Community Dental Health (2015) **32,** 137–142
Received 19 December 2014; Accepted 4 February 2015

doi:10.1922/CDH_3572Kuo06

Effect of family caregiver oral care training on stroke survivor oral and respiratory health in Taiwan: a randomised controlled trial

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Objective: To evaluate the effectiveness of home-based oral care training programs on tongue coating (TC), dental plaque (DP), and symptoms of respiratory infection (SRI) in stroke survivors. ***Methods:*** A single-blind, randomised, controlled trial conducted in a home-based setting over 2 months. Stroke survivors (n=48, experimental group) and their family caregivers received home-based oral care training programme while a control group of 46 stroke survivors and family caregivers received routine oral care education with swabs. TC, DP, and SRI were assessed at baseline and after one and two months, with results analysed using Mixed Model ANOVA. ***Results:*** Poor oral hygiene and overall neglect of home oral care practices were observed at baseline. TC and DP scores were significantly reduced in the experimental group receiving the home-base oral care training program compared to the control group, who received only routine oral care education ($P<0.001$). The group×time interaction was significant, with decreased TC and DP scores for both groups at one month and at two months of additional care (when compared to baseline). The SRI scores were not significantly different between groups ($P>0.05$). The group×time interaction did not correlate with SRI for either group when compared to the baseline and to one month and two months of additional care. No adverse events were encountered and there was no external funding. ***Conclusions:*** Home-based oral care training programme had a beneficial effect on oral health as measured by TC and DP scores. The effect on SRI requires further longitudinal study.

Key words: *oral care, stroke survivors, tongue coating, dental plague, symptom of respiratory infection*

Introduction

Stroke is the second leading cause of death worldwide and a major cause of disability (World Health Organization, 2014). Stroke survivors are often unable to manage even the simplest activities of daily living and have worse periodontal health than other healthy adults in their community (Pow *et al*., 2005). Although oral health promotion delivered to stroke patients in rehabilitation wards (Lam *et al*., 2011), and to the caregivers of dependent elders have been studied (Frenkel *et al*., 2002), home-based programs delivered to functionally-dependent stroke survivors have not been evaluated.

Poor oral hygiene leads to an increase in bacteria, resulting in oral soft tissue infections, periodontal disease and dental caries (Almståhl *et al*., 2012; Haas *et al*., 2007; de Mata *et al*., 2011). Evirgen and Kamburoğlu (2013) found that the level of oral hygiene was the strongest determinant of both Tongue Coating (TC) in general, and TC with Candida, in particular. Among the elderly, TC increases the risk for aspiration pneumonia (Abe *et al*., 2008). However, the effect of tongue cleaning with brushing decreases TC scores significantly (Tashiro *et al*., 2012). Stroke survivors also have high levels of Dental Plaque (DP) on hospital discharge (Pow *et al*., 2005). Thorough daily DP removal may be important for oral health as it will decrease DP in the gingival crevices and so reduce inflammatory response (Dickinson, 2012).

Abe *et al*. (2006) visually evaluated plaque adhering to teeth and found a high prevalence of pneumonia in the group with poor oral hygiene. Scannapieco *et al*. (2003) reported an increased risk of aspiration pneumonia was associated with DP (OR=4.2), and dependency on others for oral care (OR=2.8). Thus, poor oral hygiene predisposes the high risk stroke population to aspiration pneumonia (El-Solh, 2011; Wise and Williams, 2013). Oral health promotion can improve periodontal health, which is essential for an improved quality of life for stroke patients (Lam *et al*., 2013). Stroke patients may exhibit physical and cognitive deficits making them dependent on others for personal care, including oral care. In Taiwan, most patients are not institutionalised after a stroke and remain at home (Tang and Chen, 2002). Therefore, provision for appropriate, accurate information concerning oral care for stroke survivors has been recommended as a key component of stroke care.

