Psychological interventions for improving adherence to oral hygiene instructions in adults with periodontal diseases

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Psychological interventions for improving adherence to oral hygiene instructions in adults with periodontal diseases (Protocol)

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[Intervention Protocol]

Psychological interventions for improving adherence to oral hygiene instructions in adults with periodontal diseases

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ABSTRACT

This is the protocol for a review and there is no abstract. The objectives are as follows:

The objective of this review is to determine the impact of psychological interventions aimed at improving adherence to oral hygiene instruction in adults with periodontal diseases (including gingivitis and periodontitis).

BACKGROUND

Description of the condition

Periodontal diseases affect the tissues that support teeth. They include gingivitis (inflammation of the gums that is reversible) and periodontitis (more serious inflammation around the tooth that can lead to tooth mobility and even tooth loss).

Gingivitis is the most common form of periodontal disease. The aetiology is mostly bacterial plaque along the gingival margin causing inflammatory changes to the gingiva, with signs of oedema, bleeding and change in colour, without attachment or bone loss (Mariotti 1999). Gingivitis is acknowledged as a reversible condition; when the aetiological cause is eliminated, gingival inflammation resolves, and the gingival tissues revert to a healthy condition (Löe 1965).

Periodontitis is an inflammatory disease that is initiated and perpetuated by the subgingival microbial biofilm, which results in persisting chronic inflammation within the supporting tissues of the teeth, this can lead to progressive attachment loss and bone destruction. The consequences of a periodontal inflammation (i.e. breakdown of the supportive connective tissues and alveolar bone) are generally considered to be irreversible, even when the condition is treated and stabilised. Periodontitis can be diagnosed as chronic or aggressive. Chronic periodontitis is a slow progressing disease with patients sometimes experiencing short periods of rapid exacerbation; it is usually localised, affecting some, not all teeth, and only a small proportion of patients will go on to experience bone loss (Kinane 2006). Aggressive periodontitis is more rare and may

be localised or generalised to involve all of the patient's teeth; it progresses quickly and leads to bone destruction (Tonetti 2006). Periodontitis can have serious consequences and may have a "negative impact upon oral health, quality of life, speech, nutrition, confidence, and overall well-being and is independently associated with several systemic chronic inflammatory diseases" (Chapple 2015). Connections between systemic diseases and periodontitis have been discussed in the literature; an association between periodontitis and diabetes is widely acknowledged (Mealey 2006; Preshaw 2012). It is very likely that oral infection and inflammation represents a risk factor for systemic diseases; hence the control of oral diseases forms part of the prevention and management of these systemic conditions (Seymour 2007).

Estimates from US national surveys show that almost half of American adults may have a form of periodontitis ranging from mild to severe (Eke 2012). In many countries, the population is ageing and periodontitis is a significant and growing healthcare burden, despite continuing improvements in dental care (Steele 2000), with 85% of adults over 65 years old exhibiting clinical attachment loss (Morris 2001). Severe periodontitis is the sixth most common disease globally, with a prevalence of 11.2% (Chapple 2015; Kassebaum 2014). Periodontitis, therefore, represents a substantial public health concern (Chapple 2015; Eke 2012).

For both conditions (gingivitis and periodontitis), oral hygiene self care, i.e. the removal of plaque (biofilm) through toothbrushing, is of utmost importance (Chapple 2015; Magnusson 1984; Silness 1964). While treatment can be carried out by dentists and dental care professionals, any long-term benefit from professional treatment depends upon effective oral hygiene self care by patients.

Description of the intervention

Traditionally, those involved in health promotion have relied on education alone (i.e. raising awareness of a condition) to change behaviours; this has had little success (Gao 2014). Education may raise awareness (in the short term at least) but it does little to help an individual to overcome other barriers to behaviour change. It is known that interventions aimed at changing behaviour have more success if they have been based on theoretical models of behaviour (Abraham 2009), such as the Health Belief Model (Rosenstock 1974). These types of models have been shown to be relevant to oral hygiene behaviour (Renz 2009). However, these models can be rigid and much repetition of psychological constructs exists across them (Lippke 2008). It may therefore be more helpful to focus on the constructs that make up the models rather than the models themselves. This approach is supported by a review that investigated the effect of psychological constructs (from a number of theoretical models) on oral hygiene instruction (Newton 2015). This review found evidence to suggest that the constructs, 'perceived benefits' of the target behaviour, and 'self efficacy' (confidence in one's ability to carry out the target behaviour) were able to predict whether a behaviour was enacted (Newton 2015).

