/Objectives/Hypotheses**

Our long-term goal is to improve the health of residents, including those with dementia, so they can live and function well.

**Aim 1**. Decrease the number of clinical indications of aspiration pneumonia, e.g., fever, chest or lung infections, and related hospital transfers/admissions.

Hypothesis: Staff understanding of the ramifications of poor oral health will be associated with the provision of evidence-based oral care and decreased consequences of aspiration pneumonia.

**Aim 2**. Improve residents’ oral and nutritional health, and quality of life.

Hypothesis: Implementing oral health screening for residents and the evidence-based 2-minutes of teeth cleaning after each meal, or daily cleaning of dentures and removal for sleep, will be more effective than routine oral care.

* Staff will be assisted by on-site supervised dental and oral hygiene students and designated oral health champions at each residential aged care centre
* Each resident will be provided with timed electric or regular toothbrushes for daily denture care. For residents who cannot adjust to the electric toothbrushes, we will develop 2-minute strategies for using regular toothbrushes, e.g., brushing to a series of enjoyed and selected 2-minute recorded songs
* Daily checks by the oral health champions and students for quality control will monitor and record any visible plaque on residents’ teeth if regular tooth brushing is not being done, along with food residue, swollen or bleeding gums, and bad breath. These daily checks also will facilitate students’ learning about effective interactions in providing oral care for residents, including those with dementia. The daily checks will be complemented by monthly analyses of used toothbrushes/electric toothbrush heads and replacement of toothbrushes over the 3-month period of the study.

This resident-centred intervention is straightforward and functional. It integrates residential care staff with students from varying professions. It educates staff about the critical role of residents’ oral health to their general well-being, comfort, and quality of life. It involves residents in their own oral care as actively as possible.

**Expected outcomes**

1. Decreased number of clinical signs of aspiration pneumonia and related hospitalisations
2. Increased staff understanding of dementia and the need for evidence-based, daily oral care to maintain residents’ oral and nutritional health and quality of life
3. Improved oral and nutritional health and quality-of-life of residents, including those with dementia

**Impact.** Our research will enable us to pilot test a resident-focused, evidence-based, functional, and sustainable model of oral care to meet the oral health needs of people living in residential aged care, including those with dementia. This model has the potential to decrease the socio-economic burden from hospitalisation related to aspiration pneumonia and poor oral health.

Project Design

This project is a 2-facility trial in Tasmania in which each residential aged care centre will serve as its own control. The two residential aged care centres are the Peace Haven Home and the Fred French Home. Both centres are part of Masonic Care Tasmania, are in Launceston, and have agreed to participate.

**Participants**. Both residential care centres have approximately 100 residents, the majority with cognitive impairment. We plan for 60 participants at each centre, including those with documented cognitive impairment or diagnosed dementia. Following residents’ approval, per their signed Informed Consent Form, the documentation of their cognitive impairment, dementia, and other medical diagnoses will be confirmed by the Facility Manager at each centre from information in residents’ medical charts.

**Power**. This pilot study will assist in developing an appropriate power determination for future clinical trial studies. We will document instances of unexplained fever, chest and lung infections and other clinical signs of aspiration pneumonia, along with the number of unplanned hospital transfers/admissions related to clinical signs of aspiration pneumonia in the six (6) months prior to the 3-month intervention period, during the 3-month intervention period, and following 3-month intervention period.

Although the literature reports a range in prevalence rates for aspiration pneumonia for adults in residential care, current 12 month prevalence rates for aspiration pneumonia for adults with cognitive impairment or dementia average 61% when systematic oral health care is not in place.11 Given 120 residents (60 at each centre), we will anticipate that aspiration pneumonia (or clinical signs of this, as a diagnosis is not often given until hospitalisation) affects up to 72 residents without intervention and that our intervention will reduce this number to 24 (a relative 33% reduction). Assuming a .05 significance level and a moderate effect size, we will have power of 85% for the study. This is feasible based on Japanese studies and accounts for any loss of residents due to death or relocation. We have ample power for the resident-related outcome measures. As an example, a 2-tailed paired *t* test evaluating the change in oral health of 60 residents, with a moderate effect size of .5, and a significance level of .05, yields a power of 97%.

