

Ab Malik, 2018

**Bibliographic
Reference**

Ab Malik, N.; Mohamad Yatim, S.; Abdul Razak, F.; Lam, O. L. T.; Jin, L.; Li, L. S. W.; McGrath, C.; A multi-centre randomised clinical trial of oral hygiene interventions following stroke-A 6-month trial; Journal of Oral Rehabilitation; 2018; vol. 45 (no. 2); 132-139

Study details

Secondary publication of another included study- see primary study for details	No additional information.
Other publications associated with this study included in review	Ab Malik, N.; Abdul Razak, F.; Mohamad Yatim, S.; Lam, O. L. T.; Jin, L.; Li, L. S. W.; McGrath, C.; Oral Health Interventions Using Chlorhexidine-Effects on the Prevalence of Oral Opportunistic Pathogens in Stroke Survivors: A Randomized Clinical Trial; The Journal of Evidencebased Dental Practice; 2018; vol. 18 (no. 2); 99-109
Trial name / registration number	National Medical Research Register (Ministry of Health; Malaysia): NMRR-13-1664-17247(IIR).
Study type	Randomised controlled trial (RCT)
Study location	Malaysia.
Study setting	Five public hospitals in Malayasia.
Study dates	June 2015 to August 2016.
Sources of funding	No additional information.
Inclusion criteria	Hospitalised stroke patients managed by a stroke rehabilitation team with a Modified Barthel Index score of less than 70; cognizant to follow instructions; deemed medically stable by attending physician
Exclusion criteria	Receiving antibiotics or antimicrobial agents; edentulous
Recruitment / selection of participants	No additional information.
Intervention(s)	Oral hygiene intervention (once a day) N=38 "Intense method for plaque control" - daily powered tooth brushing (Oral B(R) Pro-Health DB4010) with a 1% Chlorhexidine gel.

Comparator	Usual care N=48 "Conventional method for plaque control" - daily manual tooth brushing (Oral B(R) - super thin and extra soft bristles) with a standardised commercial toothpaste (Colgate (R) Maximum Cavity Protection)
Number of participants	86
Duration of follow-up	6 months (reports outcomes at 3 months and 6 months, in this review we will accept outcomes reported at 3 months for inclusion in our analysis).
Additional comments	No additional information.
Subgroup 1: Severity (as stated by category or as measured by NIHSS scale)	Not stated/unclear
Subgroup 2: Type of stroke (using the Bamford scale)	Not stated/unclear
Subgroup 3: Dysphagia at baseline	Not stated/unclear
Subgroup 4: Type of intervention	Combinations of the above
Subgroup 5: People who are nil-by-mouth at baseline	Not stated/unclear
Subgroup analysis - further details	Type of stroke: Reported haemorrhagic and ischaemic (majority ischaemic). Type of intervention: Powered toothbrush and chlorhexidine toothpaste.

Study arms

Oral hygiene intervention (once a day) (N = 38)

"Intense method for plaque control" - daily powered tooth brushing (Oral B(R) Pro-Health DB4010) with a 1% Chlorhexidine gel.

Usual care (N = 48)

"Conventional method for plaque control" - daily manual tooth brushing (Oral B(R) - super thin and extra soft bristles) with a standardised commercial toothpaste (Colgate (R) Maximum Cavity Protection)

Characteristics

Arm-level characteristics

Characteristic	Oral hygiene intervention (once a day) (N = 38)	Usual care (N = 48)
% Female	n = 14 ; % = 36.8	n = 20 ; % = 41.7
Sample size		
20-39 years	n = 6 ; % = 15.8	n = 7 ; % = 14.6
Sample size		
<40 years	n = 32 ; % = 84.2	n = 41 ; % = 85.4
Sample size		
Malay ethnicity	n = 27 ; % = 71.1	n = 35 ; % = 72.9
Sample size		

Characteristic	Oral hygiene intervention (once a day) (N = 38)	Usual care (N = 48)
Less than or equal to 1 comorbidity	n = 19 ; % = 50	n = 22 ; % = 45.8
Sample size		
Greater than 2 comorbidities	n = 19 ; % = 50	n = 26 ; % = 54.2
Sample size		
Severity	NR	NR
Nominal		
Haemorrhagic stroke	n = 3	n = 6 ; % = 12.5
Sample size		
Ischaemic stroke	n = 33 ; % = 86.8	n = 42 ; % = 87.5
Sample size		
Dysphagia at baseline	NR	NR
Nominal		
People who are nil-by-mouth at baseline	NR	NR
Nominal		
Left side	n = 21 ; % = 55.3	n = 30 ; % = 62.5
Sample size		
Right side	n = 17 ; % = 44.7	n = 18 ; % = 37.5
Sample size		

Characteristic	Oral hygiene intervention (once a day) (N = 38)	Usual care (N = 48)
No/mild cognitive impairment	n = 23 ; % = 60.5	n = 30 ; % = 62.5
Sample size		
Severe cognitive impairment	n = 15 ; % = 39.5	n = 18 ; % = 37.5
Sample size		
Total/severe dependence	n = 28 ; % = 73.7	n = 33 ; % = 68.8
Sample size		
Moderate/mild/minimal dependence	n = 10 ; % = 26.3	n = 15 ; % = 31.3
Sample size		
First stroke	n = 33 ; % = 86.8	n = 42 ; % = 87.5
Sample size		
Recurrent stroke	n = 5 ; % = 13.2	n = 6 ; % = 12.5
Sample size		

Outcomes

Study timepoints

- Baseline
- 3 month (Reports data at 6 months but as this is the closest time to 3 months this time period will be reported here.)

Oral hygiene interventions (once a day) compared to usual care at ≤3 months

Outcome	Oral hygiene intervention (once a day), Baseline, N = 38	Oral hygiene intervention (once a day), 3 month, N = 38	Usual care, Baseline, N = 48	Usual care, 3 month, N = 48
Mortality	NA	3	NA	4
Nominal				
Presence of oral disease (Oral candidiasis)	NA	12	NA	13
Nominal				

Mortality - Polarity - Lower values are better

Presence of oral disease (Oral candidiasis) - Polarity - Lower values are better

Critical appraisal - Cochrane Risk of Bias tool (RoB 2.0) Normal RCT**Oral hygiene interventions (once a day) compared to usual care at ≤3 months - Mortality - Nominal - Oral hygiene intervention (once a day) - Usual care - t3**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	Some concerns
Overall bias and Directness	Overall Directness	Directly applicable

Oral hygiene interventions (once a day) compared to usual care at ≤3 months - Presence of oral disease (Oral candidiasis) - Nominal - Oral hygiene intervention (once a day) - Usual care - t3

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	Some concerns
Overall bias and Directness	Overall Directness	Directly applicable