Research Article

TESTING A PROTOCOL TO INVESTIGATE XEROSTOMIA MANAGEMENT IN A HOSPITAL PALLIATIVE CARE SETTING - A PILOT STUDY

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Abstract

Objectives: This pilot study aimed to test a clinical trial protocol to investigate xerostomia management in palliative care inpatients in Sydney, Australia.

Methods: A pilot study using a double blind randomised protocol was used to compare the effectiveness of treatment groups receiving two commercially available dry mouth gels (Group A (n=5), Group B (n=7)) against a control group (Control (n=6)) receiving sodium bicarbonate swabs over a seven day period. Pre- and post-intervention Likert scales were used to measure change in xerostomia symptoms. Data on the range of measures used for dry mouth relief at trial commencement was also collected.

Results: The protocol was feasibly applied in the palliative care setting. The dry mouth products were not significantly different in reducing the symptoms of xerostomia for inpatient palliative care patients. Participants in all three groups showed worsening of xerostomia symptoms over the trial period.

Conclusions: This pilot study provides a framework for the development of a definitive protocol for further study of dry mouth products used for xerostomia by patients in palliative and supportive care.

Keywords: Dry mouth; xerostomia; palliative care; supportive care

I. Introduction

Xerostomia, the subjective sensation of dry mouth, is one of the most common and distressing symptoms experienced by patients in the palliative or supportive care setting.[1] It is often considered by health care professionals to be of low priority in comparison to the complex care needs of patients with terminal and life threatening

diseases.[2] However, xerostomia can have a profound impact on a patient's overall morbidity, physical, social and psychological wellbeing, resulting in an additional burden impacting on the quality of life. Specifically, patients report negative functional impact on sleep, speech, taste, chewing and swallowing, resulting in social embarrassment, malnutrition and chronic discomfort.[2,3] The prevalence of xerostomia increases with age and is more common in those over the age of 65 years. It is estimated to affect 70-78% of patients in their last weeks of life and has been found to be one of the most frequent however under-reported and under-estimated adverse conditions by physicians and patients.[4-12] Xerostomia is the most common symptom of salivary gland hypofunction, which reflects an objective, measurable decrease in salivary flow.[13] However, as it is a subjective sensation, it can occur without noticeable saliva decrease and reflective of a saliva quality or perceptual problem.[5, 13]

Causes of xerostomia in the terminally ill are most commonly related to systemic disease, polypharmacy and medications, such as anticholinergic medications, antihistamines, antihypertensive agents, opioids and psychotropic agents including antidepressants and antipsychotics, which can affect salivary flow rate and composition.[5,13-15] Many of these drugs that can result in xerostomia are regularly used by patients in the palliative and supportive care setting.[3] Patients in these settings commonly have a history of head and neck radiotherapy and the salivary glands show both early and late radiation damage; quickly resulting in reductions in salivary flow rates with no significant recovery after completion of the radiation treatment schedule.[16] Changes to the amount and composition of saliva results in salivary gland hypofunction, xerostomia, salivary gland enlargement, nocturnal oral discomfort, dysarthria, dysphagia, taste disturbance, difficulty with denture use, cracked lips and increased susceptibility to oral infections such as candidiasis, burning mouth symptoms and dental caries.[17] The restriction on oral function and daily activities contribute to a negative impact on the patient's overall well-being and quality of life.[2, 5, 16]

In palliative care settings, oral care has been based on facility availability of products rather than research evidence and is frequently overlooked until symptoms affect quality of life.[3, 18] However, it has been suggested that frequency of oral hygiene in terminally ill, semi-conscious or unconscious patients should be individually assessed and determined by the needs of the patient and early diagnosis of oral conditions can minimise pain and suffering.[3, 12, 19] The fundamental role for the dentist in palliative care is in contributing to improvement of quality of life for the terminally ill patient.[6, 20]