This review will consider any intervention that aims to improve oral health by increasing adherence to oral hygiene instruction. Oral hygiene instruction refers to advice about regular tooth brushing, flossing, interdental cleaning or any other action taken by a person to control the level of plaque in their mouth. The interventions themselves may raise awareness of oral hygiene, teach skills, provide support or generally encourage participants to establish oral hygiene routines and adhere to these in the longer term.

Interventions to be included in this review may support participants to improve health behaviours though the use of behaviour change techniques (BCTs). BCTs are linked to theoretical constructs such as perceived benefits or self efficacy. A BCT is defined as "an observable, replicable, and irreducible component of an intervention designed to alter or redirect causal processes that regulate behavior" (Michie 2013). That is to say, BCTs are the 'active components' of an intervention (Michie 2015). Michie 2013 has created a taxonomy of 93 BCTs; examples include goal setting, positive reinforcement and social support. The use of BCTs in oral hygiene instruction is likely to improve adherence and make routines easier to establish.

The previous version of this review included interventions if they were designed using one of the established theoretical models (Renz 2007). In this version of the review, we plan to include any interventions that aim to increase periodontal patients' adherence to oral hygiene advice, regardless of the theoretical processes involved. Once included, we will describe and classify each intervention using the Michie 2013 taxonomy. This will broaden the scope of the review, allowing for the inclusion of interventions not reported as being based on a theoretical model, and therefore facilitating an assessment of a greater breadth of evidence. Additionally, the BCT classification process will allow for a deeper understanding of the active processes used in the interventions, and identify which of these are effective for increasing adherence to oral hygiene instruction.

How the intervention might work

A psychological intervention may work through changing clinician knowledge (what the clinician should include in advice, how advice should be delivered) or patient knowledge (what, how and when the patient should perform an oral health routine). It may also work by influencing other possible mediators of clinician or patient behaviour derived from theoretical framework(s), for example, motivation (theory of planned behaviour; Ajzen 1991), confidence (social cognitive theory; Bandura 2012), planning (implementation intention theory; Sheeran 2005) or habit (learning theory; Bouton 2007). Psychological interventions may incorporate a number of BCTs to influence identified mediating constructs derived from theoretical models.

The long-term success of periodontal treatment rests heavily on the performance of regular self care in the form of an oral hygiene routine. Oral hygiene interventions may therefore focus on helping

the clinician provide appropriate oral hygiene advice in a way that will enable participants to implement that advice. They also may be aimed at influencing the participant's performance of any one or more of the specific behaviours that constitute an evidence-based oral hygiene routine (e.g. using a powered toothbrush effectively, brushing regularly etc).

Why it is important to do this review

The Cochrane Oral Health Group undertook an extensive prioritisation exercise in 2014 to identify a core portfolio of titles that were the most clinically important ones to maintain on the Cochrane Library (Worthington 2015). Consequently, this review was identified as a priority title by the periodontal expert panel (Cochrane OHG priority review portfolio).

There is a well acknowledged need for, and desire by clinicians, to support patients to adhere to oral hygiene advice and take responsibility for their self care (Fox 2010). While a survey of how dentists deliver prevention advice identified specific barriers around implementing evidenced-based guidelines, it did not focus on dentists' skills around delivering behaviour change (Witton 2013). This review is needed to help identify effective theories and elements for an informative evidence base that could be applied to this issue. The review results would also be applicable across different outcomes as the paradigm shift away from restorative to preventive practice in all of dentistry means that there is need for evidence-based guidance about how best to work collaboratively with patients to follow good oral health advice.

In addition to the clinical need for evidence on the effectiveness of interventions aimed at improving adherence to oral hygiene instruction, this review will be the first to attempt to code the BCTs within interventions around adherence to oral hygiene instruction for adults with periodontal diseases. This systematic approach to identifying intervention components will help to inform future intervention designs. This approach to coding interventions using BCT taxonomies has been used in previous Cochrane reviews of interventions (for example, Cooper 2013 and Pal 2013).

OBJECTIVES

The objective of this review is to determine the impact of psychological interventions aimed at improving adherence to oral hygiene instruction in adults with periodontal diseases (including gingivitis and periodontitis).

METHODS

Criteria for considering studies for this review

Types of studies

We will include randomised controlled trials (RCTs) of parallel design. We will also include cluster-RCTs, where the unit of randomisation is at the level of a group. We will only include cluster trials using interventions that are carried out chairside by clinicians if randomisation occurs at the level of the clinician. This is to ensure against learned effects that could be carried over from the intervention group to the control group by the clinician. We will exclude all other study designs at the point of screening. Cross-over trials are inappropriate for this review because of the potential for carry-over or learned effects.