**Recruitment**. CI Goldberg has been visiting the two centres regularly to participate in residents’ monthly meetings and inform residents and staff about the planned study. Input from residents and staff has been instrumental in planning for staff education and training sessions. Following ethics approval, the Facility Manager at each centre will confirm the study for residents and staff, place invitations to participate around each centre, and provide residents, their families, and staff with an Information Sheet/Booklet about the study. This Information Sheet/Booklet will include Informed Consent Forms, details of the oral health screening procedures, the questionnaires to be completed by staff before and after the intervention period, and details of the oral care intervention. With residents’ permission, via their signed Informed Consent Form, information about the study will be sent to their doctors and dentists on record. These health care professionals will be identified by each Facility Manager and the Facility Managers will send out the information.

All residents at Fred French and Peace Haven communities who do not meet the exclusion criteria will be invited to participate.

**Research activities**.

1. Obtain baseline data on participating staff (nurses and point-of-care/personal care assistant) who are involved in oral care through their completion of the Dementia Knowledge Assessment Scale (DKAS; developed by the Wicking Centre) and narrative responses to five (5) oral care-related questions on a pre-study questionnaire
2. Educate and train nurses and point-of-care staff involved in oral care. Based on suggestions from staff, this education and training about oral care will be provided in a 60-minute period. CIs Goldberg and Crocombe will be on-site at both residential care centres for a week to enable staff to attend sessions scheduled at multiple times over a period of days. The education and training will be completed immediately prior to the implementation of the intervention protocol and while participating residents are being screened.
3. The Facility Manager at Fred French and Peace Haven will identify a nurse and personal care assistant at each community. These two people will work as partners in championing the oral health screening of residents and the 3-month intervention period at each centre
4. Each Facility Manager will document the number of unexplained fevers, chest and lung infections, other clinical signs of aspiration pneumonia, and unplanned transfers/admissions to hospital related to clinical signs of aspiration pneumonia in the previous 6 months at each facility. Residents will be aware of this through their signed Informed Consent Form. Residents will understand that these data will be reported as group (facility-specific) data. Residents will not be identified personally in such a report.
5. Consenting residents will undergo a screening of their oral and nutritional health and QOL using four validated measures. The intent of these four screening measures is for them to be practical, easy to administer, and thus easy to include in staff’s regular and ongoing assessment of residents’ health. We anticipate the screening will take no more than 1 hour per resident. The screening will be conducted by members of the Research Team but with nursing/carer staff invited to participate and learn as their schedules permit. The screening measures are:
	1. The Oral Health Assessment Tool (OHAT) – documents the status of residents’ lips, tongue, oral tissues, saliva, teeth, dentures, and any oral pain and indications of disease
	2. The Mini-Nutritional Assessment (MNA) – documents, over the past 3 months, residents’ food intake, unplanned weight loss, mobility, psychological stress or acute disease, neuropsychological problems, and Body Mass Index (calculated from height and weight). This measure is already in use at the two residential care centres but not related to oral health screening.
	3. The Yale Swallow Protocol – residents are asked to drink 90 mL of room temperature water from a cup through a straw without stopping to document their ability to swallow safely. Coughing indicates potential swallowing problems and the protocol is then stopped.
	4. The EuroQol-5 (EQ-5D-3L) Tool – documents residents’ perceptions of their ability to move, care for themselves, and participate in daily activities, along with any pain, discomfort or anxiety they are experiencing. Quality of life (QOL) of residents, including those with dementia, is an important component of cost-utility analysis. Self-report tools can be completed by adults with mild-to-moderate cognitive impairment, including dementia. If residents are unable to complete this QOL tool, it can be completed by family/caregiver proxy. We understand that people with dementia rate their QOL higher than caregivers, particularly if people with dementia view their overall health as high. We will acknowledge this in our interpretation of data analysis.
6. Placement of dental/oral hygiene students from James Cook University at each of the two residential care centres. Dr Jones has established a contract with James Cook University for these placements. We anticipate there will be 3-5 students at each centre.
7. A 3-month period of evidence-based, daily oral care. This daily oral care protocol will entail 2-minutes of teeth cleaning after meals for residents who have their own teeth, using timed electric or regular toothbrushes, or daily denture care. For residents who cannot adjust to the electric toothbrushes, we will develop 2-minute strategies for using regular toothbrushes, e.g., brushing to a series of enjoyed and selected 2-minute recorded songs
8. Documentation of clinical signs of aspiration pneumonia and consequences by Facility Managers during the 3-month intervention period
9. Re-administration of the oral health screening measures for residents
10. Completion of post-study questionnaire by staff
11. Documentation of clinical signs of aspiration pneumonia and unplanned hospital transfers/admissions following the 3-month period of evidence-based, daily oral care.