Management of xerostomia in general, relies on initially identification of the cause and if possible, removing any extraneous cause.[14] However in many cases where this is not possible, treatment of xerostomia is symptomatic, in the form of saliva substitutes, oral lubricants, salivary stimulants, parasympathomimetic drugs such as pilocarpine, and preventive of oral diseases secondary to salivary gland hypofunction.[3, 14] When saliva cannot be stimulated, use of wetting agents or saliva substitutes are considered appropriate care.[1] Trials using acupuncture and electrostimulation have also been undertaken with inconclusive results.[17]

Several studies involving the palliative care setting have investigated the dry mouth gel, Biotene® Oralbalance moisturizing gel, which is a water soluble saliva substitute based on synthetic polymers containing

enzymes glucose oxidase, lactoferrin and lactoperoxidase.[14] These enzymes combine with potassium thiocynate, found in saliva, to produce the hypothiocyanate ion which inhibits the growth and acid production of plaque forming bacteria.[14] This combination, dubbed the LP3 protein enzyme system, incorporates antimicrobials found naturally in human saliva; however has a lower pH reportedly ranging between 5.2 and 6.5.[14] It also has an extended duration of effect, lasting for up to four hours.[5]

Denta-Med® dry mouth gel is another commercially available dry mouth product and was less explored in the literature at time of trial commencement. The chemical composition includes three known active therapeutic agents of 0.05% Cetylpyridinium chloride, 0.22% Zinc chloride and 0.22% sodium fluoride which act as general anti-metabolic agents to bacteria.[13] It consists of a chemically stable formulation. Particularly in a dry mouth with low salivary clearance rates, for which Denta-Med® is particularly prescribed, there would be a slow progressive reduction in the concentration of these ions. Studies have indicated the gel should have a substantive action at 6hours at least and possibly longer.[13] In contrast to other gels, it has a neutral pH and is well tolerated by patients with dry mouth. Similar to other dry mouth products, it is muco-adhesive allowing binding to oral soft and hard tissues.[13]

There is no consensus or strong evidence for the most efficacious topical therapy for symptomatic relief of xerostomia.[21] This is largely a result of studies characterised by small numbers and heterogenous methods.[15] Both quantitative and qualitative research for xerostomia management in this setting has been limited particularly with reference to randomized controlled trials, and no defined protocol has been recommended for further research in this area. A feasibility study investigating dry mouth products in a palliative care setting in the United Kingdom suggested using approaches with a simple methodology, short duration of trial period, minimising unnecessary documentation for the patient and having nursing/medical staff involvement throughout.[22] However, there has been minimal research to explore these issues or in developing a local protocol for investigating xerostomia management in a palliative care setting in Australia. Despite the growth of palliative care research, there is resistance within the professional community to trials in this vulnerable setting.[22] Protocol development for future xerostomia investigation in the palliative care setting will enable more robust research to be carried out and may overcome some of the ethical and methodological challenges unique to this setting.[22]

Hence, the main aims of this study were to: (1) develop a clinical trial protocol to test dry mouth products in palliative care inpatients and (2) to test the protocol by conducting a pilot study comparing two commercial dry mouth products against a control group (undergoing the current dry mouth practice of the hospital palliative care ward) via descriptive measures. The hypothesis tested was there would be improvement in xerostomia with the use of commercial dry mouth products compared with current dry mouth practice amongst palliative care inpatients. The protocol developed aimed to adopt the suggestions proposed in the literature and to provide a framework for a definitive protocol for the investigation of xerostomia in the palliative care setting.

II. Methods and Materials

Between August 2016 to August 2017, all adult inpatients of the Concord Centre for

Palliative Care (CCPC) able to give informed consent, over 18 years of age, who self-reported suffering from oral dryness/xerostomia (subjective complaint) and had no known allergy to dry mouth products in the past, were invited to participate in the study. Suitable candidates meeting the inclusion criteria for participation were identified by the medical and nursing team at weekly multidisciplinary meetings, asked whether they were experiencing xerostomia and if so, were subsequently invited by researchers to participate in the trial. Those with potential medical interventions for example, radiotherapy, surgery to the head and neck region or chemotherapy (that might alter dry mouth symptoms) within two weeks prior or during the study period and those with cognitive impairment as determined by inability to self consent or Australia-modified Karnofsky Performance Scale (AKPS) score of 20 or less, were excluded from the study.

