Myofunctional Device Use in Oral Care and Swallowing: Protocol for a Pilot Study in an Aged Care Population

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Study Protocol

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Abstract

Background

Poor oral health is a known predictor of aspiration pneumonia in vulnerable populations such as the elderly and chronically ill and has been linked to systemic disease, morbidity, and mortality. Reduced oral health not only places individuals at a greater risk of aspiration pneumonia but may result in pain or poorer dentition which can impact on mastication and swallowing. Consequences of this may include reduced oral intake, malnutrition, poorer health outcomes and reduced quality of life. Few evidence-based protocols exist to manage oral care in aged care populations, and maintenance of good oral hygiene is difficult for nursing and care staff to facilitate. However, myofunctional devices reportedly improve oral hygiene, oral behaviours, and swallowing, along with breathing and speech. The primary aims of this study are to assess the feasibility and acceptability of using a myofunctional device to improve oral care and swallowing function in an aged care population.

Methods/Design

This project is a pilot study that involves a five-week intervention for oral hygiene and dysphagia for residents >65 years old in an aged care setting. Feasibility will be measured by number of consenting participants, trial completion rates, and treatment adherence. Acceptability will be measured through verbal surveys of aged care residents and a questionnaire of care staff assisting with the intervention. Secondary outcome measures will record changes in oral hygiene and dysphagia pre and post intervention.

Discussion

The results of this trial will provide important information regarding the acceptability and feasibility of utilising a myofunctional device to improve oral care and dysphagia in elderly patients in an aged care facility. This knowledge will further guide and inform design of a larger trial or future research.

Trial registration

This trial was registered 8/10/2021 with the Australian New Zealand Clinical Trials Registry and allocated the ACTRN: ACTRN12621001359820. Web address for trial: https://www.anzctr.org.au/ACTRN12621001359820.aspx

Background

The link between poor oral health with systemic disease, morbidity and mortality has been demonstrated extensively throughout allied health, nursing, and dental literature [1, 2, 3, 4]. Oral health is important in both children and adults. Poor oral health, such as tooth decay, gum disease and tooth loss, contributed to 4.5% of non-fatal deaths in Australia in 2015, with 78% of oral disorders in people aged 85 years and over relating to poor oral health [5]. Oral health deteriorates over a person’s lifetime, with children aged 5-10 years of age on average having 1.5 decayed, missing or filled teeth. In contrast, an adult 75+ years on average has 24.4 decayed, missing or filled teeth [6]. The rate of tooth decay has been reported to be higher in the Indigenous population and those in rural and remote areas in Australia [7]. Early-stage gum disease, known as gingivitis, is caused by an accumulation of plaque on the teeth and gum line. It can cause inflammation and irritation to the gums which if left untreated leads to more serious periodontal disease, including damage to the soft tissue and loss of teeth [8]. In 2017-2018, the proportion of adults with advanced stage gum disease, periodontitis, increased with age from 51% in those 55-74 years, to 69% in those 75 years and over [5]. Further to this, the Australian Institute of Health and Welfare (AIHW) [6] reported that between 2017-2018 there were approximately 72,000 hospitalisations in Australia for dental conditions that may have been prevented with earlier treatment.

Factors that influence poor oral health are consumption of sugar, alcohol, and tobacco; reduced access to dental services; and reduction in good oral hygiene [6]. The Australian Health Ministers Advisory Council (AHMAC) [7] identified four population groups that are at greater risk of poor oral health, including socially disadvantaged or low income; Aboriginal and Torres Strait Islander Australians; those living in rural and remote areas; and people with additional and or specialized health care needs such as those with mental illness or the frail older population. Reduced oral health and an inability to manage oral health independently is a predictor of aspiration pneumonia in vulnerable populations such as the elderly and chronically ill [9]. If oral health is reduced, not only are people at greater risk of aspiration pneumonia, but they may also have pain or poorer dentition. This impacts on mastication and swallowing, with potential for malnutrition, poorer health outcomes and reduced quality of life [10]. Reduced oral health is associated with a number of chronic diseases including stroke and cardiovascular disease [11].