**Data collection**.

* Nurses’ and carers’ scores on the DKAS before and after the 3-month period of evidence-based, daily oral care
* Nurses’ and carers’ narrative responses to care-related questions on a questionnaire before and after the 3-month intervention period
* Residents’ name, age, medical diagnoses (co-morbid medical conditions), and length of stay in the residential care centre – obtained by each Facility Manager
* Number of documented unexplained fevers, chest and lung infections, other clinical signs of aspiration pneumonia, and unplanned transfers/admissions to hospital related to clinical signs of aspiration pneumonia six-months before, during, and after the 3-month intervention period – obtained by each Facility Manager from residential care centres’ files
* Residents’ scores on the four oral health screening measures before and following the 3-month intervention period
* As residents participate in daily oral care, they may make insightful comments about the use (or non-use) of electric toothbrushes and the time needed for them to adjust to 2 minutes of teeth cleaning after meals. Such comments, without identifying information, may be documented.

Documentation of resident participant retention – we anticipate resident participant withdrawal may occur due to death or relocation, but this loss may be offset due to new residents joining the study. Data on resident participant loss will be important for the development and submission of a larger study. We understand, and will make it clear on the Informed Consent Form, that residents have the right to withdraw from the study at any time without any adverse effects on their care. If a resident chooses to withdraw from the study or refuses daily oral care, this will be respected. However, we will refer this issue to the Facility Manager at the residential care centre as withdrawal/refusal behaviour may indicate pain, confusion, and/or fatigue and these issues need to be understood by staff and addressed to promote and maintain resident health.

Documentation of staff participant retention – we anticipate that staff participant withdrawal may occur due to relocation or staff turnover. Staff turnover can be high for personal care assistants. We understand, and will make it clear on the Informed Consent Form, that staff have the right to withdraw from the study at any time without any adverse effects on their employment at Masonic Care Tasmania.

**Data management**.

All data provided by residents and staff will be de-identified. The name of each participant will be replaced by a code. The list of participants’ names and allocated codes will be kept by the primary investigator (CI Goldberg) in a locked cabinet in her office. The de-identified numerical information (scores) provided by residents and staff will be stored in a UTAS password-protected data centre. Backups of the database will be performed over a secure and encrypted connection and stored in a secure location. De-identified paper copies of data, including narrative data, will be kept in a locked file cabinet in CI Goldberg’s office at the Wicking Centre at UTAS. Stringent controls are in place to ensure the confidentiality and integrity of the data and access to it. Only members of the Research Team will have access to the data to analyse the effectiveness, including cost effectiveness, of the staff education and training and evidence-based, daily oral care.

Consent from participants will be sought only for the primary purpose of this study; thus the collected data will not be re-used or transferred.

All data will be stored for seven (7) years from the date of submission of the final report for this funded study. This period has been chosen because it is an accepted time frame for health research data storage. After this period, the computerised data will be transferred to a compact disc and the disc will then be destroyed. The original computerised data will be deleted. The paper-based data will be shredded.

In the event that CI Goldberg, the principal researcher, leaves the Wicking Centre and UTAS, the list of participant’s names and matched codes, and de-identified paper data will be transferred to a locked cabinet maintained by the Director of the Wicking Centre. Computer-based data will remain in the UTAS password-protected data centre. The password will be transferred to the Director of the Wicking Centre.

**Data analysis**.

Data collected relevant to staff understanding of dementia and the ramifications of poor oral health, residents’ clinical signs of aspiration pneumonia and their oral and nutritional health, and QOL before and after the 3-month intervention period will enable an analysis of the effectiveness, including cost effectiveness, of increased and systematic daily oral care, particularly the impact of such care in reducing aspiration pneumonia.

Each residential aged care centre will serve as its own control. Numeric data will be coded and entered into an SPSS program for analysis appropriate to the level of the data. The analysis will take into effect any missing information. Narrative data will be analysed thematically using standardised software such as Leximancer or nVIVO. The investigators are familiar with both quantitative and qualitative data analyses.

With regard to residents’ self-reported QOL data, we understand that people with dementia rate their QOL higher than do their caregivers, particularly if people with dementia view their overall health as high. We will acknowledge this in our interpretation of data analysis. We will also acknowledge the potential confounding effect of residents’ co-morbidities.