The Nursing Unit Manager (NUM) was selected as the key nursing staff representative for regular liaison with the dental team including flagging concerns throughout the trial period. Participant recruitment was carried out bedside by two members of the research team (ZM, JT) both of whom had a dental background and frequent contact with the CCPC and could be paged as required. Demographic information (age and gender) and relevant medical history (current medications known to cause dry mouth including chemotherapy or radiotherapy or surgery to the head and neck region) were recorded for each participant from their hospital patient record.

This study was a single-site project. Ethics approval was obtained from the Sydney Local Health District Human Research Ethics Committee, Concord Repatriation General Hospital. No sample size estimation was carried out given the pilot study design. Participants consented to the study for treatment and control groups. Blinding of researchers, clinical staff and participants was facilitated through discolouration of dry mouth gels which were de-identified into dispensing bottles. Sydney Local Health District Concord Pharmacy Trials randomised the participants in a 1:1:1 schedule. This was a clinician initiated trial.

All participants were given information on what xerostomia is, possible causes of dry mouth and the products available in the Australian market for its symptomatic relief. This was done prior to group allocation. Participants were randomly allocated to one of three groups and given either a blinded dry mouth gel (Group A dry mouth gel* or Group B dry mouth gel**) or allocated to the control group (Group C) who received the current practice on the ward (the use of sodium bicarbonate swabs***). The dry mouth gels to be tested were selected for their differing properties in order to assess potential benefit for the palliative care population.

Pre-intervention questionnaires were given to all consenting participants to assess baseline symptoms of xerostomia in the CCPC. The pre-intervention questionnaire comprised a series of eight (8) statements with response options on a five-point Likert scale of: never; seldom; sometimes; often; always. The eight questions were: (1) My mouth feels dry; (2) My mouth feels dry when eating a meal; (3) I have trouble swallowing; (4) I have trouble with eating dry foods; (5) My lips feel dry; (6) I have trouble sleeping due to my dry mouth; (7) It's hard to talk to people due to my dry mouth; and (8) My dry mouth affects the quality of my life. The first five questions were directly from the Summated Xerostomia Inventory which has been tested in a number

of diverse samples and appears to be a valid measure for discriminative use in clinical and epidemiological research.[23] The summated version was chosen to minimise likelihood of participant survey fatigue in their vulnerable state.

The remaining three questions were from existing approaches to investigating xerostomia in the literature which had increased relevance to the palliative care setting through assessing the individual's functional capacity and quality of life.[15, 24] Scores were calculated before and after the intervention period as mean ranks of the total scores and confidence intervals were presented on box plot analysis.

The pre-intervention questionnaire assessed the current measures participants used for their dry mouth by way of water, commercially available dry mouth products, chewing gum, mints and sweets. To determine participants' degree of independence and potential requirement for assistance with dry mouth products, participants were given a score using the AKPS, which has been validated for use in the palliative care clinical setting.[25] The AKPS is a graduated scale of performance capacity (independence to complete dependence) of an individual.[25] It is particularly applicable to palliative care clinical practice and is composed of score categories from 0 (deceased) through to 100 reflecting normal activity. For any patient with a score of less than 50, recommendations for dry mouth product use were reinforced to both the patient and their social supports.

The trial period ran for a total of seven days. During this period, each intervention was applied four times per day by nursing staff on the ward and additionally as required by participants themselves or assisted by their family or carers. Participants were encouraged to use the dry mouth products, instead of water, and asked to refrain from the use of any other commercial dry mouth product during the trial period. For the duration of the study, alternative dry mouth products were removed from the medication charts of all participants. Plain swabs replaced the sodium bicarbonate swabs in each room where the patient was allocated to group A or B, so as to not contaminate the use of the blinded dry mouth gels. Palliative care nurses were informed and trained by two members of the research team (ZM, JT) in the administration and use of the dry mouth gels and swabs and how to record comments.

