Oral hygiene interventions for people with disabilities: A Scoping Review, a Cochrane Review and a Realist Review

Volume II: Appendices

A thesis submitted to the University of Dublin, Trinity College, for the Degree of Doctor of Philosophy.

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Appendix 1: An overview of behavioural change theories and techniques

Theories such as the theory of reasoned action and its extension, the theory of planned behaviour (TPB), focused on the goal or intention as the motivator to change (Ajzen & Fishbein 1980, Ajzen 1991). Social learning theory additionally identified the roles of self-efficacy and self-evaluation as mechanisms that improve the attainment of goals (Bandura & Cervone 1983). The stronger the intention and the perceived control of the behaviour, the more likely was the change in behaviour to occur.

These theories are considered to be “continuum” based models, placing the person along a continuum, based on a set of predetermined predictors in relation to the likelihood of action. The limitations of these theories, when applied in health promotion, are that they assume that everyone will react in the same way using a “one size fits all” approach (Schwarzer 2008, Schwarzer et al 2011).

Despite decades of research using the TPB, there is still some doubt as to the reliability of intention as a predictor of change. It is a necessary element, but not a guarantee of change. It has been shown to change beliefs or attitudes, but not necessarily change behaviour in oral hygiene practices (Tedesco et al 1991). This may result in an “intention/behaviour gap” (Sniehotta et al 2006).

Implementation planning (IMP) of the behaviour change, by considering an ‘if / then’ scenario, has been shown to improve the outcome. For it to be effective, the cues and responses need to be identified by the person who is planning the behaviour change. Coping plans to identify critical situations when intention might waver and self-regulation to monitor adherence to the plan, may also improve the outcome (Sniehotta et al 2006, Sniehotta, 2009).

The mechanisms that may fire action in these situations include the perception of free choice (by implementing their own plan, the strength of the intention is increased), increased self-perception of commitment (by
implementing a plan the person believes that they must really want to achieve the intention), increased *self-belief* (by implementing a plan, the intention seems easier to achieve). The frequency of the ‘if’ cue has been shown to influence behavioural change, for example, if the intention is to eat less sweets and the implementation plan is to think about the negativity of needing a filling at the next trip to the dentist every time the opportunity of eating a sweet occurs, the sooner this if /then cue/response occurs and the more often the person can apply this response, the more likely it is to effect the outcome. Additionally, the strength of the link between the cue and the response, for example, how strongly the person’s feelings are about the response i.e. needing a filling at the next trip to the dentist, will affect their sweet eating, the goal directed response (Webb & Sheeran 2008).

The transtheoretical model (TTM), first outlined by DiClemente & Prochaska, is one of the more familiar “stage” based models and regards behavioural change as a process rather than an event, breaking the process into five distinct stages and placing great importance on identifying the specific processes of change that prompt an individual to progress from stage to stage (Redding *et al* 2000, Schwarzer 2008). The advantage of this model in health promotional interventions is that individuals or groups of individuals can be assessed as being at distinct stages and the intervention designed to have stage-matched interventions. The TTM is not without its critics, with some arguing that the stages are merely arbitrary subdivisions of a continuous process (Schwarzer 2008).

The health action process approach (HAPA) combines elements of both the continuum and stage-based models. It attempts to fill the intention/behaviour gap. It breaks the process of change into only two phases: The Motivational phase and the Volitional phase. It uses the term ‘phase’ rather than ‘stage’ to imply the bi-directional nature of the process. It identifies three levels of self-efficacy that are required to move from the first phase to the second and onwards. The ‘action self-efficacy’ aids motivation to make the change, while ‘maintenance and recovery self-efficacy’ assists when barriers are encountered or when failure or relapse occurs. HAPA also identifies two levels of planning, action and coping: the when, where and how
elements of the behaviour change are considered in the action planning, the if/then scenarios are considered in the coping planning (Schwarzer et al 2011).

An individual’s levels of self-efficacy and planning can be assessed to determine at what phase they are at in relation to the intervention, thus allowing the intervention to be tailored to them, but also providing a greater understanding of the mechanisms and elements of the intervention affecting its success (Schwarzer 2008).

Given the multitude of behaviour change models in the literature, confusion may arise regarding which one to apply when attempting to understand or change health behaviour. Michie and colleagues have in recent times propelled thinking on behaviour change in an attempt to address this issue. In a seminal paper this team proposed that all interventions that are attempting to change behaviour must have a theoretical basis underpinned by evidence from the existing literature and to include a modelling phase, where the determinants of behaviour (the what) and the techniques to change these determinants (the how) are identified, before any intervention is implemented (Michie et al 2008).

In eliciting change, there is an underlying process that takes place, involving interaction, persuasion and reasoning. It is essential to gain an understanding of the contexts: the resources, culture and opportunity structures that might influence the outcomes. Behavioural change theory in research is often used to explain behaviour rather than change it. This does not help us understand if, why and how an intervention succeeded (Michie et al 2008).

Over a series of studies, Michie, Abraham and others have developed a list of the behavioural determinants (Table 5) and taxonomy of behaviour change techniques (BCTs), linked to the theoretical frameworks with which to influence these determinants (Table 6). This taxonomy should assist non-psychologists and those new to the field of behavioural change, to identify the techniques in the literature even when the studies themselves fail to

**Table 1: Behavioural determinants**

<table>
<thead>
<tr>
<th>Behavioural Determinants (Michie &amp; Abraham 2004)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Social/professional role and identity</td>
</tr>
<tr>
<td>Knowledge</td>
</tr>
<tr>
<td>Skills</td>
</tr>
<tr>
<td>Beliefs about capabilities</td>
</tr>
<tr>
<td>Beliefs about consequences</td>
</tr>
<tr>
<td>Motivation and goals</td>
</tr>
<tr>
<td>Memory, attention and decision processes</td>
</tr>
<tr>
<td>Environmental context and resources</td>
</tr>
<tr>
<td>Social influences</td>
</tr>
<tr>
<td>Emotion</td>
</tr>
<tr>
<td>Action planning</td>
</tr>
</tbody>
</table>

**Table 2: Behaviour change techniques**

<table>
<thead>
<tr>
<th>Definitions of 26 behaviour change techniques and illustrative theoretical frameworks</th>
<th>Technique (Theoretical Framework) Definition (Abraham &amp; Michie 2008)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Theoretical Frameworks Key: Theory of Reasoned Action (TRA), Theory of Planned Behaviour (TPB), Social Cognitive Theory (SCogT), Information-Motivation Behavioural Skills model (IMB), Control Theory (CT), Operant conditioning (OC), Social Comparison Theory (SCompT)</td>
<td>General information about behavioural risk, e.g., susceptibility to poor health outcomes or mortality risk in relation to the behaviour.</td>
</tr>
<tr>
<td>1. Provide information about behaviour-health link. (IMB)</td>
<td>Information about the benefits and costs of action or inaction, focusing on what will happen if the person does/does not perform the behaviour.</td>
</tr>
<tr>
<td>2. Provide information on consequences (TRA, TPB, SCogT, IMB)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Description</td>
</tr>
<tr>
<td>---</td>
<td>-------------</td>
</tr>
<tr>
<td>3</td>
<td>Provide information about others’ approval (TRA, TPB, IMB)</td>
</tr>
<tr>
<td>4</td>
<td>Prompt intention formation (TRA, TPB, SCogT, IMB)</td>
</tr>
<tr>
<td>5</td>
<td>Prompt barrier identification (SCogT)</td>
</tr>
<tr>
<td>6</td>
<td>Provide general encouragement (SCogT)</td>
</tr>
<tr>
<td>7</td>
<td>Set graded tasks (SCogT)</td>
</tr>
<tr>
<td>8</td>
<td>Provide instruction (SCogT)</td>
</tr>
<tr>
<td>9</td>
<td>Model/ demonstrate the behaviour (SCogT)</td>
</tr>
<tr>
<td>10</td>
<td>Prompt specific goal setting (CT)</td>
</tr>
<tr>
<td>11</td>
<td>Prompt review of behavioural goals (CT)</td>
</tr>
<tr>
<td>12</td>
<td>Prompt self-monitoring of behaviour</td>
</tr>
<tr>
<td>(CT)</td>
<td>specified behaviour/s (e.g., in a diary).</td>
</tr>
<tr>
<td>---------------------------------------------------</td>
<td>------------------------------------------</td>
</tr>
<tr>
<td>13. Provide feedback on performance (CT)</td>
<td>Providing data about recorded behaviour or evaluating performance in relation to a set standard or others’ performance. Person received feedback.</td>
</tr>
<tr>
<td>14. Provide contingent rewards (OC)</td>
<td>Praise, encouragement or material rewards that are be explicitly linked to the achievement of specified behaviours.</td>
</tr>
<tr>
<td>15. Teach to use prompts/ cues (OC)</td>
<td>Teach the person to identify environmental cues which can be used to remind them to perform a behaviour, including times of day, contexts or elements of contexts.</td>
</tr>
<tr>
<td>16. Agree behavioural contract (OC)</td>
<td>Agreement (e.g., signing) of a contract specifying behaviour to be performed so that there is a written record of the person’s resolution witnessed by another.</td>
</tr>
<tr>
<td>17. Prompt practice (OC)</td>
<td>Prompt the person to rehearse and repeat the behaviour or preparatory behaviours.</td>
</tr>
<tr>
<td>18. Use follow up prompts</td>
<td>Contacting the person again after the main part of the intervention is complete.</td>
</tr>
<tr>
<td>19. Provide opportunities for social comparison (SCompT)</td>
<td>Facilitate observation of non-expert others’ performance e.g., in a group class or using video or case study.</td>
</tr>
<tr>
<td>20. Plan social support/ social change (social support theories)</td>
<td>Prompting consideration of how others could change their behaviour to offer the person help or (instrumental) social support, including “buddy” systems – and/or providing social support.</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>21. Prompt identification as role model</td>
<td>Indicating how the person may be an example to others and influencing their behaviour or providing an opportunity for the person to set a good example.</td>
</tr>
<tr>
<td>22. Prompt self-talk</td>
<td>Encourage use self-instruction and self-encouragement (aloud or silently) to support action.</td>
</tr>
<tr>
<td>23. Relapse prevention (Relapse Prevention Therapy)</td>
<td>Following initial change, help identify situations likely to result in re-adopting risk behaviours or failure to maintain new behaviours and help the person plan to avoid or manage these situations.</td>
</tr>
<tr>
<td>24. Stress management (stress theories)</td>
<td>May involve a variety of specific techniques (e.g., progressive relaxation) which do not target the behaviour but seek to reduce anxiety and stress.</td>
</tr>
<tr>
<td>25. Motivational interviewing</td>
<td>Prompting the person to provide self-motivating statements and evaluations of their own behaviour to minimize resistance to change.</td>
</tr>
<tr>
<td>26. Time management</td>
<td>Helping the person make time for the behaviour (e.g., to fit it into a daily schedule).</td>
</tr>
</tbody>
</table>
Appendix 2: Cochrane Search strategies

1 Search strategies for identification of studies

Cochrane Oral Health's Trials Register search strategy
Cochrane Oral Health's Trials Register is available via the Cochrane Register of Studies. For information on how the register is compiled, see https://oralehealth.cochrane.org/trials

1. MESH DESCRIPTOR Intellectual disability EXPLODE ALL AND INREGISTER
2. MESH DESCRIPTOR Developmental disability AND INREGISTER
3. ((intellectual or mental) and "developmental disorder") AND INREGISTER
4. ((intellectual* or mental* or learning) NEAR5 (disabilit* or disabiliti* or deficien* or impair* or handicap*)) AND INREGISTER
5. ((deficien* or low*) NEAR3 (cognition or "cognitive function" or reason* or intelligence))
6. ("special needs" or (special NEAR3 child*) or retard* or "slow learner") AND INREGISTER
7. ("Down" syndrome or mongol or "De Lange syndrome" or "Prader Willi syndrome" or "Labbart Willi syndrome" or "Royer syndrome" or "Rubinstein-Taybe syndrome" or "Rubinstein syndrome" or "WAGR syndrome" or "Williams syndrome" or "Broad Thumb Hallux syndrome") AND INREGISTER
8. #1 or #2 or #3 or #4 or #5 or #6 or #7

Cochrane Central Register of Controlled Clinical Trials (CENTRAL) search strategy

1. MESH DESCRIPTOR Dental care for disabled AND CENTRAL:TARGET
2. MESH DESCRIPTOR Oral hygiene EXPLODE ALL AND CENTRAL:TARGET
3. MESH DESCRIPTOR Oral health AND CENTRAL:TARGET
4. MESH DESCRIPTOR Periodontal diseases EXPLODE ALL AND CENTRAL:TARGET
5. CENTRAL:TARGET
6. MESH DESCRIPTOR Periodontics EXPLODE ALL AND CENTRAL:TARGET
7. (periodont* or gingiv*) AND CENTRAL:TARGET
8. MESH DESCRIPTOR Dental Health Surveys EXPLODE ALL AND CENTRAL:TARGET
9. (toothbrush* or tooth-brush* or floss* or "chewing stick" or "wood stick" or toothpick*) AND CENTRAL:TARGET
10. (caries or carious) AND CENTRAL:TARGET
11. MESH DESCRIPTOR Dental caries EXPLODE ALL AND CENTRAL:TARGET
12. ((dental or oral or mouth or interdental or interproximal or tooth or teeth or orthodontic or denture* or brace* or bracket*) NEAR3 (irrigat* or clean* or brush* or clens* or aid*)) AND CENTRAL:TARGET
13. (oral or dental) NEAR2 (hygiene or care)) AND CENTRAL:TARGET
14. ((mouth or teeth) NEAR3 care) AND CENTRAL:TARGET(plaque* NEAR5 (remov* or control*)) AND CENTRAL:TARGET
15. ((dental plaque index* or "dental plaque indices" or "DMF Index" or "DMF Indices" or "dmf* index" or "dmf* indices" or "periodontal indices" or "periodontal indices" or "oral hygiene index" or "oral hygiene indices" or "gingival index") AND CENTRAL:TARGET
16. MESH DESCRIPTOR Dental plaque AND CENTRAL:TARGET
17. MESH DESCRIPTOR Health Education, Dental AND CENTRAL:TARGET
18. ((health* NEAR3 promot*) and (dental or teeth or mouth or periodont* or gingival* or "oral health")) AND CENTRAL:TARGET
19. #1 or #2 or #3 or #4 or #6 or #7 or #8 or #9 or #10 or #11 or #12 or #13 or #14 or #15 or #16 or #17 or #18
MEDLINE Ovid search strategy

1. Dental care for disabled/
2. exp Oral hygiene/
3. Oral health/
4. exp Periodontal disease/
5. exp Periodontics/
6. (periodont* or gingiv*)ti,ab.
7. exp Dental health surveys/
8. (toothbrush* or tooth-brush* or floss* or "chewing stick" or "wood stick" or toothpick*).ti,ab.
9. (caries or carious).ti,ab.
10. exp dental caries/
11. ((dental or oral or mouth) and interdental or interproximal or tooth or teeth or orthodontic or denture* or brace* or brackets*).adj3 (irrigat* or clean* or brush* or clean* or braces* or aid*).ti,ab. 12. ((oral or dental) adj2 (hygiene or care)).ti,ab.
13. (mouth or teeth) adj3 care).ti,ab.
14. (plaque* adj5 (remov* or control*)).ti,ab.
15. (("dental plaque index" or "dental plaque index" or "DMFS index" or "DMF index" or "DMF index" or "DMF index" or "DMF index" or "periodontal index" or "periodontal indices" or "oral hygiene index" or "oral hygiene index" or "oral hygiene index")).ti,ab.
16. Dental plaque/
17. Health education, dental/
18. ((health* adj3 promote) and (oral or teeth or mouth or periodont* or gingiv* or "oral health").ti,ab.
19. or/1-18

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Oral hygiene programmes for people with intellectual disabilities

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20. exp Intellectual disability/
21. Developmental disabilities/
22. (intellectual or mental) and "developmental disorder":ti,ab.
23. ((intellectu$ or mental$ or learning) adj5 (disabil$ or disabi$l$ or deficien$ or impair$ or handicap$) )ti,ab.
24. ((deficien$ or low$) adj3 (cognition or "cognitive function$" or reason$ or Intelligence))ti,ab.
25. ("special needs" or (special adj3 child$) or retard$ or "slow learner$")ti,ab.
26. ("Down$ syndrome" or mongol$ or "De Lange syndrome" or "Prader Willi syndrome" or "Labbart Willi syndrome" or "Royer syndrome" or "Rubinstein-Taybe syndrome" or "Rubinstein syndrome" or "WAGR syndrome" or "Williams syndrome" or "Broad Thumb Hallux syndrome")ti,ab.
27. or 20-26
28. 18 and 27

Embase Ovid search strategy

1. Mouth hygiene/
2. exp Periodontal disease/
3. exp Periodontics/
4. (periodont$ or gingiv$)ti,ab.
5. (toothbrush$ or tooth-brush$ or floss$ or "chewing stick$" or "wood stick$" or toothpick$)ti,ab.
6. (caries or carious)ti,ab.
7. exp dental caries/
8. ((dental or oral or mouth or interdental or interproximal or tooth or teeth or orthodontic or denture$ or brace$ or bracket$) adj3 (irritat$ or clean$ or brush$ or clean$))ti,ab.
9. (dentifrice$ or mouthwash$ or mouthrin$ or mouth-wash$ or mouth- rinse$)ti,ab.
10. ((oral or dental) adj2 (hygiene or care$))ti,ab.
11. ((mouth or teeth) adj3 care$)ti,ab.
12. (plaque$ adj5 (remove$ or control$))ti,ab.
13. ("dental plaque index" or "dental plaque indice" or "DMFS index" or "DMF indices" or "dmfs index" or "dmf$ indices" or "periodontal index" or "periodontal indices" or "oral hygiene index" or "oral hygiene indices" or "gingival index")ti,ab.
14. Tooth plaque/
15. Dental health education/
16. ((health$ adj3 promot$) and (dental or oral or mouth or periodont$ or gingival$ or "oral health")ti,ab. 17.
17. or 1-16
18. exp Intellectual impairment/
19. Developmental disorder/
20. (intellectual or mental) and "developmental disorder":ti,ab.
21. ((intellectu$ or mental$ or learning) adj5 (disabil$ or disabi$l$ or deficien$ or impair$ or handicap$) )ti,ab.
22. ((deficien$ or low$) adj3 (cognition or "cognitive function$" or reason$ or Intelligence))ti,ab.
23. ("special needs" or (special adj3 child$) or retard$)ti,ab.
24. ("Down$ syndrome" or mongol$ or "De Lange syndrome" or "Prader Willi syndrome" or "Labbart Willi syndrome" or "Royer syndrome" or "Rubinstein-Taybe syndrome" or "Rubinstein syndrome" or "WAGR syndrome" or "Williams syndrome" or "Broad Thumb Hallux syndrome")ti,ab.

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Oral hygiene programmes for people with intellectual disabilities

PsycINFO Ovid search strategy
1. Oral health/
2. (periodontal or gingiv$).ti.ab.
3. (toothbrush$ or tooth-brush$ or floss$ or "chewing stick$" or "wood stick$" or toothpick$).ti.ab.
4. (caries or carious).ti.ab.
5. ((dental or oral or mouth or interdental or interproximal or tooth or teeth or orthodontic or denture$ or brace$ or bracket$).adj3 (irrigat$ or clean$ or brush$ or cleans$)).ti.ab.
6. (dentifrices or mouthwash$ or mouthrin$ or mouth-wash$ or mouth-rin$).ti.ab.
7. ((oral or dental).adj2 (hygiene or care)).ti.ab.
8. (((mouth or teeth).adj3 care)).ti.ab.
9. (plaque$ adj2 (remov$ or control$)).ti.ab.
10. ("dental plaque index" or "dental plaque indices" or "DMFS index" or "DMFS indices" or "dmfs index" or "dmfs indices" or "periodontal index" or "periodontal indices" or "oral hygiene index" or "oral hygiene indices" or "gingival index").ti.ab.
11. ((health$ adj2 promote$) and (dental or teeth or mouth or periodont$ or gingival$ or "oral health")).ti.ab.
12. or/1-11
13. exp Intellectual development disorder/
14. exp Developmental disabilities/
15. exp Learning disorders/
16. (("Intellectual or mental") and "developmental disorder").ti.ab.
17. (("Intellectual or mental").adj0 (disability$ or disable$ or deficiency$ or impair$ or handicapped)).ti.ab.
18. ((cognition$ or low$).adj2 (cognition or "cognitive function$" or reason$ or intelligence)).ti.ab.
19. ("special needs" or (special adj3 child$) or retard$).ti.ab.
20. ("Down syndrome" or mongol$ or "De Lange syndrome" or "Prader-Willi syndrome" or "Lambert-Eaton syndrome" or "Royer syndrome" or "Rubinstein-Taybi syndrome" or "Rubinstein syndrome" or "WAGR syndrome" or "Williams syndrome" or "Broad Thumb Hallux syndrome").ti.ab.
21. or/13-20
22. 12 and 21

US National Institutes of Health Ongoing Trials Register (ClinicalTrials.gov) search strategy
intellectual and "oral health"
i ntellectual and dental
"developmental disorder" and "oral health"
"developmental disorder" and dental

World Health Organization International Clinical Trials Registry Platform search strategy
intellectual and "oral health"
intellectual and dental
"developmental disorder" and "oral health"
"developmental disorder" and dental
"special needs" and "oral health"

Review Manager 5.3

Oral hygiene programmes for people with intellectual disabilities

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"special needs" and dental

Review Manager 5.3
Appendix 3: Characteristics of Cochrane studies template

<table>
<thead>
<tr>
<th>Characteristics of included Studies Table Template</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Methods</strong></td>
</tr>
<tr>
<td>Study design:</td>
</tr>
<tr>
<td>Date of study:</td>
</tr>
<tr>
<td>Study duration:</td>
</tr>
<tr>
<td>Setting:</td>
</tr>
<tr>
<td>Ethical Approval:</td>
</tr>
<tr>
<td>Consent:</td>
</tr>
</tbody>
</table>

| **Participants**                                 |
| Description of ID used:                          |
| Conversion to ICD description:                   |
| Age Range (Mean):                                |
| Gender:                                          |
| Co-morbidity reported/details:                  |
| Number of participants at baseline:             |
| Number of participants at final evaluation:     |
| Selection of the participants for the intervention: |
| Country:                                        |

| **Intervention**                                 |
| Comparison:                                      |
| Group 1                                          |
| Group 2 etc.                                     |

| **Outcomes**                                     |
| Outcomes measured:                               |
| 1.                                                |
| 2.                                                |
| Timing of outcome assessments:                   |