There are several factors that impact on oral hygiene and swallowing ability. An oral breathing pattern may result in a dry oral cavity and reduced oral hygiene, which further impacts on swallowing and may increase the risk of aspiration pneumonia [12]. Reduced oral hygiene may lead to pain, and/or increased difficulties with mastication, further leading to decreased muscle bulk and poor tolerance of diet consistency [12]. The need for change of diet consistency may be influenced by the risk of aspiration or choking, and in populations such as the elderly these diet changes may lead to increased risk of malnutrition, dehydration and consequently, a reduction in quality of life [13]. Researchers [12] explored the impact of myofunctional devices on speech, swallowing and quality of life in the elderly, noting that a reduction in lip tone in the elderly population may further influence an oral breathing pattern over nasal breathing, which can result in a dryer oral cavity. The lack of knowledge of oral healthcare in nursing staff in Australia was noted by Ajwani and colleagues [3] in their scoping review of integrated oral care for stroke patients. This scoping review of the literature highlighted the importance of oral health post stroke in reducing risk of aspiration pneumonia, the need for integrated oral health programs, and discussed the need for maintaining optimal oral health due to the links between gingivitis and cerebrovascular infarction as well as periodontal disease and stroke [3].
Currently there are limited oral care protocols with measurable outcomes that are used in hospitals and care facilities in Australia [14]. These protocols have been described as ad-hoc and often not prioritised in patient care [14]. This is of concern to speech pathologists due to the impact of poor oral health on mastication, swallowing function and increased risk of aspiration. However, a recent literature review [15] found that improvements in oral hygiene, oral behaviours, and swallowing, along with breathing and speech have been found to be associated with the use of orofacial myofunctional therapy and myofunctional devices [16].

In a study by Shortland and colleagues (manuscript in preparation) into speech pathologists’ use and outcomes of myofunctional devices in therapy programs, there was found to be both similarities and differences in the use of myofunctional devices, and the therapy programs in which these devices are incorporated. This varied across intervention areas, caseloads and diagnoses amongst speech pathologists who utilized them. Shortland and Colleagues (manuscript in preparation) noted that the type of myofunctional device, timing of introduction, utilisation in isolation, adherence, and dosage variation of myofunctional devices used contributed to successful outcomes for swallowing, oral hygiene, breathing and speech. However, further education and research into myofunctional device use and guidelines to direct their use in speech pathology intervention was recommended, along with a coordinated approach and team input in assessment and intervention.

Despite this increase of evidence, there is limited research in speech pathology that addresses the use and outcomes of myofunctional devices in clinical practice [15]. The potential impact of improvement on orofacial function, including oral hygiene and swallowing, has already been identified with the use of myofunctional devices in literature from various health disciplines [17]. As well as this, there is a link between reduced oral hygiene and aspiration pneumonia [18], and the impact of a reduction in oral hygiene on quality of life [19]. It is relevant to further explore treatment dosage, utilisation, and outcomes of a myofunctional device in a population such as the elderly who make up a large proportion of those whose oral health and swallowing function may be impacted on [20].

This pilot study will provide necessary information to undertake a randomised control trial. The current research protocol will allow analysis of feasibility by testing procedures of myofunctional device use for acceptability, recruitment, and retention of participants. It will also determine sample size required for a larger clinical trial to evaluate the use and outcomes of a myofunctional device in oral care and dysphagia treatment in an adult population in care facilities.

**Methods**

**Design Overview**

This is a single-arm pilot study designed to examine the feasibility and acceptability of the use of a myofunctional device in improving in oral health and dysphagia in a residential, aged care population. The protocol presented is based on both the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) [21] and Consolidated Standards of Reporting Trials (CONSORT) [22] guidelines, to conduct an acceptability and feasibility pilot study. The proposed protocol is for a 5-week intervention period that involves twice daily use of a myofunctional device called MyoMunchee. There have been no previous trials using the MyoMunchee for management of oral hygiene and dysphagia with residents of an aged care setting. However, the intervention protocol was based on previous research, a cluster randomised control trial utilised a myofunctional device to promote lip closure and nasal breathing for oral neuromuscular training for those 65 years and older in short term care units with impaired swallowing [17]. The results indicated that swallowing function significantly improved for those in the intervention group immediately following 5 weeks of therapy and a significant reduction in signs of aspiration 6 months post treatment was found compared to the control group.

If this trial is found to be acceptable and feasible, the results will provide information for calculating the sample size needed for a randomised control trial [23, 24]. An overview of the study procedures is provided in Figure 1.