A post-intervention questionnaire was given to participants in all groups, which included the pre-intervention eight (8) questions to re-assess symptoms of xerostomia. All responses were converted into numerical values for analysis. Mean Likert scale scores pre-intervention were subtracted from post-intervention scores. A Kruskal-Wallis H test was conducted to determine whether there were differences in oral dryness scores between groups of participants allocated to the different interventions.

III. Results

Recruitment and feasibility:

A total of 26 participants were recruited to the study over a six month period and completed the pre-intervention questionnaire. Of these, 18 participants completed the seven day trial with Group A (n=5), Group B (n=7) and Control (n=6). Withdrawals were even across groups B and C however were in greater number in group A (*see Figure 1*). The reasons for non-completion included patient death during the trial period, patient discharge prior to completion of the post-intervention data collection or withdrawal from participation, usually due to their

deteriorating health condition. Given the randomised allocation of participants to groups, the greater number of withdrawals in group A was not clinically significant and unrelated to any additional study variable in this group.

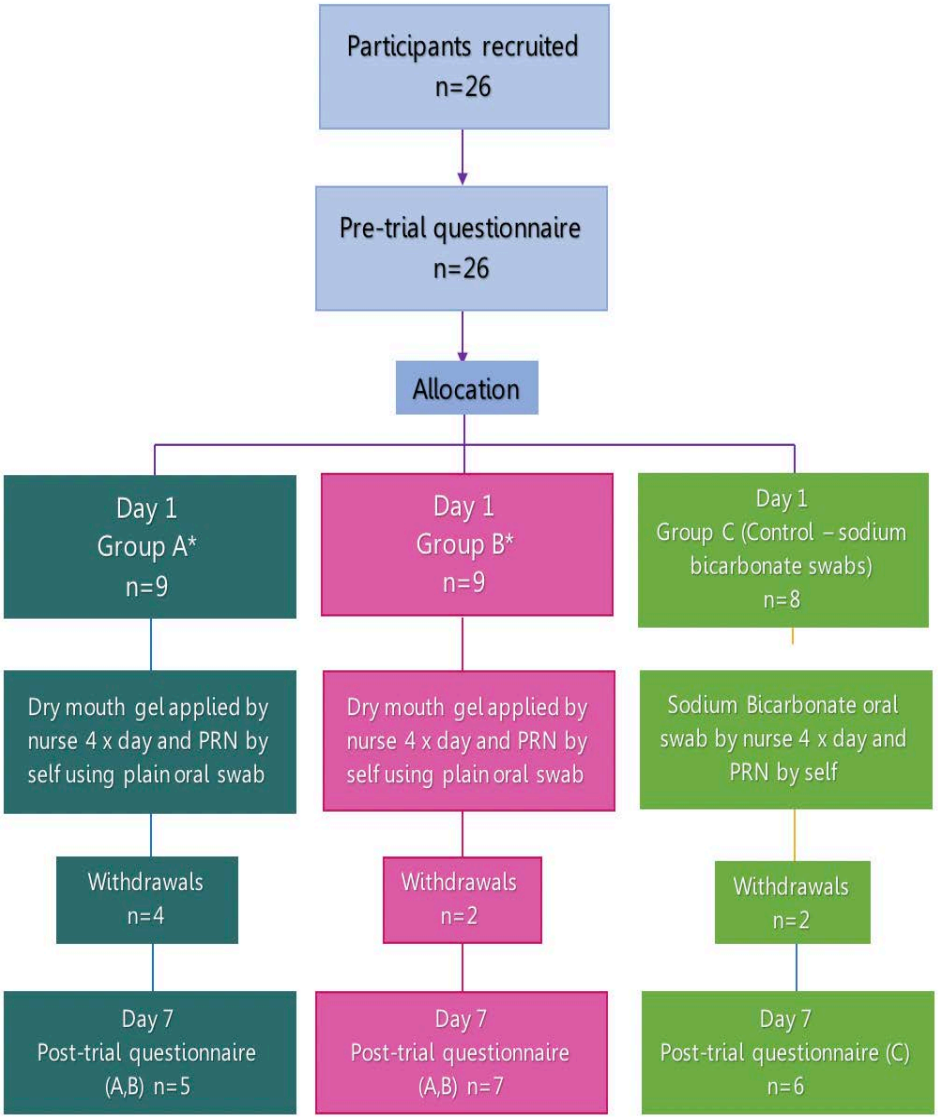

Figure 1: Study methodology and group allocation to interventions including number of participants per study group

Demographic characteristics:

The patient sample investigated in the CCPC showed a predominance of female (66.7%) compared with male (33.3%) participants, ranging in age from 58-91 years (*see Table 1*).