**COM-B system characteristics**

| **Stakeholder involvement**                      |
| Formal or non-formal cares:                      |
| With or without dental professional involvement: |
| Other stakeholder involvement:                   |

| **Notes**                                        |
| Strengths & Weakness:                            |
| Modifications to the intervention:              |
| Adverse effects reported:                        |
| Funding Source:                                  |
### Appendix 4: Cochrane Summary of Findings tables

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Cochrane summary of findings</th>
<th>Effect size (95% CI)</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>-</td>
<td>Oral hygiene programmes for people with intellectual disabilities</td>
<td>Relative risk (RR)</td>
<td>Certainty of the evidence (GRADE)</td>
</tr>
<tr>
<td>-</td>
<td>Special manual toothbrush compared to a conventional manual toothbrush for people with intellectual disabilities</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>-</td>
<td>Oral hygiene programme compared to a conventional manual toothbrush for people with intellectual disabilities</td>
<td>-</td>
<td>-</td>
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</tbody>
</table>

**Cochrane Summary of Findings tables**

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</tr>
</tbody>
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<td>-</td>
<td>-</td>
</tr>
<tr>
<td>-</td>
<td>Oral hygiene programme compared to a conventional manual toothbrush for people with intellectual disabilities</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>
# Oral hygiene programmes for people with intellectual disabilities

**28-Jan-2019**

<table>
<thead>
<tr>
<th>QOL: Experience of carer when brushing</th>
<th>MD 0.7 higher (0.15 lower to 1.65 higher)</th>
<th>18 (1 RCT)</th>
<th>LOW 3, 4</th>
<th>A special manual toothbrush (Superbrush) may provide a better experience for the carers when using it. Some small benefits were also shown in relation to frequency of brushing, carers handling of the special manual toothbrush and level of resistance of the people with ID when having their teeth brushed. Overall a special manual toothbrush may improve quality of life for both the people with ID and their carers.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dental caries - not reported</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>One study reported having assessed the level of dental caries using the DMFT index, but did not report the findings in the published article.</td>
</tr>
</tbody>
</table>

*The risk in the intervention group (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).*

Ct: Confidence interval; RR: Risk ratio; OR: Odds ratio;

### GRADE Working Group grades of evidence

**High certainty:** We are very confident that the true effect lies close to that of the estimate of the effect.

**Moderate certainty:** We are moderately confident in the estimate of the effect: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

**Low certainty:** Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect.

**Very low certainty:** We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of the effect.

### Footnotes

1. Imprecision - findings based on only one study with 25 participants
2. Assessments were not calibrated and baseline scores were different in this study
3. Imprecision - based on one study with 18 participants and with CI
4. Unclear risk of bias in two domains (performance and selective reporting)
5. Assessment tool was not validated

---

Review Manager 5.3
## Summary of findings tables

### 2 Electric toothbrush compared to manual toothbrush for people with intellectual disabilities

#### Electric toothbrush compared to manual toothbrush for people with intellectual disabilities

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Anticipated absolute effects (95% CI)</th>
<th>Relative effect (95% CI)</th>
<th>N of participants (studies)</th>
<th>Certainty of the evidence (GRADE)</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gingival inflammation short term (&lt; 6 weeks)</td>
<td>0 (0 to 0)</td>
<td>-</td>
<td>(4 RCTs)</td>
<td>LOW (2)</td>
<td>Using an electric toothbrush versus a manual toothbrush showed no difference on gingival inflammation short term (&lt; 6 weeks) for people with ID. Data from the four studies could not be included in a meta-analysis. The certainty of the evidence is low. Four NRS similarly found no difference between toothbrushes.</td>
</tr>
<tr>
<td>Gingival inflammation medium term (6 weeks to 12 months)</td>
<td>MD 0.02 higher [0.00 to 0.09 higher]</td>
<td>-</td>
<td>120 (2 RCTs)</td>
<td>MODERATE</td>
<td>An electric toothbrush appears to result in little to no difference in gingival inflammation medium term (6 weeks to 12 months). Two of the three RCTs were included in the meta-analysis and found no effect, the third study using a subjective assessment of gingival inflammation showed findings in favour of the electric toothbrush. Four NRS had consistent findings at 6 months, data not suitable for meta-analysis. One NRS found no effect at 12 months (MD: 0.00, 95% CI: -0.15 to 0.15).</td>
</tr>
<tr>
<td>Plaque short term (&lt; 6 weeks)</td>
<td>0 (0 to 0)</td>
<td>-</td>
<td>(4 RCTs)</td>
<td>VERY LOW (1.2,3)</td>
<td>We are uncertain about the effect of using an electric toothbrush versus a manual toothbrush on plaque short term (&lt; 6 weeks) for people with ID. None of the studies presented data that could be included in a meta-analysis. Two studies showed some benefit in favour of the electric toothbrush, two studies showed no difference between the two toothbrushes.</td>
</tr>
<tr>
<td>Plaque medium term (6 weeks to 12 months)</td>
<td>SMD 0.26 SD higher [0.07 to 0.65 higher]</td>
<td>-</td>
<td>120 (2 RCTs)</td>
<td>MODERATE</td>
<td>An electric toothbrush versus a manual toothbrush probably results in little difference on plaque medium term (6 months). Two studies included in the meta-analysis found a small effect in favour of the manual toothbrush at six months, one other RCT not included in the meta-analysis, which used a subjective assessment of oral hygiene, showed an improvement in favour of the electric toothbrush. Five NRS found broadly similar results to the meta-analysis, showing little or no effect.</td>
</tr>
<tr>
<td>Calculus medium term (6 weeks to 12 months)</td>
<td>SMD 0.04 SD lower [0.01 to 0.07 higher]</td>
<td>-</td>
<td>120 (2 RCTs)</td>
<td>MODERATE</td>
<td>An electric toothbrush versus a manual toothbrush probably results in little to no difference in calculus medium term (6 weeks to 12 months) for people with ID. Two of the three studies were included in the meta-analysis and showed no difference, the third study using a subjective assessment of calculus levels found in favour of the electric toothbrush.</td>
</tr>
</tbody>
</table>
Oral hygiene programmes for people with intellectual disabilities

| Quality of Life - not measured | - | - | - | - | - | - | - | - | No studies assessed quality of life changes formally although some made comments in the results or discussion sections of the reports. |
| Dental Caries - not reported | - | - | - | - | - | - | - | - | One RCT reported have assessed dental caries using the DMFT index but did not report their findings. |

*The risk in the intervention group (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI). |

CI: Confidence interval; RR: Risk ratio; OR: Odds ratio;

**GRADE Working Group grades of evidence**

**High certainty:** We are very confident that the true effect is close to that of the estimate of the effect.

**Moderate certainty:** We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there may be a possibility that it is substantially different.

**Low certainty:** Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect.

**Very low certainty:** We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect.

**Footnotes**

1. Several ‘Unclear’ elements in relation to risk of bias

2. Blinding of participants and personnel was not possible in three of the studies

3. Findings were inconsistent between studies
## Summary of findings tables

### 3 Training of carers compared to no training of carers for people with intellectual disabilities

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Anticipated absolute effect</th>
<th>Risk with no training of carers</th>
<th>Risk with Training of carers</th>
<th>N of participants (studies)</th>
<th>Certainty of the evidence (GRADE)</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gingival inflammation medium term (6 weeks to 12 months) assessed with Modified Los &amp; Silness Gingival Index Scale from: 0 to 3 follow up: range 8 weeks to 9 months</td>
<td>MD 0.24 lower (0.43 lower to 0.05 lower)</td>
<td>-</td>
<td>99 (2 RCTs)</td>
<td>LOW 1 2 3</td>
<td>Training of carers may result in a slight reduction in gingival inflammation for the people with ID for whom they care medium term (6 weeks to 12 months). The findings of the two studies were inconsistent and the certainty of the evidence is low.</td>
<td></td>
</tr>
<tr>
<td>Plaque medium term (6 weeks to 12 months) assessed with Modified Silness &amp; Loes Plaque Index Scale from: 0 to 3 follow up: range 8 weeks to 9 months</td>
<td>MD 0.07 lower (0.26 lower to 0.13 higher)</td>
<td>-</td>
<td>99 (2 RCTs)</td>
<td>LOW 1 2 3</td>
<td>The evidence from the two RCTs suggests that training of carers does not reduce the plaque levels for people with ID for whom they care medium term (6 weeks to 12 months). The certainty of the evidence is low. One NRCT found plaque levels of people with ID were reduced after training of their carers, particularly if carers were made accountable for their performance. An ITS found broadly consistent findings to the NRCT. The certainty of these NRS was very low.</td>
<td></td>
</tr>
<tr>
<td>Knowledge short term (&lt;6 weeks) assessed with Questionnaire - higher score is good Scale from: 0 to 20 follow up: mean 1 days</td>
<td>MD 0.59 higher (0.8 lower to 1.98 higher)</td>
<td>-</td>
<td>24 (1 RCT)</td>
<td>MODERATE 3</td>
<td>Training carers in oral hygiene care may result in a moderate increase in oral health care knowledge short term (&lt;6 weeks).</td>
<td></td>
</tr>
<tr>
<td>Knowledge medium term (6 weeks to 12 months) assessed with Questionnaire - higher score is good Scale from: 0 to 10 follow up: range 8 weeks to 11 months</td>
<td>MD 0.69 higher (0.31 higher to 1.08 higher)</td>
<td>-</td>
<td>199 (2 RCTs)</td>
<td>LOW 1 2 6</td>
<td>Training carers in oral hygiene care may result in moderate increase in oral health care knowledge medium term (6 weeks to 12 months). The certainty of the evidence is low.</td>
<td></td>
</tr>
<tr>
<td>Behaviour, Attitude and Self-Efficacy assessed with Questionnaire - higher score is good Scale from: 0 to 14 follow up: range 8 weeks to 11 months</td>
<td>MD 0.36 higher (0.08 lower to 0.81 higher)</td>
<td>-</td>
<td>199 (2 RCTs)</td>
<td>LOW 1 2 3</td>
<td>Training carers may improve their Behaviour, Attitude and Self-Efficacy in relation to providing oral hygiene care to people with ID. One RCT assessing behaviour alone showed similar findings. The certainty of the evidence is low. Two NRS assessing the behaviour of the carers and people with ID showed evidence in favour of training in all outcomes assessed; the certainty of that evidence is very low.</td>
<td></td>
</tr>
</tbody>
</table>
### Oral hygiene programmes for people with intellectual disabilities

<table>
<thead>
<tr>
<th>Quality of Life (Not measured)</th>
<th>-</th>
<th>(studies)</th>
<th>No studies formally reported quality of life measures, some studies commented on quality of life issues in the discussion and conclusion section of the reports</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dental Caries (Not measured)</td>
<td>-</td>
<td>(studies)</td>
<td>No studies measured dental caries</td>
</tr>
</tbody>
</table>

*The risk in the intervention group (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).*

- CI: Confidence interval; RR: Risk ratio; OR: Odds ratio;
- **GRADE Working Group grades of evidence**
  - **High certainty**: We are very confident that the true effect lies close to that of the estimate of the effect.
  - **Moderate certainty**: We are moderately confident in the effect estimate. The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
  - **Low certainty**: Our confidence in the effect estimate is limited. The true effect may be substantially different from the estimate of the effect.
  - **Very low certainty**: We have very little confidence in the effect estimate. The true effect is likely to be substantially different from the estimate of effect.

### Footnotes
1. Several 'Unclear' elements in relation to risk of bias
2. One study was a cluster RCT
3. Findings were inconsistent between studies
4. Index was modified to an extent that it may have impacted on the results
5. Study was a quasi-randomized controlled trial
6. High levels of attrition in both studies
### Summary of findings Tables

#### Oral hygiene programmes for people with intellectual disabilities

**Oral hygiene programmes for people with intellectual disabilities**

**Patient or population:** people with intellectual disabilities  
**Setting:**  
**Intervention:** oral hygiene training  
**Comparisons:** no oral hygiene training

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Anticipated absolute effects (95% CI)</th>
<th>Relative effect (95% CI)</th>
<th>N of participants (studies)</th>
<th>Certainty of the evidence (GRADE)</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gingival inflammation short term (&lt;6 weeks)</td>
<td>MD 0.20 lower (0.09 to 0.34 higher)</td>
<td>-</td>
<td>10 (1 RCT)</td>
<td>2</td>
<td>One RCT included in a meta-analysis showed training of people with ID may result in a slight reduction in gingival inflammation short term (&lt;6 weeks). The certainty of the evidence is low. Four NRS assessed tooth brushing behaviour following skills training of people with ID, three of which showed improved tooth brushing behaviour, no measure of gingival inflammation levels were recorded in these studies.</td>
</tr>
<tr>
<td>Plaque short term (&lt;6 weeks)</td>
<td>MD 0.47 lower (0.02 to 0.02 lower)</td>
<td>-</td>
<td>10 (1 RCT)</td>
<td>2</td>
<td>One RCT included in a meta-analysis showed training of people with ID may result in a moderate reduction in plaque short term (&lt;6 weeks). Another RCT not included showed broadly similar reductions in plaque levels following training. Four NRS assessed tooth brushing behaviour following skills training of people with ID, three of which showed improved tooth brushing behaviour, no measure of plaque levels were recorded in these studies.</td>
</tr>
</tbody>
</table>

*The risk in the intervention group (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).*

**CIs:** Confidence interval  
**RR:** Relative risk  
**OR:** Odds ratio  
**GRADE Working Group grades of evidence**

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**Footnotes**

- Several 'Unclear' elements in relation to risk of bias.
- Impression - based on the findings of one study with 10 participants and wide CI.
Summary of findings tables

5 Dental recall intervals compared to usual care for people with intellectual disabilities

Dental recall intervals compared to usual care for people with intellectual disabilities

Patient or population: people with Intellectual disabilities
Setting: 
Intervention: Dental recall intervals
Comparison: usual care

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Anticipated absolute effects* (95% CI)</th>
<th>Relative effect (95% CI)</th>
<th>No of participants (studies)</th>
<th>Certainty of the evidence (GRADE)</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>One, three and six monthly dental recalls - Gingival pocketing long term (&gt;12 months) assessed with: WHO technical report</td>
<td>MD 0.6 lower (0.97 lower to 0.23 lower)</td>
<td>-</td>
<td>304 (1 RCT)</td>
<td>LOW</td>
<td>One monthly dental recall intervals may reduce gingival pocketing long term (24 months). Gingival pocket reductions at three and six monthly intervals are broadly similar. The certainty of the evidence is low.</td>
</tr>
<tr>
<td>Scale from: 0 to 2 follow up: mean 24 months</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>One, three and six monthly dental recalls - Gingival bleeding long term (&gt;12 months) assessed with: WHO technical report</td>
<td>MD 0.2 lower (0.86 lower to 0.46 higher)</td>
<td>-</td>
<td>304 (1 RCT)</td>
<td>LOW</td>
<td>One monthly dental recall intervals may result in a slight reduction in gingival bleeding long term (24 months). Three and six monthly dental recall intervals have a broadly similar effect. The certainty of the evidence is low.</td>
</tr>
<tr>
<td>Scale from: 0 to 1 follow up: mean 24 months</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>One, three and six monthly dental recalls - Plaque long term (&gt;12 months) assessed with: WHO plaque index</td>
<td>MD 0.7 lower (1.28 lower to 0.12 lower)</td>
<td>-</td>
<td>304 (1 RCT)</td>
<td>LOW</td>
<td>One monthly dental recall intervals may reduce plaque levels long term (24 months). Plaque reductions at three and six monthly recall intervals were broadly similar. The certainty of the evidence is low.</td>
</tr>
<tr>
<td>Scale from: 0 to 3 follow up: mean 24 months</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>One, three and six monthly recall intervals - Calculus long term (&gt;12 months) assessed with: WHO technical report</td>
<td>MD 2 lower (2.64 lower to 1.36 lower)</td>
<td>-</td>
<td>304 (1 RCT)</td>
<td>LOW</td>
<td>One monthly dental recall intervals appears to reduce calculus long term (24 months), similar reductions are seen at 3 monthly recall intervals and a lower but still favourable effect is seen at six monthly recall intervals. The certainty of the evidence is low.</td>
</tr>
<tr>
<td>Scale from: 0 to 1 follow up: mean 24 months</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Knowledge, Behaviour, Attitude &amp; Self-efficacy - not reported</td>
<td>-</td>
<td>-</td>
<td></td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>Quality of Life - not reported</td>
<td>-</td>
<td>-</td>
<td></td>
<td>-</td>
<td></td>
</tr>
</tbody>
</table>
Oral hygiene programmes for people with intellectual disabilities

<table>
<thead>
<tr>
<th>Dental Caries</th>
<th>not reported</th>
</tr>
</thead>
</table>

*The risk in the intervention group (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).*

CI: Confidence interval; RR: Risk ratio; OR: Odds ratio;

**GRADE Working Group grades of evidence**

- **High certainty:** We are very confident that the true effect lies close to that of the estimate of the effect.
- **Moderate certainty:** We are moderately confident in the effect estimate. The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
- **Low certainty:** Our confidence in the effect estimate is limited. The true effect may be substantially different from the estimate of the effect.
- **Very low certainty:** We have very little confidence in the effect estimate. The true effect is likely to be substantially different from the estimate of the effect.

**Footnotes**

1. Several "unclear" elements in relation to risk of bias
2. Imprecision - based on one study, with wide CI
### Summary of findings tables

#### 6 Clinical photographs as OH motivators compared to placebo for people with intellectual disabilities

**Clinical photographs as OH motivators compared to placebo for people with intellectual disabilities**

- **Patient or population:** people with intellectual disabilities
- **Setting:** Clinical photographs as OH motivators
- **Comparison:** placebo

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Anticipated absolute effects (95% CI)</th>
<th>Relative effect (95% CI)</th>
<th>% of participants evidence (studies)</th>
<th>Certainty of the evidence (GRADE)</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plaque mean tert (6 weeks to 12 months)</td>
<td>MD 0.1 lower (0.66 lower to 0.66 higher)</td>
<td>-</td>
<td>29 (1 RCT)</td>
<td>LOW</td>
<td>Clinical photographs as oral hygiene motivators may result in little to no difference in plaque levels medium tert (6 weeks to 12 months). Broadly similar findings were observed for extrinsic plaque levels. The certainty of the evidence is low.</td>
</tr>
<tr>
<td>Knowledge, Behaviour, Attitude &amp; Self-efficacy - not reported</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Quality of Life - not reported</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Dental Caries - not reported</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

*The risk in the intervention group (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).*

**CI:** Confidence interval; **RR:** Risk ratio; **OR:** Odds ratio.

**GRADE Working Group grades of evidence**

- **High certainty:** We are very confident that the true effect lies close to that of the estimate of the effect
- **Moderate certainty:** We are moderately confident in the effect estimate. The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
- **Low certainty:** Our confidence in the effect estimate is limited. The true effect may be substantially different from the estimate of the effect
- **Very low certainty:** We have very little confidence in the effect estimate. The true effect is likely to be substantially different from the estimate of the effect

**Footnotes**

1 Several "unclear" or "high" elements in relation to risk of bias
2 Imprecision - based on findings of one study with wide CI
### Summary of findings tables

#### 7 Daily tooth brushing compared to twice weekly or once weekly tooth brushing for people with intellectual disabilities

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Impact</th>
<th>n of participants (studies)</th>
<th>Certainty of the evidence (GRADE)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plaque (short term) assessed with: LoE and Inflammation Gingival Index follow-up: mean 21 days</td>
<td>For people with intellectual disabilities whose teeth are brushed for them by dental professionals, brushing daily will most likely reduce gingival inflammation more effectively than twice weekly and even more effectively than once weekly, in the short term (21 days).</td>
<td>80 (1 RCT)</td>
<td>MODERATE 1</td>
</tr>
<tr>
<td>Knowledge, Behaviour, Attitude &amp; Self-efficacy - not reported</td>
<td></td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Quality of Life - not reported</td>
<td></td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Dental Caries - not reported</td>
<td></td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

*The risk in the intervention group (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI). CI: Confidence Interval; RR: Risk ratio; OR: Odds ratio;*  

**GRADE Working Group grades of evidence**  
High certainty: We are very confident that the true effect lies close to that of the estimate of the effect  
Moderate certainty: We are moderately confident in the effect estimate. The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different  
Low certainty: Our confidence in the effect estimate is limited. The true effect may be substantially different from the estimate of the effect  
Very low certainty: We have very little confidence in the effect estimate. The true effect is likely to be substantially different from the estimate of effect

**Footnotes**

1. Imprecision - no SD data reported
Summary of findings tables

8 A toothpaste with a plaque disclosing agents compared to a conventional toothpaste for children with mild and moderate intellectual disabilities

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Impact</th>
<th>n of participants (studies)</th>
<th>Certainty of the evidence (GRADE)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gingival Inflammation (short term') assessed with: Almato &amp; Bays' Gingival Bleeding Index follow-up: mean 10 days</td>
<td>Using a toothpaste with a plaque disclosing agents for children with mild and moderate intellectual disabilities may reduce gingival inflammation slightly in the short term (10 days), however the certainty of the evidence is very low.</td>
<td>60 (1 observational study)</td>
<td><strong>GRADE</strong> VERY LOW 1 2 3</td>
</tr>
<tr>
<td>Plaque (short term') assessed with: Simplified Green &amp; Vermillion Plaque Index follow-up: mean 10 days</td>
<td>Using a toothpaste with a plaque disclosing agents for children with mild and moderate intellectual disabilities, may reduce plaque levels in the short term (10 days), however the certainty of the evidence is very low.</td>
<td>60 (1 observational study)</td>
<td><strong>GRADE</strong> VERY LOW 1 2 3</td>
</tr>
<tr>
<td>Knowledge, Behaviour, Attitude &amp; Self-efficacy - not reported</td>
<td></td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Quality of Life - not reported</td>
<td></td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Dental Caries - not reported</td>
<td></td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

*The risk in the intervention group (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI). C/I: Confidence Interval; RR: Risk ratio; OR: Odds ratio; **GRADE** Working Group grades of evidence: High certainty: We are very confident that the true effect lies close to that of the estimate of the effect. Moderate certainty: We are moderately confident in the effect estimate. The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different. Low certainty: Our confidence in the effect estimate is limited. The true effect may be substantially different from the estimate of the effect. Very low certainty: We have very little confidence in the effect estimate. The true effect is likely to be substantially different from the estimate of effect.
# Summary of findings tables

## Individualised care plans compared to no individualised care plan for people with mixed levels of intellectual disabilities

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Impact</th>
<th>n of participants (studies)</th>
<th>Certainty of the evidence (GRADE)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plaque (medium term) assessed with subjective oral hygiene rating and improvement Differential follow-up: mean 12 months</td>
<td>The use of individualised oral care plans for people with intellectual disabilities may reduce plaque levels over a period of 12 months, the level of certainty is very low.</td>
<td>79 (1 observational study)</td>
<td>VERY LOW: 1, 2, 3</td>
</tr>
<tr>
<td>Knowledge, Behaviour, Attitude &amp; Self-efficacy - not reported</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Quality of Life - not reported</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dental Caries - not reported</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*The risk in the intervention group (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).

