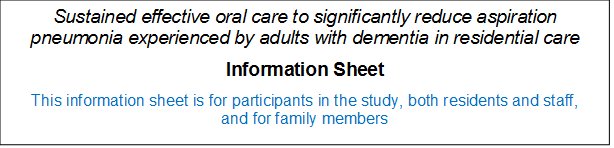
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**1. Invitation**

You are invited to participate in this research study focused on improving the oral health of people with dementia who live in residential aged care. You have been invited to participate because you either live or work at Fred French or Peace Haven Masonic Care communities in Launceston. If you work at Fred French or Peace Haven, you are involved in providing oral care to people who live in these two aged care communities. Your participation in this project is entirely voluntary. If you decide not to participate now, or if you withdraw at a later time, this will not affect your life or employment at Masonic Care Tasmania in any way.

**2. What is the purpose of this study?**

The purpose of this study is to decrease the risk of developing aspiration pneumonia for people living in residential aged care. Aspiration pneumonia is a lung infection for which people are often hospitalised, and people with dementia seem to be particularly vulnerable. Aspiration pneumonia develops when food, liquid and/or saliva containing harmful oral bacteria is misdirected (aspirated) into the airway and then into the lungs and the lungs cannot clear the aspirated material. Studies show that keeping the mouth clean plays a critical role in preventing aspiration pneumonia. Keeping the mouth clean is best done by conducting an oral health screening to see how healthy each person’s mouth is, taking care of any immediate oral and/or dental problems, and then ensuring that people residing in aged care clean their teeth for 2 minutes after each meal or clean their dentures each day and remove them for sleep. Masonic Care Tasmania, through the Fred French and Peace Haven Homes, has agreed to participate with researchers at the University of Tasmania and Oral Health Services Tasmania in this oral health study. Our aim is to see if oral health screening followed by 2 minutes of teeth cleaning after meals or daily cleaning of dentures with removal for sleep reduces clinical signs of aspiration pneumonia, especially for people with dementia who live at Masonic Care Tasmania/Launceston.

**3. Who is responsible for this study?**

Dr Lyn Goldberg, Associate Professor Leonard Crocombe, and Dr Ioan Jones are responsible for this study and will be working with residents and staff at Masonic Care Tasmania/Launceston. Lyn is a researcher at the Wicking Dementia Research and Education Centre (University of Tasmania); Len is a researcher at the Centre for Rural Health (University of Tasmania) and Ioan is a dentist with Oral Health Services Tasmania. This research is being funded by the National Health and Medical Research Council/National Institute of Dementia Research (NNIDR). Additional members of the team who will not be at Masonic Care Tasmania but who will be involved in the analysis of the information you provide are Professor Andrew Robinson, Dr Emma Lea, Dr Juanita Westbury, Professor Andrew Palmer, and Professor Fran McInerney. All are employed by the University of Tasmania.

**4. What will you be asked to do?**

First, you will be asked to provide your Informed Consent to participate. If you are a resident, a member of your family may provide consent on your behalf. You can find a copy of the Informed Consent form at the end of this Information Sheet.

**If you are a resident**, you will then be asked to complete the following screening measures with members of the research team:

**(a) Oral health**: We will look at your face and lips and then ask you to open your mouth so we can look at your tongue, gums, oral tissues, teeth or dentures, and saliva to rate how healthy they are and whether you need any immediate and specific oral or dental care. We will shine a small light into your mouth so we can see. We also may place a soft wooden tongue depressor on the front of your tongue to keep it steady and gently hold your cheek to one side in the oral examination. If we hold your tongue and/or cheeks in place, we will do this for a short time, only seconds.

**(b) Mini-Nutritional Assessment (MNA)**: We will ask you (or your family member, nurse or carer who knows you well) the following questions to determine your risk for being malnourished:

• Has your food intake declined over the past 3 months due to loss of appetite, digestive problems, chewing or swallowing difficulties?

• Have you lost weight unintentionally during the last 3 months?

• How easily are you able to get out of bed and move?

• Have you suffered psychological stress or acute distress in the past 3 months?

• Are you experiencing any neuropsychological problems such as depression and/or dementia?

• What is your height and weight so we can calculate your Body Mass Index (BMI)?

**(c) Yale Swallow Protocol**: We will give you a cup containing 90 mL (3 ounces) of room temperature water and ask you to drink the water through a straw without stopping. If you begin to cough while drinking, we will ask you to stop drinking. This measure helps us determine how well your swallow is coordinated and any risk for material (food, liquid, or saliva) going into your lungs instead of into your stomach.