Table 1: Baseline participant characteristics by group; age and for entire cohort; gender and AKPS scores.

Variable	Entire cohort N = 18	Group A N =5	Group B N =7	Group C N =6	P value
Age (median, IQR±)	79 (74.3-84.5)	83 (77-85)	79 (73.5-83.5)	79.5 (76-80)	>0.05
Gender – female (number, % within group)	12 (66.7)	1 (20)	5 (71.4)	6 (100)	>0.05
AKPS score (median, IQR±)	50 (40-60)	40 (40-40)	50 (40-60)	60 (52.5-60)	>0.05

±IQR = interquartile range

Baseline participant characteristics:

The participants' AKPS scores ranged from 20-80 (median 50 (interquartile range 40-60). There was no significance of AKPS scores by age (p>0.05) ***(see Table 1)***.

All participants were deemed to require palliative or supportive care by virtue of their admission to the CCPC. All 18 (100%) participants were taking an opioid or tricyclic antidepressant medication for their medical conditions. Eight of the 18 (44.4%) participants had a history of chemotherapy reported within the last 5 years. There was also a history of radiotherapy to the head and neck region for the majority of the patient cohort (14/18) (77.8%), 12 of whom received this radiation in the previous 12 months.

Baseline interventions for xerostomia:

At baseline, 18 (100%) of the participants across all groups reported frequent consumption of water for relief of oral dryness. A range of measures to relieve mouth dryness were reported by participants including commercially available dry mouth products, chewing gum, mints and sweets, however reported to be used less commonly by participants in all groups (*see Figure 2*).