CI: Confidence Interval; RR: Risk ratio; OR: Odds ratio;

**GRADE Working Group grades of evidence**

- **High certainty**: We are very confident that the true effect lies close to that of the estimate of the effect.
- **Moderate certainty**: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
- **Low certainty**: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect.
- **Very low certainty**: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect.

---

**Footnotes**

1. Several high elements in Risk of Bias
2. Subjective assessment tool used
3. Imputation - no SD reported

Review Manager 5.3
# Appendix 5: Characteristics of included studies

### Oral hygiene programmes for people with intellectual disabilities

#### Characteristics of studies

**Characteristics of included studies**

**Abraham 1972**

| Methods          | Study design: repeat measures  
|------------------|-------------------------------|
|                  | Date of study: not given, pre 1972  
|                  | Study duration: unclear  
|                  | Setting: residential  
|                  | Ethical approval: none reported  
|                  | Consent: none reported  

| Participants     | Description of ID used: "Severely Retarded"  
|------------------| The mean MA (Mental Age) as measured by the Peabody Picture Vocabulary Test was 2 years and 8 months. The mental ages ranged from 2 years 2 months to 4 years 1 months  
|                  | Conversion to ICD description: severe  
|                  | Age Range (mean): 6 years 3 months to 14 years 8 months (12y-4m)  
|                  | Sex: male  
|                  | Comorbidity reported/details: none reported  
|                  | Number of participants at baseline: 8  
|                  | Number of participants at final evaluation: 8  
|                  | Selection of the participants for the intervention: no details  
|                  | Country: USA  

| Interventions    | Comparison: Training of people with intellectual disability versus no training of people with intellectual disabilities  
|------------------| Intervention: Teach dental hygiene techniques to people with ID using discrimination, reinforcement and modelling training. Brushing behaviour based on a checklist of 10 items  

| Outcomes         | Outcomes measured:  
|------------------| 1. Sessions required to reach discrimination  
|                  | 2. Steps achieved in a 10 step toothbrushing routine using modelling and reinforcement with rewards  
|                  | Timing of outcome assessments: 8 observations at baseline and 8 post training  

| COM-B System Characteristics | Potential sources of behaviour change: capability (physical), motivation (reflective)  
|------------------------------| Potential Intervention functions: training, modelling, incentivisation  

| Stakeholder Involvement     | Formal or non-formal carer: formal  
|------------------------------| With or without dental professional involvement: without  
|                              | Other stakeholders: one counsellor (staff member) trained in the use of the check list of 10 steps to brushing.  

| Notes                       | Strengths & weaknesses: duration of the intervention is unclear  
|------------------------------| Modifications to the intervention: none reported  
|                              | Adverse effects reported: none reported  
|                              | Funding Source: "Supported by Grant RD-2200-P0803 of the Social and Rehabilitation Services, Dept of Health, Education and Welfare" Comment: unlikely to be a conflict  

---

Review Manager 5.3
### Oral hygiene programmes for people with intellectual disabilities

**Risk of bias table**

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors’ judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Unclear risk</td>
<td>Comment: None stated; other changes or events may have influenced the outcomes, study duration is unclear</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
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<td></td>
</tr>
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<td>Blinding of participants and personnel (performance bias)</td>
<td>Unclear risk</td>
<td></td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias)</td>
<td>Unclear risk</td>
<td></td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias)</td>
<td>Unclear risk</td>
<td></td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Unclear risk</td>
<td></td>
</tr>
<tr>
<td>Was the intervention independent of other changes? (ITT)</td>
<td>Unclear risk</td>
<td>Comment: None stated; other changes or events may have influenced the outcomes, study duration is unclear</td>
</tr>
<tr>
<td>Was the shape of the intervention effect pre-specified? (ITT)</td>
<td>Low risk</td>
<td>Comment: The point of analysis is the point of intervention</td>
</tr>
<tr>
<td>Was the intervention unlikely to affect data collection? (ITT)</td>
<td>Low risk</td>
<td>Comment: The intervention did not affect either the sources or method of data collection</td>
</tr>
<tr>
<td>Was knowledge of the allocated interventions adequately prevented during the study? (ITT)</td>
<td>High risk</td>
<td>Comment: Not possible to blind, all subjects in the intervention known to rater and researcher</td>
</tr>
<tr>
<td>Were incomplete outcome data adequately addressed? (ITT)</td>
<td>Low risk</td>
<td>Comment: One participant did not complete the training, moved from the setting. Unlikely to affect outcomes</td>
</tr>
<tr>
<td>Was the study free from selective outcome reporting? (ITT)</td>
<td>Low risk</td>
<td>Comment: All outcome data were reported</td>
</tr>
</tbody>
</table>

**Albino 1979**

**Methods**

- Study design: RCT
- Date of study: not given, pre Winter 1978
- Study duration: 5 weeks
- Setting: School
- Ethical approval: not reported
- Consent: not reported

**Participants**

- Description of ID used: “Severely retarded children” “IQ between 20 and 40”
- Conversion to ICD description: moderate and severe
- Age range (mean): 3 to 21 years
- Sex: both
- Comorbidity reported/detected: Yes *Down syndrome, Tay-Sachs disorder, epilepsy*
Oral hygiene programmes for people with intellectual disabilities

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Interventions
Comparison: training versus no training of people with intellectual disabilities
Intervention: orientation and desensitisation (11 sessions), social (verbal and physical praise) and tangible (large teddy for small toy) reinforcement. Individualization and parental involvement; individual feedback on their children’s progress along with suggestions that they might use at home to enhance and reinforce learning. Schwartz 1978 Pg 20
Control: orientation and desensitisation (11 sessions) only

Outcomes
Plaque Index - Kobyashi & Ash (8 teeth scored) (V). This index is a modification of Ramfors and Solnick & Ash
Timing of outcome assessments: baseline and final

COM-Ho System Characteristics
Potential sources of behaviour change: capability (physical/psychological), opportunity (social/physical), motivation (reflexive)
Potential intervention functions: training, enablement, incentivisation, environmental restructuring

Stakeholder Involvement
Formal or non-formal carer: both
With or without dental professional involvement: with - dental instructors, dental student, paediatric patient
Other stakeholder involvement: parents, director of centre

Notes
Strengths and weaknesses: high attrition rate
Modifications to the intervention: the intervention was continuously modified to meet the needs of individual participants. Quote “It soon became obvious that all children were not able to master the toothbrushing technique and attention was given to individualisation” Schwartz 1978 Pg 20
Adverse effects reported: none reported
Funding Source: Quote: “Funding for this study was provided in part by a grant from Johnson and Johnson, Inc.” Albino 1979 Pg 28, C2. Comment: unlikely to be a conflict

Risk of bias table

<table>
<thead>
<tr>
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<th>Support for judgement</th>
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<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Low risk</td>
<td>Quote “Half the children were randomly assigned to a control group and the other half to an experimental group” Schwartz 1978 Pg 18</td>
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<tr>
<td>Allocation concealment (selection bias)</td>
<td>Unclear risk</td>
<td>Comment: no details reported</td>
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</table>

Review Manager 5.3
### Oral hygiene programmes for people with intellectual disabilities

<table>
<thead>
<tr>
<th>Risk of Bias Item</th>
<th>Rating</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blinding of participants and personnel (performance bias)</td>
<td>Unclear</td>
<td>Comment: no details provided but control group did receive some intervention</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias)</td>
<td>High</td>
<td>Comment: examiner was not blinded</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias)</td>
<td>High</td>
<td>Comment: level of attrition likely to impact on outcome effect</td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>High</td>
<td>Comment: criteria for scoring plaque was modified due to difficulties in recording all surfaces. Reduced from 12 to 8 surfaces, no SD given</td>
</tr>
<tr>
<td>Was the intervention independent of other changes? (ITC)</td>
<td>Unclear</td>
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</tr>
<tr>
<td>Was the shape of the intervention effect pre-specified? (IT5)</td>
<td>Unclear</td>
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</tr>
<tr>
<td>Was the intervention unlikely to affect data collection? (IT5)</td>
<td>Unclear</td>
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</tr>
<tr>
<td>Was knowledge of the allocated interventions adequately prevented during the study? (IT5)</td>
<td>Unclear</td>
<td></td>
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<tr>
<td>Were incomplete outcome data adequately addressed? (IT5)</td>
<td>Unclear</td>
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</tr>
<tr>
<td>Was the study free from selective outcome reporting? (IT5)</td>
<td>Unclear</td>
<td></td>
</tr>
</tbody>
</table>

### Altabet 2003

**Methods**

- Study design: NRCT "2 x 2 repeated measures factorial design with two groups (x, no x) both measured over two distinct time periods." Pg 144
- Date of study: March 20 1999 to March 20 2000
- Study duration: 12 months
- Setting: residential
- Ethical approval: not reported
- Consent: not reported

**Participants**

- Description of ID used: mild - moderate and severe - profound "range of mental retardation"  
- Conversion to ICD desription: mixed  
- Age range (mean): 22 to 57 years  
- Sex: male (64), female (35)  
- Comorbidity reported: details: none
- Number of participants at baseline: 75
- Number of participants at final evaluation: 70
- Selection of the participants for the intervention: those residents who attended for s

**Review Manager 5.3**
Oral hygiene programmes for people with intellectual disabilities

11-Jan-2019

<table>
<thead>
<tr>
<th>Bias / Bias</th>
<th>Risk Level</th>
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<td>Blinding of participants and personnel (performance bias)</td>
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<td>Comment: no details provided but control group did receive some intervention</td>
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<td>Blinding of outcome assessment (detection bias)</td>
<td>High risk</td>
<td>Comment: examiner was not blinded</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Quote: &quot;The examiner was also the student dentist acting as instructor in the program.&quot; Albino 1976 Pg 27</td>
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<tr>
<td>Incomplete outcome data (attrition bias)</td>
<td>High risk</td>
<td>Comment: level of attrition likely to impact on outcome effect</td>
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<tr>
<td></td>
<td></td>
<td>Quote: &quot;Attrition rate of subjects particularly when it was occasioned by fear and lack of appropriate behavior, was discouraging.&quot; Albino 1976 Pg 27</td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>High risk</td>
<td>Comment: criteria for scoring plaque was modified due to difficulties in recording all surfaces. Reduced from 12 to 6 surfaces, no SD given</td>
</tr>
</tbody>
</table>

Was the intervention independent of other changes? (ITS) | Unclear risk |
Was the shape of the intervention effect pre-specified? (ITS) | Unclear risk |
Was the intervention unlikely to affect data collection? (ITS) | Unclear risk |
Was knowledge of the allocated interventions adequately prevented during the study? (ITS) | Unclear risk |
Were incomplete outcome data adequately addressed? (ITS) | Unclear risk |
Was the study free from selective outcomes reporting? (ITS) | Unclear risk |

Altabet 2003

Methods
Study design: NRCT “2 x 2 repeated measures factorial design with two groups (x, no) both measured over two distinct time periods.” Pg 144
Data of study: March 2000 to March 2000
Study duration: 12 months
Setting: residential
Ethical approval: not reported
Consent: not reported

Participants
Description of ID used: mild – moderate and severe - profound “range of mental retardation”
Conversion to ICD description: mixed
Age range (mean): 22 to 57 years
Sex: male (44), female (25)
Complications reported/details: none
Number of participants at baseline: 79
Number of participants at final evaluation: 79
Selection of the participants for the intervention: those residents who attended for a
## Oral hygiene programmes for people with intellectual disabilities

**selective reporting (reporting bias)**

<table>
<thead>
<tr>
<th>Question</th>
<th>Risk</th>
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<tbody>
<tr>
<td>Was the intervention independent of other changes? (ITT)</td>
<td>Unclear risk</td>
</tr>
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<td>Unclear risk</td>
</tr>
<tr>
<td>Was the study free from selective outcome reporting? (ITT)</td>
<td>Unclear risk</td>
</tr>
</tbody>
</table>

**Bickley 1990**

**Methods**
- Study design: RCT
- Date of study: not reported, pre 1990
- Study duration: 6 months
- Setting: day centre
- Ethical approval: not reported
- Consent: Quote: "Clients agreement to participate was confirmed". Pg 4, C1, Paragraph 3

**Participants**
- Description of ID used: "Mentally handicapped"
- Conversion to ICD description: unclear
- Age range (mean): not reported
- Sex: not reported
- Comorbidity reported/details: none reported
- Number of participants at baseline: 30
- Number of participants at final evaluation: 20
- Selection of the participants for the intervention: following a routine dental examination, identified as having poor oral hygiene
- Country: UK

**Interventions**
- Comparison: individual clinical photographs used as motivators compared to no motivators for people with intellectual disabilities
- Group 1: monthly photographic records of individuals, with their plaque disclosed, used to compare and discuss their oral hygiene from visit to visit, with related oral hygiene instruction
- Group 2: monthly photographic records of individuals, with their plaque disclosed, but not used to compare, general oral hygiene instruction

**Outcomes**
- 1. Plaque, calculus, pocketing, bleeding indices of 6 teeth based on WHO diagnostic criteria
- 2. Extrinsic Stain Index (Shaw & Murray 1977) (V)
- 3. Cognitive and perceptual learning (Interviews)

**Review Manager 5.3**

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**Oral hygiene programmes for people with intellectual disabilities**

### Timing of outcome assessments: 1. baseline and final, 2. monthly

#### COM-B System Characteristics
- Potential sources of behaviour change: capability (physical/psychological), motivation (reflective)
- Potential intervention functions: enablement, persuasion, environmental restructuring

#### Stakeholder Involvement
- Formal or non-formal carer: N/A
- With or without dental professional involvement: with dental hygienist
- Other stakeholder involvement: none

#### Notes
- Strengths and weaknesses: lack of direct contact between investigators and carers was a disadvantage
- Modifications to the intervention: none
- Adverse effects reported: none
- Funding source: quote: "For the provision of toothbrushes and toothpaste, we gratefully acknowledge the following companies Oral B, Colgate and Gibo Mentadent."
- Comment: no likely conflict

### Risk of bias table

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<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Low risk</td>
<td>Quote: &quot;after the baseline examination the subjects were allocated using a random numbers table into the test or the control group&quot; Pg 4 C1, P2</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Unclear risk</td>
<td>Comment: no details provided</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias)</td>
<td>Unclear risk</td>
<td>Comment: no details provided</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias)</td>
<td>Low risk</td>
<td>Comment: assessor was not involved in the study in any way</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias)</td>
<td>Low risk</td>
<td>Comment: unclear why one participant dropped out, but unlikely to affect outcome</td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>High risk</td>
<td>Comment: only the plaque index is reported from the full assessments. Results of cognitive and perceptual interviews not reported. Poor reporting of measures used. Unable to contact author for more details</td>
</tr>
<tr>
<td>Was the intervention independent of other changes? (ITS)</td>
<td>Unclear risk</td>
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</table>
### Oral hygiene programmes for people with intellectual disabilities

<table>
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<tr>
<th>Item</th>
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<tbody>
<tr>
<td>Were incomplete outcome data adequately addressed? (ITT)</td>
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<td>Was the study free from selective outcome reporting? (ITT)</td>
<td>Unclear</td>
</tr>
</tbody>
</table>

#### Bildt 2010

**Methods**
- **Study design:** RCT
- **Date of study:** not given, pre August 2010
- **Study duration:** 4 months
- **Setting:** unclear
- **Ethical approval:** yes, "approved by the Medical Ethics Review Committee of the University Medical Center Groningen (Registration number: NL 26661.042.09)"
- **Consent:** unclear. Carers were asked for "permission". No report of consent from participants

**Participants**
- **Description of ID used:** IQ ≤ 50, "entirely dependent on another for their oral care"
- **Conversion to ICD description:** moderate to severe
- **Age range:** not provided. Mean age: male 20, female 31
- **Sex:** males 12, females 9
- **Comorbidity reported/assessed:** physical disabilities
- **Number of participants at baseline:** 13
- **Number of participants at final evaluation:** 13
- **Selection of the participants for the intervention:** from two centres for Special Care Dentistry
- **Country:** The Netherlands

**Interventions**
- **Comparison:** a special three-headed manual toothbrush versus a conventional manual toothbrush used by carer
- **Group 1:** Superbrusht used by carer on PID following oral hygiene instruction
- **Group 2:** Oral B Indicator used by carer on PID following oral hygiene instruction

**Outcomes**
1. Green & Vermillion Plaque Index (scale 0 to 18 - mean of six standard teeth)
2. Ainamo & Bay Gingival Bleeding Index (scale 0 to 1, 6 teeth, % of positive sites)
3. Questionnaire for carers, 5 questions (experience when handling the toothbrush and when brushing the teeth of people with ID), where is most difficult to brush, the frequency of brushing by the carer and resistance to brushing by the person with ID.
- **Timing of outcome assessments:** baseline and 4 months

**COM-B System Characteristics**
- **Potential sources of behaviour change:** capability (physical), opportunity (physical)
- **Potential intervention functions:** training, enablement, environmental restructuring

**Stakeholder Involvement**
- **Formal or non-formal carer:** both
- **With or without dental professional involvement:** with - dentist
- **Other stakeholder involvement:** no

**Notes**
- **Strengths and weaknesses:** small sample, dentists not calibrated, some differences in baseline scores.
- **Modifications to the intervention:** no
- **Adverse effects reported:** as covered in carers questionnaire

Review Manager 5.3
### Risk of bias table

<table>
<thead>
<tr>
<th>Bias</th>
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<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Low risk</td>
<td>Quote: &quot;unsealed envelopes&quot;</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Low risk</td>
<td>Comment: use of unsealed envelopes probably ensured allocation concealment</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias)</td>
<td>Low risk</td>
<td>Comment: some attempt to blind carers as new toothbrushes and CHI were given to control group. Blinding or not of the participants may not have impacted on the outcome as teeth were brushed by the carers.</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias)</td>
<td>Low risk</td>
<td>Comment: assessors were blinded to the group allocations</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias)</td>
<td>Low risk</td>
<td>Comments: no missing data</td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Unclear risk</td>
<td>Comment: no protocol, but all outcomes in Methods section reported</td>
</tr>
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<td>Was the intervention independent of other changes? (ITS)</td>
<td>Unclear risk</td>
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<td>Unclear risk</td>
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</table>

### Bouter 1979

#### Methods
- Study design: Repeat Measure Study
- Date of study: Not reported, pre 1979
- Study duration: Unclear - varied from participant to participant - max 100 days
- Setting: Residential
- Ethical approval: Not reported
- Consent: Not reported

#### Participants
- Description of ID used: "IQ varied from <5 to 46"
- Conversion to IQ: Description: Moderate
- Age Range (mean): 20-25yr (25yr)
- Gender: Male - 4, Female - 4
- Co-morbidity reported/details: None reported

Review Manager 5.3 9
Oral hygiene programmes for people with intellectual disabilities

Number of participants at baseline: 5
Number of participants at final evaluation: 7
Selection of the participants for the intervention: “Selected on their ability to imitate non-verbal behaviours and to understand verbal instruction.” Pg 93
Country: The Netherlands

Interventions

Comparison: Training of people with intellectual disabilities versus no training of people with intellectual disabilities
Group 1: Acquisition and duration training in 15 steps of a toothbrushing routine with 5 levels of assistance and 4 levels of feedback/praise during the acquisition stage.
Duration training - all steps completed without assistance or feedback

Outcomes

Outcomes measured:
1. Acquisition of 15 steps in tooth brushing routine and the number of sessions required to achieve these steps. Trainer recorded (a) type of assistance technique required and (b) type of feedback used
2. Measure of level of maintenance of the skill over a period of a least one week.
Timing of outcome assessments: Varied between participants - Baseline to final - at least 5 measures per week reported for all. Follow-up / duration stage was measured at increasing intervals, progressed from 2, 3, 4, 6, 8 day intervals.

