

**Kuo, 2016****Bibliographic Reference**

Kuo, Y. W.; Yen, M.; Fetzer, S.; Chiang, L. C.; Shyu, Y. I.; Lee, T. H.; Ma, H. I.; A home-based training programme improves family caregivers' oral care practices with stroke survivors: a randomized controlled trial; International Journal of Dental Hygiene; 2016; vol. 14 (no. 2); 82-91

**Study details**

<b>Secondary publication of another included study- see primary study for details</b>	No additional information.
<b>Other publications associated with this study included in review</b>	No additional information.
<b>Trial name / registration number</b>	No additional information.
<b>Study type</b>	Randomised controlled trial (RCT)
<b>Study location</b>	Taiwan
<b>Study setting</b>	Home based.
<b>Study dates</b>	September 2012 and February 2013.
<b>Sources of funding</b>	There was no external funding for this study.
<b>Inclusion criteria</b>	The family caregivers if their family member had experienced a stroke (ICD 9 430-438); had a Barthel index score of less than 60 and were unable to intake orally. Each family caregiver was actively caring for their stroke survivor for at least 8 hours per day and was able to communicate in Mandarin or Taiwanese.

<b>Exclusion criteria</b>	If their stroke survivor had a confirmed diagnosis of pulmonary infection or a diagnosis of oral or tongue pathology. The family caregivers who were unable to open their stroke survivor's mouth were also not eligible for this study; this is because stroke survivors with unstable conditions will increase intervention risk.
<b>Recruitment / selection of participants</b>	People contacted through nursing directors of three hospital-based home healthcare institutions.
<b>Intervention(s)</b>	<p>Oral hygiene intervention (twice a day) N=50</p> <p>Home-based oral care training programme. Guided by the PRECEDE-PRO-CEED model for planning, implementation and evaluation of the programme. The programme included an oral care overview (a 20-min oral care health and disease verbal presentation based on an oral care educational pamphlet), discussion of basic oral care procedures and the risks, face-to-face education at the family caregiver's home, provision of oral care products that included a dual action tongue cleaner (Sunstar American, Inc.) and a finger toothbrush, teaching strategies for the family caregivers that included assessment, method, skill, frequency and time of oral care, demonstrations, return demonstrations and a reminder mechanism with daily record sheets for oral care and follow-up phone calls. In this training programme, the family caregivers' feelings about providing oral care were taken seriously, because most family caregivers often feel unprepared to provide care, have inadequate knowledge to deliver proper care and receive little guidance from the healthcare providers.</p> <p>Elements of care:</p> <p>Oral care overview: An educational pamphlet related to oral care was provided to the family caregivers of the intervention group.</p> <p>Discussion of basic oral care procedures and risks: Based on the oral care educational pamphlet provided to the family caregivers of the intervention group, a 20-min verbal presentation was followed by a discussion of basic oral care procedures and risks.</p> <p>Providing oral care products: Two kinds of oral care products: Intervention group were provided with two kinds of oral care products: a dual action tongue cleaner and a finger toothbrush.</p>

	<p>Teaching content: Emphasize the importance of home-based oral care. Assist the family caregivers in planning and assessment the oral care of stroke survivors. Provide guidance for appropriate cleaning techniques of dentures, natural teeth and tongue.</p> <p>Teaching strategies: The health care programme emphasizes the need for well trained and skilled caregivers who have the knowledge, attitude and self-efficacy in stroke survivors. An ideal teaching of oral care would have several strategies that are listed below: 1) twice (after breakfast and before sleep) a day; 2) two minutes per time; 3) learning brushing sequence (from teeth to tongue); 4) learning tongue cleaning (distinguishing six regions, from left-middle-right of the anterior tongue to left-middle-right of the posterior tongue); 5) learning how to use the equipment (tongue cleaner and finger toothbrush); 6) checking the dental cavities; 7) confirming the method of toothbrush; 8) using the technique of Bass brushing and oral mucosa cleaning.</p> <p>Demonstration: The provider demonstrated the method of toothbrushing and tongue cleaning to family caregivers.</p> <p>Return demonstrations: The provider return demonstrations of these techniques.</p> <p>Reminder mechanism for oral care: Provide the daily record sheet for oral care.</p> <p>Follow-up: Telephone follow-up at one month to reinforce oral care practices. Family caregivers' feelings about providing oral care were investigated and discussed during a 20-min conversation with the provider.</p> <p>Assess oral care behaviour: Assessed by a trained research assistant with a nursing background. The Behaviour of Oral Care questionnaire was used based on the provider intervention protocol.</p>
<b>Comparator</b>	<p>Usual care N=50</p> <p>People were encouraged to maintain their routine oral care practices (included oral cleaning with cotton swabs) during the two months of the intervention period. After the two months of the intervention period, this group also received the home-based oral care training programme.</p>
<b>Number of participants</b>	<p>100. The participants were the family caregivers with stroke survivors. However, the study reports the mortality for the stroke survivors separately. The characteristics table will show the characteristics of the family caregivers.</p>
<b>Duration of follow-up</b>	<p>2 months</p>