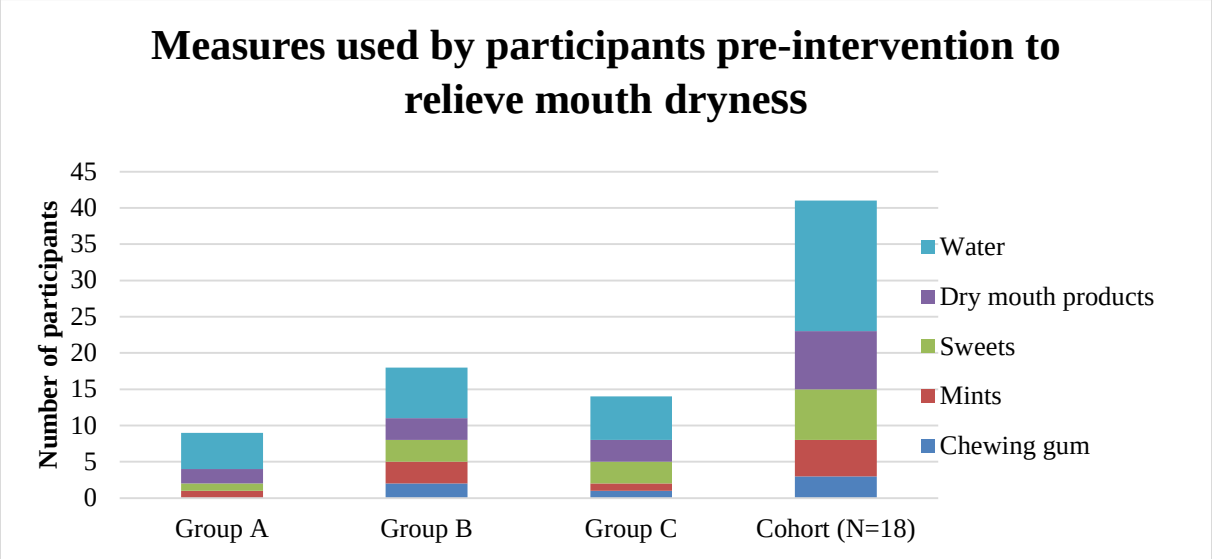

Figure 2: Measures used by participants pre-intervention to relieve mouth dryness.

Intervention experience

The results of the Kruskal-Wallis H test showed differences in mean rank scores (post-intervention minus pre-intervention) were not similar for all groups, as assessed by visual inspection of the boxplots (*see Figure 3*). These oral dryness scores varied from Group A (mean rank 13.90), Group B (mean rank 6.93), control Group C (mean rank 8.83), reflecting increases in oral dryness scores over the seven day period for all groups. The differences between groups were not statistically significant, chi-square χ^2 distribution = 5.205, p= 0.074 (p>0.05).

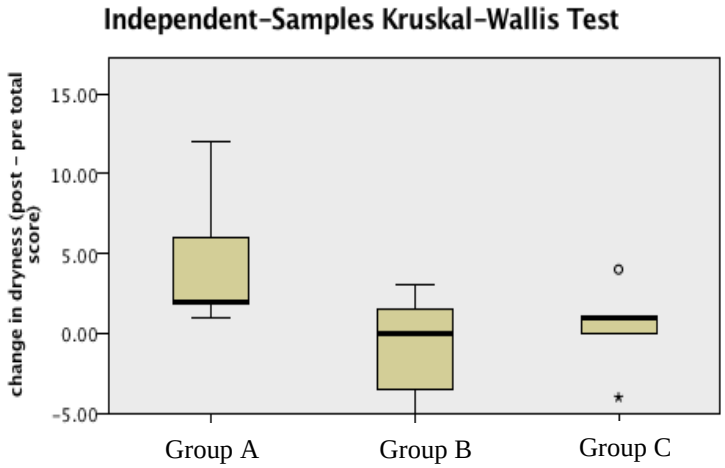

Figure 3: Change in mouth dryness following intervention by study group

IV. Discussion

This pilot study showed both dry mouth gels and oral swabs used for xerostomia management resulted in improvement in symptom relief for some participants. However, all groups demonstrated an overall increase in dryness scores over the seven day trial period. The results from control group C showed improvement in dry mouth scores over the study period. This contrasts with the two intervention groups A and B where relatively more participants reported worsened or unchanged dry mouth scores, although this was not of statistical significance. Statistical testing in a small pilot study trial may not lead to a clear null hypothesis outcome, however, it was used in this study to illustrate the need for such tests in a large-scale clinical trial.

This pilot study was limited by low numbers of participants in each group and recruitment rate and withdrawals were a challenge in this patient population. The patients were often too unwell to be recruited, participation in the trial was not of high priority or patients progressively worsened rapidly following admission. Additionally, all losses were due to participant deaths prior to the end of the trial period or early discharge due to rapid decline in general health. The context of this study served the main difference in the framework utilised compared with previous studies, limiting the study period to a maximum of 7 days based on the average expected remaining lifespan which was on average 10-14 days following admission to the ward. Other studies examining use of dry mouth gels differed mainly with reference to

trial periods for longer duration (two weeks to three months), frequency of application (recommending before sleep, as often as desired or four times a day only) and different examined populations (such as those affected by radiation induced xerostomia[7] or the institutionalised elderly).[4]