**Primary Aims**

The primary aims of this pilot study are to determine the acceptability of the device and intervention, feasibility of recruitment and adherence to intervention, and the preliminary effect of the device and intervention on oral hygiene and swallowing function.

- **Aim 1.** The acceptability of the new treatment intervention will be determined by treatment adherence, participant experience using the device and resident satisfaction with the treatment intervention.
- **Aim 2.** The feasibility of the treatment intervention will be determined by consenting rates, intervention completion rates, and intervention adherence.
- **Aim 3.** Determine the extent to which the device and treatment improve oral health, the reduction of perceived dysphagia symptoms and presence of dysphagia.

**Study Setting and Recruitment**

This will be a single intervention site study, conducted at an aged care facility (ACF) in Newcastle, Australia, with data analysis occurring at the University of Newcastle, Australia. The ACF consists of residents ranging in level of care including self-assisted retirement village living, residential care, low to high need dementia care and palliative care.

Participants will be recruited with the assistance of care staff (nursing/allied health professionals) at the ACF, by the provision of recruitment flyers and participant information statements outlining the study to residents/legal guardians who meet the inclusion criteria.
All residents and care staff who meet the selection criteria will be eligible to participate in this study. They will be identified by the Nursing Unit Managers (NUM) and the speech pathologist/s at the ACF and provided with an information flyer. The contact details for the study team have been provided on all flyers and information statements inviting prospective participants/legal guardians to contact the study team prior to enrolment in the study.

Care staff will be assisting in providing the intervention as part of their routine care for residents but will be invited to participate in a post intervention questionnaire through study flyers placed in break rooms and following intervention education sessions by the study team. All care staff will be supervising and assisting with the intervention for residents who consent to the research, as part of their usual oral care routine. This is approved and directed by management at trial site as part of their employee role. Care staff will be invited to participate a post intervention questionnaire regarding their experience of supervising and assisting residents with the trial intervention. Care staff who wish to participate in the post intervention questionnaire will need to complete a consent form and questionnaire which will be provided by the Nursing Unit Manager (NUM) of their ward.

The residents/families of residents/care staff will be provided with a participant information statement regarding the study, and then followed up by the NUM/speech pathologist for interest in study participation. There will be an opportunity for residents, family of residents, and care staff to ask questions before and after consenting to participate. Questions regarding the study can be directed by the staff at the ACF to the Principal Investigator. Residents/family of residents/care staff will be required to sign and provide written consent for participation. Time for consideration and return of consent for participation in the study will be 7 days after initial contact.

Explanation will be provided to residents/family of residents that their usual oral health care and dysphagia treatment will not vary with or without participation in this study. Further to this, a statement will be provided to participants that based on the results of the pilot study, a larger clinical trial using the intervention may not be performed.

This research will involve the use of information without personal identifiers, and it will be obtained from individuals or gathered from medical files by care staff appointed by the ACF.

As this is a feasibility pilot study utilising a myofunctional device not previously trialled in this setting, all consenting residents will receive the treatment intervention to better understand acceptability of the device and feasibility of completing a larger trial. No randomisation of participants will occur. The aim is to recruit 50 residents and 10 staff as participants in this research. This is based on the available recruitment pool, and the number of residents who may not give consent. Because this is a feasibility study this does not require a sample size base.

The expected period to recruit participants is four weeks.

**Participants**

Participants will include a sample of 50 residents from the ACF and 10 care staff (nursing and/or allied health staff) who will oversee the daily use of the device during the treatment period.

Residents at the ACF who meet the following selection criteria and who consent to participating in the study will receive the treatment.

1. age ≥ 65 years
2. Ability to understand English and follow instructions for timed water swallow test and use of the myofunctional device
3. Residents receiving texture modified diets (including normal cut up, easy chew, minced moist, and puree diets) and/or fluids
4. Residents with natural teeth, dentures (partial and full), and edentulous

Residents will be excluded for the following reasons:
1. Inability to provide informed consent including diminished understanding or comprehension, or inadequate English proficiency to follow directions for the intervention
2. On an end of life/palliative care pathway
3. Conditions that interfere with a patient's ability to comply with all treatment(s) and procedure(s) and to follow study guidelines
4. Identified Temporomandibular Dysfunction
5. Identified by the visiting oral health professional to have tooth mobility

Care staff will be included if they are care staff approved by the ACF to participate in monitoring the intervention as part of their usual duties. Care staff will be excluded if they are not nursing or allied health professionals.