<b>Additional comments</b>	No additional information.
<b>Subgroup 1: Severity (as stated by category or as measured by NIHSS scale)</b>	Not stated/unclear
<b>Subgroup 2: Type of stroke (using the Bamford scale)</b>	Not stated/unclear
<b>Subgroup 3: Dysphagia at baseline</b>	Not stated/unclear
<b>Subgroup 4: Type of intervention</b>	Combinations of the above
<b>Subgroup 5: People who are nil-by-mouth at baseline</b>	People who are nil-by-mouth at baseline
<b>Subgroup analysis - further details</b>	Type of intervention: Education programme, tongue cleaner, tooth brushing.

## Study arms

### ***Oral hygiene intervention (twice a day) (N = 50)***

Home-based oral care training programme. Guided by the PRECEDE-PRO-CEED model for planning, implementation and evaluation of the programme. The programme included an oral care overview (a 20-min oral care health and disease verbal presentation based on an oral care educational pamphlet), discussion of basic oral care procedures and the risks, face-to-face education at the family caregiver's home, provision of oral care products that included a dual action tongue cleaner (Sunstar American, Inc.) and a finger toothbrush, teaching strategies for the family caregivers that included assessment, method, skill, frequency and time of oral care,

demonstrations, return demonstrations and a reminder mechanism with daily record sheets for oral care and follow-up phone calls. In this training programme, the family caregivers' feelings about providing oral care were taken seriously, because most family caregivers often feel unprepared to provide care, have inadequate knowledge to deliver proper care and receive little guidance from the healthcare providers.

### ***Usual care (N = 50)***

People were encouraged to maintain their routine oral care practices (included oral cleaning with cotton swabs) during the two months of the intervention period. After the two months of the intervention period, this group also received the home-based oral care training programme.

## **Characteristics**

### ***Arm-level characteristics***

<b>Characteristic</b>	<b>Oral hygiene intervention (twice a day) (N = 50)</b>	<b>Usual care (N = 50)</b>
<b>% Female</b>	n = 32 ; % = NA	n = 27 ; % = NA
Sample size		
<b>Mean age (SD)</b>	52.71 (11.29)	53.91 (16.74)
Mean (SD)		
<b>Ethnicity</b>	NR	NR
Nominal		
<b>Comorbidities</b>	NR	NR
Nominal		

<b>Characteristic</b>	<b>Oral hygiene intervention (twice a day) (N = 50)</b>	<b>Usual care (N = 50)</b>
<b>Severity</b>	NR	NR
Nominal		
<b>Type of stroke</b>	NR	NR
Nominal		
<b>Dysphagia at baseline</b>	NR	NR
Nominal		
<b>People who are nil-by-mouth at baseline</b>	NA	NA
Nominal		

Baseline characteristics reported in the study has a different number of participants (oral hygiene intervention = 48, usual care = 46).

## **Outcomes**

### ***Study timepoints***

- Baseline
- 2 month

**Oral hygiene intervention (twice a day) compared to usual care at ≤3 months**

<b>Outcome</b>	<b>Oral hygiene intervention (twice a day), Baseline, N = 50</b>	<b>Oral hygiene intervention (twice a day), 2 month, N = 50</b>	<b>Usual care, Baseline, N = 50</b>	<b>Usual care, 2 month, N = 50</b>
<b>Mortality</b> Oral hygiene intervention: 1 death within the first month. Control: 4 deaths within the two months.  Nominal	NA	1	NA	4

Mortality - Polarity - Lower values are better

**Critical appraisal - Cochrane Risk of Bias tool (RoB 2.0) Normal RCT****Oral hygiene intervention (twice a day) compared to usual care at ≤3 months - Mortality - Nominal - Oral hygiene intervention (twice a day) - Usual care - t2**

<b>Section</b>	<b>Question</b>	<b>Answer</b>
Overall bias and Directness	Risk of bias judgement	Some concerns
Overall bias and Directness	Overall Directness	Directly applicable