Types of participants

Participants will be adults (aged 18 years and over) diagnosed with periodontal disease. Diagnosis will have been made by a clinician and both diagnoses of gingivitis and periodontitis (including chronic and aggressive forms of periodontitis of varying extents and severity) will be included. We will consider all types of participants, including those at higher risk of periodontal diseases (including gingivitis and periodontitis) such as pregnant women, smokers and people with diabetes. Participants may also be clinicians, whereby the intervention attempts to change the behaviour of members of the dental team in order to improve periodontal patient outcomes.

Types of interventions

It is acknowledged that psychological interventions are wide-ranging and encompass a variety of approaches including cognitive, behavioural, emotional focused and counselling techniques. The focus of this review however, will primarily be on behavioural interventions. These interventions seek to change behaviour using evidence-based behaviour change techniques (BCTs). Usually the targets of BCTs are taken from psychological theories of behaviour, which identify possible mediators of behaviour change, for example, knowledge, beliefs (e.g. attitude, motivation) or emotions. This was the focus of the earlier version of this review (Renz 2007). However, many theories have mediators in common, and it is possible that interventions have been designed to change a common theoretical mediator without specifying a theoretical derivation. A broader approach may capture these studies. The focus of this review will be interventions aimed at changing patients' oral health behaviours; we will consider any intervention with this aim for inclusion whether or not it contains BCTs. We will code interventions for BCTs using the BCT taxonomy (Michie 2013). In addition, we will code interventions using the COMPASS checklist (Hodges 2011). The COMPASS checklist offers a systematic way in which to describe interventions by specified domains (content, mechanism, outcome, mode of delivery).

Types of outcome measures

Outcome measures for this review will primarily be clinical markers of periodontal health with measures of behaviour change as secondary outcomes.

Primary outcomes

- Bleeding on probing or gingivitis score
- Any other clinical markers of periodontal diseases (for example, plaque score, probing depths, clinical attachment loss, recession, BPE (basic periodontal examination) scores

Secondary outcomes

- Self reported measures of oral health-related behaviour
- Self reported beliefs about and attitudes to oral health-related behaviour

Search methods for identification of studies

To identify studies for this review, we will develop detailed search strategies for each database to be searched. These will be based on the search strategy developed for MEDLINE (see Appendix 1), but revised appropriately for each database to take account of differences in controlled vocabulary and syntax rules. We will use a combination of controlled vocabulary and free text terms. The search strategy will combine the subject search with the Cochrane Highly Sensitive Search Strategy (CHSSS) for identifying randomised trials in MEDLINE: sensitivity maximising version (2008 revision) as referenced in Chapter 6.4.11.1 and detailed in box 6.4.c of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011).

In the search we will attempt to identify all relevant studies, irrespective of language or date. We will translate non-English papers.

Electronic searches

We will search the following databases.

- The Cochrane Oral Health Group Trials Register (to date).
- The Cochrane Central Register of Controlled Trials (CENTRAL) (current issue).
- MEDLINE via OVID (1946 to date) (see Appendix 1).
- EMBASE via OVID (1980 to date).
- PsycINFO via OVID (1806 to date).
- Web of Science (limited to Conference Proceedings) (1990 to date).

Searching other resources

We will identify ongoing trials by searching the following trials registries.

- US National Institutes of Health Trials Registry (http://clinicaltrials.gov).
- The WHO International Clinical Trials Registry Platform (http://apps.who.int/trialsearch/default.aspx).

Data collection and analysis

Selection of studies

At least two review authors will independently screen all titles and abstracts retrieved by the search to select studies for this review, and any discrepancies will be discussed by the review team. We will obtain full-text articles for all titles marked either as potential includes or unclear and a screening tool will be used by at least two review authors to assess these articles for inclusion. We will resolve any disagreements by discussion among the review team.

Data extraction and management

We will develop a data extraction tool for this review and this will be piloted by the review team, after which any necessary alterations will be made. At least two review authors will independently conduct data extraction. We will translate study reports in languages other than English through translators connected to the Cochrane Oral Health Group.

From each of the included studies, we will extract the following details.

