

**Lam, 2013****Bibliographic Reference**

Lam, O. L.; McMillan, A. S.; Samaranayake, L. P.; Li, L. S.; McGrath, C.; Randomized clinical trial of oral health promotion interventions among patients following stroke; Archives of Physical Medicine & Rehabilitation; 2013; vol. 94 (no. 3); 435-43

**Study details**

<b>Secondary publication of another included study- see primary study for details</b>	Not applicable.
<b>Other publications associated with this study included in review</b>	Lam, O. L.; McMillan, A. S.; Samaranayake, L. P.; Li, L. S.; McGrath, C.; Effect of oral hygiene interventions on opportunistic pathogens in patients after stroke; American Journal of Infection Control; 2013; vol. 41 (no. 2); 149-54

<b>Trial name / registration number</b>	Hong Kong Clinical Trial Register No: HKCTR-1159. United States National Institutes of Health Clinical Trial Registry Number: NCT01265043.
<b>Study type</b>	Randomised controlled trial (RCT)
<b>Study location</b>	Hong Kong.
<b>Study setting</b>	The rehabilitation unit at Tung Wah Hospital in Hong Kong.
<b>Study dates</b>	July 2008 to January 2011.
<b>Sources of funding</b>	Supported by the Committee of Research and Conference Grants of the University of Hong Kong.
<b>Inclusion criteria</b>	People with stroke, Barthel Index <70, aged 50 years and older, admission to the rehabilitation unit up to 7 days previously.
<b>Exclusion criteria</b>	Edentulous; presented with communication difficulties (unable to follow a 1-step command) or severe cognitive impairment (Mini-Mental State Examination score $\leq 9$ ); had an indwelling nasogastric feeding tube.
<b>Recruitment / selection of participants</b>	No additional information.
<b>Intervention(s)</b>	Oral hygiene instruction (twice a day and additional treatment twice a week) N=35  Oral hygiene intervention and chlorhexidine mouthrinse twice daily (0.2%, 10mL) and assistance with toothbrushing 2 times per week for a 3 week period  Oral hygiene intervention (twice a day) N=34  Oral hygiene instruction and chlorhexidine mouthrinse twice daily (0.2%, 10mL) for a 3 week period
<b>Comparator</b>	Usual care N=33  Oral hygiene instruction only.
<b>Number of participants</b>	102

<b>Duration of follow-up</b>	3 weeks
<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 not nil-by-mouth at baseline
<b>Subgroup analysis - further details</b>	Subgroup 5: People who are nil-by-mouth at baseline: Presumed that people are not nil-by-mouth as they exclude people who had an indwelling nasogastric tube.

### Study arms

#### ***Oral hygiene instruction (twice a day and additional treatment twice a week) (N = 35)***

Oral hygiene intervention and chlorhexidine mouthrinse twice daily (0.2%, 10mL) and assistance with toothbrushing 2 times per week for a 3 week period

**Oral hygiene intervention (twice a day) (N = 34)**

Oral hygiene instruction and chlorhexidine mouthrinse twice daily (0.2%, 10mL) for a 3 week period

**Usual care (N = 33)**

Oral hygiene instruction only.

**Characteristics****Arm-level characteristics**

Characteristic	Oral hygiene instruction (twice a day and additional treatment twice a week) (N = 35)	Oral hygiene intervention (twice a day) (N = 34)	Usual care (N = 33)
% Female	n = 11 ; % = 36.7	n = 10 ; % = 38.5	n = 9 ; % = 36
Sample size			
Mean age (SD) (years)	71 (11.7)	69.4 (9.6)	68.9 (11.4)
Mean (SD)			
Ethnicity	NR	NR	NR
Nominal			
Comorbidities	NR	NR	NR
Nominal			
Severity	NR	NR	NR

<b>Characteristic</b>	<b>Oral hygiene instruction (twice a day and additional treatment twice a week) (N = 35)</b>	<b>Oral hygiene intervention (twice a day) (N = 34)</b>	<b>Usual care (N = 33)</b>
Nominal			
<b>Ischaemic</b>	27	22	19
Nominal			
<b>Haemorrhagic</b>	3	4	6
Nominal			
<b>Dysphagia at baseline</b>	NR	NR	NR
Nominal			
<b>People who are nil-by-mouth at baseline</b>	NR	NR	NR
Nominal			

## Outcomes

### *Study timepoints*

- Baseline
- 3 week

**Oral hygiene intervention (twice daily with additional treatment twice a week) compared to oral hygiene intervention (twice daily) compared to usual care - dichotomous outcome**

Outcome	Oral hygiene instruction (twice a day and additional treatment twice a week), Baseline, N = 35	Oral hygiene instruction (twice a day and additional treatment twice a week), 3 week, N = 35	Oral hygiene intervention (twice a day), Baseline, N = 34	Oral hygiene intervention (twice a day), 3 week, N = 34	Usual care, Baseline, N = 33	Usual care, 3 week, N = 33
Occurrence of pneumonia	NA	0	NA	0	NA	0
Nominal						

Occurrence of pneumonia - Polarity - Lower values are better

**Oral hygiene intervention (twice daily with additional treatment twice a week) compared to oral hygiene intervention (twice daily) compared to usual care - continuous outcome**

Outcome	Oral hygiene instruction (twice a day and additional treatment twice a week), Baseline, N = 35	Oral hygiene instruction (twice a day and additional treatment twice a week), 3 week, N = 30	Oral hygiene intervention (twice a day), Baseline, N = 34	Oral hygiene intervention (twice a day), 3 week, N = 26	Usual care, Baseline, N = 33	Usual care, 3 week, N = 25
Presence of oral disease (gingival bleeding index) Scale range unclear (half mouth design with each tooth being examined at 6 sites but actual scale not clear). Final value.	16.7 (NA)	7.6 (0.003)	18.8 (NA)	10 (0.002)	16.7 (NA)	17.7 (0.9)
Mean (p value)						

Presence of oral disease (gingival bleeding index) - Polarity - Lower values are better

**Critical appraisal - Cochrane Risk of Bias tool (RoB 2.0) Normal RCT**

**Oral hygiene intervention (twice daily with additional treatment twice a week) compared to oral hygiene intervention (twice daily) compared to usual care - dichotomous outcome - Occurrence of pneumonia - Nominal - Oral hygiene instruction (twice a day and additional treatment twice a week) - Oral hygiene intervention (twice a day) - Usual care - t3**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High
Overall bias and Directness	Overall Directness	Partially applicable (Intervention indirectness - reports an intervention that was not specified in the protocol but does represent an increased intensity of oral hygiene intervention so was included)

**Oral hygiene intervention (twice daily with additional treatment twice a week) compared to oral hygiene intervention (twice daily) compared to usual care - continuous outcome - Presence of oral disease (gingival bleeding index) - Mean P Value - Oral hygiene instruction (twice a day and additional treatment twice a week) - Oral hygiene intervention (twice a day) - Usual care - t3**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High
Overall bias and Directness	Overall Directness	Indirectly applicable (Downgraded due to outcome being a continuous outcome when dichotomous outcomes were prioritised and Intervention indirectness - reports an intervention that was not specified in the protocol but does represent an increased intensity of oral hygiene intervention so was included)