Cornejo-Ovalle *et al*. (2013) in their cross-sectional study of elderly caregivers found that caregivers did not fully appreciate the importance of oral care of the elderly. The frequency of this care depended on whether caregivers were trained to perform these activities, the importance given to oral health, and the existence of oral health protocols for elderly persons. Two studies found limited data on the efficacy of oral health promotional activities for stroke survivors (Lam *et al*., 2013; Shi *et al*., 2013). We hypothesised that home-based oral care training programme (HOCP) would improve oral and respiratory health compared to usual oral healthcare.

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Methods

This randomised, controlled single-blind trial examined the effect of an HOCP on stroke survivor's tongue coating (TC), dental plaque (DP) and Symptoms of Respiratory Infection (SRI) related to the HCOP oral care intervention by family caregivers and was conducted between September, 2012 and February, 2013. The home-based oral care training programme was provided only to the experimental group. The control group received only routine oral care. This study was conducted in three home care organizations that served over 100 patients in central Taiwan. Stroke survivors were eligible if they had experienced an ICD 9 diagnosis ranging from 430 to 438, had a Barthel Index score (measure performance in activities of daily living) less than 60, and had dysphagia. Patients were excluded if they were diagnosed with a pulmonary infection, had a diagnosis of oral or tongue pathology, or had used antimicrobial mouthwash in the past three months. The family caregivers were included if they cared for the patient at least 8 hours per day and were able to communicate in Mandarin or Taiwanese. Cohen's (1992) criteria were used to compare the means of two groups. A sample size of 26 caregivers was required for a power of 0.8 and α=0.05. Considering an estimated dropout rate of 25%, the required sample size was 33 stroke survivors per group. The study protocol was conducted according to the principles of the Declaration of Helsinki and approved by the Institutional Review Board of Changhua Christian Hospital. Family caregivers verbally consented during a telephone interview. Written informed consent was obtained during the first home visit by the home health care nurse, hereafter simply 'nurse'.

Verbal consent was provided by 100 family caregivers and a computer-generated random number schedule determined the allocation schedule. During this study, six participant family caregivers - stroke survivors, pairs were lost to follow-up: one due to later refusal to participate and five due to death. At the end of two months, 48 pairs in the experimental (HOCP) group and 46 control pairs (routine oral care) were analysed in this study (Figure 1). The research protocol and delivery of the HOCP were conducted by a trained nurse with 10 years of experience. Data collection was conducted by a trained research assistant with a nursing background.

The evidence-base for the HOCP for training family caregivers of came from our systematic review and the program was described elsewhere (Kuo *et al.,* 2013; 2015) as: *Step one*, oral care overview; an educational pamphlet related to oral care was provided to family caregivers of the experimental group. Family caregivers were educated on six dimensions of oral care: the nature of the task; frequency with which the task is performed; hours of care provided each day; skills, knowledge, and abilities to perform tasks; the extent to which tasks can be made routine and thus incorporated into daily schedules; and the support received from other family members (Schumacher *et al.,* 2000). *Step two*, discussion of basic oral care procedures and risks; based on the educational pamphlet of oral care, a 20 minute verbal presentation was followed by a discussion of oral care procedures and risks. *Step three,* providing oral care products; the experimental group was provided with two kinds of oral care products: a dual action tongue cleaner (Sunstar American, Inc.) and a toothbrush with instructions on their use. *Step four,* explain the teaching content and strategies; assess and instruct family caregiver in planning and assessment the oral care of stroke survivors. The HOCP was followed by individual face-to-face training in techniques for cleaning dentures, natural teeth and the tongue, and in the importance of oral care and oral cavity assessment. Teaching strategies for family caregivers included two sessions a day (two-minutes after breakfast and again before sleep) with two minutes of each 20-minute session being devoted to learning the brushing sequence (from teeth to tongue) tongue cleaning (the latter focusing on distinguishing six regions, from left-middle-right of anterior tongue to left-middle-right of posterior tongue), knowledge of the equipment used (tongue cleaner and toothbrush), and toothbrush method (using the Bass brushing technique) (Harnacke *et al.,* 2012). *Step five,* demonstration; the nurse demonstrated tooth brushing and tongue cleaning care to the family caregivers. *Step six,* caregiver demonstration in return.

