

Chen, 2019**Bibliographic Reference**

Chen, H. J.; Chen, J. L.; Chen, C. Y.; Lee, M.; Chang, W. H.; Huang, T. T.; Effect of an Oral Health Programme on Oral Health, Oral Intake, and Nutrition in Patients with Stroke and Dysphagia in Taiwan: A Randomised Controlled Trial; International Journal of Environmental Research & Public Health [Electronic Resource]; 2019; vol. 16 (no. 12); 24

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	Clinicaltrials.gov ID: NCT03219346
Study type	Randomised controlled trial (RCT)

Study location	Taiwan.
Study setting	Primary care - four rehabilitation units of a medical centre in Taiwan.
Study dates	Not stated/unclear.
Sources of funding	This research received no external funding.
Inclusion criteria	People following a first-time stroke in four rehabilitation units in northern Taiwan, who received swallowing treatment. The people also had to be able to communicate in Chinese (Mandarin or Taiwanese), comply with the instructions and be willing to participate in this study. People had nasogastric tubes inserted at baseline.
Exclusion criteria	History of dysphagia because of oral cancer or head and neck cancer; having already received more than 6 months of swallowing treatment.
Recruitment / selection of participants	No additional information.
Intervention(s)	<p>Oral care group (3 times a week) N=33</p> <p>Provided the usual oral care and manual provided to the control group, and received oral health care 30 minutes before the swallowing training three times a week for 3 weeks. The primary author instructed the caregiver on how to perform the oral health procedure until the caregiver was confident in performing the procedure independently, taking 10-15 minutes each time. Before providing oral health care, the caregiver had to prepare the necessary oral health tools (such as water, toothbrush, dental floss, and interdental brush) and suction equipment (including saliva pipette) and help the patient sit in an upright position. First, the person's sputum in the oral cavity was assessed. A suction was used to clear the saliva when necessary. Next, an oral cleaning tool (dental floss and/or interdental brush) was used, and the patient's teeth were brushed using the Bass method. Finally, a fluoride toothpaste (fluoride >1000ppm, <0.5cm used to prevent cavities) was used to coat all teeth. This intervention will be considered as indirect evidence (as it is not once a day up to hourly oral care as specified in the protocol)</p> <p>Concomitant therapy: Usual care was provided to both study arms.</p>
Comparator	Usual care N=33

	Usual oral care provided in the unit (e.g. tooth brushing or sponge stick cleaning) twice a day (morning and evening) and were provided with an instructional manual to promote eating (including information such as food choice and safe eating tips).
	Concomitant therapy: Usual care was provided to both study arms.
Number of participants	66
Duration of follow-up	6 weeks
Additional comments	No additional comments
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	People who are nil-by-mouth at baseline

Subgroup analysis - further details	Type of stroke: Separate by infarction (35) and haemorrhagic (31). Type of intervention: Mixture of suctioning, oral swabbing, toothbrushing, floss and interdental brushes before swallowing therapy. People who are nil-by-mouth at baseline: Presumed nil-by-mouth due to nasogastric tube insertion at baseline.
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Study arms

Oral care group (3 times a week) (N = 33)

Provided the usual oral care and manual provided to the control group, and received oral health care 30 minutes before the swallowing training three times a week for 3 weeks. The primary author instructed the caregiver on how to perform the oral health procedure until the caregiver was confident in performing the procedure independently, taking 10-15 minutes each time. Before providing oral health care, the caregiver had to prepare the necessary oral health tools (such as water, toothbrush, dental floss, and interdental brush) and suction equipment (including saliva pipette) and help the patient sit in an upright position. First, the person's sputum in the oral cavity was assessed. A suction was used to clear the saliva when necessary. Next, an oral cleaning tool (dental floss and/or interdental brush) was used, and the patient's teeth were brushed using the Bass method. Finally, a fluoride toothpaste (fluoride >1000ppm, <0.5cm used to prevent cavities) was used to coat all teeth. This intervention will be considered as indirect evidence (as it is not once a day up to hourly oral care as specified in the protocol)

Usual care (N = 33)

Usual oral care provided in the unit (e.g. tooth brushing or sponge stick cleaning) twice a day (morning and evening) and were provided with an instructional manual to promote eating (including information such as food choice and safe eating tips).