**Study Intervention**
Aged care resident participants will complete a 5-week intervention program using the MyoMunchee® Badge. The device will be used twice daily (morning and evening recommended at the time of usual oral care routine) by the participants. This will require active use of the device with the action of chewing following the placement of the device in the oral cavity. The duration for device use will start at 1 minute twice a day in the first week, and increase by one minute each week, to 5 minutes twice a day by the fifth week of intervention (as seen in Table 1).

Care staff will facilitate the delivery of the 5-week intervention, 7 days per week, with daily monitoring and twice daily documentation of the use of the device. The research team will provide the residents/care staff with instructions and a guide for the use of the device with education regarding familiarization and instructions for use of the device (MyoMunchee®), cleaning and storage of the device, and documentation of device use. Explanation regarding the cleaning, cleaning schedule and storage of this will be provided as per MyoMunchee® cleaning protocol, which includes rinsing the device in water before and after use, shaking dry and storing in the provided storage container.

Table 1 Overview intervention schedule

| Training and Intervention | Content                                                                 | Staff Responsibility                                                                 |
|---------------------------|-------------------------------------------------------------------------|--------------------------------------------------------------------------------------|
| Week 1                    | Device use twice daily for 1 minute (morning and evening)                | Supervision with device use and documentation of completion of intervention twice daily. This will continue from weeks 1-5. |
| Week 2                    | Device use twice daily for 2 minutes (morning and evening)               |                                                                                      |
| Week 3                    | Device use twice daily for 3 minutes (morning and evening)               |                                                                                      |
| Week 4                    | Device use twice daily for 4 minutes (morning and evening)               |                                                                                      |
| Week 5                    | Device use twice daily for 5 minutes (morning and evening)               |                                                                                      |

Treatment Fidelity

Twice daily use of the myofunctional device will be recorded by the care staff at the ACF via a checklist. An example of the first week of intervention checklist is provided in the appendix (Appendix A.). The NUMs for each area of the ACF will ensure care staff are accurately documenting intervention completion. The daily checklist will be collected by the care staff at the ACF at the end of each week of intervention and replaced with a new checklist for the corresponding week of intervention which includes instructions on the duration of device use for that week. The study team will be available to answer questions from the care staff regarding the intervention during the five weeks and monitor for deviations from the study protocol such as the use of the device or adherence of the participant or the study site staff.

Participant Retention

Strategies used to maximise participant retention include education and training provided to care staff who will be responsible for facilitating the delivery of the intervention, ensuring the intervention is completed twice daily for the specified duration. Participants will be provided with the device for the duration of the intervention and will also be permitted to retain the device following the intervention period.

Safety Monitoring

This study involves a new intervention with a vulnerable population. However, the intervention uses a device that has Australian Therapeutic Goods Approval and the residents who will be using this device will be monitored by care staff during the intervention as per Table 2. below.

Table 2 Potential Risks and Solutions for residents undertaking intervention
Details of each of these measures are provided in Table 4. Exploratory measures include oral health, aspiration risk, mastication ability, presence of dysphagia, functional oral intake, self-perception of eating, and cognitive function. Details of each of these measures are provided in Table 4.

Outcome measures to provide preliminary data on the effect of the treatment on oral care and swallowing function will be collected 1-week pre and post intervention. Feasibility of intervention will be measured by the number of potential participants versus consented, intervention completion rates, and adherence to the treatment protocol.

Assessment results, daily monitoring by care staff and review of daily data sheets to prevent adverse events.

Monitoring and reporting of adverse events (AE), serious adverse events (SAE) and unexpected events (UE) will be conducted as per the ACF incident reporting system ‘iOnMY’ (governance, risk management, compliance platform), and entered by care staff as per the ACF incident reporting guidelines. Events will be reported to the principal investigator within 24 hours of the UE/AE/SAE and entered into the University of Newcastle adverse events form in Research Information Management System within 72 hours of being reported as per NHMRC guidelines [25]. All UE/AE/SAE will be assessed by the principal investigator using the University of Newcastle risk assessment matrix and NHMRC [25] guidelines of level of severity and reported to the sponsor and trial site by the principal investigator within 24 hours of the principal investigator becoming aware of any urgent safety concerns.