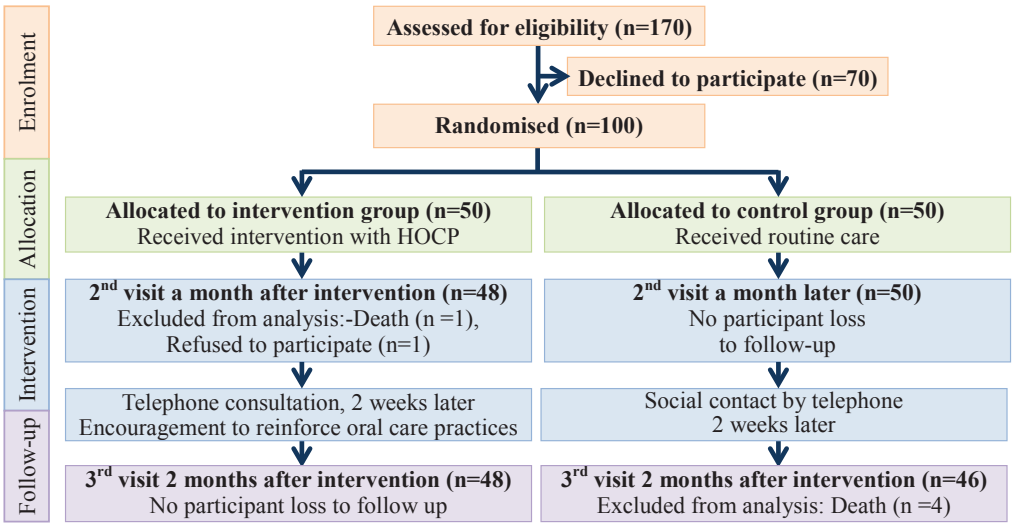

Figure 1. *Flowchart of enrolment, allocation, and follow-up*

Seventh step, provision of daily record sheets as a reminder mechanism for oral care. During the training program, repeat demonstrations of these techniques, daily record sheets and telephone follow-up at two weeks after second visit were provided to reinforce oral care practices.

Maintaining routine oral care was encouraged in the control group and included physical assessment, information on stroke and its consequences, prevention, management options and oral cleaning with cotton swabs during the two-month interventional period. The family caregivers' feelings about providing oral care were investigated and discussed during a 20-minute conversation with the nurse in two groups.

Outcomes measures were stroke survivors' TC, DP, and SRI. Outcome measures for the caregivers (oral care knowledge, attitude, self-efficacy and behavior) have been published (Kuo *et al*., 2015).

Tongue coating, TC, was assessed using the Winkel Tongue Coating Index (WTCI) (Winkel *et al.,* 2003), an adequate measure with internal consistency and content validity (Van Tornout *et al.,* 2013). The dorsum of the tongue was divided into 6 areas (3 posterior, 3 anterior) and each assessed as having: 0, no coating; 1, light coating; 2, severe coating. Summing the scores gives the WTCI (range 0–12). In this study, the internal consistency (Cronbach's α) was 0.82.

The dental Plaque Index (PI), an indicator of oral hygiene, (Taani *et al*., 2003) has proven internal consistency and content validity when used with oral health education (Smiech-Slomkowska and Jablonska-Zrobek, 2007). The PI assessed permanent teeth 16, 12, 24, 36, 32, and 44. The four surfaces of the teeth (buccal, lingual, mesial, and distal) were scored: 0, no plaque; 1, a film of plaque adhering to the free gingival margin and adjacent area of the tooth; 2, moderate accumulation of soft deposits within the gingival pocket, or the tooth and gingival margin, which can be seen with the naked eye; 3, abundance of soft matter within the gingival pocket and/or on the tooth and gingival margins. The PI is the sum of the mean scores for the six teeth (range 0-18). In this study, the internal consistency (Cronbach's α) was 0.88.