COM-B System Characteristics

Potential sources of behaviour change: Capability (Physical/Psychological), Opportunity (Physical), Motivation (Reflective)
Potential intervention functions: Training, Modelling, Persuasion, Environmental Restructuring

Stakeholder Involvement

Formal or non-formal carer: Formal
With or without dental professional involvement: Without
Other stakeholder involvement: None

Notes

Strengths & Weakness: Time involved in training - “It is not expected that most care workers will have even that much time available (10 - 20 minutes) for each individual subject.” Pg 98
Modifications to the intervention: Yes, for 3 participants, steps required to progress to next step was reduced from 15 to 14 and feedback was not reduced until each step was completed on 3 consecutive occasions.
Adverse effects reported: Unlikely - One subject felt ill - possible delaying tactic - given incentive of an orange. Pg 99
Funding Source: None reported

Risk of bias table

<table>
<thead>
<tr>
<th>Bias</th>
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</tr>
</tbody>
</table>

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### Oral hygiene programmes for people with intellectual disabilities

#### Evaluation

| Incomplete outcomes data (attrition bias) | Unclear risk |
| Selective reporting (reporting bias) | Unclear risk |
| Was the intervention independent of other changes? (ITS) | Unclear risk | Comment: None stated, other changes or events may have influenced the outcomes |
| Was the shape of the intervention effect pre-specified? (IT5) | Low risk | Comment: point of analysis is the point of intervention |
| Was the intervention unlikely to affect data collection? (IT5) | Low risk | Comment: intervention did not affect either the source or method of data collection |
| Was knowledge of the allocated interventions adequately prevented during the study? (IT5) | High risk | Comment: Not possible to blind |
| Were incomplete outcome data adequately addressed? (IT5) | Low risk | Comment: participant who did not complete the intervention was fully documented |
| Was the study free from selective outcome reporting? (IT5) | Unclear risk | Comment: the trainer scored the participants but appears to be completely impartial |

#### Brapel 1991

**Methods**
- Study design: NRCT - no evidence of randomisation
- Date of study: None stated, pre 1988
- Study duration: 10 months
- Setting: Mixed
- Ethical approval: No
- Current: No

**Participants**
- Description of ID used: “mentally handicapped adults” Brapel 1988 Pg 23/24
- Conversion to ICD description: Moderate
- Age Range (mean): 21-2 years (9.3 SD)
- Gender: Male - 13, Female - 10
- Co-morbidity report/diagnosis: None reported
- Number of participants at baseline: 23
- Number of participants at final evaluation: 23 (except for one outcome, see Table 3 Lost to follow-up = 1 in Group 3) Brapel 1991 Pg 9
- Selection of the participants for the intervention: Selected group of patients from the dental hospital recall system. Brapel 1988 Pg 20
- Country: Sweden

**Interventions**
- Comparison: Electric toothbrush versus manual toothbrush
- Description: Standard oral health information provided to all. Oral hygiene instruction (OHI) according to Bass technique provided to participants and demonstrated in their own mouth (adapted to type of brush). Instructed to brush at least morning and night
- Group 1: E1 - Electric toothbrush (Ivonol Dental C3) unaided i.e. no help when brushing.
- Group 2: E2 - Electric toothbrush (Ivonol Dental C3) aided i.e. with help from parents or staff. OHI given to parents and staff and demonstrated in patients own mouth and practiced by them under supervision.
- Group 3: C1 - Manual toothbrush unaided.
- Group 4: C2 - Manual toothbrush aided, as in E2.
## Oral hygiene programmes for people with intellectual disabilities

### Outcomes
- Outcomes measured:
  1. Salivary & Plaque Index (V).
  2. Loe & Silness Gingival Index (V).
  3. Supervision of care and fear on toothbrushing.
  4. Diary of participants brushing kept by parent/staff.
  5. Questionnaire at baseline to assess current oral hygiene routines.
  6. Interview with those using electric toothbrush to assess their experiences using it.
- Timing of outcome assessments: Baseline, 1 week, 4 weeks, 12 weeks and 16 months.

### COM-B System Characteristics
- Potential sources of behaviour change: Capability (Physical / Psychological).
- Opportunity (Social / Physical).
- Potential Intervention functions: Education, Training, Modelling, Enablement, Environmental Restructuring.

### Stakeholder Involvement
- Formal or non-formal carer: Both.
- With or without dental professionals involvement: With - dentist, dental hygienist.
- Other stakeholder involvement: Parents and staff carers involved in acting groups E2 and C2.

### Notes
- Strengths & Weaknesses: Issues with provision of aid by parent/staff; some found it difficult to do.
- Modifications to the intervention: None reported.
- Adverse effects reported: Yes, all in relation to electric toothbrush: “Patients reported some discomfort during brushing,” “difficult to control the force and position of the electric toothbrush” Brait 1988 Pq 20, “toothbrush out of order (2 weeks).” Patients reported some discomfort during brushing at the 3 month follow-up” Brait 1989 Pq 6.
- Funding Source: None reported.

### Risk of bias table

<table>
<thead>
<tr>
<th>Bias</th>
<th>Author's judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Unclear risk</td>
<td>Quote: “a selected group of patients from the recall system” Patients were divided into two examination groups and two control groups” Brait 1988 Pq 24. Comment: no mention of randomisation</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>High risk</td>
<td>Comment: Not possible, those with more severe ID were asked (C2 and C2). Brait 1988 Pq 24</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias)</td>
<td>Unclear risk</td>
<td>Comment: Not reported but different settings, most likely unaware of what other groups were doing</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias)</td>
<td>Unclear risk</td>
<td>Comment: All clinical measures were recorded by the lead author; no mention of blinding</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias)</td>
<td>Low risk</td>
<td>Comment: No missing data - diary entries were summarised.</td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Unclear risk</td>
<td>Comment: No protocol but all listed outcomes reported.</td>
</tr>
</tbody>
</table>
### Oral hygiene programmes for people with intellectual disabilities

**Carr 1997**

**Methods**
- Study design: cluster RCT - the group homes were the unit of randomisation Pg 134
- Data of study: not stated, pre 1997
- Study duration: 12 months
- Setting: residential
- Ethical approval: no
- Consent: yes, "Written consent was obtained" Pg 133

**Participants**
- Description of ID used: "Mental Retardation/Developmental Disability" (pg 134)
- Conversion to ICD description: unclear
- Age range (mean): 26 to 54 years (38.6)
- Sex: male 52; female 24
- Comorbidity reported/details: yes, cerebral palsy 5, deaf 1, visually impaired 2
- Number of participants at baseline: not given
- Number of participants at final evaluation: "96 residents...completed the study"
- Selection of the participants for the intervention: no details given
- Country: USA

**Interventions**
- Comparison: electric toothbrush versus manual toothbrush
  - All groups - mental OH provided, then one-to-one instruction using the designated brush and practice on a typodont during initial instruction. Those requiring assistance were determined by testing their capability (Pg 134)
  - Group 1: self-brushing with interplak electric TE
  - Group 2: self-brushing with manual TB (Oral B 40)
  - Group 3: assisted brushing with interplak electric TR
  - Group 4: assisted brushing with manual TB (Oral B 40)

**Outcomes**
- Outcomes measured: (an selected tooth "Gingival of #3, #4 and #14, Lingual of #10, Facial of #30" Pg 135)
  1. Gingival Index (Loe) (V)
  2. Simplified Oral Hygiene Index (Green and Vermillion) (V)
  3. Calculus measurement Pg 135 C2
- Timing of outcome assessments: baseline, 3 months, 6 months, 9 months and 12 months
### Oral hygiene programmes for people with intellectual disabilities

**COM-B System Characteristics**
- Potential sources of behaviour change: capability (physical), opportunity (physical)
- Potential intervention functions: training, modelling, environmental restructuring

**Stakeholder Involvement**
- Formal or non-formal carer: formal
- With or without dental professional involvement: with - dental hygienist
  - Other stakeholder involvement: carers in group homes for those requiring assistance throughout study

**Notes**
- Strengths and weaknesses: quote: “The validity and reliability of the oral hygiene techniques used in the study must be regarded as limited. The examiners could not be present at all toothbrushing sessions and relied on staff for the implementation of tooth brushing protocols” P136
- Modifications to the intervention: none reported
- Adverse effects reported: unclear - quote: “some subjects dismissed from study” P136
- Funding source: none reported

### Risk of bias table

<table>
<thead>
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<tr>
<td>Random sequence generation (selection bias)</td>
<td>Unclear risk</td>
<td>Quote: “Each group home was randomly divided into two study groups, one using the Interplak and the second using a manual TB” P134 No further details provided</td>
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<td>Allocation concealment (selection bias)</td>
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<td>Comment: no details provided</td>
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<tr>
<td>Blinding of participants and personnel (performance bias)</td>
<td>Unclear risk</td>
<td>Comment: Unclear if personnel were blinded, study was a cluster study so participants were most likely blinded.</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias)</td>
<td>Unclear risk</td>
<td>Quote: “The data were obtained by a single examiner (SE), a dental hygienist who did not know to which test group the residents had been assigned.” but “Comparisons were made at the time of examination, along with specific recommendations for improvement of oral hygiene” P136</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias)</td>
<td>Unclear risk</td>
<td>Quote: “Some initial subjects had to be dismissed from the study because they either lost their Interplak for a time, it malfunctioned and/or they had to undergo hospitalization, thus interrupting the oral hygiene protocol” P136 Comment: no details of how many were dismissed</td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Unclear risk</td>
<td>Comment: no protocol but all listed outcomes reported</td>
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<tr>
<td>Was the intervention independent of other changes? (ITT)</td>
<td>Unclear risk</td>
<td></td>
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<tr>
<td>Was the scope of the intervention affect pre-specified? (ITT)</td>
<td>Unclear risk</td>
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### Oral hygiene programmes for people with intellectual disabilities

<table>
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<tr>
<th>Question</th>
<th>Risk</th>
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<td>Was the intervention unlikely to affect data collection? (ITS)</td>
<td>Unclear risk</td>
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<td>Was knowledge of the allocated interventions adequately prevented during the study? (ITS)</td>
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</tr>
<tr>
<td>Were incomplete outcome data adequately addressed? (ITS)</td>
<td>Unclear risk</td>
</tr>
<tr>
<td>Was the study free from selective outcome reporting? (ITS)</td>
<td>Unclear risk</td>
</tr>
</tbody>
</table>

### Christen 2007

**Methods**
- Study design: RCT, 3-way cross-over trial
- Data of study: not stated, prior to or during 2007
- Study duration: 2 weeks for each arm, with two-week washouts, 12 weeks in total
- Setting: residential and home
- Ethical approval: yes
- Consent: yes

**Participants**
- Description of ID used: "Varying degrees of intellectual and/or physical impairments" - Author confirmed by email that all participants had an ID
- Conversion to ICD description: mixed
- Age range: 15 to 45 years
- Sex: 22 male, 14 female
- Comorbidity reported: details: "Varying degrees of intellectual and/or physical impairments", Fig 8A
- Number of participants at baseline: 38
- Number of participants at final evaluation: 36
- Selection of the participants for the intervention: All attended a university clinic for patients with special needs
- Country: Germany

**Interventions**
- Comparison: electric toothbrush versus manual toothbrush
- Comparison: manual toothbrush versus another manual toothbrush
  - Group 1: Dentisare-Sonodent electric toothbrush, with verbal and written instruction
  - Group 2: Superbrush special manual toothbrush with verbal and written instruction
  - Group 3: Oral B cross manual toothbrush with verbal and written instruction
  - The same toothpaste was used by all groups

**Outcomes**
1. Modified Quigley-Hein Plaque Index (MQHI) (V)
2. Approximal Plaque Index (API) (V)
3. Papilla Bleeding Index (PBI) (V)

**COM-B System Characteristics**
- Potential sources of behaviour change: capability (physical), opportunity (physical)
- Potential intervention functions: training, enabling, environmental restructuring

**Stakeholder Involvement**
- Formal or non-formal carer: both
- With or without dental professional involvement: with - dentist
- Other stakeholder involvement: none reported
## Oral hygiene programmes for people with intellectual disabilities

**Notes**
- Strengths and weaknesses: short duration
- Modifications to the intervention: none reported
- Adverse effects reported: yes, informally
- Funding source: none reported

### Risk of bias table

<table>
<thead>
<tr>
<th>Bias</th>
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<th>Support for judgement</th>
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</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Low risk</td>
<td>Quote: “In order to ensure the reliability, the classification into order groups and the allocation of the test toothbrushes was carried out by means of a lottery procedure by a third person”</td>
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<tr>
<td>Allocation concealment (selection bias)</td>
<td>Low risk</td>
<td>Quote: “The allocation of the test toothbrushes was carried out by means of a lottery procedure by a third person”</td>
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<tr>
<td>Blinding of participants and personnel (performance bias)</td>
<td>High risk</td>
<td>Comment: not possible to blind participants or personnel</td>
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<tr>
<td>Blinding of outcome assessment (detection bias)</td>
<td>Low risk</td>
<td>Quote: “The examining dentist therefore at no time knew which toothbrush was being tested by a subject” Pg 59</td>
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<tr>
<td>Incomplete outcome data (attrition bias)</td>
<td>Low risk</td>
<td>Comment: no missing data</td>
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<tr>
<td>Selective reporting (reporting bias)</td>
<td>Unclear risk</td>
<td>Comment: no protocol, but all listed outcomes were reported</td>
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<tr>
<td>Was the intervention independent of other changes? (ITT)</td>
<td>Unclear risk</td>
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<tr>
<td>Was the shape of the intervention effect prescribed? (ITT)</td>
<td>Unclear risk</td>
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<td>Unclear risk</td>
<td></td>
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</table>

*Dögan 2004*
Oral hygiene programmes for people with intellectual disabilities

Methods
Study design: RCT - stratified randomization, cross-over with 3 arms
Date of study: not stated, but prior to 2004. Received for publication 1st October 2004
Study duration: 5 weeks (i.e. 2 weeks washout)
Setting: School
Ethical approval: yes - Pg 251, Column 1, Paragraph 1
Consent: yes

Participants
Description of ID used: "mild mental disability", according to their IQ level. Pg 251
Conversion to ICD description: mild
Age range: 6 to 18 years (mean not given)
Sex: not reported
Comorbidity reported/detected: not reported
Number of participants at baseline: 30
Number of participants at final evaluation: unclear
Selection of the participants for the intervention: children attending the same class
Country: Turkey

Interventions
Comparison: electric toothbrush versus manual toothbrush
Comparison: special manual toothbrush versus conventional manual toothbrush
Group 1: Oral B Braun Electric Toothbrush, with instruction
Group 2: Superbrush special manual toothbrush with instruction
Group 3: Oral B Cross Action manual toothbrush with instruction
Brushing time: 3 minutes, frequency twice a day, same toothpaste was used during the entire study for all groups

Outcomes
1. Modified Quigley-Hein Plaque Index (V)
2. Approximal Plaque Index (Y)
Timing of outcome assessments: baseline, week 1, week 3 and week 6

COM-B System Characteristics
Potential sources of behaviour change: capability (physical), opportunity (physical)
Potential intervention functions: training, environmental restructuring

Stakeholder involvement
Formal or non-formal care: unclear
With or without dental professional involvement: with - dental profession unclear
Other stakeholders: unclear, no mention of who supervised brushing

Notes
Strengths and weaknesses: only final time point reported, test time is very short
Modifications to the intervention: none reported
Adverse effects reported: none reported
Funding source: "Thanks to Braun and Denta Co. AS for their free sample supplements"

Risk of bias table

<table>
<thead>
<tr>
<th>Bias</th>
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<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Unclear risk</td>
<td>Quote: &quot;The children were randomly assigned to three groups&quot; Pg 251 Comment: no further details provided</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Unclear risk</td>
<td>Comment: no further details provided</td>
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</table>
### Oral hygiene programmes for people with intellectual disabilities

**Blinding of participants and personnel (performance bias)**
- High risk
  - Comment: not possible to blind participants or personnel

**Blinding of outcome assessment (detection bias)**
- Unclear risk
  - Comment: the same examiner, whose identity was concealed to the children? Pg 36 Comment: confusing statement

**Incomplete outcome data (attrition bias)**
- Unclear risk
  - Comment: no details of dropouts reported

**Selective reporting (reporting bias)**
- Unclear risk
  - Comment: no protocol but all listed outcomes reported

**Was the intervention independent of other changes? (ITS)**
- Unclear risk

**Was the shape of the intervention effect pre-specified? (ITS)**
- Unclear risk

**Was the intervention unlikely to affect data collection? (ITS)**
- Unclear risk

**Was knowledge of the allocated interventions adequately prevented during the study? (ITS)**
- Unclear risk

**Were incomplete outcome data adequately addressed? (ITS)**
- Unclear risk

**Was the study free from selective outcome reporting? (ITS)**
- Unclear risk

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### Ferozali 2007

#### Methods
- Study design: RCT - participants assigned to groups randomly
- Date of study: not stated, but after 2000 and pre 2007. Quote: “In 2000 prior to the current study…”
- Study duration: 90 days
- Setting: residential
- Ethical approval: yes. Quote: “local and state institutional review board approval” Pg 190 Comment: assumed adequate
- Consent: yes

#### Participants
- Description of ID used: “developmentally disabled with profound mental retardation”
- Conversion to ICD description: profound
- Age range (mean): 31 to 70 years (53.6)
- Sex: male 29, female 10
- Comorbidly reported/details: quote: “Enteral feeding, hiatal hernia, emesis, gastroesophageal reflux disease or swallowing problems”
- Number of participants at baseline: 38
- Number of participants at final evaluation: 32
- Selection of the participants for the intervention: dependent on nursing staff to carry out activities of daily living
- Country: USA
**Interventions**

Comparisons: special manual toothbrush versus conventional manual toothbrush

- **Group 1:** oral cleansing with a single-use suction toothbrush with sodium bicarbonate and 1.5% hydrogen peroxide solution. Intermittent oral suctioning was given during the cleansing procedure.
- **Group 2:** toothbrushing with a traditional toothbrush with sodium bicarbonate and 1.5% hydrogen peroxide solution. Intermittent oral suctioning was provided as needed with a tonsil suction device during the cleansing procedure.
- **Group 3:** oral cleansing with a traditional toothbrush and regular fluoride toothpaste was provided as before the study. Intermittent oral suctioning was provided as needed with a tonsil suction device during the cleansing procedure.

**Outcomes**

2. Bacterial load was assessed using oral cultures (V)

**Timing of outcome assessments:** 1. baseline, midway and day 60; 2. baseline and final.

**COM-B System Characteristics**

Potential sources of behaviour change: opportunity (physical), potential intervention functions: environmental restructuring.

**Stakeholder Involvement**

Formal or non-formal care: formal

- With or without dental professional involvement: with—dentist and dental hygienist
- Other stakeholder involvement: nursing staff carried out the toothbrushing.

**Notes**

Strengths and weaknesses: quote: "All groups were brushed for one minute" twice daily.

Modifications to the intervention: none reported.

Adverse effects reported: quote: "Excessive saliva production occasionally led to mouth, teeth, or gingiva irritation." No adverse effects reported. Pg 170, C3.2.1

Funding source: quote: "Sage Products donated the suction brushes, but provided no additional funding (Sage Products, Inc., Cary, IL)." Pg 165.

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**Risk of bias table**

<table>
<thead>
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<tr>
<td>Random sequence generation (selection bias)</td>
<td>Low risk</td>
<td>Quote: &quot;Assignment to groups was determined by a computer-generated table of purely random numbers.&quot; Pg 165, C3.2.2</td>
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<tr>
<td>Allocation concealment (selection bias)</td>
<td>Low risk</td>
<td>Comment: no details provided but probably done, as randomisation process was good</td>
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<tr>
<td>Blinding of participants and personnel (performance bias)</td>
<td>Unclear risk</td>
<td>Comment: no details provided, teeth were brushed by carers so blinding of participants unlikely to be a factor</td>
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<tr>
<td>Blinding of outcome assessment (detection bias)</td>
<td>Low risk</td>
<td>Oral health - quote: &quot;scores according to observations made by the dental hygienist who was blinded to the group membership of the participants.&quot; Bacterial load - quote: &quot;investigator who was blinded to group membership.&quot; Pg 175, C3.2.1</td>
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<tr>
<td>Incomplete outcome data (attrition bias)</td>
<td>Low risk</td>
<td>Comment: missing data fully explained</td>
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</table>

Review Manager 5.3
### Oral hygiene programmes for people with intellectual disabilities

<table>
<thead>
<tr>
<th>Item</th>
<th>Risk</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Unclear</td>
<td>Comment: no protocol but all listed outcomes reported</td>
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<td>Was the intervention independent of other changes? (ITC)</td>
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<td>Was the study free from selective outcome reporting? (ITC)</td>
<td>Unclear</td>
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</table>

### Garcia-Carrillo 2016

#### Methods
- Study design: cluster RCT - quote: "Cluster-randomised single-blinded (examiner) clinical trial"
- Date of study: April 2014
- Study duration: 6 months
- Setting: school
- Ethical approval: quote: "The regional ethical committee approved (13/002-E, 7th August 2013) the informed consents and the protocol" Pg 2
- Consent: yes

#### Participants
- Description of ID used: "The mean IQ was 50.5, ranging between 44 and 87" Pg 4
- "Only two categories of ID were included, light (n = 54) and limit (n = 10)" Pg 4
- Conversion to ID categories: mild and moderate
- Age range (mean): 13 to 65 years (34.6)
- Sex: 54 male, 30 female
- Comorbidity reported/ocassional: anxiety disorder, epilepsy, ocular tension, chronic bronchitis, asthma, hepatitis C, hypertension and depression, right leg hemiparesis, type 2 diabetes, hypothyroidism, paranoid schizophrenia, thyroid problems Pg 4
- Number of participants at baseline: 84
- Number of participants at final evaluation: 60
- Selection of the participants for the intervention: support groups (clusters) for those with limited or moderate ID were recruited
- Country: Spain

#### Interventions
- Comparison: electric toothbrush versus manual toothbrush
- Both groups brushed for two minutes, monitored by a trained supervisor with written instructions, for the first three months
- Group 1: Sonicare, Philips electric toothbrush
- Group 2: Vitis Access, manual toothbrush
Oral hygiene programmes for people with intellectual disabilities

**Outcomes**

Outcomes measured: "were scored four sites per tooth in two randomly (by coin toss) selected quadrants (one in the upper jaw, one in the lower jaw, contralateral - Bentley & Disney 1996"

1. Gingival index (Loe & Silness 1963)
2. Plaque index (Sillness & Loe 1964)
3. Calculus - presence or absence
4. Presence of adverse effects was assessed by a visual inspection at each study visit

Timing of outcome assessments: baseline, 3 months, 6 months

**COM-BI System Characteristics**

Potential sources of behaviour change: capability (physical/psychological), opportunity (physical)
Potential intervention functions: training, persuasion, environmental restructuring

**Stakeholder Involvement**

Format or non-formal care; formal
With or without dental professional involvement: without
Other stakeholder involvement: trained monitor ("special educators, with different university degrees in pedagogy"). Pg 2

**Notes**

Strengths and weaknesses: quote: "The obtained results, therefore, should be interpreted with caution and only should be extrapolated to populations with mild ID and fine motor skills." Pg 8
Modifications to the intervention: none reported
Adverse effects reported: none reported from either toothbrushes, some bleeding related to periodontal status. Pg 9
Funding source: quote: "This study was supported by an unrestricted grant from the Philips Oral Healthcare, by means of a research contract (382/2013) with University Complutense."