Discontinuation of intervention for a participant may occur if an AE or medical condition occurs such that participation in the study would not be in the best interest of the participant or the participant met an exclusion criterion (newly developed or not identified on consent) that precludes further study participation.

Assessments and Measures

Acceptability of the intervention will be measured by administering a resident acceptability survey to all enrolled residents, regarding the participant experience of ease of use, comfort with use, and if there were perceived changes to oral health or swallowing following the use of the device. The survey of the residents receiving the intervention regarding experience using the device, will use a 5-point Likert scale (very difficult – very easy), and dichotomous questions (yes – no). Assistance in reading the survey for residents with visual impairment, aphasia, and cognitive and intellectual impairment will be provided by a staff member at the ACF. Acceptability will be further measured through the administration of a care staff acceptability questionnaire to those assisting with the intervention, as well as perceived acceptance of the device by residents.

Feasibility of intervention will be measured by the number of potential participants versus consented, intervention completion rates, and adherence to the intervention (monitored by care staff through supervision of the intervention, and completion of daily intervention sheets). Feasibility will be further measured on the care staff questionnaire to rate the ease of use and cleaning of the device, and the impact on workload. This questionnaire will use both a 5-point Likert scale (very difficult – very easy), dichotomous questions (yes – no), and free text.

Outcome measures to provide preliminary data on the effect of the treatment on oral care and swallowing function will be collected 1-week pre and post intervention. Exploratory measures include oral health, aspiration risk, mastication ability, presence of dysphagia, functional oral intake, self-perception of eating, and cognitive function. Details of each of these measures are provided in Table 4.

| Potential Concern                      | Strategy                                                                 |
|----------------------------------------|--------------------------------------------------------------------------|
| Device labelling/identification        | Devices will be stored as per dentures in storage container specifically for the MyoMunchee, labelled with the participant’s identification number. The MyoMunchee will be stored as per the ACF protocol for storage and identification of usual oral hygiene products. |
| Lost/misplaced device                  | In the event of the MyoMunchee being misplaced/lost a new replacement device will be provided |

Further considerations have been made regarding storage and labelling of the devices to minimise infection control risks (as per Table 3.)
Table 4 Secondary outcome measures for collection 1-week pre and 1-week post intervention

| Outcome Measure                                      | Reference | Outcome          | Description                                                                                                                                                                                                 |
|------------------------------------------------------|-----------|------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Oral Health Assessment Tool (OHAT)                   | [28]      | Oral health      | Reliable and valid screening tool for use in aged care and with cognitive impairment; Approximately 7-8 minutes to administer; 8 items, Rating scale – 0 = healthy, 1 = changes, 2 = unhealthy; Total score out of 16, The higher the score the worse the oral health; Items that score 1 indicate intervention is required, and items scoring 2 indicate referral to a dental professional is required |
| Timed Water Swallow Test (TWST)                      | [27]      | Aspiration risk  | Swallow speed is a sensitive indicator for identifying patients at risk of swallow dysfunction; Choking in 100ml WST may be a potential indicator for follow up aspiration; Measures swallow time, number of swallows and observes for signs of choking; Abnormal swallow is defined as a speed below 10ml/s (amount of water divided by elapsed time); Count the number of swallows taken to consume 100mls water, Time taken to consume 100mls water |
| Test of Mastication and Swallowing Solids (TOMASS)   | [28]      | Mastication ability | Quantitative assessment of solid bolus ingestion; Sensitive in detecting changes in performance ability of mastication; High interrater and test-retest reliability; Count number of bites, number of masticatory cycles per bite, number of swallows per bite; More likely to identify patients with subtle oral phase impairment or bolus transition issues; Normative ranges in older adults: number of bites (male 1.47/female 1.87), time in seconds (male 32.61/female 41.85), total number of swallows (male 3.61/female 3.5), masticatory cycle (male 37.6/female 41.65) |
| Mann Assessment of Swallowing Ability (MASA)         | [29]      | Identify swallowing disorders | Screening bedside tool to identify eating and swallow disorders in stroke and other diseases; Used to quantify aspiration risk; 24 clinical items; 4 components of the assessment include, general patient examination, oral preparation, oral phase, and the pharyngeal phase; 5-10 point rating scale; score out of /200, >178 = normal, 168-177 = mild, 139-167 = moderate, <138 = severe; risk of aspiration is defined on a sum of the 4 scores/categories, >170 = normal, 149-169 = mild, 141-148 = moderate, <140 = severe |
| Functional Oral Intake Scale (FOIS)                  | [30]      | Functionality     | 7-point ordinal scale; Functional level of oral intake of food and liquid; Interrater reliability high and sensitive to changes; Levels 1-3 relate to non-oral feeding; Levels 4-7 relate to varying degrees of oral feeding; All levels focus on what is/not consumed orally |
| Eating Assessment Tool (EAT-10)                      | [31]      | Self-perceived symptoms | Screen self-perceived oropharyngeal dysphagia symptoms: Scores range from 0-40; Scores >3 are indicative of dysphagia; 10 questions rated on a 5 point scale, 0 = no problem, 4 = severe problem; Scores >15 indicative of aspiration risk; An elevated EAT-10 score indicates a higher self-perception of dysphagia |
| Mini Mental State Examination (MMSE)                 | [32]      | Cognitive function | Widely used screening test of mental function; Evaluates cognitive impairment in older adults; 10 minutes to complete; normal = 30-25, mild = 24-21, moderate < 21-10, severe < 9-0 |