For the Symptoms of Respiratory Infection, SRI, a 7-item symptom questionnaire assessed respiratory infection in the home care environment (Freda and Libby, 2000). Family caregivers were asked and stroke survivors were assessed by nurses if there was a new or increased cough, new or increased sputum production, new or increased purulence of sputum, fever ≥38°C, pleuritic chest pain, new or increased physical findings on chest examination (i.e. rales, rhonchi, bronchial breathing), and change in status (new or increased shortness of breath, increased respiratory rate, worsening mental or functional status). Items required Yes/No responses, with only 'yes' answer scored as a one. In this study, the internal consistency (K-R 20) was 0.80. The family caregiver of any patient who was hospitalised during the study period was queried as to the discharge diagnosis of the patient. Any patient with a diagnosis of pneumonia was noted.

SPSS v19.0 was used for analyses with demographic data analysed using χ^2 and Student's t-tests. Mixed Model ANOVA were performed to calculate the differences between experimental and control groups with regards to TC, DP, and SRI at one and two months. A $P \leq 0.05$ was considered statistically significant.

Results

The experimental group, mean age of 74.5 years (SD 11. 1 years), were 48 stroke survivors, including 23 women. The control group, mean age of 77.9 years (SD=12.6 years), numbered 46 and included 17 women. Baseline characteristics for stroke survivors (gender, Barthel index, age, TC, DP, and SRI) and family caregivers (gender, age) were similar between groups (Table 1). Descriptive statistics for each outcome variable at baseline, and at the end of one and two months of intervention are shown in Table 2. Stroke survivors in the experimental group reported continued decreasing TC (9.1→4.0→1.8) and DP (12.5→6.2→2.4) scores (Table 2).

In the control group, the TC (9.2→8.9→9.0) and DP scores 12.6→10.5→10.7) showed no significant changes. Mean SRI scores were similar for experimental and control groups at one month and two months and showed no significant trends in either group.

The results from Mixed Model ANOVA analysis are shown in Table 3. The TC scores showed significantly greater improvement over time in the experimental group vs. the control group (t=-13.98, p<0.01) and for the DP scores (t=-9.21, p<0.01) but not the SRI scores (t=-0.99, p>0.05). The group × time interaction was significant for TC (p<0.01) and DP (p<0.01) variables for both groups at one month and two month, when compared to baseline. Therefore, the HOCP intervention showed a positive effect on patients' TC and DP. The group × time interaction was not significant for the SRI variable for both groups at both one and two months. The control group spent twice as many days in hospital for pneumonia than the intervention group (74 vs. 35).

Table 1. Demographic characteristics of stroke survivors and family caregivers by group (n=94)

			Experimental group, (n=48)		*Control group, (n=46)*		χ^2	*P*
			n	*%*	*n*	*%*		
Stroke survivors	Gender	Female	23	48	17	37	0.08	ns
		Male	25	52	29	63		
	Barthel Index	0-20	48	100	44	96	0.15	ns
		21-60	0	0	2	4		
Family caregivers	Gender	Female	16	33	19	41	0.64	ns
		Male	32	67	27	59		
			Mean	*SD*	*Mean*	*SD*	*t*	*P*
Age (years)	Stroke survivors		74.5	11.1	77.9	12.6	-1.40	0.17
	Family caregivers		52.7	11.3	53.9	16.7	-0.41	0.68

Table 2. Descriptive outcome statistics at baseline, at one month, and at two months of intervention for stroke survivors (n=94)

Variables (Range)	*Experimental group (n=48)*			*Control group (n=46)*		
	Baseline	*One month*	*Two months*	*Baseline*	*One month*	*Two months*
	Mean (SD)	*Mean (SD)*	*Mean (SD)*	*Mean (SD)*	*Mean (SD)*	*Mean (SD)*
Tongue coating, WTCI (0-12)	9.1 (2.4)	4.0 (3.0)	1.8 (2.1)	9.2 (2.4)	8.9 (2.7)	9.0 (2.7)
Dental plaque, PI (0-18)	12.5 (5.7)	6.2 (4.1)	2.4 (2.7)	12.6 (4.9)	10.5 (4.0)	10.7 (3.7)
Symptoms of respiratory infection, SRI (0-7)	0.6 (1.0)	0.4 (0.9)	0.4 (0.7)	0.5 (0.8)	0.5 (0.8)	0.6 (0.7)