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**Risk of bias table**

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<td>Quote: &quot;a computer-generated randomization list, by an external agent&quot; Pg 2</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Low risk</td>
<td>Quote: &quot;a computer-generated randomization list, by an external agent&quot; Pg 2 Comment: allocation concealment probably achieved</td>
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<tr>
<td>Blinding of participants and personnel (performance bias)</td>
<td>Unclear risk</td>
<td>Comment: Unclear if personnel were blinded, study was a cluster study so participants were most likely blinded.</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias)</td>
<td>Low risk</td>
<td>Quote: &quot;by a single calibrated and trained examiner, blinded to the group allocation.&quot; &quot;The clinical evaluators were not aware of the group assignment or involved in the randomization process.&quot; Pg 3</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias)</td>
<td>Low risk</td>
<td>Comment: all outcomes reported, detailed levels of reporting, low levels of attrition, reasons for loss not related to outcomes</td>
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</tbody>
</table>

Review Manager 5.3

21
### Oral hygiene programmes for people with intellectual disabilities

<table>
<thead>
<tr>
<th>Selective reporting (reporting bias)</th>
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<td>Unclear risk</td>
</tr>
</tbody>
</table>

**Comment:** No protocol but all listed outcomes reported

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### Gertenrich 1967a

**Methods**
- Study design: NRCT - Quote: "children were divided into two groups" Pg 145
- Date of study: Not stated, pre 1967
- Study duration: 21 - 28 weeks
- Setting: Residential
- Ethical approval: Not reported
- Consent: Not reported

**Participants**
- Description of IQ used: “Mongoloid and others possessing an average IQ of 20.” Comment: later described as an IQ from 0 - 20
- Conversion to ICD description: Severe or Profound
- Age Range (mean): 5 - 25
- Gender: Males 52, Females 18 (Table 1, Pg 146)
- Comorbidity reported/detected: Quote: "Requiring intensive care". Not other details provided
- Number of participants at baseline: 75 (Table 2 and 3 Pg 148 - numbers do not match Table 1)
- Number of participants at final evaluation: 72
- Selection of the participants for the intervention: No details reported
- Country: USA

**Interventions**
- Comparison: Electric toothbrush versus manual toothbrush
- Comparison: Staff monitored versus staff not monitored
- Group 1: Subjects with Down syndrome had teeth brushed twice a day with an Oral B Automatic Toothbrush - Accurate actions by attendants who were told oral hygiene would be monitored after initial 8 weeks
- Group 2: Subjects with Down syndrome had teeth brushed twice a day with manual toothbrush by attendants who were told oral hygiene would be monitored
- Group 3: Subjects with "Low IQ" had teeth brushed twice a day with an Oral B Automatic Toothbrush - Accurate actions by attendants who were told the intervention was finished and oral hygiene would be not be monitored after initial 8 weeks
- Group 4: Subjects with "Low IQ" had teeth brushed twice a day with a manual
### Oral hygiene programmes for people with intellectual disabilities

**Outcomes**
- Outcomes measured:
  1. Oral hygiene categories: Good, Fair, Poor and Very Poor. 1 - 4. Higher scores are poorer (UV).
  2. Gingival Inflammation categories: Absent, obvious gingivitis, decrease in severity (UV).
  3. Some subjective feedback from attendants (UV).
- Timing of outcome assessments: 1. Weekly, for 20 to 26 weeks. 2. Baseline 8 to 10 week time-point and 20 to 25 week time-point.

**COM-B System Characteristics**
- Potential sources of behaviour change: Opportunity (Physical), Motivation (Reflective).
- Potential Intervention functions: Coercion, Environmental Restructuring.

**Stakeholder Involvement**
- Formal or non-formal carer: Formal.
- With or without dental professional involvement: With - dentist and dental hygienist.
- Other stakeholder involvement: Attendants brushed the participants teeth.

**Notes**
- Strengths & Weaknesses Comment: Subjective measure of oral hygiene and gingival inflammation.
- Modifications to the intervention: Unclear; the interval of follow-up may have been extended due to the outbreak of mumps and measles in two groups.
- Adverse effects reported: Comment: Authors refer to "apparent disadvantages" of using an electric toothbrush, but it is unclear if these disadvantages arose in this study. Pg 165 C1.
- Funding Source: None reported.

### Risk of bias table

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors' judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>High risk</td>
<td>Comment: No report of randomisation - participants were divided equally, with equal numbers of males and females in each group.</td>
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<tr>
<td>Allocation concealment (selection bias)</td>
<td>Unclear risk</td>
<td>Comment: No details provided.</td>
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<td>Blinding of participants and personnel (performance bias)</td>
<td>Unclear risk</td>
<td>Comment: No details provided.</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias)</td>
<td>Low risk</td>
<td>Comment: Assessors did not know to which group the subjects were assigned. Pg 147.</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias)</td>
<td>Unclear risk</td>
<td>Comment: Three drop-outs but no reasons given. Unlikely to effect outcome.</td>
</tr>
<tr>
<td>Detection reporting (reporting bias)</td>
<td>Unclear risk</td>
<td>Comment: No protocol but all listed outcomes reported.</td>
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<td>Was the intervention independent of other changes? (TTS)</td>
<td>Unclear risk</td>
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Review Manager 5.3
Oral hygiene programmes for people with intellectual disabilities

<table>
<thead>
<tr>
<th>Question</th>
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<tr>
<td>Was the shape of the intervention effect pre-specified? (ITC)</td>
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<td>Was the intervention unlikely to affect data collection? (ITC)</td>
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<tr>
<td>Was knowledge of the allocated interventions adequately prevented during the study? (ITC)</td>
<td>Unclear risk</td>
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<tr>
<td>Were incomplete outcome data adequately addressed? (ITC)</td>
<td>Unclear risk</td>
</tr>
<tr>
<td>Was the study free from selective outcome reporting? (ITC)</td>
<td>Unclear risk</td>
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</tbody>
</table>

_Gertenrich 1967b_

**Methods**
- Study design: NRCT - Quote: "Each group were divided into two equal sub groups" Pg 151
- Date of study: Not stated, pre 1967
- Study duration: 34 weeks
- Setting: Residential
- Ethical approval: Not reported.
- Consent: Not reported

**Participants**
- Description of ID used: IQ range of 0 -20 (Level V AAMD) "Only a few could talk and none was self-fed or toilet-trained" Pg 150 C 2
- Conversion to ICD description: Severe - Profound
- Age Range (mean): 2 -12
- Gender: Male 24, Female 24
- Co-morbidity reported/documented: All patients were non ambulatory Pg 150
- Number of participants at baseline: 48
- Number of participants at final evaluation: 48
- Selection of the participants for the intervention: "Selected at random" Pg 150
- Country: USA

**Interventions**
- Comparison: Electric toothbrush versus manual toothbrush
- All attendants were given training in tooth brushing techniques.
  - Group 1: Hydrocephaly and seizure unit participants had their teeth brushed by the attendants, using an "Oral B Automatic Toothbrush - Arrasite actions" electric toothbrush
  - Group 2: Hydrocephaly and seizure unit participants had their teeth brushed by the attendants, using a manual toothbrush
  - Group 3: Pediatric unit participants had their teeth brushed by the attendants, using an "Oral B Automatic Toothbrush - Arrasite actions" electric toothbrush
  - Group 4: Pediatric unit participants had their teeth brushed by the attendants, using manual toothbrush

**Outcomes**
- Outcomes measured:
  1. Oral hygiene categories: Good, Fair, Poor and Very Poor: 1 - 4, higher scores are poorer (UV)
  2. Gingival Inflammation categories observed: absent, obvious gingivitis, decrease in severity (UV)

Review Manager 5.3
Oral hygiene programmes for people with intellectual disabilities  

Timing of outcome assessments: Baseline, weekly for 8 weeks, Follow-up 20 and 34 weeks. Reported 0, 8, 20 and 34 weeks.

**COM-B System Characteristics**

Potential sources of behaviour change: Capability (Physical), Opportunity (Physical), Motivation (Reflective)
Potential Intervention functions: Training, Enablement, Coaction, Environmental Restructuring

**Stakeholder Involvement**

Formal or non-formal carer. Formal With or without dental professional involvement. With - dentist and dental hygienists Other stakeholder involvement: Attendants brushed the participants teeth

**Notes**

Strengths & Weakness: No effort made to certify that each subject was brushed twice daily as instructed. Researcher suspected it was not happening in some groups. Modifications to the intervention: Findings of the study were discussed with groups 1 & 2 at 20 weeks due to the attendants failing to brush twice daily or even daily in these groups. This resulted in changes to the organisation of the attendants, which may have impacted on the 28 week time-point results. Pg 150 C1
Adverse effects reported: None reported
Funding Source: None reported

**Risk of bias table**

<table>
<thead>
<tr>
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<th>Authors' judgement</th>
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<td>Random sequence generation (selection bias)</td>
<td>High risk</td>
<td>Comment: No reported randomisation - groups divided equally</td>
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<tr>
<td>Allocation concealment (selection bias)</td>
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<td>Blinding of participants and personnel (performance bias)</td>
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<tr>
<td>Blinding of outcome assessment (detection bias)</td>
<td>Low risk</td>
<td>Comment: Assessors did not know to which group the subjects were assigned. Pg 147</td>
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<tr>
<td>Incomplete outcome data (attrition bias)</td>
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<td>selective reporting (reporting bias)</td>
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Review Manager 5.3
### Oral hygiene programmes for people with intellectual disabilities

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<th>Were incomplete outcome data adequately addressed? (ITS)</th>
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<tbody>
<tr>
<td>Was the study free from selective outcome reporting? (ITS)</td>
<td>Unclear risk</td>
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</tbody>
</table>

**Gertenrich 1967c**

**Methods**
- Study design: NRCT - Quote: "were divided into four equal groups" Pg 105
- Data of study: Not stated, pre 1967
- Study duration: 20 weeks
- Setting: Residential
- Ethical approval: Not reported
- Consent: Not reported

**Participants**
- Description of ID used: "Cerebral palsied patients and mentally retarded but trainable patients" with IQ ranging from 30 to 65 for CP and 30 to 60 for MR. Pg 155 C2
- Conversion to IQ: Description: mixed with some above IQ of 70
- Age Range (mean): 15 to 30
- Gender: 50 Male, 8 Female
- Co-morbidity reported/detected: Cerebral palsy
- Number of participants at baseline: 39
- Number of participants at final evaluation: 38
- Selection of the participants for the intervention: No details given
- Country: USA

**Interventions**
- Comparison: Electric toothbrush versus manual toothbrush
- Comparison: Self brushed versus carer brushed
- Group 1a: Cerebral palsy unit - attendants brushed with Oral B Automatic Toothbrush
- Group 2a: "Trainable" unit - attendants brushed with Oral B Automatic Toothbrush
- Arousal actions electric toothbrush
- Group 2b: "Trainable" unit - self brushed with Oral B Automatic Toothbrush
- Arousal actions electric toothbrush
- Group 2c: "Trainable" unit - attendants brushed with a manual toothbrush
- Group 2d: "Trainable" unit - self brushed with a manual toothbrush
- Group 1 had IQ ranging from 30 to 65, Group 2 had IQ ranging from 30 to 50.

**Outcomes**
- Outcomes measured:
  1. Oral hygiene categories: Good, Fair, Poor and Very Poor. 1 - 4, higher scores are poorer (LM)
  2. Gingival inflammation categories observed: absent, obvious gingivitis, decrease in severity (UV)
  3. Some subjective feedback from attendants (LM)
- Timing of outcome assessments: Baseline, weekly for 8 weeks, final at W8 and follow-up at W20 (Reported 3)

**COM-B System Characteristics**
- Potential sources of behaviour change: Capability (Physical), Opportunity (Physical), Motivation (Reflective)
- Potential intervention functions: Training, Enablement, Coercion (for carers only), Environmental Restructuring
### Stakeholder Involvement
- Formal or non-formal carer: Formal
- With or without dental professional involvement: With - dentist and dental hygienists
- Other stakeholder involvement: Attendants who brushed the subjects teeth

### Notes
- Strengths & Weakness: Multiple modifications to the intervention
- Modifications to the intervention: In the “trainable units” using the electric toothbrush, both attendant brushed and self-brushers returned to using manual brushes for the follow-up period. The improvements in both the cerebral palsy groups occurred “due to the direct supervision by members of the institution’s nursing staff” Pg 109 G2
- Adverse effects reported: None reported
- Funding Source: None reported

### Risk of bias table

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<thead>
<tr>
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<tr>
<td>Blinding of outcome assessment (detection bias)</td>
<td>Low risk</td>
<td>Comment: Assessors did not know to which group the subjects were assigned. Pg 147</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias)</td>
<td>Low risk</td>
<td>Comment: One drop out, no reason given, unlikely to have affected outcomes</td>
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<td>Selective reporting (reporting bias)</td>
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**Gertnerich 1967d**

**Methods**
- Study design: NRCT
- Data of study: Not stated, p. 1067
- Study duration: 24 weeks
- Setting: Residential
- Ethical approval: Not reported.
- Consent: Not reported

**Participants**
- Description of ID used: “Mildly retarded patients, educable group, classed as “slow learners”.
- Conversion to ICD description: Mild or above IQ of 70
- Age range (mean): 15-18
- Gender: 22 male, 22 female
- Co-morbidity reported/details: None reported
- Number of participants at baseline: 43
- Number of participants at final evaluation: 41
- Selection of participants for the intervention: No details reported
- Country: USA

**Interventions**
- Comparison: Electric toothbrush versus manual toothbrush
- “Attendants were trained in the proper techniques and provided supervision and assistance” Pp 191-192
- Group 1: Self brushed with an Oral B Automatic Toothbrush Arcuate actions electric toothbrush
- Group 2: Self brushed with a manual toothbrush

**Outcomes**
- Outcomes measured:
  1. Oral hygiene categories: Good, Fair, Poor and Very Poor: 1 - 4, higher scores are poorer (UV)
  2. Gingival Inflammation - categories observed: absent, obvious gingivitis, decrease in severity (UV)
- Timing of outcome assessment: Baseline, 8 weeks and 24 weeks. No report of the weekly assessment from 0 to 8 weeks but it does appear to have been recorded in the graphs

**COM-B System Characteristics**
- Potential sources of behaviour change: Capability (Physical, Psychological), Opportunity (Physical)
- Potential Intervention functions: Training, Enablement, Persuasion, Environmental Restructuring

**Stakeholder involvement**
- Formal or non-formal care: Formal
- With or without dental professional involvement: With - dentist and dental hygienists
- Other stakeholder involvement: Attendants who supervised and assisted

**Notes**
- Strengths & Weaknesses: IQ level of some participants in this study may be above 70
- Modifications to the intervention: None reported
- Adverse effects reported: None reported
- Funding source: None reported
Risk of bias table

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</tr>
<tr>
<td>Incomplete outcome data (attrition bias)</td>
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<td>Comment: two drop outs, one from each group; no reason given, but unlikely to have impacted on outcomes</td>
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<tr>
<td>Selective reporting (reporting bias)</td>
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<td>Comment: No protocol but all listed outcomes reported</td>
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<td>Unclear risk</td>
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</table>

Glassman 2006

Methods

Study design: NR5 - “multiple baseline design”
Date of study: Not given, pre 2006
Study duration: 142 to 150 days, plus one month post study phone call follow-up
Setting: Residential
Ethical approval: None reported
Comment: Quote: “Informed consent documents were obtained for all participants” Pg 20

Participants

Description of ID used: “With developmental disabilities” Pg 36 “Mild to moderate mental retardation” Pg 40 Moderate, Severe (Table 1)
Conversion to IDO description: Mild, Moderate, and Severe
Age Range (mean): Clients 20 - 54 years Carers: 27 - 84 years
Gender: Clients 8 female, 3 male. Carers: 7 female, 3 male

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| Co-morbidity reported/details: Yes, blind, deaf, heart defect, seizures, Cerebral palsy |
| Number of participants at baseline: 11 clients and 10 carers |
| Number of participants at final evaluation: 11 clients and 10 carers |
| Selection of the participants for the intervention: Selected to participate, carers interested in improving their knowledge of preventive dentistry. Pg 39 |
| Country: USA |

### Interventions

**Comparison:** Training of carer versus no training of carer

**Comparison:** Training of people with ID versus no training of people with ID

**Group 1:** Carers received two three-hour classes in preventive dentistry and basic applied behavioral principles using a training package "Overcoming obstacles to Dental Health." Pg 41. Field observers provided ongoing verbal feedback and made supportive suggestions during the intervention. Toothbrushing sessions were video taped. - Three settings.

### Outcomes

**Outcomes measured:**
1. Social Validation of client's abilities with regard to oral hygiene - 8 questions on a 6 point scale completed by carers.
2. Carers' Perception of training - 6 open ended questions via telephone
3. Plaque score
4. Carers presence during toothbrushing
5. Observed % of tooth surfaces brushed
6. Duration of brushing

**Details and tables unclear. Details requested from authors (no response).**

### COMBI System Characteristics

- Potential sources of behaviour change: Carer: Capability (Physical, Psychological), Opportunity (Social, Physical), Motivation (Reflective). People with ID: Capability (Physical), Opportunity (Physical), Motivation (Reflective).

### Stakeholder Involvement

- Formal or non-formal carer: Formal
- With or without dental professional involvement: With - dental assistant, dental hygienist
- Other stakeholder involvement: Carers

### Notes

- Strengths & Weaknesses: Quote "The issue of caregiver participation was problematic for the researchers throughout the project" Pg 45. Carers received compensation for their participation, no conflict likely. Intervention developers appear to have evaluated their own intervention.
- Modifications to the intervention: A specific instruction to the carers to apply the training in practice was added to the intervention Pg 44 C2
- Adverse effects reported: None reported
- Funding Source: None reported

Risk of bias table
### Bias

<table>
<thead>
<tr>
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<td>Was the intervention independent of other changes? (ITS)</td>
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<td>Comment: No details provided. Length of intervention makes it possible that other changes have occurred</td>
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<td>Low risk</td>
<td>Comment: The point of analysis is the point of intervention. The direction of the outcomes were clearly stated. Pg 40-41</td>
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<tr>
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<td>Low risk</td>
<td>Comment: The intervention did not affect either the source or method of data collection</td>
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<td>Comment: Not possible to blind participants or personnel</td>
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<td>Low risk</td>
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<tr>
<td>Was the study free from selective outcome reporting? (ITS)</td>
<td>Unclear risk</td>
<td>Comment: Image quality of data is poor (Table 1).</td>
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</table>

### Gonzalez 2013

**Methods**
- Study design: RCT
- Date of study: no details given, pre 2003
- Study duration: 30 or 90 minutes
- Setting: residential - Pg 203
- Ethical approval: expedited approval was obtained from the Human Research Review Committee (HRRRC) at the University of New Mexico prior to the initiation of this study.
- Study and protocol number: HRRRC: 00-456, 00-454 C1
- Consent: yes - “After consent forms were obtained” Pg 294 C2, 292

**Participants**
- Description of ID used: “developmental disabilities”
- Conversion to ICD description: unclear
- Age range (mean): not reported
- Sex: male 8, female 14, not reported for two participants
Oral hygiene programmes for people with intellectual disabilities

Number of participants at baseline: 30
Number of participants at final evaluation: 24
Selection of the participants for the intervention: a convenient sample.
Country: USA

**Interventions**
Comparison: training of carers versus no training of carers
Group 1: a 60 minute lecture and hands-on seminar were presented covering topics in oral health for people with developmental disabilities including tooth brushing techniques, plaque removal, progression of periodontal disease and techniques on how to approach a patient with challenging behaviour when performing oral hygiene.
Group 2: a 30 minute discussion among the participants on similar topics.

**Outcomes**
1. Knowledge and comprehension regarding oral health topics - 20 questions
   Timing of outcome assessments: Immediately pre- and post-intervention.

**COM-B System Characteristics**
Potential sources of behaviour change: capability (physical/psychological), opportunity (social/physical), motivation (reflective)
Potential intervention functions: education, training, modelling, enablement

**Stakeholder Involvement**
Formal or non-formal carer; formal
With or without dental professional involvement: with - dental hygienist
Other stakeholder involvement: none reported

**Notes**
Strengths and weaknesses: existing knowledge high. Confusion regarding answer options and response. Validity of tool is unclear; two different questionnaires were used for baseline and final.
Modifications to the intervention: none reported
Adverse effects reported: no. "No harms were expressed by any of the participants at the conclusion of the study." Pg 290
Funding source: caregivers received compensation for participation, no likely conflict of interest.

**Risk of bias table**

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<tr>
<td>Random sequence generation (selection bias)</td>
<td>Low risk</td>
<td>Quote: &quot;Enrollment was established on voluntary participation and assigning participants randomly to either group A (experimental) or group B (control) based on phone calls. Random assignment of the research subjects to one of two sites was completed by the health coordinator/recruiter of ARCA.&quot; Pg 294 Comment: probably done</td>
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<td>Quote: &quot;Enrollment was established on voluntary participation and assigning participants randomly to either group A (experimental) or group B (control) based on phone calls. Random assignment of the research subjects to one of two sites was completed by the health coordinator/recruiter of ARCA.&quot; Pg 294 Comment: probably done</td>
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### Oral hygiene programmes for people with intellectual disabilities

<table>
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<td>Was the study free from selective outcome reporting? (ITS)</td>
<td>Undeclared risk</td>
</tr>
</tbody>
</table>

**Jaiman 1983**

**Methods**  
Study design: Interrupted Time Series  
Data of study: Not stated, pre 1983  
Study duration: 29 - 30 weeks  
Setting: Residential  
Ethical approval: Not reported  
Consent: Not reported

**Participants**  
Description of ID used: "Moderately to severely mentally retarded"  
Conversion to ICD descriptor: Severe  
Age range (mean): 14-87 (21.5)  
Gender: Mixed  
Co-morbidity reported/details: Yes, cerebral palsy, all but two required a wheelchair or upright walker  
Number of participants at baseline: 40  
Number of participants at final evaluation: 40  
Selection of the participants for the intervention: Participants were living on the same unit in a residential facility  
Country: USA

**Review Manager 5.3**
Oral hygiene programmes for people with intellectual disabilities

Interventions

Comparison: Training for people with ID versus no training of people with ID
Development of 5 skills in a morning personal care routine, of which only one skill, the toothbrushing skill, was relevant
Group 1: Use of reinforcement procedures, token reinforcement programs, single response contingency and chained response contingency, in developing a toothbrushing routine. Pg 114

Outcomes

Outcomes measured:
1. Performance of the skill at each stage of training
2. Improvement scores for individuals
Timing of outcome assessments: Daily, reported as mean at week 7 (baseline), week 25 (single contingency) and week 26 (chained contingency)

COM-B System Characteristics
Potential sources of behaviour change: Capability (Physical), Opportunity (Physical), Motivation (Reflective)
Potential intervention functions: Training, Enablement, Persuasion, Incentivization, Environmental Restructuring

Stakeholder involvement
Formal or non-formal carer: Formal
With or without dental professional involvement: Without
Other stakeholder involvement: Unit director, supervisors, attendants

Notes
Strengths & Weaknesses: "Intensive instruction had been provided to each resident prior to the beginning of the study and all residents exhibited some initial competence in each skill." Pg 119, "Individual performance criteria was seen as an essential consideration." Pg 119 - 120.
Modifications to the intervention: None reported
Adverse effects reported: None reported
Funding Source: "The research was supported in part by Grand #00917-15-0 from the Maternal and Child Health Service."

