

Chipps, 2014

Bibliographic Reference

Chipps, E.; Gatens, C.; Genter, L.; Musto, M.; Dubis-Bohn, A.; Gliemmo, M.; Dudley, K.; Holloman, C.; Hoet, A. E.; Landers, T.; Pilot study of an oral care protocol on poststroke survivors; Rehabilitation Nursing Journal; 2014; vol. 39 (no. 6); 294-304

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	No additional information.
Trial name / registration number	No additional information.
Study type	Randomised controlled trial (RCT)
Study location	United States of America.
Study setting	A free-standing 60-bed acute rehabilitation hospital that is part of a major academic medical center in the Midwest.
Study dates	No additional information.
Sources of funding	This project was funded through Sigma Theta Tau International and the Rehabilitation Nurses Foundation.
Inclusion criteria	Age 18 years or older, able to communicate in English and able to give informed consent; primary diagnosis of a stroke within 30 days of admission to the rehabilitation unit; admitted directly from an acute care facility; oral or pharyngeal dysphagia identified by a bedside swallow exam by a Speech-Language Pathologist (SLPs), Modified Barium Swallow, or Fiberoptic Endoscopic Evaluation of Swallowing.
Exclusion criteria	Current comorbid diagnosis of pneumonia; known infection of the oral cavity and/or receiving therapy for infection of the oral cavity; documented history of a haematological disorder; medically restricted fluid intake; allergy to Listerine(TM) or other study products; currently wearing dentures; pregnant or nursing mothers; a history of MRSA infection or colonization.
Recruitment / selection of participants	No additional information.
Intervention(s)	Enhanced oral care (twice a day) N=29 Care provided by a registered nurse trained by dentist and dental hygienist in use of equipment and approach with periodic monitoring and feedback on oral care technique. Care included: battery-operated toothbrush, Braun Oral B with timer(TM) twice daily, Timed toothbrushing for 30 seconds in each quadrant of the mouth, Crest-Pro-Health(TM) toothpaste, Listerine(TM) 10-15mL once per day, Glide Disposable Floss Picks (TM), Sunstar(TM) Dual Action Tongue Cleaner and Carmex(TM) lip balm. Care provided twice a day.

Comparator	Usual care N=22 Care provided by a nursing assistant once/twice daily or as clinically appropriate. Toothbrushing with a hospital toothbrush Sage(TM), twice daily using Sage Oral Care Sodium Bicarbonate Mouthpaste (toothpaste), Careline(TM) alcohol free mouthwash once a day (rinse and spit), and lip care with regular Chaplet(TM).
Number of participants	51
Duration of follow-up	10 days
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	Presence of dysphagia at baseline
Subgroup 4: Type of intervention	Combinations of the above
Subgroup 5: People who are nil-by-mouth at baseline	Mixed
Subgroup analysis - further details	Subgroup 5: people who are nil-by-mouth at baseline - 4 participants were at Functional Oral Intake Scale 1-3.

Study arms

Enhanced oral care (twice a day) (N = 29)

Care provided by a registered nurse trained by dentist and dental hygienist in use of equipment and approach with periodic monitoring and feedback on oral care technique. Care included: battery-operated toothbrush, Braun Oral B with timer(TM) twice daily, Timed toothbrushing for 30 seconds in each quadrant of the mouth, Crest-Pro-Health(TM) toothpaste, Listerine(TM) 10-15mL once per day, Glide Disposable Floss Picks (TM), Sunstar(TM) Dual Action Tongue Cleaner and Carmex(TM) lip balm. Care provided twice a day.

Usual care (N = 22)

Care provided by a nursing assistant once/twice daily or as clinically appropriate. Toothbrushing with a hospital toothbrush Sage(TM), twice daily using Sage Oral Care Sodium Bicarbonate Mouthpaste (toothpaste), Careline(TM) alcohol free mouthwash once a day (rinse and spit), and lip care with regular Chaplet(TM).

Characteristics

Arm-level characteristics

Characteristic	Enhanced oral care (twice a day) (N = 29)	Usual care (N = 22)
% Female	n = NR ; % = 47.8	n = NR ; % = 34.5
Sample size		
Mean age (SD)	62.54 (13.5)	63.74 (15.6)
Mean (SD)		
Caucasian	n = NR ; % = 77.8	n = NR ; % = 65.2
Sample size		

Characteristic	Enhanced oral care (twice a day) (N = 29)	Usual care (N = 22)
African American	n = NR ; % = 22.2	n = NR ; % = 30.4
Sample size		
Asian American	n = NR ; % = 0	n = NR ; % = 4.3
Sample size		
Comorbidities	NR	NR
Nominal		
Severity	NR	NR
Nominal		
Type of stroke	NR	NR
Nominal		
Dysphagia at baseline	NA	NA
Nominal		
People who are nil-by-mouth at baseline	2	2
Nominal		

Outcomes

Study timepoints

- Baseline
- 10 day (End of intervention)

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

Outcome	Enhanced oral care (twice a day), Baseline, N = 29	Enhanced oral care (twice a day), 10 day, N = 29	Usual care, Baseline, N = 22	Usual care, 10 day, N = 22
Oral health outcome scales (revised-THROAT) Scale range: 7-21. Final value. P value reported is for the difference between the two when adjusted for interaction of time and group. Mean (p value)	NA (NA)	10.1 (0.08)	NA (NA)	10.9 (NA)
Oral health outcome scales (revised-THROAT) Scale range: 7-21. Final value. P value reported is for the difference between the two when adjusted for interaction of time and group. Mean (SD)	10.8 (2.6)	NA (NA)	12.2 (2.1)	NA (NA)

Oral health outcome scales (revised-THROAT) - Polarity - Lower values are better

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

Outcome	Enhanced oral care (twice a day), Baseline, N = 29	Enhanced oral care (twice a day), 10 day, N = 29	Usual care, Baseline, N = 22	Usual care, 10 day, N = 22
Requirement for enteral feeding support Taken as people still requiring enteral feeding support at the end of the trial, indicated by FOIS score of 1-3. Nominal	2	1	2	2

Outcome	Enhanced oral care (twice a day), Baseline, N = 29	Enhanced oral care (twice a day), 10 day, N = 29	Usual care, Baseline, N = 22	Usual care, 10 day, N = 22
Dysphagia severity (progression in Function Intake Oral scale from 4-5 to 6-7) Dichotomous version of a continuous outcome. Will be downgraded for indirectness as this is not the preferred reporting method. Nominal	NR	10	NR	7

Requirement for enteral feeding support - Polarity - Lower values are better

Dysphagia severity (progression in Function Intake Oral scale from 4-5 to 6-7) - Polarity - Higher 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 - continuous outcomes - Oral health outcomes scales (revised-THROAT) - Mean P Value - Enhanced oral care (twice a day) - Usual care - t10

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

Oral hygiene intervention (twice a day) compared to usual care at ≤3 months - dichotomous outcomes - Requirement for enteral feedings support - Nominal - Enhanced oral care (twice a day) - Usual care - t10

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

Oral hygiene intervention (twice a day) compared to usual care at ≤3 months - dichotomous outcomes - Dysphagia severity (progression in Function Intake Oral scale from 4-5 to 6-7) - Nominal - Enhanced oral care (twice a day) - Usual care - t10

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High
Overall bias and Directness	Overall Directness	Partially applicable (Downgraded as the outcome is a dichotomous outcome while we prioritised continuous reporting)