**(d) The Euro-Qol-5 Dimension (EQ-5D-3L) Tool**: We will ask you (or a family member, nurse, or carer who knows you well) to rate any difficulty you have with mobility (movement), personal care, usual activities (e.g., housework or leisure activities), pain or discomfort, and anxiety or depression. Then we will ask you to draw a line on a scale (rather like a ruler or thermometer) to show us how good, or bad, you feel your health is.

You can find examples of these screening measures or explanatory pictures of them at the end of this Information Sheet.

**If you are a resident**, after the screening measures are complete, you will be assisted to clean your teeth for 2-minutes after each meal for the 3-month study period. Family members can help you with this if you wish. Dental and oral hygiene students also may be available to assist you, especially after lunch. We will ask you to use a timed electric toothbrush as this is the easiest way to clean teeth for 2 minutes. We will show you how to use this toothbrush. If you are uncomfortable with this electric toothbrush, you can use a regular toothbrush. We will work with you to develop strategies to use a regular toothbrush for 2 minutes, such as cleaning your

teeth while listening to favourite songs. If you wear dentures, you will be helped to clean them each day and to make sure you take them out any time you are going to sleep.

If you have listed your doctor and dentist in your Masonic Care Tasmania record, staff will send them information about the study and what you are being asked to do.

**If you are a resident**, when the 3-month study period ends, we will ask you to complete the four screening measures again. This will help us determine if any changes have occurred in your oral health, eating and swallowing, quality of life, and risk for aspiration pneumonia.

**If you are a staff member**, you will be asked to attend a 60-minute education session prior to helping residents clean their teeth for 2 minutes after meals or clean their dentures daily and remove them for sleep. In this education session, you will be asked to complete the 27-item Dementia Knowledge Assessment Scale (DKAS), developed by the Wicking Centre, and to write a brief narrative about your experiences in providing oral care for people with dementia. During this education session, members of the Research Team will explain the purpose of the screening measures and how each is administered. When the 3-month study period ends, you will be asked to write another brief narrative about your experiences with this oral health study and your insights into oral care for people with dementia.

**If you are a staff member**, you will be asked to help residents use a timed electric toothbrush, or a regular toothbrush, to clean their teeth for 2-minutes after meals. If you are caring for people who wear dentures, you will be asked to ensure that the dentures are cleaned daily and taken out of the mouth when residents go to sleep.

**If you are a staff member**, you may be asked to serve as a designated oral care champion at the Fred French or Peace Haven community. If you agree to this role, you will be asked to assist with daily checks of residents to ensure that the timed teeth cleaning after meals or daily denture cleaning is being done.

**5. Are there any possible benefits from participating in this study?**

If you live at the Fred French or Peace Haven aged care communities, need assistance with teeth or denture cleaning, have difficulty with thinking and remembering or have been diagnosed with dementia, you will benefit from this study. Cleaning your teeth for 2 minutes after meals or cleaning your dentures each day and taking them out when you sleep will reduce harmful bacteria in your mouth and remove any food that might remain under your tongue, in your cheeks, or between your teeth and gums. If any saliva is misdirected into your airway and into your lungs when you swallow, this saliva will be coming from your clean mouth. Your risk of developing a lung infection and fever, and needing antibiotic treatment or hospitalisation will be much less. Having a clean mouth will help to reduce any oral pain or discomfort and help you to eat better. Eating better will help you maintain weight and not become frail. If you feel strong, or stronger, you may be able to move about more easily.

If you are a member of the nursing or care staff at the Fred French and Peace Haven communities, you will benefit by working closely with residents to assess their oral health through the oral health screening and then by helping to provide 2-minutes of teeth cleaning after meals or daily cleaning of dentures with removal for sleep. We anticipate that improved

oral health will result in less ill health for residents, particularly from aspiration pneumonia. Improved oral health also will enable residents to eat without discomfort, eat more textured foods, and maintain weight. Residents’ improved eating and improved health will help to decrease the amount of care you provide (decreasing the burden on you) and allow you more time for other responsibilities. Your insights from your experiences in this study will be valuable in helping nursing and care staff in other residential aged care communities understand the importance of daily oral care for residents and the relationship between oral health, reduced risk of aspiration pneumonia, and increased overall health, particularly for people with dementia.

**6. Are there any possible risks from participation in this study?**

We feel there are no foreseeable risks or harm that will come to you from participating in this study.

**If you are a resident**, you are familiar with being asked to open your mouth for a dentist to look inside, drinking liquid, and answering questions. These routine activities are part of the oral health screening in this study. If you do not wish to answer questions about any anxiety, depression, or pain you are experiencing, or become uncomfortable answering such questions, please tell us. We will let staff at Fred French or Peace Haven know and they will provide you with appropriate support.