Risk of bias table

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors' judgement</th>
<th>Support for judgement</th>
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<td>Blinding of outcome assessment (detection bias)</td>
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<tr>
<td>Incomplete outcome data (attrition bias)</td>
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<td></td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Unclear risk</td>
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<tr>
<td>Was the intervention independent of other changes? (ITS)</td>
<td>High risk</td>
<td>Comment: The training method was being used for 5 other personal skills at the same time</td>
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<tr>
<td>Was the shape of the intervention effect pre-specified? (ITS)</td>
<td>Low risk</td>
<td>Comment: the point of analysis is the point of intervention</td>
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</table>

Review Manager 5.3  34
**Kaschke 2005**

**Methods**
- Study design: RCT 3-way cross-over trial.
- Data of study: not stated, prior to 2004 (Thesis by Zeller, A).
- Study duration: 2 weeks for each arm, with two-week washouts, 12 weeks in total.
- Setting: unclear.
- Ethical approval: Yes.
- Consent: not reported.

**Participants**
- Description of ID used: "Varying degrees of intellectual and/or physical impairments" - author confirmed by email that all participants had an ID.
- Conversion to ICD description: mixed.
- Age range (mean): 16 to 45 years.
- Sex: not reported.
- Comorbidity reported: yes.
- "Varying degrees of intellectual and/or physical impairments", Fig 00.
- Number of participants at baseline: 30.
- Number of participants at final evaluation: 30.
- Selection of the participants for the intervention: all attended a university clinic for patients with special needs.
- Country: Germany.

**Interventions**
- Comparison: electric toothbrush versus manual toothbrush.
- Comparison: manual toothbrush versus another manual toothbrush.
- Group 1: Telehyne Waterpik Sonic Toothbrush, with verbal and written instruction.
- Group 2: Superbrush special manual toothbrush with verbal and written instruction.
- Group 3: Oral B Cross manual toothbrush with verbal and written instruction.
- The same toothpaste was used by all groups.

**Outcomes**
- 1. Modified Quigley-Hein Plaque Index (MQHI) (V).
- 2. Approximal Plaque Index (API) (V).
- 3. Papilla Bleeding Index (PBI) (V).
- Timing of outcome assessments: week 2 for each arm.

**COM-B System Characteristics**
- Potential sources of behaviour change: capability (physical), opportunity (social).
- Potential intervention functions: training, enabling, environmental restructuring.

**Stakeholder Involvement**
- Formal or non-formal care: both.
- With or without dental professional involvement: with - dentist.
- Other stakeholder involvement: none reported.
Oral hygiene programmes for people with intellectual disabilities 11-Jan-2019

Notes
Strengths and weaknesses: short duration
Modifications to the intervention: none reported
Adverse effects reported: yes
Funding source: none reported

Risk of bias table

<table>
<thead>
<tr>
<th>Bias</th>
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<td>Comments: no details provided</td>
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<tr>
<td>Allocation concealment (selection bias)</td>
<td>Unclear risk</td>
<td>Quote: “Blind study”</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Comment: unclear who was blinded</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias)</td>
<td>High risk</td>
<td>Comment: cross-over trial, not possible to blind participants or personnel</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias)</td>
<td>Low risk</td>
<td>Quote: “All examinations of the oral hygiene status were conducted by one examiner who had no knowledge about the toothbrush used by each subject.” Pg 07</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias)</td>
<td>Low risk</td>
<td>Comment: no missing data</td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Unclear risk</td>
<td>Comment: no protocol but all listed outcomes reported, no baseline data reported</td>
</tr>
</tbody>
</table>

Kelner 1963

Methods
- Study design: RCT
- Data of study: not provided, pre-1963
- Study duration: 4 months
- Setting: School, day centre
- Ethical approval: not reported
- Consent: yes

Review Manager 5.3 36

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Oral hygiene programmes for people with intellectual disabilities

Participants

- Description of ID used: "mental retardation"
- Conversion to ICD description: unclear
- Age range (mean): 4 to 32 years
- Sex: not reported
- Comorbidity reported: details not reported
- Number of participants at baseline: 108
- Number of participants at final evaluation: 100
- Selection of participants for the intervention: participants were enrolled in a nursery or work training centre sponsored by a local service organisation
- Country: USA

Interventions

- Comparison: Electric toothbrush versus manual toothbrush
  - Group 1: automated electric toothbrush (Brossoident) with instruction
  - Group 2: conventional toothbrushes with instruction

Outcomes

1. Hygiene deposits (subjective) (UV)
2. Gingival condition (subjective) (UV)
3. General evaluation (UV)
4. Timing of outcome assessments: baseline, month 4

COM-S System Characteristics

- Potential sources of behaviour change: capability (physical), opportunity (physical)
- Potential intervention functions: education, training, enablement, environmental restructuring

Stakeholder involvement

- Formal or non-formal carer: non-formal
- With or without dental professional involvement: with - dentist and dental student
- Other stakeholder involvement: none reported

Notes

- Strengths and weaknesses: use of subjective assessments
- Modifications to the intervention: none reported
- Adverse effects reported: none reported
- Funding Source: Brossoident supplied by DR Squibb and Sons (manufacturer)

Risk of bias table

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<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Unclear risk</td>
<td>Quote: &quot;Selections were made at random&quot; Pg 103. No details of randomisation process</td>
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<tr>
<td>Allocation concealment (selection bias)</td>
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<td>Comment: no details provided</td>
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<tr>
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<td>Low risk</td>
<td>Comment: Parents were doing the brushing at home, both groups given OHI.</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias)</td>
<td>Low risk</td>
<td>Quote: Groups...&quot;were made known to the examiner upon the completion of the follow-up examination.&quot; Pg 103</td>
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<tr>
<td>Incomplete outcome data (attrition bias)</td>
<td>Low risk</td>
<td>Comment: dropouts were unrelated to the study</td>
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</table>

Review Manager 5.3
### Oral hygiene programme for people with intellectual disabilities

**11-Jan-2019**

<table>
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<tr>
<th>Selective reporting (reporting bias)</th>
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<tbody>
<tr>
<td>Comment: all outcomes in the methodology were not reported (brushing frequency, who brushed, dental treatment received during the 4-month trial)</td>
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</table>

**Kissel 1983**

**Methods**
- Study design: Interrupted Time Series
- Date of study: Not stated, pre 1983
- Study duration: 100 days
- Setting: Residential
- Ethical approval: None reported
- Consent: Unclear - staff recommended for training and agree to participate

**Participants**
- Description of ID used: "severely and profoundly retarded .. (IQ range = 5 to 21)"
- Conversion to IQ: description: Severe and Profound
- Age Range (mean): Staff Mean 26, Residents: age 9 to 16
- Gender: Staff: Female 4, Residents: Male 9, Female 3, (Fig 2, 4 and B)
- Comorbidity reported/details: None reported
- Number of participants at baseline: 4 staff and 12 residents
- Number of participants at final evaluation: 4 staff and 12 residents
- Selection of the participants for the intervention: Staff recommended for training by the supervisors based on their perceived need for training
- Country: USA

**Interventions**
- Comparison: Training of people with ID versus no training of people with ID
  - Group 1: Staff were trained and given written materials necessary to teach their residents in a 9 step toothbrushing routine using verbal instruction, physical guidance and contingent reinforcement, received feedback on this teaching using a video of the teaching sessions, Fig. 3
  - Two intensive training sessions were given to the staff, one at the start of the treatment session and one at the start of the maintenance sessions

**Outcomes**
- Outcomes measured:
  1. Staff scored on use of the three levels of skills used when training residents;
  2. Residents scored on their response at three levels - self initiated, verbally instructed or physically guided responses
  3. Residents scored on the number of steps achieved in the toothbrushing programme

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**Review Manager 5.3**

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Oral hygiene programmes for people with intellectual disabilities

4. Staff Acceptability Questionnaire (Table 3)
   Timing of outcome assessments: Daily

**COM-B System Characteristics**
Potential sources of behaviour change: Staff: Capability (Physical / Psychological), Opportunity (Social / Physical), Motivation (Reflective). Residents: Capability (Physical), Opportunity (Physical), Motivation (Reflective)
Potential intervention functions: Staff: Training, Modelling, Enablement, Incentivisation, Coercion, Restriction. Residents: Training, Modelling, Enablement, Environmental Restructuring

**Stakeholder Involvement**
Formal or non-formal care: Formal
With or without dental professional involvement: Without
Other stakeholder involvement: Observers (two administrators, a speech and hearing therapist, a graduate student intern)

**Notes**
Strengths & Weakness: “Continual presence of observers could have affected outcomes”, “use of video tape feedback greatly aided staff learning.” The training program was found to be very time efficient, with each participant receiving only 3.4 hours of individual instruction from the experimenter during the 8 months of the project.” Pg 414
Modifications to the intervention: One staff member and one resident started the programme later than the others at the session 36 time-point.
Adverse effects reported: None reported
Funding Source: “This research was supported in part by a training grant from the National Institute of Health (1 T32 HD07184-02).” Pg 306

**Risk of bias table**

<table>
<thead>
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<td>Low risk</td>
<td>Comment: the point of analysis is the point of intervention</td>
</tr>
<tr>
<td>Was the intervention unlikely to affect data collection? (ITS)</td>
<td>Low risk</td>
<td>Comment: the intervention did not affect either the source or method of data collection</td>
</tr>
<tr>
<td>Was knowledge of the allocated interventions adequately prevented during the study? (ITS)</td>
<td>High risk</td>
<td>Comment: Not possible to blind</td>
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</tbody>
</table>

Review Manager 5.3
### Lange 1985

#### Methods
- Study design: quasi-RCT
- Date of study: not stated, pre 1981
- Study duration: 11 weeks
- Setting: residential
- Ethical approval: unclear, “Prior to beginning the study the research proposal was reviewed by the administrative staff of L.O.M.R. dissertation” Thesis Pg 28
- Consent: Yes, “informed consents had to be obtained from subjects and their guardians”, “a release of information was signed by the subject and his/her guardian” Thesis pg 28

#### Participants
- Description of ID used: mild and moderate mentally retarded. Thesis Pg 30
- Conversion to ICD description: mild (9) and moderate (6)
- Age range (mean): 16 to 39 years
- Sex: male 7, female 8
- Comorbidity reported/detials: none reported
- Number of participants at baseline: 15
- Number of participants at final evaluation: 15
- Selection of the participants for the intervention: no details
- Country: USA (based on author address)

#### Interventions
- Comparison: training of people with ID versus no training of people of ID
  - Group 1: carers disclosed and recorded plaque levels, participants trained by carers to remove all disclosed plaque by toothbrushing. Verbal and physical instruction was provided if needed. Praise given as feedback and faded as steps achieved. Maintenance - participants warned they would be monitored on a regular basis
  - Group 2: carers disclosed and record plaque levels after the participant had brushed; no training provided to participants
  - Group 3: no regular recording of plaque levels or training

#### Outcomes
1. Plaque Index scored 0 to 3
2. Gingival Index scored 0 to 3
3. Timing of outcome assessments: plaque - daily, gingival - weekly

#### COM-B System Characteristics
- Potential sources of behaviour change: capability (physical/psychological), motivation (reflective)
- Potential intervention functions: training, modelling, enablement, persuasion, environmental restructuring

#### Stakeholder Involvement
- Formal or non-formal carer: formal
- With or without dental professional involvement without - assessor was trained in the use of the periodontal probe
- Other stakeholder involvement: house parents and aides in homes

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Review Manager 5.3
**Oral hygiene programmes for people with intellectual disabilities**

**Notes**

Strengths and weaknesses: self-help skills process was already in use in the facility for other life skills. Group 3 outcomes were only recorded at final time point. Modifications to the intervention: participants were to record their own plaque scores, but none were able to achieve this skill, so it was recorded by the staff. The baseline period need to be extended due to unstable plaque levels. Some participants continued to require cues to complete the toothbrushing task throughout the study. Adverse effects reported: none reported. Funding source: none reported.

**Risk of bias table**

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<tbody>
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<td>Unseen risk</td>
<td>Quote: “Randomised into matching groups by age, sex and functioning ability.” Comment: no further details provided</td>
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<tr>
<td>Allocation concealment (selection bias)</td>
<td>Unseen risk</td>
<td>Comment: no details provided</td>
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<td>Blinding of participants and personnel (performance bias)</td>
<td>Unseen risk</td>
<td>Comment: not possible to blind personnel, unclear if participants were blinded</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias)</td>
<td>High risk</td>
<td>Quote: “Throughout the study each subject’s plaque and gingival indexes were measured and recorded by the staff and/or the investigator.” Thesis Pg 30</td>
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<tr>
<td>Incomplete outcome data (attrition bias)</td>
<td>Low risk</td>
<td>Comment: no missing data</td>
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<tr>
<td>Selective reporting (reporting bias)</td>
<td>Unseen risk</td>
<td>Comment: no protocol but all listed outcomes reported. Group 3 had only one time point measured (final)</td>
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<td>Unseen risk</td>
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</table>
### Methods
- **Study design:** RCT
- **Date of study:** Not stated, pre 2000
- **Study duration:** 21 days
- **Setting:** Residential
- **Ethical approval:** None reported
- **Consent:** "After explaining the study to the parents and/or legal guardians of the clients, the researchers provided the institution administration with a signed informed consent for each client included in the study." Pg 207

### Participants
- **Description of ID used:** "Moderately to profoundly mentally retarded" Pg 207
- **Contribution to ICD:** Description: Mild to Profound
- **Age Range (mean):** Intervention group mean 43 years SD 12, Control Group mean 42 years, SD 12.
- **Gender:** Male 42 Female 34
- **Co-morbidity reported/notes:** None reported
- **Number of participants at baseline:** 84
- **Number of participants at final evaluation:** Paired data 80 / 81
- **Selection of the participants for the intervention:** Selected by unit directors
- **Country:** USA

### Interventions
- **Comparison:** Training of carers versus no training of carers
- **New policy for toothbrushing twice a day introduced, old policy indicated four times a day**
  - **Group 1:** Training with accountability - care staff were trained by dental professionals to help clients brush, to brush for non-compliant clients and disclose and chart the plaque levels and informed about new policy. Feedback was given and copies given to the unit leaders.
  - **Group 2:** Training without accountability - care staff were trained by staff development personnel on how to brush and monitor their own oral hygiene and informed about new policy. They were instructed to report changes to their clients and trained to monitor the clients’ progress.
  - **Group 3:** No training, so no informed about change to toothbrushing policy

### Outcomes
- **Outcomes measured:**
  - PLAQUE INDEX: Modified Ramfjord’s Periodontal Disease Index—plaque only, on 0 standard teeth, with disclosing solution. Pg 206
  - Timing of outcome assessments: Group 1 and 2: Baseline, 7, 14 and 21 days. Group 3: Baseline and 21 days

### COM-B System Characteristics
- **Potential sources of behaviour change:** Capability (Physical, Psychological), Opportunity (Physical), Motivation (Reflective)
- **Potential intervention functions:** Education, Training, Modelling, Enablement, Incentivisation, Coercion, Environmental Restructuring

### Stakeholder involvement
- **Formal or non-formal carer:** Formal
- **With or without dental professional involvement:** With - dental assistant, dental hygienist
- **Other stakeholder involvement:** Administration, Living unit directors, staff development department, RN, dental department staff, carers
<table>
<thead>
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<th>Support for judgement</th>
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<td>High risk</td>
<td>Comment: Authors acknowledge that randomization was not possible. Pg 207 C3</td>
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<tr>
<td>Allocation concealment (selection bias)</td>
<td>Low risk</td>
<td>Quote: The unit director drew numbers to determine if their unit would be the control, training with accountability (experimental group I) or training without accountability (experimental group II). They were not told the status of their unit. Pg 208. Comment: assumed to be done correctly.</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias)</td>
<td>Low risk</td>
<td>Quote: “Living unit staff, other than through staff development, had no opportunity to interact with staff from other living units” Pg 208</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias)</td>
<td>Low risk</td>
<td>Quote: “The examiner did not know the client’s group status at the time of the plaque assessment.” 206</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias)</td>
<td>Low risk</td>
<td>Comment: Missing data are clearly explained, unlikely to effect outcomes</td>
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<tr>
<td>Selective reporting (reporting bias)</td>
<td>Unclear risk</td>
<td>Comment: no protocol but all listed outcomes reported</td>
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### Oral hygiene programmes for people with intellectual disabilities

**Mac Giolla Phadraig 2015**

#### Methods
- **Study design:** cluster RCT - the unit of randomisation was the residential unit MacGiolla Phadraig 2015 Pg 93
- **Date of study:** July 2008 to September 2009
- **Study duration:** 6 to 11 months
- **Setting:** residential
- **Ethical approval:** "Ethical approval for the study was received from the relevant research ethics bodies." - Pg 93 (2015)
- **Consent:** Yes - "consent and assent" figure 2 pg 94 (2015) "consent forms were sent to all care staff in the last organization two to 6 weeks before training was delivered to the intervention group." Pg 165 C1, P3 (Mac Giolla Phadraig 2013)

#### Participants
- **Description of ID used:** 'carer-reported severity of ID (mild to profound)'
- **Conversion to ICD description:** mild to profound - mixed
- **Age range (mean):** people with ID - intervention group: mean 43 years SD 12, Control group: mean 42 years, SD 12
- **Sex:** Carers: not reported, people with ID: 42 male 34, Female Pg 96 Table 1 (2015)
- **Comorbidities reported/diagnosed:** none reported
- **Number of participants at baseline:** people with ID 64, carers 197, number of residential units 50
- **Number of participants at final evaluation:** people with ID - paired data 60/61, carers 154
- **Selection of the participants for the intervention:** randomly selected from a large ID service provider
- **Country:** Ireland

#### Interventions
- **Comparison:** training of carer versus no training of carer
- **Group 1:** a day-long education and training session provided by oral health trainers. with practical sessions and a specifically designed training pack to train their peers with motivational discussion, a moral agreement with dental team and offer of ongoing support if needed
- **Group 2:** no training

#### Outcomes
- 1. **Knowledge, behaviour, attitude and self-efficacy of carers via a questionnaire**
- 2. **Modified Gingival Index**
- 3. **Modified Sliness & Löe Plaque Index - "no probe used / only surfaces visible to the researcher"** Pg 94 (2015)

#### COM-B System Characteristics
- **Potential sources of behaviour change:** capability (physical/psychological), opportunity (physical), motivation (reflective)
- **Potential intervention functions:** education, training, modelling, enabling, environmental restructuring

#### Stakeholder Involvement
- **Formal or non-formal carer:** formal
- **With or without dental professional involvement:** with - dentist, dental hygienist, oral health promoters
- **Other stakeholder involvement:** care staff, management

#### Notes
- **Strengths and weaknesses:** "Almost a quarter of post-test respondents from the intervention group reported not having received training." Modifications to Plaque Index: "which decreased sensitivity at the lower end of the scale". Pg 94 (2015)
- **Modifications to the intervention:** none reported
Oxidative stress may contribute to the development of various diseases. Several studies have shown that chronic oxidative stress can lead to the development of metabolic syndrome, cardiovascular diseases, and neurodegenerative disorders. The mechanism of action of oxidants is complex and involves the formation of reactive oxygen species (ROS), which can damage cellular structures and trigger inflammation.