1. Trial methods: (a) method of allocation; (b) blinding of participants and outcomes; (c) exclusion of participants after randomisation and proportion of losses at follow-up.
2. Setting and when the trial was conducted.
3. Participants: (a) country of origin; (b) sample size; (c) age; (d) gender; (e) inclusion and exclusion criteria (type and severity of periodontal disease, risk factors such as smoking or diabetes and whether pregnant women are excluded).
4. Interventions (and control condition where applicable): (a) exposure to the intervention, for example number of sessions; (b) we will code information about the techniques used in the intervention according to the most recent taxonomy of BCTs (Michie 2013); (c) we will describe interventions using the COMPASS checklist (Hodges 2011).
5. Outcomes: primary and secondary outcomes as outlined in the Types of outcome measures section of this protocol. We will report the longest-term data available.
6. Any adverse effects documented.

We will record the sources of funding of any of the included studies, if provided.

We will use this information to assess the clinical diversity of included studies and generalisability of the findings. We will attempt to retrieve any missing data from the original authors. We will dis-

cuss any disagreements and, if necessary, consult with other members of the review team to resolve inconsistencies.

Assessment of risk of bias in included studies

Two review authors will independently assess the risk of bias of the included studies using a simple contingency form following the domain-based evaluation described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). We will then compare and discuss our independent evaluations, and resolve any disagreements through discussion. If necessary, we will consult a third review author to resolve any disagreements.

We will assess the domains of:

1. sequence generation (selection bias);
2. allocation concealment (selection bias);
3. blinding of participants and personnel (performance bias);
4. blinding of outcome assessors (detection bias);
5. incomplete outcome data (attrition bias);
6. selective outcome reporting (reporting bias); and
7. other bias.

In terms of blinding, the participant and the intervention provider will generally know which group the participant has been randomised to, however the outcome assessor may be blinded.

We will categorise the overall risk of bias of individual studies according to:

- low risk of bias (plausible bias unlikely to seriously alter the results) if all domains are at low risk of bias;
- unclear risk of bias (plausible bias that raises some doubt about the results) if one or more domains has an unclear risk of bias; or
- high risk of bias (plausible bias that seriously weakens confidence in the results) if one or more domains is at high risk of bias.

Measures of treatment effect

For dichotomous outcomes (for example, flossing or not), we will express the estimate of effect of a psychological intervention as a risk ratio (RR) together with 95% confidence interval (CI). For continuous outcomes, we will use means and standard deviations to summarise the data for each group using mean differences and 95% CIs. We will calculate standardised mean differences for outcomes using different tools to measure the same outcome, e.g. gingivitis/plaque scales.

Unit of analysis issues

This review will include both RCTs and cluster-RCTs, therefore within the analysis, we will take into account the level at which randomisation takes place. Where appropriate, we will use intracluster correlation coefficients to estimate the variability between and within clusters as detailed in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011) .

Dealing with missing data

Where data are missing from published reports, we will attempt to retrieve the information from the original study authors. Where data are missing and cannot be obtained, we will use methods for estimating missing standard deviations as described in section 7.7.3 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011).

Assessment of heterogeneity

If a sufficient number of studies are included in any meta-analyses, we will assess clinical heterogeneity by examining the characteristics of the studies, and the similarity between the types of participants, the interventions and the outcomes, as specified in the criteria for included studies. We will assess statistical heterogeneity using a Chi^2 test and quantify it using the I^2 statistic, where I^2 values over 50% indicate moderate to high heterogeneity (Higgins 2003). We will consider heterogeneity statistically significant if the P value is less than 0.10 for the Chi^2 test.

Assessment of reporting biases

If a sufficient number of studies are included in any meta-analyses, we will assess publication bias according to the recommendations on testing for funnel plot asymmetry (Egger 1997), as described in section 10.4.3.1 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). If asymmetry is identified, we will assess other possible causes as well.

Data synthesis

We will conduct meta-analysis only if there are studies of similar comparisons, reporting similar outcome measures. We will combine RRs for dichotomous data, and mean differences or standardised mean differences for continuous data, using random-effects models if there are at least four studies in a meta-analysis; we will use fixed-effect models if there are less than four studies and if heterogeneity is reasonably low.

Subgroup analysis and investigation of heterogeneity

We plan to conduct subgroup analysis by:

1. age, i.e. 18 to 30 years versus 30+;
2. number or combinations of BCTs;
3. exposure to the intervention, i.e. intensity of intervention;
4. disease type, i.e. periodontitis or gingivitis.

Sensitivity analysis

If a sufficient number of studies can be included in any meta-analyses, we will undertake sensitivity analyses to assess the robustness of the results by excluding studies with an unclear or high risk of overall bias.