You are also familiar with being helped to clean your teeth or dentures as this is part of your regular care. If you have your own teeth, we are encouraging you to use a timed electric toothbrush, with soft bristles, to clean them. This electric toothbrush will vibrate and beep every 30 seconds. This beep is your clue to move the toothbrush to another place on your teeth. We will show you where. If you do not like the feel of the vibration or the beeping sound, you are welcome to clean your teeth using a regular, soft toothbrush.

If you are used to cleaning your teeth for less than 2 minutes after meals, you might find you need to build up to 2 minutes of teeth cleaning over time. Staff will help you with this.

**If you are a staff member**, you are familiar with answering survey questions and documenting your opinion or perceptions in the continuing education that is part of the regular accreditation of Masonic Care Tasmania. You are also familiar with assisting residents to clean their teeth or dentures, and the strategies needed to encourage some residents to open their mouth. The difference in this oral health study, compared to routine oral care, is our aim to assist residents to clean their teeth for longer, i.e., 2 minutes, after meals, or clean their dentures daily and remove them for sleep.

**7. Will the information I provide be anonymous?**

Yes. Whether you live or work at Fred French or Peace Haven communities, you will not be identified by name in any study materials. Your name will be matched to a code number and this number will be written on any document that contains information about you. Lyn, the lead investigator on the Research Team, will keep the list of names and matched codes in a locked cabinet. When the information you provide is analysed at the end of the study, this information will be analysed by group, not individually. There will be no way that the information you have provided can be identified as yours. As an example, we might report, “An analysis of residents’

oral health showed that…” or “The average score on the Dementia Knowledge and Assessment Scale for care staff was …”

**8. What if I change my mind during or after the study?**

You are free to withdraw from this study at any time. You will not need to give any reason for doing so and there will be no negative effects on your life or employment at Masonic Care Tasmania. If you choose to withdraw, please inform Di McIntee (at Fred French) or Zane Healy (at Peace Haven). Di and Zane will let Lyn know. Lyn will be able to match your coded information to your name and then destroy the information you have provided.

**9. What will happen to my information when the study is over?**

All information collected as part of this study will be treated in a confidential manner and will only be accessed by members of the Research Team for analysis and writing reports or journal articles about the study. The paper-based and de-identified information you provide will be kept in a locked cabinet in the primary investigator (Lyn)’s office. This information also will be transferred to computer files and held in University of Tasmania secure cloud storage backed up to a secure server. The paper- and computer-based information will be held for seven (7) years after we have begun to publish reports and journal articles about the study. After this seven year period, we will shred the paper records, and delete the data from the server. We also will transfer the computer-based information to a disc and this disc will be destroyed.

**10. How will results of the study be reported and published?**

When the study has concluded, members of the Research Team will conduct a workshop or a series of meetings at Fred French and Peace Haven communities to let you know about the findings and what they might mean. This will give you an opportunity to let us know what you think about the study. We will value your comments.

To let the professional community know about the study, we plan to publish articles about the results in specialist academic journals in 2018. We will share copies of any publications with you. You will not be able to be identified in any publication of the results.

To inform the community-at-large about the results of the study, we may use social media, television interviews, and short reports in local newspapers.

**11. What if I have questions about this study?**

If you have further questions about this study, you can contact the following members of the Research Team:

Dr Lyn Goldberg

Phone: 6226 6953, Email: [Lyn.Goldberg@utas.edu.au](file:///D:\Lyn.Goldberg@utas.edu.au)

Associate Professor Leonard Crocombe

Phone: 0419 597 756, Email: [Leonard.Crocombe@utas.edu.au](file:///D:\Leonard.Crocombe@utas.edu.au)

Dr Ioan Jones

Phone: 1300011013, Email: [Ioan.jones@ths.tas.gov.au](file:///D:\Ioan.jones@ths.tas.gov.au)

This study has been approved by the Health and Medical Human Research Ethics Committee (HREC). If you have concerns or complaints about the conduct of this study, please contact the Executive Officer of the HREC (Tasmania) Network on (03) 6226 6254 or email human.ethics@utas.edu.au. The Executive Officer is the person nominated to receive complaints from research participants. You will need to quote ethics reference number H0016399.

**This Information Sheet is for you to keep**

**The Informed Consent forms**

**and other explanatory documents are on the following pages**

If you are living at the Fred French or Peace Haven communities and would like to participate in the study, you will need to sign the Informed Consent form or have a family member sign on your behalf. If you sign the form yourself, you will also need a witness to sign the form.

If you are a staff member who is involved in providing oral care to people living at the Fred French or Peace Haven communities and would like to participate in the study, please sign the Informed Consent form.

Please return your signed Informed Consent form to:

Di McIntee (at Fred French)

or

Zane Healy (at Peace Haven)

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