Table 3. Mixed model ANOVA analysis of variance for tongue coating, dental plaque, and symptoms of respiratory infection (SRI) between experimental (n=48) and control (n=46) groups

Outcome variable	*β*	*SE*	*t*	*P*	*95% CI*
Tongue coating,WTCI					
Group 1 (Group 2)	-7.21	0.52	-13.98	**<0.01**	-8.22,-6.19
Time 0 (Time 2)	0.24	0.44	0.55	0.58	-0.62, 1.10
Time 1 (Time 2)	-0.11	0.35	-0.31	0.76	-0.81, 0.58
Group 1 x Time 0	7.07	0.61	11.59	**<0.01**	5.87, 8.28
Group 1 x Time 1	2.34	0.49	4.77	**<0.01**	1.37, 3.31
Dental plaque, PI					
Group 1 (Group 2)	-8.17	0.89	-9.21	**<0.01**	-9.92,-6.41
Time 0 (Time 2)	2.04	0.57	3.59	**<0.01**	0.92, 3.17
Time 1 (Time 2)	-0.01	0.43	-0.15	0.88	-0.90, 0.78
Group 1 x Time 0	8.14	0.80	10.22	**<0.01**	6.57, 9.71
Group 1 x Time 1	3.89	0.60	6.51	**<0.01**	2.72, 5.08
SRI					
Group 1 (Group 2)	-0.17	0.17	-0.99	0.32	-0.51, 0.17
Time 0 (Time 2)	0.04	0.16	0.27	0.79	-0.27, 0.36
Time 1 (Time 2)	-0.02	0.14	-0.16	0.87	-0.29, 0.25
Group 1 x Time 0	0.19	0.22	0.83	0.41	-0.25, 0.62
Group 1 x Time 1	0.13	0.19	0.66	0.51	-0.25, 0.50

Note: Experimental Group=Group 1; Control group=Group 2; Baseline data=time 0; one month data=time 1; two month data=time 2

Discussion

Our findings indicated that an evidence-based and structured home-based oral care training program for stroke survivors can positively impact on TC and DP. The composition of the study sample was similar in gender ratio to stroke survivors in the US and in age composition to those elsewhere including Sweden and the US (Glader *et al.,* 2003; Godwin *et al*., 2013). At baseline, stroke survivors had high TC and DP scores reflecting their inability to care for their own teeth and their lack of assistance. During regular home health care visits, the health providers and family caregivers were not aware of these shortcomings. It is essential that the health providers receive evidence-based oral care education so that they can guide family caregivers in improving patient outcomes.

Tongue coating has been associated with a number of salivary bacteria and has been implicated in the development of pneumonia-related health problems (Abe *et al.,* 2008). Oral care with tongue cleaning can efficiently remove coating on the dorsum of the tongue, and further reduce the likelihood of developing pneumonia. A systematic review demonstrated that mechanical approaches, such as tongue brushing or tongue scraping to clean the dorsum of the tongue, have the potential to successfully reduce breath odour and TC (Kuo *et al.,* 2013). In our study, the top surface of the tongue was cleaned using a tongue cleaner, and the TC score for the experimental group was reduced by 7.35 points at two months, as compared to baseline, whereas that of the control group was reduced by only 0.2 points. However, tongue cleaning is not usually included in regular oral care, especially in stroke survivors with motor function disability.

The structured home-based oral care training program, including the tongue-cleaning procedure, is simple and fast with benefits for most stroke survivors which far outweigh the small investment and time required to carry out this procedure. Therefore, we suggest that health providers should apply evidence-based oral care practice guidelines to at carefully assess, and provide effective patient and family education and self-management support. A potential hazard of tongue cleaning should be explained when training family caregivers as there have been cases of TC triggering vomiting or the gag-reflex if certain sensitive areas are touched. This reaction can be easily avoided by relaxing the tongue and throat muscles and/or exhaling during cleaning.