The improvement in the control group may be attributed to nursing staff adopting the standard practice which may have facilitated the application of swabs more effectively and have introduced bias. The use of a crossover design or application of both gels and swabs for each participant may have helped overcome this weakness. However, the inclusion of a crossover design to allow a suitable washout period was unable to be accommodated given the short duration of the trial period. Slight variation in gel amount in addition to variations in participant self-application of both dry mouth gels and swabs, may have confounded the results. Self-application of dry mouth interventions may have been limited by difficulty of use by some patients or by their deteriorating medical condition. It is possible that an overall deterioration of patient's health could have contributed to a natural history of worsening xerostomia over the one week trial in this palliative population. AKPS scores were not assessed at the conclusion of the trial period to assess this deterioration and this would be an important measure to include in an updated protocol. This pilot trial also did not assess the oral health status of participants or other oral conditions reported in the literature amongst palliative care patients and if they were more important to them than xerostomia.[12, 26] Those with a perceived level of severe xerostomia could have been selected for further evaluation.

The methodology of this study additionally aimed to provide participants with information on measures to relieve xerostomia, which has been a limitation reported by participants in other studies.[12] However, the study remained limited in not assessing the impact of education of participants and evaluating if this was successful in their adopting other available dry mouth products following completion of the trial. It is clear there is a role for education in this setting for patients, support workers and health professionals. The literature has been clear regarding ongoing insufficient documentation of patients' oral status and the lack of oral care protocols in the medical record for palliative care patients.[12, 27] Dental personnel or those with training in oral care are infrequently included in palliative care teams.[16] Our study highlighted having collaboration with dental professionals on the ward (dentist with special needs dentistry training and hospital based oral health therapist) allowed for early detection of oral problems and enabled participants to have timely access to some form of symptomatic management. It would be useful for further incorporation of oral health training in the training of palliative care nursing staff and for dental professionals to develop oral health interventions for patients in palliative care.[28]

The results of this pilot study are consistent with another study with a similar sample size of 19 participants, which involved asking participants to use a dry mouth gel a minimum of four times a day, and did not find any difference in symptom improvement with the frequency or the quantity of dry mouth gel application.[1] It is useful to know that a protocol including different measures in the form of gels and swabs can be used in a busy inpatient palliative care setting given practicality is a predominant consideration for patients and nursing staff.[22] Other protocols have similarly utilised nursing staff to apply

products thinly around the mouth using a foam brush,[5] however have not delved into the issues of frequency of application or adjunctive self-application which this pilot study incorporated. Nursing staff training demonstrating the amount of dry mouth gel use and dictating frequency of application was necessary in this pilot study. Utilising plain swabs as a delivery system for dry mouth gels aimed to take advantage of a an already acquired skill of nurses in providing basic oral care. Measures requiring minimal effort, that can be readily implemented by non-dentally trained nursing staff and can allow family and carers to partake in improving the patient's quality of life, are typically best received. Future research is required to investigate how often the gels need to be re-applied to maximise xerostomia management for patients in the palliative care setting. The trial should utilise the full spectrum of commercially available dry mouth products including gels, rinses, swabs and water in its various forms such as ice chips and the use of spray bottles should additionally be investigated for their feasibility in a palliative or supportive care setting.

V. Conclusions

This pilot study demonstrated feasibility in an Australian inpatient palliative care setting and a framework for developing a definitive protocol for further study of xerostomia management. It provides guidance for estimating sample size required for a large-scale trial in a palliative care or geriatric hospital ward setting. It highlighted likely challenges, need for practical flexibility and dental professional involvement for future studies in this patient population. Further research with larger, more robust sampling and from multi-site palliative inpatient settings is necessary to evaluate the efficacy of dry mouth products and their optimum frequency for improvement in xerostomia in the last days of an individual's life, which remains an important measure to test.

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Footnotes

*Group A = Denta-Med® Dry Mouth Gel; Denta-Med Technology Australia; Moorabbin, VIC, Australia

** Group B = Biotene® Oralbalance Moisturizing Gel; GlaxoSmithKline; Ermington, NSW, Australia

***Group C = Control, Oraswab®; Confident Care Products, Ingleburn, NSW, Australia

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