Data collection

The number residents approached to participate in the study versus those who consented to participate will be collected in the recruitment period before pre intervention assessments commence (as per Table 4). The intervention completion rate of those who consented to participate and those who completed the five-week intervention will be collected following the five-week intervention and collection of post intervention assessment. Data will be collected for adherence to the intervention during the five-week study period by way of daily checklist completion by the care staff that residents have completed the intervention twice daily for the specified amount of time. The checklist will be collected at the end of each week and entered in an electronic database each week by the principal investigator. Further to this a survey of the residents completing the intervention, as well as a questionnaire for the care staff assisting participants with the intervention will be taken at the completion of the five-week intervention trial.

Pre and post intervention outcome measures collected for comparison to observe changes in oral hygiene and swallowing function. Data collection of outcome measures will be completed by a qualified clinical speech pathologist/principal investigator (with over 17 years clinical experience). Reliability checking of pre and post outcome measure collection of 10% of residents will occur onsite at the ACF by a qualified clinical speech pathologist from the University of Newcastle, independent of the study.

Resident participant’s demographic data (see Figure 2.) will be extracted from the medical files of each consenting participant by an employee appointed by the ACF. The data will be deidentified using a code and then provided to the research team.

Data Analysis

A sample size calculation is not appropriate for this study as it is a Stage 1 Pilot study. However, our target sample size is 50 residents and 10 care staff which is based on the available recruitment pool. Assessment of consenting rates versus intervention completion rates will involve statistical analyses and will be performed using SPSS, version 22. The primary outcome will be reported as numbers and percentages. Outcome measures will be summarised using mean (SD) for normally distributed data, median (interquartile range) for non-normally distributed data and number (percent for categorical data). Pre and post-intervention comparisons will be performed using a paired t-test. Effect size and 95% confidence interval will be calculated. The significance level will be set at p<0.05. In addition, for each of the secondary outcome measures, linear regression will be used to measure changes in secondary variables while controlling for age, cognition, adherence, comorbidities, and ability to implement the MyoMunchie independently.
Data collected through post intervention survey of residents and care staff questionnaires will use qualitative content analysis as described by Graneheim and Lundman [33] to analyse participants’ free text responses. Free text data will be transcribed verbatim and analysed with NVivo 12.0 Software to assist with the identification of patterns in the text segments of the care staff questionnaire. For questions using a Likert scale data will be analysed descriptively using distribution of responses provided by participants.

Discussion

The link between oral health and the inability to manage this independently is a known predictor of aspiration pneumonia in vulnerable populations such as the elderly and chronically ill [18]. The links between poor oral health with systemic disease, morbidity and mortality has been demonstrated extensively throughout allied health, nursing, and dental literature [5]. If oral health is reduced, people are not only at greater risk of aspiration pneumonia, but they may have pain or poorer dentition which impacts on mastication and swallowing, and reduced oral intake, with potential for malnutrition, poorer health outcomes and reduced quality of life [19].

The results of Shortland and colleagues [15] systematic review reported improvements in oral hygiene, oral behaviours, and swallowing, along with breathing and speech to be associated with the use of myofunctional devices. Therefore, it would be relevant to further explore treatment dosage, utilisation, and outcomes of a myofunctional device in a population such as the elderly who make up a large proportion of those whose oral health and swallowing function may be impacted [20].