Statistical power calculation. Although the literature reports a range in prevalence rates for aspiration pneumonia for adults in residential care, current 12 month prevalence rates for aspiration pneumonia for adults with dementia average 61% when systematic oral health care is not in place.11 Given 120 residents (60 at each centre), we will anticipate that aspiration pneumonia affects up to 72 residents without intervention and that our intervention will reduce this number to 24 (a relative 33% reduction). Assuming a .05 significance level and a moderate effect size, we will have power of 85% for the study. This is feasible based on Japanese studies and accounts for any loss of residents due to death or relocation. We have ample power for the staff- and resident-related outcome measures. As an example, a 2-tailed paired t test evaluating the change in oral health of 60 residents, with a moderate effect size of .5, and a significance level of .05, yields a power of 97%.

Health economics. We expect the direct costs of our protocol to be offset by the decreased costs of care related to clinical signs of aspiration pneumonia (including fewer unplanned GP visits), and fewer aspiration pneumonia-related hospital transfers and admissions. Cost data are usually skewed so the Kruskal-Wallis one-way ANOVA will be used to test the difference in costs before and after the 3-month period of evidence-based, daily oral care. The transformed cost variable will be the dependent variable in a multivariate ordinary least squares (OLS) regression model. The significance level will be p < .05 or smaller where adjusted for multiple comparisons. This analysis is vital to knowledge translation and recommending changes in service delivery.

Data linkage. N/A

Outcome measures.

* Decreased number of clinical signs of aspiration pneumonia and related hospitalisations
* Increased staff understanding of dementia and the need for evidence-based, daily oral care to maintain residents’ oral and nutritional health and quality of life
* Improved oral and nutritional health and quality-of-life of residents, including those with dementia

**Results, Outcomes, and Future Plans**

Following the analyses of pre- and post-study data, we will develop a final report, based on grouped data, to share results of the study with residents, their families, and staff at Fred French and Peace Haven communities. Input from residents, family members, and staff will be integral to the final report we develop for the funding agency.

It is important to note that residents’ completion of the four oral health screening procedures, particularly at baseline, may indicate that some residents have an immediate need for off-site dental care or on-site referral to professionals for care, e.g., a speech pathologist for evident swallowing and/or communication difficulties; a dietitian for inadequate food and liquid intake and unexplained weight loss; and/or a professional skilled in addressing evident psychological stress issues and pain. Should such issues occur, we will immediately notify the Facility Manager to arrange a meeting with the residents concerned and their family members.

We will aim to submit three articles for publication in high-impact, peer-reviewed and clinically significant journals (2018). Appropriate journals include *Age and Ageing* (Q1), *Journal of Clinical Nursing* (Q1), and the *Medical Journal of Australia* (Q1).

We will develop presentations, based on the written articles, to disseminate results and recommendations to clinical, administrative, and legislative audiences. Potential conferences include: (1) Aged and Community Services Tasmania 2018/19, with a local clinical and residential centre -management audience; and (2) Alzheimer’s Australia National Conference 2018/19, with academic and clinical audiences. Presentations also will be developed for state and national legislators.

Documentation of the effectiveness of our oral health protocol will enable the development of residential centre-based guidelines and recommendations to ensure its sustainability in the two participating centres, and consideration for acceptance in other residential care centres in Tasmania. Such guidelines have the potential to facilitate positive changes in services provided to residential aged care centres by government-supported dental and oral health professionals. Importantly, documentation of the success of this project will strengthen our application for an NHMRC Project Grant to implement the oral health protocol nationally.

This project will build the capacity of Facility Managers to support care staff in driving clinical innovation. It has the potential to increase the capacity of nurses and point-of-care staff to provide evidence-based daily oral care for residents, including those with dementia. It has the potential to increase the capacity of residents, including those with dementia, to participate actively in their own care. Further, it has the potential to increase the capacity of dental and oral health students to work effectively with adults living in residential aged care. The success of this current Tasmania-based project also may facilitate funding from philanthropic organisations to support the purchase of timed electric toothbrushes for adults living in residential care.

From our academic publications, we will develop short articles for the lay press, e.g., *Women’s Day*; *Australian Ageing Agenda*. Such publications are valuable vehicles for disseminating needed information about the critical importance of sustained effective oral care for adults living in residential aged care communities, particularly those with dementia.