Summarising findings and assessing the quality of the evidence

We aim to develop a 'Summary of findings' table for each comparison and for the following outcomes: bleeding on probing, gingivitis score, plaque score, clinical attachment loss, recession and self reported oral health related behaviour, following GRADE methods (GRADE 2004), using GRADEProGDT software (GRADEproGDT 2015). We will assess the quality of the body of evidence with reference to the overall risk of bias of the included studies, the directness of the evidence, the consistency of the results, the precision of the estimates and the risk of publication bias. We will categorise the quality of the body of evidence for each of the main outcomes for each comparison as high, moderate, low or very low.

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* *Indicates the major publication for the study*

APPENDICES

Appendix 1. MEDLINE (OVID) search strategy

1. exp Behavior therapy/
2. Health education, dental/
3. Patient education as topic/
4. self efficacy/
5. Motivation/
6. Cues/
7. exp Health behavior/
8. Attitude to health/
9. Health knowledge, attitudes, practice/
10. Intention/
11. Motivational interviewing/
12. Goals/
13. exp Reinforcement, psychology/
14. Social support/
15. Habits/
16. Problem solving/
17. (psycholog$ or psychosocial or "cognitive therap$").ti,ab.
18. ((oral or dental) adj5 (educat$ or teach$ or train$)).ti,ab.
19. ((behav$ or conditioning or reinforc$ or reward$ or motivat$) adj5 (demonstrat$ or modif$ or chang$ or compliance or comply or adher$ or cooperat$ or co-operat$ or perform$)).ti,ab.
20. (intent$ or incent$ or cue$ or prompt$ or goal$ or "behavioural contract$" or "motivational interview$" or self-monitor$ or self-regulat$ or biofeedback or habit$).ti,ab.
21. (problem$ adj3 solv$).ti,ab.
22. (action adj plan$).ti,ab.
23. (social adj comparison$).ti,ab.
24. (role adj model$).ti,ab.
25. (graded adj task$).ti,ab.
26. (social adj support).ti,ab.
27. (mental adj rehearsal$).ti,ab.
28. or/1-27
29. exp Oral hygiene/
30. Oral health/
31. exp Periodontal diseases/
32. exp Periodontics/
33. (periodont$ or gingiv$).ti,ab.
34. exp Dental health surveys/
35. (toothbrush$ or tooth-brush$ or floss$).ti,ab.
36. ((dental or oral or mouth or interdental or interproximal) adj3 (irrigat$ or clean$ or brush$ or clens$)).ti,ab.
37. exp Dentifrices/
38. exp Mouthwashes/
39. (dentifrice$ or mouthwash$ or mouthrins$ or mouth-wash$ or mouth-rins$).ti,ab.
40. ((oral or dental) adj2 (hygiene or care)).ti,ab.
41. (plaque$ adj5 (remov$ or control$)).ti,ab.
42. Dental plaque/
43. or/29-42
44. 28 and 43

The above subject search will be linked to the Cochrane Highly Sensitive Search Strategy (CHSSS) for identifying randomized trials in MEDLINE: sensitivity maximising version (2008 revision) as referenced in Chapter 6.4.11.1 and detailed in box 6.4.c of *The Cochrane Handbook for Systematic Reviews of Interventions,* Version 5.1.0 [updated March 2011] (Higgins 2011).

1. randomized controlled trial.pt.
2. controlled clinical trial.pt.
3. randomized.ab.
4. placebo.ab.
5. drug therapy.fs.
6. randomly.ab.
7. trial.ab.
8. groups.ab.
9. or/1-8
10. exp animals/ not humans.sh.
11. 9 not 10

CONTRIBUTIONS OF AUTHORS

All authors were involved in the development and writing up of the protocol. Health psychology expertise was provided by Debbie Bonetti (DB) and Pauline Adair (PA) and clinical expertise was provided by Pia-Merete Jervøe-Storm (PJ-S) and Philip Preshaw (PP).

Co-ordination of review: Lucy O'Malley (LO).

Identification of studies: LO, DB, PA, PJ-S, PP.

Data extraction: LO, DB, PA, PJ-S, PP.

Assessment of risk of bias: LO, DB, PA, PJ-S, PP.

Data input and analysis: LO.

Writing of discussion and conclusions: LO, DB, PA, PJ-S, PP.

DECLARATIONS OF INTEREST

Lucy O'Malley: none known.

Debbie L Bonetti: none known.

Pauline Adair: none known.

Pia-Merete Jervøe-Storm: none known.

Philip M Preshaw: Prof Preshaw is a member of an advisory panel for Colgate Palmolive (Europe), with consultancy fees paid by Colgate to Newcastle University for this role.

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- Cochrane Oral Health Group Global Alliance, Other.

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