Tongue microorganisms may contribute to DP formation. Stroke survivors had more plaque on hospital discharge and after six months than other elderly people (Pow *et al*., 2005). Toothbrushing can significantly decrease DP in assistance-dependent elderly who have difficulties brushing their own teeth (Tashiro *et al*., 2012). In our study, the PI score for the experimental group was reduced by 80% at two months, as compared to baseline, whereas that of the control group was not significantly reduced (15%), and these results are similar to findings from the above studies.

In this study, 95.6% of stroke survivors had a Barthel index <20 (Table 1). When oral functions are almost completely suppressed due to unconsciousness or tube feeding, the mucosal secretions and saliva begin to mix with the residue in the oral epithelium to form a sticky paste that adheres to the oral cavity membranes, tongue, and teeth. Research has shown that high levels of oral aerobic gram-negative bacteria were seen in acute stroke patients and may predispose them to aspiration pneumonia (Millns *et al*., 2003). Home-based patients found it inconvenient to obtain a chest X-ray or sputum culture to examine the condition of their chest, thus, the SRI score was more convenient and cheaper to use in a community setting. In our study, the stroke survivors' SRI scores were not significantly different between experimental and control groups and this may be related to the limited duration of the study.

The slight decrease in both TC and DP scores in the control group from baseline to one month may have occurred due to attention to oral care by nurses, and may reflect a short-term Hawthorne effect. Both outcome indicators returned to baseline at two months, implying a lack of continued attention on the part of the family caregivers to the oral care of stroke survivors over time. Moreover, the control group was not routinely provided oral care products, thus, it is not surprising that TC and DP scores did not continue to decrease at two months. On the other hand, both TC and DP scores were almost halved at one month and better than halved again at two months. Home-based oral care provided to stroke survivors by family caregivers is a basic care necessity but our findings raise concerns. The last few years have brought forth scores of devices and gadgets to clean the tongue. The concept is so simple that prevention-oriented people should need only minimal encouragement to incorporate tongue cleaning into their oral care routine. However, most stroke survivors did not have supplies, and family caregiver did not attempt to obtain them, suggesting that oral care was not a norm. A dual action tongue cleaner (Sunstar American, Inc.) and a toothbrush with instructions on their use were recommended. Documentation of oral care, evidence of care planning, and monitoring of oral care delivery on an ongoing basis by primary home health care nurses must be part of practice guidelines for oral care in home health care.

One limit of our study was that we attempted to reduce observer bias by using observers not involved in treatment assignments or patient care, interactions with nurses which would have risked disclosure of treatment assignments during assessments. Another limitation of this study was lack of extended follow-up beyond the two month period and given the encouraging finding that HOCP enhances oral care behavior in the home setting we recommend that future researchers investigate the longer-term effects.

This study was based on standards for home-based oral care established following a systematic review. In Taiwan, regular dental assessment by a dentists or nurses is not covered by health insurance so oral assessment and care are often neglected. We suggest that the role of dental hygienists might be established to provide oral health care in Taiwan. Collaboration between dental hygienists, dentists, nurses, physical and occupational therapists might provide an adequate interdisciplinary team to provide home oral health support.

Conclusion

A randomised controlled study evaluated the effect of a two-month home-based oral care training programme for stroke survivors with a focus on TC, DP and SRI as outcome measures. A significant decrease in both TC and DP scores was observed in the experimental group of stroke survivors compared to controls but not for SRI. The two-month oral care program was effective in improving the oral health of stroke survivors. Thus, regular oral assessment and reinforcement of routine oral care by primary family caregivers and health care providers are important for improved quality of care in stroke survivors.

Acknowledgements

We acknowledge the contributions made by all the hospital-based home health care institutions and home health care nurses, as well as the patients and family caregivers who participated in this study. The authors would also like to especially thank dentist Po-Yuan Chen and family medicine physician Yu-Wen Yang for their professional advice. The authors declare no potential conflict of interest. The authors received no external funding for this study.

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