To add the table:

<table>
<thead>
<tr>
<th>Bias</th>
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<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Low risk</td>
<td>Quote: “Each group was then randomly allocated as either control or intervention.” Pg 184 C1,P1 (2013) Comment: probably done</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Low risk</td>
<td>Comment: no details of randomisation method but probably done</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias)</td>
<td>Unclear risk</td>
<td>Comment: no details provided in relation to blinding of personnel</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias)</td>
<td>Unclear risk</td>
<td>Quote: “One experienced dentist carried out all examinations following calibration exercises.” Pg 84 (2015) Comment: questionnaires were anonymous but no details of key holder</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias)</td>
<td>High risk</td>
<td>Comment: attrition rate of caries was high, no clear reason for drop-outs identified</td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Unclear risk</td>
<td>Comment: no protocol but all listed outcomes reported</td>
</tr>
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<td>Was the intervention independent of other changes? (ITS)</td>
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<td>Was the study free from selective outcome reporting? (ITS)</td>
<td>Unclear risk</td>
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</tbody>
</table>

Using the methods:

**Methods**
- Study design: RCT
- Date of study: Sept 2007 to Feb 2008
- Study duration: 4-weeks
- Setting: residential
- Ethical approval: not reported
- Consent: not reported

Review Manager 5.3
**Oral hygiene programmes for people with intellectual disabilities**

**Participants**
- Description of ID used: *special needs*
- Conversion to ICD description: unclear
- Age range (mean): 28 to 74 years (48.5)
- Sex: male 69; female 106
- Comorbidity reported/details: none reported
- Number of participants at baseline: 193
- Number of participants at final evaluation: 193
- Selection of the participants for the intervention: invited to attend from a list of persons with disabilities in a city
- Country: Germany

**Interventions**
- Comparison: training of carers versus no training of carers
- Group 1: carer and participant were provided with theoretical and practical training on oral hygiene
- Group 2: usual care

**Outcomes**
- 1. Type of toothbrush used
- 2. Type of toothpaste used
- 3. Frequency of fluoride application
- 4. Timing of toothbrushing
- 5. Duration of toothbrushing
- Timing of outcome assessments: baseline, week 4

**COM-B System Characteristics**
- Potential sources of behaviour change: capability (physical/psychological), opportunity (physical), motivation (reflective)
- Potential intervention functions: education, training, motivation, enablement, environmental restructuring

**Stakeholder Involvement**
- Formal or non-formal carer: formal
- With or without dental professional involvement: with - dentist and dental assistant
- Other stakeholder involvement: none reported

**Notes**
- Strengths and weaknesses: short duration, followed up for 5 years, but the control group received the intervention immediately after this study so no long-term control
- Modifications to the intervention: none reported
- Adverse effects reported: none reported
- Funding source: yes. "The project has been carried out since 2005 by the non-profit "Berliner Helfwerk Zahnmedizin e.V. with the support of the Senate Department for Health and Social Affairs" Olmos 2017"

---

### Risk of bias table

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors' judgement</th>
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<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Unkown risk</td>
<td>Quota &quot;randomised assignment of the participants to a control and an intervention group&quot; Comment: No details provided</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Unkown risk</td>
<td>Comment: Randomly assigned but no details provided</td>
</tr>
</tbody>
</table>

Review Manager 5.3
**Phyloco 2016**

**Methods**
- Study design: RCT
- Date of study: not stated, prior to 2010
- Study duration: 8 weeks
- Setting: Residential
- Ethical approval: Yes
- Consent: Yes - “For every selected resident, the parents or guardian granted their permission to participate.” Pg 5

**Participants**
- Description of ID used: Severe to profound ID
- Conversion to ICD description: Severe, Profound
- Age Range (mean): Not reported
- Gender: Not reported
- Co-morbidity reported/details: Not reported
- Number of participants at baseline: 56 cases
- Number of participants at final evaluation: 34 cases
- Selection of the participants for the intervention: Not reported
- Country: Belgium

**Interventions**
- Comparison: Training of carers versus no training of carers
  - Group 1: Carers provided with an information booklet and information session with practical skills
  - Group 2: Usual care
Oral hygiene programmes for people with intellectual disabilities

Outcomes

Outcomes measured:
1. Knowledge, Behaviour, Attitude and Self-Efficacy of Carers
2. Plaque index of people with ID
3. Gingival index of people with ID

Timing of outcome assessments: 3 weeks before the intervention, 5 weeks post

Communication System Characteristics

Potential sources of behaviour change: Capability (Physical/ Psychological), Opportunity (Physical), Motivation (Reflective)
Potential Intervention functions: Education, Training, Enablement, Environmental Restructuring

Stakeholder Involvement

Formal or non-formal carer: Formal
With or without dental professional involvement: With - dental students
Other stakeholder involvement: None reported

Notes

Strengths & Weakness: High attrition rate, short duration. A panel discussion with the resident dentists and director at baseline may have influenced the control group
Modifications to the intervention: None reported
Adverse effects reported: None reported
Funding Source: None reported

Risk of bias table

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<tr>
<td>Random sequence generation (selection bias)</td>
<td>Unclear risk</td>
<td>Quote: “Randomly selected to be clinically examined” Fig 4 Comment: no details of process</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
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<td>Comment: no details provided</td>
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<tr>
<td>Blinding of participants and personnel (performance bias)</td>
<td>Unclear risk</td>
<td>Comment: no details provided</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias)</td>
<td>Unclear risk</td>
<td>Comment: no details provided</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias)</td>
<td>High risk</td>
<td>Comment: high attrition rate, unclear why there were such high numbers who failed to complete assessment questionnaire or read the booklet</td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Unclear risk</td>
<td>Comment: no protocol, but all listed outcomes reported</td>
</tr>
<tr>
<td>Was the intervention independent of other changes? (ITT)</td>
<td>Unclear risk</td>
<td></td>
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<tr>
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<td>Unclear risk</td>
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</tbody>
</table>
### Sauvetre 1995

**Methods**

- Study design: RCT
- Date of study: not stated, pre 1995
- Study duration: 21 days
- Setting: day centre
- Ethical approval: "The study got the permission of the "Helsinki Committions of the Brugmann University Hospital", "The authors respected all though the study the "Helsinki declaration" - (1989)" Pg 116 C1 to 2
- Consent: none reported, but assumed as per Helsinki declaration

**Participants**

- Description of ID used: "mental retardation" pg 115
- Conversion to ICD description: unclear
- Age range (mean): 18 to 40 years
- Sex: not reported
- Comorbidities reported/details: none reported
- Number of participants at baseline: 25
- Number of participants at final evaluation: 25
- Selection of the participants for the intervention: randomly chosen from a day centre
- Country: Belgium

**Interventions**

- Comparison: a special manual toothbrush versus a conventional manual toothbrush
- All participants received instruction on how to brush "using the simplest method (horizontal movements with short strokes)." Asked to brush twice a day for at least 60 seconds. Reinstructed on day 7
- Group 1: Superbrush, three-headed toothbrush
- Group 2: standard toothbrush, Oral B P35

**Outcomes**

- Outcomes measured:
  1. Plaque Index (Löe and Silness 1964)
  2. Bleeding Index (Saxer and Muhlemann 1975) for 6 standardised teeth
  (Randjard 1959). From 3 sites - buccal, mesial and lingual. Pg 116 C2
- Timing of outcome assessments: baseline, Day 7 and day 21

**COM-B System Characteristics**

- Potential sources of behaviour change: capability (physical), opportunity (physical)
- Potential intervention functions: training, environmental restructuring

**Stakeholder Involvement**

- Formal or non-formal carer: not reported
- With or without dental professional involvement: with - periodontist, dental hygienist
- Other stakeholder involvement: none reported
### Risk of bias table

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<tr>
<td>Random sequence generation (selection bias)</td>
<td>Low risk</td>
<td>Comment: reports randomly selected, double blind, probably done</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Low risk</td>
<td>Comment: reports that the brushes were distributed by an oral hygienist immediately after the baseline assessment, but they were not the assessor Py 1/6 C2. &quot;Double Blind trial&quot; - probably done</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias)</td>
<td>Low risk</td>
<td>Comment: control group were also asked to do something that was not usual care</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias)</td>
<td>Low risk</td>
<td>Comment: double-blind trial - probably done</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias)</td>
<td>Unclear risk</td>
<td>Comment: five &quot;intention to treat&quot; participants were excluded as they were unable to follow the training</td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Unclear risk</td>
<td>Comment: no protocol but all listed outcomes reported</td>
</tr>
<tr>
<td>Was the intervention independent of other changes? (ITS)</td>
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<td>Was the shape of the intervention affect pre-specification? (ITS)</td>
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<td>Was the study free from selective outcome reporting? (ITS)</td>
<td>Unclear risk</td>
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</tbody>
</table>
### Shaw 1993

| **Methods** | Study design: RCT, cross-over trial  
|            | Date of study: Not stated, pre 1990  
|            | Study duration: 4 weeks for each arm of the trial  
|            | Setting: School  
|            | Ethical approval: Not reported  
|            | Consent: Parents gave consent for the project Pg 5, C1  
| **Participants** | Description of ID: last: Severely or moderately retarded Pg 4, C2, P3  
|            | Conversion to ICD description: Savanar  
|            | Age Range (mean): 0 - 16 years  
|            | Gender: Not reported  
|            | Co-morbidity reported/detected: "a range of handicapping conditions" Pg 4, C2, P3  
|            | Number of participants at baseline: 60  
|            | Number of participants at final evaluation: 53  
|            | Selection of the participants for the intervention: The schools agreed to participate, children selected by the staff Country: UK  
| **Interventions** | Comparison: Electric toothbrush versus a manual toothbrush  
|            | Individual oral hygiene instruction with a disclosing solution using the designated toothbrush. No specific technique was taught, but instructed to "get the stem off" and encouraged to adopt a systematic approach. All children brushed their own teeth, but with initial guidance and assistance. Brushing was carried out in the classroom for 5 minutes every day  
|            | Group 1: Braun Electric rechargeable electric toothbrush  
|            | Group 2: Oral B 30 manual toothbrush  
| **Outcomes** | Outcomes measured:  
|            | 1. Plaque Index - Gillies & Lüe (Y)  
|            | 2. Bleeding Index, (WHO Technical Report No 521, 1971) on six selected teeth (Y)  
|            | Timing of outcome assessments: Baseline, 4 weeks, (wash out period during "a prolonged school holiday"), 4 weeks later  
| **COM-B System Characteristics** | Potential sources of behaviour change: Capability (Physical/ Psychological), Opportunity (Social / Physical), Motivation (Reflective)  
|            | Potential interventional functions: Training, Enablement, Persuasion, Incentivisation, Environmental Restructuring  
| **Stakeholder Involvement** | Formal or non-formal carer: Formal  
|            | With or without dental professional involvement: With - dental and dental therapists  
|            | Other stakeholder involvement: Teachers  
| **Notes** | Strengths & Weakness: "The teaching staff saw the project as one of socialisation and the development of self-care skills which they regarded as important. Class charts which were filled in with stars when the children had completed their brushing for the day served as a useful reminder for the staff and as motivation for the children." Pg 5  
|            | Modifications to the intervention: None reported  
|            | Adverse effects reported: None reported  
|            | Funding Source: "We are grateful to Braun Electric (UK) Ltd for the provision of rechargeable electric toothbrushes and to Cooper Health Products for the Oral B 30 toothbrushes." Pg 5
Oral hygiene programmes for people with intellectual disabilities  11-Jan-2019

Risk of bias table

<table>
<thead>
<tr>
<th>Bias</th>
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<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Low risk</td>
<td>Quote: &quot;The school staff randomly selected 88 children. randomly allocated to test or control&quot; Pg 4</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Low risk</td>
<td>Comment: as above</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias)</td>
<td>High risk</td>
<td>Comment: Not possible to blind participants or personnel</td>
</tr>
<tr>
<td>Blinding of outcome assessment (selection bias)</td>
<td>Low risk</td>
<td>Quote: &quot;At no time was the examiner aware of the group to which the children had been assigned&quot; Pg 4</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias)</td>
<td>High risk</td>
<td>Comment: 20% attrition unexplained</td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Unclear risk</td>
<td>Comment: Unclear if results are reported for the combined arms. Some mild way results provided in text</td>
</tr>
<tr>
<td>Was the intervention independent of other changes? (ITS)</td>
<td>Unclear risk</td>
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<td>Unclear risk</td>
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</table>

Shaw 1991

Methods
- Study design: Cluster RCT
- Date of study: 1988 - 1988
- Study duration: 2 years
- Setting: Day centre
- Ethical approval: None reported
- Consent: Yes, Pg 140 (Shaw 1991)

Participants
- Description of ID used: "with mental handicaps" Pg 139 - 140
- Conversion to ICD description: Unclear
- Age Range (mean): mean 30.0 +/- 10.1
- Gender: Males 188 Female 161 (Shaw 1990) pg 137
- Co-morbidity reported/details: Yes, "54.1% had a comorbidity reported", "Physical handicap, epilepsy, Down syndrome, speech difficulties and miscellaneous". Pg 138

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Oral hygiene programmes for people with intellectual disabilities

Shaw 1990
Number of participants at baseline: 329
Number of participants at final evaluation: 304
Selection of the participants for the intervention: Four largest training centres for adults in a UK city approached
Country: UK

Interventions
Comparison: One monthly dental visit versus 3 monthly dental visits versus usual care
Group 1: No specific treatment
Group 2: Daily toothbrushing supervised by staff in the centre and reinforced oral hygiene instruction every 6 months
Group 3: Daily toothbrushing supervised by staff with prophylaxis and reinforcement of oral hygiene every month
Group 4: Daily toothbrushing supervised by staff with prophylaxis and reinforcement of oral hygiene every 3 months

Outcomes
Outcomes measured:
1. DMFT - only reported at baseline
2. WHO Technical Report using 8 standard teeth
3. Calculus
4. Periodontal pocketing
5. Bleeding
Timing of outcome assessments: Baseline, 3, 6, 12, 18 and 24 months

COM-B System Characteristics
Potential sources of behaviour change: Care and people with ID; Capability (Physical, Psychological), Opportunity (Physical), Motivation (Reflective)
Potential intervention functions: Care, Environmental ReStructuring, People with ID, Training, Enablement, Persuasion, Environmental ReStructuring

Stakeholder Involvement
Formal or non-formal carer: Formal
With or without dental professional involvement: With - dental hygienist
Other stakeholder involvement: Staff supervising toothbrushing

Notes
Strengths & Weaknesses: The difference in time involvement, was very significant when cost assessments were made long-term, with applied models of professional support. Modifications to the intervention: None reported
Adverse effects reported: None reported
Funding Source: This project was supported by a grant from the West Midlands Regional Health Authority. Pg 140 (1990)

Risk of bias table

<table>
<thead>
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<tr>
<td>Random sequence generation (selection bias)</td>
<td>Unclear risk</td>
<td>Quote: &quot;Each of the centres was then randomly allocated to one of four treatment regimens&quot;. Pg 140 Comment: No further details provided</td>
</tr>
</tbody>
</table>

Review Manager 5.3

53
### Oral hygiene programmes for people with intellectual disabilities

**Allocation concealment (selection bias)** | Unclear risk | Comment: No details provided
---|---|---
**Blinding of participants and personnel (performance bias)** | Low risk | Comment: Unlikely that each centre would have been aware of what the other centres were doing
**Blinding of outcome assessment (detection bias)** | Unclear risk | Comment: unclear if blinded or not
**Incomplete outcome data (attrition bias)** | Low risk | Quote: “All participants were examined at intervals of 3, 6, 12, 18, and 24 months by the same examiner (MJS).” 
Comment: Details of numbers of participants only provided at baseline and final measure (Table 1 pg 141), but clear reasons given for drop-outs. Drop outs occurred in all groups and were unlikely to affect outcomes
**Selective reporting (reporting bias)** | Unclear risk | Comment: No protocol but all listed outcomes reported

#### Snell 1989

**Methods**
- Study design: Repeat Measure Study
- Date of study: Not stated, pre 1989
- Study duration: 3 years
- Setting: School
- Ethical approval: None reported
- Consent: None reported

**Participants**
- Description of ID used: "Severe mental retardation." and "Profound mental retardation"
- Conversion to ICD description: Severe (2) and Profound (1)
- Age Range (mean): 5 - 11 years
- Gender: Males 2, Females 1
- Co-morbidity reported/detected: Yes, severe quadriplegic, athetoid cerebral palsy, spastic cerebral palsy, visual impairment
- Number of participants at baseline: 3
- Number of participants at final evaluation: 2 (one lost at the 19 month follow-up)
- Selection of the participants for the intervention: No details provided
- Country: USA
Oral hygiene programmes for people with intellectual disabilities  11-Jan-2019

Interventions

Comparison: Training of people with ID
Group 1: Training in three tasks - toothbrushing (12 steps), rinsing (3 steps) and wiping mouth (2 steps) with verbal and physical prompting, which were gradually faded as the training continued. 20 minutes each school day. Praise and tokens were used as motivators which were faded over time. Maintenance started once the skills were completed without prompts for 3 to 5 days. In this phase praise was only given on completion of the entire task. Training was reinstated if needed.

Outcomes

Outcomes measured:
1. Number of steps achieved for each task
2. Number of training sessions it took for the skill to be performed with out prompting
3. Parents awareness of changes in oral hygiene routine
4. Teachers survey, 3 years post intervention, "questioned on students skill retention" Pg 221
Timing of outcome assessments: Baseline, Training (unclear -120 days), 4/7 months post, 10 month post, 3 years post

COM-B System Characteristics

Potential sources of behaviour change: Capability (Physical), Opportunity (Physical), Motivation (Reflective)
Potential intervention functions: Training, Enablement, Persuasion, Incentivisation, Environmental Restructuring

Stakeholder Involvement

Formal or non-formal carer: Formal
With or without dental professional involvement: Without
Other stakeholder involvement: Teachers, speech therapist and occupational therapist
Pg 217-218

Notes

Strengths & Weaknesses. Small study, inconsistent measures at baseline, modifications to the training, provision of booster training during maintenance phase, Modifications to the intervention: Yes, as above
Adverse effects reported: Yes - Reference to 2 participants displaying sensitivity to mouth being held open. Pg 220
Funding Source: None reported

Risk of bias table

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</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Unclear risk</td>
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<tr>
<td>Was the intervention independent of other changes? (ITT)</td>
<td>Unclear risk</td>
<td>Comment: This type of training is used for other skills in the school</td>
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</tbody>
</table>

Review Manager 5.3  55
### Oral hygiene programmes for people with intellectual disabilities

<table>
<thead>
<tr>
<th>Question</th>
<th>Risk</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Was the shape of the intervention pre-specified? (ITT)</td>
<td>Low</td>
<td>Comment: The point of analysis is the point of intervention</td>
</tr>
<tr>
<td>Was the intervention unlikely to affect data collection? (ITT)</td>
<td>Low</td>
<td>Comment: The intervention did not affect either the source of method of data collection</td>
</tr>
<tr>
<td>Was knowledge of the allocated interventions adequately prevented during the study? (ITT)</td>
<td>High</td>
<td>Comment: Not possible to blind participants or personnel</td>
</tr>
<tr>
<td>Were incomplete outcome data adequately addressed? (ITT)</td>
<td>Low</td>
<td>Comment: Loss of one participant at the 3 year follow-up was explained</td>
</tr>
<tr>
<td>Was the study free from selective outcome reporting? (ITT)</td>
<td>Low</td>
<td>Comment: All outcome data were reported</td>
</tr>
</tbody>
</table>

### Swallow 1969

#### Methods
- **Study design:** RCT
- **Date of study:** Not stated, pre 1969
- **Study duration:** 21 days
- **Setting:** Residential
- **Ethical approval:** None reported
- **Consent:** None reported

#### Participants
- **Description of ID used:** "Mentally subnormal" Pg 376, "Mentally Retarded" Pg 376, "Varying mental ability" Pg 377
- **Conversion to ICD description:** Mixed
- **Age Range (mean):** 15 - 30
- **Gender:** 40 male, 40 female
- **Co-morbidity reported/diagnosis:** None reported
- **Number of participants at baseline:** 80
- **Number of participants at final evaluation:** 60
- **Selection of the participants for the intervention:** Total sample of patients in the setting examined in "an unbiased order" until 40 males and 40 females meeting the inclusion criteria were found. Pg 377
- **Country:** UK

#### Interventions
- **Comparison:** Electric toothbrush versus a manual toothbrush
- "Teeth" were brushed in their own wards after breakfast or after the midday meal. brushed on alternate occasions by one of the two operators, in order to avoid bias. Pg 377
- **Males and Females were in two separate sub groups:**
  - **Group 1:** Teeth brushed once a day with an "automatic toothbrush" (supplied by Ronsos Products Ltd)
  - **Group 2:** Teeth brushed once a day with a manual toothbrush (Colgate-Palmolive)
  - **Group 3:** Teeth brushed twice a week with an "automatic toothbrush" (supplied by Ronsos Products Ltd)
  - **Group 4:** Teeth brushed twice a week with a manual toothbrush (Colgate-Palmolive)
  - **Group 5:** Teeth brushed once a week with an "automatic toothbrush" (supplied by Ronsos Products Ltd)
  - **Group 6:** Teeth brushed once a week with a manual toothbrush (Colgate-Palmolive)
  - **Group 7:** Usual care - "rarely received any regular form of oral hygiene"
### Oral hygiene programmes for people with intellectual disabilities

**Outcomes**

Outcomes measured:
1. Gingival index (Löe and Silness) - “only the interdental papillae and the intervening gingiva on the buccal surfaces of all standing teeth were scored.” Pg 377
2. Time spent brushing teeth


**COM-B System Characteristics**

Potential sources of behaviour change: Opportunity (Physical)
Potential intervention functions: Environmental Restructuring

**Stakeholder Involvement**

Formal or non-formal carer: Formal
With or without dental professional involvement: With - final year dental students, dentist
Other stakeholder involvement: None reported

**Notes**

Strengths & Weaknesses: Short intervention
Modifications to the intervention: None reported
Adverse effects reported: None reported
Funding Source: “Toothbrushed and toothpaste kindly supplied by Colgate-Palmolive.
Toothbrushes kindly supplied by Ronson Products Ltd.” Pg 377 footnote

### Risk of bias table

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors' judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Low risk</td>
<td>Quota: “Randomly allocated into 2 groups comprising 5 males and 5 females.” Comment: Probably done</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Low risk</td>
<td>Comment: Probably done</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias)</td>
<td>Unclear risk</td>
<td>Comment: Not possible to blind personnel, brushing was carried out by dental students, participants may have been blinded as brushing was carried out in their own bathrooms/units.</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias)</td>
<td>Low risk</td>
<td>Quota: “Subjects were again examined by the same independent observer (INS) who had no knowledge of the grouping of the patients” Pg 377</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias)</td>
<td>Low risk</td>
<td>Comment: all subjects completed the study. Pg 377</td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Unclear risk</td>
<td>Comment: No protocol but all listed outcomes reported</td>
</tr>
<tr>
<td>Was the intervention independent of other changes? (ITS)</td>
<td>Unclear risk</td>
<td></td>
</tr>
<tr>
<td>Was the shape of the intervention effect pre-specified? (IT)</td>
<td>Unclear risk</td>
<td></td>
</tr>
<tr>
<td>Was the intervention unlikely to affect data collection? (IT)</td>
<td>Unclear risk</td>
<td></td>
</tr>
<tr>
<td>Was knowledge of the allocated interventions adequately prevented during the study? (IT)</td>
<td>Unclear risk</td>
<td></td>
</tr>
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</table>
### Oral hygiene programmes for people with intellectual disabilities

11-Jan-2019

<table>
<thead>
<tr>
<th>Question</th>
<th>Risk</th>
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</thead>
<tbody>
<tr>
<td>Were incomplete outcome data adequately addressed? (ITS)</td>
<td>Unclear risk</td>
</tr>
<tr>
<td>Was the study free from selective outcome reporting? (ITS)</td>
<td>Unclear risk</td>
</tr>
</tbody>
</table>

#### Teitelbaum 2009

**Methods**

- Study design: NIRCT - Blind cross-over trial - only two of the four groups are relevant to this review
- Date of study: Not stated, pre 2008
- Study duration: 65 days of which 45 days were the washout periods
- Setting: Residential
- Ethical approval: "This study was approved by the Joint Research and Ethics Committee of the Ponta Grossa State University: Protocol: 05885/06 Fg 464"
- Consent: "They signed a consent form, according to the Helsinki II Declaration and the Dentistry Ethical Code (CONEPY M3, Brazil): Pg 494"