Characteristics

Arm-level characteristics

Characteristic	Oral care group (3 times a week) (N = 33)	Usual care (N = 33)
% Female	n = 14 ; % = 42.4	n = 9 ; % = 27.3
Sample size		
Greater than or equal to 65 years	n = 18 ; % = 54.5	n = 18 ; % = 54.5
Sample size		
Less than 65 years	n = 15 ; % = 45.5	n = 15 ; % = 45.5
Sample size		
Comorbidities	NR	NR
Nominal		
Severity	NR	NR
Nominal		
Infarction	n = 18 ; % = 54.5	n = 17 ; % = 51.5
Sample size		
Haemorrhagic	n = 15 ; % = 45.5	n = 16 ; % = 48.5
Sample size		
Dysphagia at baseline	33	33
Nominal		

Characteristic	Oral care group (3 times a week) (N = 33)	Usual care (N = 33)
People who are nil-by-mouth at baseline	33	33
Nominal		
Mild	n = 12 ; % = 36.4	n = 12 ; % = 36.4
No of events		
Moderate	n = 14 ; % = 42.4	n = 14 ; % = 42.4
No of events		
Severe	n = 7 ; % = 21.2	n = 7 ; % = 21.2
No of events		
Right	n = 20 ; % = 60.6	n = 14 ; % = 42.4
Sample size		
Left	n = 12 ; % = 36.4	n = 16 ; % = 48.5
Sample size		
Time interval from stroke onset to date of the oral health programme (Months)	0.5 to 2	0.5 to 2
Range		
Time interval from stroke onset to date of the oral health programme (Months)	0.5 (NR)	0.5 (NR)
Mean (SD)		

Outcomes

Study timepoints

- Baseline
- 6 week (Shall be included in the ≤ 3 months period)

Oral hygiene intervention (less than once per day) compared to usual care at ≤ 3 months - Continuous outcomes

Outcome	Oral care group (3 times a week), Baseline, N = 33	Oral care group (3 times a week), 6 week, N = 33	Usual care, Baseline, N = 33	Usual care, 6 week, N = 33
Oral health outcome scales (Oral Health Assessment Tool) Scale range: 0-16 Mean (SD)	5.64 (2.54)	3.42 (1.89)	5.24 (1.77)	5.99 (2.14)
Dysphagia severity (Functional Oral Intake Scale) Scale range: 1-7 Mean (SD)	3.15 (2.06)	3.94 (2.38)	3.15 (1.79)	3.52 (1.92)

Oral health outcome scales (Oral Health Assessment Tool) - Polarity - Lower values are better

Dysphagia severity (Functional Oral Intake Scale) - Polarity - Higher values are better

Oral hygiene intervention (less than once per day) compared to usual care at ≤ 3 months - Dichotomous outcomes

Outcome	Oral care group (3 times a week), Baseline, N = 33	Oral care group (3 times a week), 6 week, N = 33	Usual care, Baseline, N = 33	Usual care, 6 week, N = 33
Requirement of enteral feeding support (nasogastric tube removal)	NA	7	NA	2

Outcome	Oral care group (3 times a week), Baseline, N = 33	Oral care group (3 times a week), 6 week, N = 33	Usual care, Baseline, N = 33	Usual care, 6 week, N = 33
Nominal				

Requirement of enteral feeding support (nasogastric tube removal) - Polarity - Higher values are better

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

Oral hygiene intervention (less than once per day) compared to usual care at ≤ 3 months - Continuous outcomes - Oral health outcomes scales (Oral Health Assessment Tool) - Mean SD - Oral care group (3 times a week) - Usual care - t6

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High
Overall bias and Directness	Overall Directness	Partially applicable (Downgraded for intervention indirectness as it is provided at less than the smallest frequency stated by the committee in the protocol)

Oral hygiene intervention (less than once per day) compared to usual care at ≤ 3 months - Continuous outcomes - Dysphagia severity (Functional Oral Intake Scale) - Mean SD - Oral care group (3 times a week) - Usual care - t6

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

Section	Question	Answer
Overall bias and Directness	Overall Directness	Partially applicable <i>(Downgraded for intervention indirectness as it is provided at less than the smallest frequency stated by the committee in the protocol)</i>

Oral hygiene intervention (less than once per day) compared to usual care at ≤3 months - Dichotomous outcomes - Requirement of enteral feedings support (nasogastric tube removal) - Nominal - Oral care group (3 times a week) - Usual care - t6

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	Some concerns
Overall bias and Directness	Overall Directness	Partially applicable <i>(Downgraded for intervention indirectness as it is provided at less than the smallest frequency stated by the committee in the protocol)</i>