The outcomes from this study of acceptability and feasibility of test procedures for the use of a myofunctional device in improving oral health and dysphagia in an aged care population, will further guide the design of a randomized control trial.

Abbreviations

ACF: Aged Care Facility; OHAT: Oral Health Assessment Tool; WST: Timed Water Swallow Test; TOMASS: Test of Mastication and Swallowing Solids; MASA: Mann Assessment of Swallowing Ability; FOIS: Functional Oral Intake Scale; EAT-10: Eating Assessment Tool; MMSE: Mini Mental State Examination; NUM: Nursing Unit Manager; AE: Adverse Events; SAE: Serious Adverse Events; UE: Unexpected Events; PIS: Participant Information Statement; AIHW: Australian Institute of Health and Welfare; AHMAC: Australian Health Ministers Advisory Council.

Declarations

Ethics Approval

The study will be conducted in full conformance with principles of the National Statement on Ethical Conduct in Human Research (NHMRC, 2007), Australian Code for the Responsible Conduct of Research (2007) and within the laws and regulations Australia.

Ethics approval was granted on 30th September 2021 by the University of Newcastle Human Research Ethics Committee (Approval number H-2021-0250).

Consent for publication

All participants/guardians are required to provide signed consent to participate in this study and agree to the publication of unidentifiable group data.

Availability of data and materials

The study will adhere to The Australian Code for the Responsible Conduct of Research (2018) as well as the University of Newcastle Data management policy (2017).

Following the publication of the pilot study the datasets used and analysed will be available from the author on reasonable request.

Competing Interests

A scholarship between the University of Newcastle and an industry partner MyoMunchee has been provided to the first author completing a higher degree of research. The authors alone are responsible for the recruitment of participants, collection and analysis of data, and the content and writing of the paper.

Funding

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Author’s contributions
HS, SH, and GW planned the project, developed the research design. SH, GW and AV were responsible for supervising HS (higher degree research student) in the design of this protocol. HS wrote the first draft of the manuscript, and SH and GW were responsible for revisions. All authors revised the final manuscript for submission.

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**Figures**
Figure 1
Flowchart of study procedures
| Variable                                               | Justification          |
|--------------------------------------------------------|------------------------|
| Resident ID number                                     |                        |
| Male/Female/Non-binary                                |                        |
| Date of Birth/age                                      |                        |
| Identifies as Aboriginal or Torres Strait Islander    | Yes/No                 |
| Underlying Medical Diagnosis                          |                        |
| - CVA - year                                          |                        |
| - Dementia                                            |                        |
| - Parkinson’s Disease                                  |                        |
| - Cardiovascular disease                              |                        |
| - Cancer - specify                                     |                        |
| - COPD                                                 |                        |
| - Diabetes                                             |                        |
| - Multiple Sclerosis                                   |                        |
| - Epilepsy                                             |                        |
| - Hypertension                                         |                        |
| - Osteoporosis                                         |                        |
| - Arthritis                                            |                        |
| - Depression                                           |                        |
| - Asthma                                               |                        |
| - Motor Neuron Disorder                                |                        |
| - Polymyositis                                         |                        |
| - Other                                                |                        |
| Dentition (own, edentulous, dentures)                 | Own/Dentures/Edentulous |
| Diet/Fluid consistency                                 |                        |
| - NBM                                                  |                        |
| - PEG                                                  |                        |
| - JJ Tube                                              |                        |
| - Other                                                |                        |
| - Liquidized                                           |                        |
| - Puree                                                |                        |
| - Minced Moist                                         |                        |
| - Soft Bite Sized                                      |                        |
| - Easy Chew                                            |                        |
| - Normal Diet                                          |                        |
| - Extremely Thick                                      |                        |
| - Moderately Thick                                     |                        |
| - Mildly Thick                                         |                        |
| - Slightly Thick                                       |                        |
| - Thin Fluids                                          |                        |
| MMSE score/date last assessment                        | Score: Date:          |
| Independence in oral care                             | Yes/no/maybe/unsure    |
| Living status                                          | Independent Living/ACF |

**Figure 2**

Resident data collection form

**Supplementary Files**

This is a list of supplementary files associated with this preprint. Click to download.

- AppendixA.Protocol.docx