

Dai, 2017**Bibliographic Reference**

Dai, R.; Lam, O. L. T.; Lo, E. C. M.; Li, L. S. W.; McGrath, C.; A randomized clinical trial of oral hygiene care programmes during stroke rehabilitation; Journal of Dentistry; 2017; vol. 61; 48-54

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	Dai, R.; Lam, O. L. T.; Lo, E. C. M.; Li, L. S. W.; McGrath, C.; Effect of oral hygiene programmes on oral opportunistic pathogens during stroke rehabilitation; Oral Diseases; 2019; vol. 25 (no. 2); 617-633 Dai, R.; Lam, O. L. T.; Lo, E. C. M.; Li, L. S. W.; McGrath, C.; Corrigendum to "A randomized clinical trial of oral hygiene care programmes during stroke rehabilitation" [J. Dent. 61 (2017) 48-54]; Journal of Dentistry; 2017; vol. 64; e1
Trial name / registration number	Hong Kong Clinical Trial Register: 003900. Clinicaltrials.gov: NCT03003871

Study type	Randomised controlled trial (RCT)
Study location	Hong Kong
Study setting	The Mrs Ng Wah Memorial Day Outpatients Centre, Tung Wah Hospital in Hong Kong SAR.
Study dates	No additional information.
Sources of funding	This study was supported by General Research Fund, Hong Kong (Project number 774012).
Inclusion criteria	Being admitted to the outpatient rehabilitation programme within six months; having moderate to severe functional disability - Barthel Index scores of <70; being able to follow a one-step command (as an assessment of communication)
Exclusion criteria	Being edentulous; more than mild cognitive impairment - Mini Mental State Examination ≤ 18 ; indwelling naso-gastric feeding tubes
Recruitment / selection of participants	People who were discharged from the hospital and had sustained functional impairments were referred to this centre for further rehabilitation involving a multidisciplinary team.
Intervention(s)	Oral hygiene intervention (twice a day) N=47 An advanced oral hygiene care programme - supply of a powered toothbrush (Oral-B (R) AdvancePower(TM) 400 series), 0.2% chlorhexidine gluconate mouth rinse (Corsodyl (R)), a standardised tooth paste (Colgate (R) Maximum Cavity Protection), and oral hygiene training.
Comparator	Usual care N=47 Conventional oral hygiene care programme - supply of a manual toothbrush (Oral-B (R) Pro-Health All-In-One), a standardised tooth paste (Colgate Maximum Cavity Protection), and oral hygiene training.
Number of participants	94
Duration of follow-up	3 months of treatment, additional 3 months of follow up (6 months in total). Only data from the 3 months follow up will be included in our analysis.
Additional comments	No additional information.
Subgroup 1: Severity (as stated)	Not stated/unclear

by category or as measured by NIHSS scale)	
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: States that 70.2% had an ischaemic stroke and 29.8% had a haemorrhagic stroke. Type of intervention: Mouthwash and powered toothbrush.

Study arms

Oral hygiene intervention (twice a day) (N = 47)

An advanced oral hygiene care programme - supply of a powered toothbrush (Oral-B (R) AdvancePower(TM) 400 series), 0.2% chlorhexidine gluconate mouth rinse (Corsodyl (R)), a standardised tooth paste (Colgate (R) Maximum Cavity Protection), and oral hygiene training.

Usual care (N = 47)

Conventional oral hygiene care programme - supply of a manual toothbrush (Oral-B (R) Pro-Health All-In-One), a standardised tooth paste (Colgate Maximum Cavity Protection), and oral hygiene training.

Characteristics**Study-level characteristics**

Characteristic	Study (N = 94)
Ethnicity	NR
Nominal	
Comorbidities	NR
Nominal	
Severity	NR
Nominal	
Dysphagia at baseline	NR
Nominal	
People who are nil-by-mouth at baseline	NR
Nominal	

Arm-level characteristics

Characteristic	Oral hygiene intervention (twice a day) (N = 47)	Usual care (N = 47)
% Female	n = 18 ; % = 38.3	n = 19 ; % = 40.4
Sample size		
Mean age (SD)	66.3 (11.2)	66.9 (10.6)
Mean (SD)		
Ischaemic	n = 31 ; % = 66	n = 35 ; % = 74.5
No of events		
Haemorrhagic	n = 16 ; % = 34	n = 12 ; % = 25.5
No of events		

Outcomes**Study timepoints**

- Baseline
- 3 month

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

Outcome	Oral hygiene intervention (twice a day), Baseline, N = 47	Oral hygiene intervention (twice a day), 3 month, N = 44	Usual care, Baseline, N = 47	Usual care, 3 month, N = 30
Occurrence of pneumonia	NA	0	NA	0
Nominal				

Occurrence of pneumonia - 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 - dichotomous outcomes - Occurrence of pneumonia - Nominal - Oral hygiene intervention (twice 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