**Participants**

- Description of ID used: "moderate mental retardation ("trainable" category, intelligence quotient 40 to 65)"
- Conversion to IQ description: Mild to moderate
- Age Range (mean): 7 to 13 years
- Gender: Mixed
- Comorbidities reported/detected: Exclusion criteria - Excluded if any systemic disease
- Number of participants at baseline: 40
- Number of participants at final evaluation: 40
- Selection of the participants for the intervention: Participants were "invited to participate"
- Country: Brazil

**Interventions**

- Comparison: Disclosing agent versus no disclosing agent
- Interventions: Under the guidance of oral hygiene instructors, provided with a child's toothbrush, toothpaste and detailed instructions. Instructed to brush three times a day. During the washout phase, carers returned to usual habits, using fluoridated toothpaste and toothbrush
- Group 1: Fluoridated toothpaste
- Group 2: Fluoridated toothpaste with disclosing agent

**Outcomes**

- Outcomes measured:
  1. Plaque Index (Giesano & Varni) (V)
  2. Gingival Bleeding Index (Ainsworth & Dale) (V)
- Timing of outcome assessments: Baseline and day 10 for each of four phases

**COM- E System Characteristics**

- Potential sources of behaviour change:
  1. Capability (Physical/ Psychological)
  2. Opportunity (Physical), Motivation/ Reflective
- Potential Intervention functions: Training, Enablement, Environmental Restructuring

**Stakeholder involvement**

- Formal or non-formal carer. Both
- With or without dental professional involvement: With - dentist, dental assistant
- Other stakeholder involvement: Parents, formal carers, participants own dentist (ODF) and dental assistant
**Risk of bias table**

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors' judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Unclear risk</td>
<td>Comment: no details provided</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Unclear risk</td>
<td>Comment: no details provided</td>
</tr>
<tr>
<td>Binding of participants and personnel (performance bias)</td>
<td>Low risk</td>
<td>Quote: &quot;The experimental dentifrices were packed into plain white 50-c plastic tubes and coded according to each group.&quot; Parents did not know which of the four experimental dentifrices they were using for their children.&quot; Pg 466 C1. Comment: Probably done</td>
</tr>
<tr>
<td>Binding of outcome assessment (detection bias)</td>
<td>Unclear risk</td>
<td>Quote: &quot;Clinical examinations were performed by a previously trained examiner.&quot; Pg 466. Comment: Unclear if &quot;blind&quot; trial refers to the assessor or the parents. Pg 464</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias)</td>
<td>Low risk</td>
<td>Comment: No missing data</td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Unclear risk</td>
<td>Comment: No protocol but all listed outcomes reported</td>
</tr>
<tr>
<td>Was the intervention independent of other changes? (ITS)</td>
<td>Unclear risk</td>
<td></td>
</tr>
<tr>
<td>Was the shape of the intervention effect pre-specified? (ITS)</td>
<td>Unclear risk</td>
<td></td>
</tr>
<tr>
<td>Was the intervention unlikely to affect data collection? (ITS)</td>
<td>Unclear risk</td>
<td></td>
</tr>
<tr>
<td>Was knowledge of the allocated interventions adequately prevented during the study? (ITS)</td>
<td>Unclear risk</td>
<td></td>
</tr>
<tr>
<td>Were incomplete outcome data adequately addressed? (ITS)</td>
<td>Unclear risk</td>
<td></td>
</tr>
<tr>
<td>Was the study free from selective outcome reporting? (ITS)</td>
<td>Unclear risk</td>
<td></td>
</tr>
</tbody>
</table>
Williams 1988

**Methods**
- Study design: NRCT
- Date of study: Not stated, pre 1988
- Study duration: 3 months
- Setting: Residential
- Ethical approval: None reported
- Consent: None reported

**Participants**
- Description of ID used: “Profoundly mentally retarded” Pg 2
- Conversion to ICD description: Profound
- Age Range (mean): 4 - 36 years
- Gender: Male 6, Female 15
- Co-morbidity reported/details: None reported
- Number of participants at baseline: 24
- Number of participants at final evaluation: Unclear
- Selection of the participants for the intervention: Participants were “selected”
- Country: USA

**Interventions**
- Comparison: A special manual toothbrush versus a conventional manual toothbrush
  - Group 1: Brushed daily with Colgate Curved toothbrush by student dental assistant using the Colgate Curved Scrub Method
  - Group 2: Brushed daily with conventional toothbrush by student dental assistant using the Modified Stillman Method

**Outcomes**
- Outcomes measured:
  - 1. Simplified Glaas & Varnien Oral Hygiene Index - plaque only (Scale 0-3) (Y)
- Timing of outcome assessments: Baseline and 3 months

**COMBI System Characteristics**
- Potential sources of behaviour change: Opportunity (Physical)
- Potential Intervention functions: Environmental Restructuring

**Stakeholder Involvement**
- Formal or non-formal carer: Formal
- With or without dental professional involvement: With - student dental assistant, dentist
- Other stakeholder involvement: None reported

**Notes**
- Strengths & Weakness: Brushing carried out by a dental professional
- Modifications to the intervention: None reported
- Adverse effects reported: None reported
- Funding Source: None reported

### Risk of bias table

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors' judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Unclear risk</td>
<td>Quote: “equally divided into control and experimental groups” Pg 2 Comment: No evidence of randomisation</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Unclear risk</td>
<td>Comment: No details provided</td>
</tr>
</tbody>
</table>

Review Manager 5.3

60
<table>
<thead>
<tr>
<th>Category</th>
<th>Risk</th>
<th>Comment</th>
</tr>
</thead>
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<tr>
<td>Blinding of participants and personnel (performance bias)</td>
<td>High</td>
<td>Not possible to blind personnel</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias)</td>
<td>Undeek</td>
<td>Data collected by the dentist in the facility, unclear if blinded. Pg 2</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias)</td>
<td>Low</td>
<td>Assumed no missing data (Table 2 pg 282)</td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Undeek</td>
<td>No protocol but all listed outcomes reported</td>
</tr>
<tr>
<td>Was the intervention independent of other changes? (ITS)</td>
<td>Undeek</td>
<td></td>
</tr>
<tr>
<td>Was the shape of the intervention affect pre-specified? (ITS)</td>
<td>Undeek</td>
<td></td>
</tr>
<tr>
<td>Was the intervention unlikely to affect data collection? (ITS)</td>
<td>Undeek</td>
<td></td>
</tr>
<tr>
<td>Was knowledge of the allocated interventions adequately prevented during the study? (ITS)</td>
<td>Undeek</td>
<td></td>
</tr>
<tr>
<td>Were incomplete outcome data adequately addressed? (ITS)</td>
<td>Undeek</td>
<td></td>
</tr>
<tr>
<td>Was the study free from selective outcome reporting? (ITS)</td>
<td>Undeek</td>
<td></td>
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</tbody>
</table>
Appendix 6: Cochrane Data Extraction Form Templates

<table>
<thead>
<tr>
<th>Author / Year</th>
<th>Description as stated in report/paper</th>
<th>Location in text</th>
</tr>
</thead>
<tbody>
<tr>
<td>Comparison</td>
<td>a description of what is being compared and how it is being assessed</td>
<td></td>
</tr>
<tr>
<td>Description of Outcome Measured (V)</td>
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</tr>
</tbody>
</table>

**Baseline data**

<table>
<thead>
<tr>
<th>Detailed Title of Group</th>
<th>Mean</th>
<th>SD</th>
<th>No. participants</th>
</tr>
</thead>
</table>

| Mean (or other variance) | |

Add more rows if needed.

<table>
<thead>
<tr>
<th>Final/ repeat data</th>
</tr>
</thead>
</table>

**Tick whether**

- Mean
- Mean Diff

<table>
<thead>
<tr>
<th>Detailed Title of Group</th>
<th>Time point</th>
<th>Mean</th>
<th>SD</th>
<th>No. participants</th>
</tr>
</thead>
</table>

| Mean (or other variance) | |

No. missing participants and reasons

Any other results reported

<table>
<thead>
<tr>
<th>Unit of analysis</th>
</tr>
</thead>
</table>

| (e.g., mm, scales, and if by individual or group) |

| Statistical methods used and appropriateness of these methods (e.g., adjustment for correlation) |

<table>
<thead>
<tr>
<th>Reanalysis required?</th>
</tr>
</thead>
</table>

| (if yes, specify why) |

| Reanalysis possible? | Yes/No/ Unclear |

| Yes/No/Unclear |

Reanalysed results
### Dichotomous data form for RCT and NRCT

<table>
<thead>
<tr>
<th>Author / Year</th>
<th>Description as stated in report/paper</th>
<th>Location in text (p. &amp;/or table)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Comparison</td>
<td></td>
<td></td>
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<tr>
<td>Description of Outcome Measured</td>
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</tr>
<tr>
<td>Comments:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Baseline data

**Add more rows if needed**

Give a clear description of what event is being recorded i.e. if Yes, is the change of interest, State this and the no. of events.

<table>
<thead>
<tr>
<th>Detailed title of groups</th>
<th>Intervention</th>
<th>No. events</th>
<th>No. participants</th>
<th>Comparison</th>
<th>No. events</th>
<th>No. participants</th>
<th>Location in text (p. &amp;/or table)</th>
</tr>
</thead>
</table>

#### Final/ Repeat data

**Add more rows if needed**

<table>
<thead>
<tr>
<th>Detailed title of groups</th>
<th>Intervention</th>
<th>No. events</th>
<th>No. participants</th>
<th>Comparison</th>
<th>No. events</th>
<th>No. participants</th>
<th>Location in text (p. &amp;/or table)</th>
</tr>
</thead>
</table>

- **No. missing participants and reasons**
- **Any other results reported**
- **Unit of analysis**
  - (e.g. mm, Scale and if by Individual or group)
- **Statistical methods used and appropriateness of these methods**
- **Reanalysis required?** Yes/No/Unclear
- **Reanalysis possible?** Yes/No/Unclear
- **Reanalysed results**
## interrupted Time Series form from EPOC

<table>
<thead>
<tr>
<th>Author /Year</th>
<th>Description as stated in report/paper</th>
<th>Location in text (pg &amp; #/fig/table)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Comparison</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Description of outcome measured</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Comments:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Length of timepoints measured (e.g. days, months)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total period measured</td>
</tr>
<tr>
<td>No. participants measured</td>
</tr>
<tr>
<td>No. missing participants and reasons</td>
</tr>
<tr>
<td>No. timepoints measured</td>
</tr>
<tr>
<td>Mean value (with variance measure)</td>
</tr>
<tr>
<td>Difference in means (post – pre)</td>
</tr>
<tr>
<td>Percent relative change</td>
</tr>
<tr>
<td>Result reported by authors (with variance measure)</td>
</tr>
<tr>
<td>Unit of analysis</td>
</tr>
<tr>
<td>i.e. mm, scale, and if individuals or cluster/ groups</td>
</tr>
<tr>
<td>Statistical methods used and appropriateness of these methods</td>
</tr>
<tr>
<td>Reanalysis required? (specify)</td>
</tr>
<tr>
<td>Reanalysis possible?</td>
</tr>
<tr>
<td>Individual timepoint results</td>
</tr>
<tr>
<td>Read from figure?</td>
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<td>Reanalysed results</td>
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<tr>
<td>Change in level</td>
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</table>
### Before and After Form from EPOC

<table>
<thead>
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<th>Location in text</th>
</tr>
</thead>
<tbody>
<tr>
<td>Comparison</td>
<td></td>
</tr>
<tr>
<td>Description of outcome measured</td>
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</tr>
<tr>
<td>Post-intervention or change from baseline?</td>
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<tr>
<td>Comments:</td>
<td></td>
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</table>

<table>
<thead>
<tr>
<th>Detailed title of group</th>
<th>Intervention result</th>
<th>SD (or other variance)</th>
<th>Control result</th>
<th>SD (or other variance)</th>
<th>Location in text</th>
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<tbody>
<tr>
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<td></td>
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<td>Overall results</td>
<td>SE (or other variance)</td>
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</table>

<table>
<thead>
<tr>
<th>No. participants</th>
<th>Intervention</th>
<th>Control</th>
</tr>
</thead>
<tbody>
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<td></td>
<td></td>
</tr>
</tbody>
</table>

| No. missing participants and reasons | |
|-------------------------------------| |
| No. participants moved from other group and reasons | |
| Any other results reported | |

<p>| Unit of analysis (individuals, cluster/groups or body parts) | |
|-------------------------------------------------------------| |
| Statistical methods used and appropriateness of these methods | |
| Reanalysis required? (specify) | Yes/No/Unclear |
| Reanalysis possible? | Yes/No/Unclear |
| Reanalysed results | |</p>
<table>
<thead>
<tr>
<th>Year/Location</th>
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<th>2006</th>
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<td>-</td>
</tr>
<tr>
<td>Sample</td>
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<td>0.5</td>
</tr>
<tr>
<td>N</td>
<td>20</td>
<td>20</td>
</tr>
</tbody>
</table>

Any other results

Description of results in context of paper

Continuous data from ACT and reading (PROC score)
## Characteristics of Studies

### Characteristics of Excluded Studies

<table>
<thead>
<tr>
<th>Study</th>
<th>Year</th>
<th>Reason for Exclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Andras 1990</td>
<td></td>
<td>Conference abstract only. Data in a format that could not be used. Efforts to contact authors were unsuccessful</td>
</tr>
<tr>
<td>Badra 1973</td>
<td></td>
<td>Title only. All attempts to source full text and contact authors were unsuccessful</td>
</tr>
<tr>
<td>Borgin 1969</td>
<td></td>
<td>Title only. Efforts to source full article and contact authors were unsuccessful</td>
</tr>
<tr>
<td>Brody 1975</td>
<td></td>
<td>Unclear data in the published report regarding study design. Efforts to contact authors were unsuccessful</td>
</tr>
<tr>
<td>Bui 2003</td>
<td></td>
<td>One subgroup possibly eligible for inclusion. Contact with 2nd author (Antonia Scott), too few measures for NRS design</td>
</tr>
<tr>
<td>Favell 1975</td>
<td></td>
<td>Relevant data were not presented in the published report. Attempts to contact the author were unsuccessful</td>
</tr>
<tr>
<td>Gertenreich 1972</td>
<td></td>
<td>Data in published report was in a format that could not be used. Contact with the author. The data are no longer available</td>
</tr>
<tr>
<td>Haran 2014</td>
<td></td>
<td>Contact with author; study does not meet the required study design</td>
</tr>
<tr>
<td>Horner 1975</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Study/Reason</td>
<td>Description</td>
<td></td>
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<tr>
<td>--------------</td>
<td>-------------</td>
<td></td>
</tr>
<tr>
<td>Reason for exclusion Interrupted time series study with unclear data; two participants appeared to have only two baseline measures, post intervention time frame was different for each participant, no clear finish time point. Unable to contact the author to clarify.</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>ISRCTN10044161</strong></td>
<td>Trial registration only. Thesis published by the author, unable to contact the author or access the thesis</td>
<td></td>
</tr>
<tr>
<td><strong>Kaschke 2008</strong></td>
<td>Contact with author, this stage of the long-term project is not meeting the required study design</td>
<td></td>
</tr>
<tr>
<td><strong>Lesmana 2014</strong></td>
<td>Abstract only, contact made with author, the data are no longer available</td>
<td></td>
</tr>
<tr>
<td><strong>Lopez 1994</strong></td>
<td>Title only, unable to contact the author or access the article</td>
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</tr>
<tr>
<td><strong>Meador 1979</strong></td>
<td>No data provided in the published report, unable to contact the author</td>
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<tr>
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<tr>
<td><strong>Ofeda 2010</strong></td>
<td>Conference abstract only, data were in a format that could not be used, unable to contact the authors</td>
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</tr>
<tr>
<td><strong>Ribeiro 2011</strong></td>
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</tr>
<tr>
<td>Study</td>
<td>Reason for exclusion</td>
<td></td>
</tr>
<tr>
<td>--------------</td>
<td>----------------------------------------------------------------------------------------</td>
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<tr>
<td>Schmidt 1981</td>
<td>Data in the published report was in a format that could not be used. Contact made with author (JF O’Donnell), the data are no longer available</td>
<td></td>
</tr>
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<td>Thornton 1991</td>
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<td></td>
</tr>
<tr>
<td>Zaksek 2014</td>
<td>Not meeting the required study design</td>
<td></td>
</tr>
</tbody>
</table>
Appendix 9: Email to Local Experts for Realist Review

Dear

I am planning a qualitative review (a Realist Synthesis) of oral hygiene interventions for people with intellectual disability, with a particular focus on carer-led interventions.

The first step is to develop a list of concepts that identify the crucial elements of a successful oral health intervention, particularly for the population with ID. These concepts might be in relation to elements such as: the setting, the people involved, the resources available and how the information or training was provided. This review is not focused on whether the intervention worked but rather the why, when and for whom it worked, or not.

I would greatly value your input in relation to any experiences you have had when designing, implementing or carrying out any oral health intervention for people with disabilities.

At this early stage of the review I am looking for your recollections, gut instincts and/or experiences in relation to what you felt helped or hindered the success of the intervention(s).

I would be happy either to have a chat over the phone at an agreed suitable time or ask you to complete a short form on the topic. Either way, it should not take more than 30 minutes. Any and all thoughts would be most welcome.

If you could let me know by email, text or phone call if you can give me some of your time within thenext two weeks and whether a phone call or written recollection would suit you best.

With thanks,

Catherine Waldron
PhD Student
Mobile: 087XXXXXXX
Email: waldrocg@tcd.ie
Appendix 10: Local Expert Information Form

Concepts in relation to oral health interventions for people with disabilities

1. The Intervention — what was it (aim); a brief summary of who was targeted and what was involved in rolling out the intervention. Details of objectives or outcomes measured are not required, although any insight into intended specific outcomes to be assessed, if not explicit in the aim, would be helpful.

2. Facilitators — any elements you felt helped the intervention, this may have been part of the design of the intervention or an element that occurred or existed in your particular situation.

3. Barriers — any elements you felt hindered the intervention, this may have been part of the design of the intervention or an element that occurred or existed in your particular situation.

4. General thoughts — any thoughts you have from your experience that might impact on the success or failure of an intervention; what you would do differently if you were to do this again.

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Please feel free to be as brief or as detailed as your time permits.
Appendix 11: Expert Panel background information sheet

What is it about carer led oral hygiene interventions for people with intellectual disabilities that works and why; A Realist Review.

Rationale for the Review

Oral hygiene routines carried out on a daily basis are essential to maintaining oral health and preventing oral diseases. People with intellectual disability (ID) often have more difficulty attaining this goal than the general population, as they may require the assistance of others to perform the oral hygiene. Carers providing oral hygiene assistance or carrying out oral hygiene routines for people with ID may not have the skills or motivation required for this task.

Background work leading to this review

This realist review is limited to carer-led oral hygiene interventions for people with ID, specifically with the intention of focusing on people with moderate, severe or profound intellectual disabilities, who require assistance and/or another person to carry out routine oral hygiene measures for them. These interventions are particularly complex, as the primary outcome of improved oral hygiene of the person with ID is dependent on the secondary outcome of engagement by the carer.

A scoping review of all types of oral health interventions, completed as part of this PhD, showed that carers, who include formal carers and non-formal carers (parents, siblings etc.), play a major role in these interventions. Very often they are the target of the intervention, involving education or skills training. A Cochrane review of oral hygiene interventions for people with an intellectual disability is currently in progress; early findings suggest that carer-led interventions are successful in the short term but fail to be sustained long-term or the intervention is not evaluated long-term. Both the Scoping Review already conducted and the Cochrane Systematic have helped to determine the focus of this realist review.

Why a realist review is needed

It is essential that we develop a better understanding of why these interventions are shown to work in some instances and not others or why they seem to work in the short-term but fail to be sustained. To understand these elements, we need to think about evaluation differently. Firstly, why and how was the intervention supposed to work? Are there contexts that might influence the long-term outcomes? Do they work for some carers but not others? Are there elements that work and others that don't? These are the type of questions that realist reviews answer. It is the theory of why and how the intervention was supposed to work which is the unit of analysis in a realist review, not the intervention.

More formally, we could say that a realist review aims to identify what it is about interventions that generate change (i.e., the mechanisms) and under which circumstances the mechanisms are triggered (i.e., the contexts), which result in changes in the behaviour of the participants and/or implementers of the intervention (i.e., the outcome). These three elements, context, mechanism and outcome, are presented together as a statement or theory which attempts to describe what needs to happen for the interventions to work.
The aim of this Realist Review

The aim of this realist review is to identify the contexts, mechanisms and outcomes that influence the implementation and sustainability of carer-led oral hygiene interventions for people with intellectual disabilities.

The research questions are:

- What types of carer-led oral hygiene interventions for people with an intellectual disability have been implemented?
- What are the mechanisms by which carer-led oral hygiene interventions are believed to result in their intended outcomes?
- What are the important contexts that determine whether the different mechanisms produce their intended outcome?
- What are the intended and unintended outcomes?
- In what circumstances are carer-led interventions most likely to be effective?

Having determined the focus of the realist review, ten initial programme theories have been developed by the review team, based on their knowledge of the subject area, on input from local dental professional experts who have experience in the field and from extensive reading around the population and interventions of interest.

What we need from the Expert Panel

We need you, the expert panel, to review these theories and provide some feedback on Survey Monkey using your own knowledge and personal experience in the field. You will be asked to use a visual analogue scale (slider) to indicate your thoughts in relation to; how well you understand each theory, the relevance of the theory and how feasible you think it would be to apply the theory in practice. You will then be asked to comment and/or amend each theory; you may agree or disagree with them, suggest amendments you feel would improve them in relation to clarity and focus or simply make a general comment.

We will then revise the theories based on your feedback and test them for verification against a range of interventions identified from a search of the literature. In addition to conventional searches there will be a search of the grey literature, theses, narrative articles and opinion pieces and use of “snowballing” from these sources. We will be particularly searching for sources that might provide more detailed descriptions of the contexts, mechanisms and outcomes of the interventions.

Once we have completed this stage, we will revise the theories once again and send them to you for your final comments.