

Title: A systematic review to assess the effectiveness of interventions delivered by mobile phones in improving adherence to oral hygiene advice for children and adolescents

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ABSTRACT:

Background: Mobile phones are potentially an invaluable tool in addressing the global challenge associated with dental caries as they may elicit behaviour change by incorporating numerous behaviour change techniques to address an individual's capability, opportunity and motivation. **Methods:** The methodology for this review is published on the PROSPERO database. **Results:** Two randomised controlled trials were included, both were undertaken with orthodontic patients and both reported significantly reduced plaque scores in the intervention group compared with the control at final follow-up. One study also reported statistically significantly lower gingival bleeding scores and caries in the intervention group at final follow-up. The risk of bias was 'unclear' for both studies and neither study intervention appeared to be based on specific theories of behaviour change. Of 93 BCTs available, only six were utilised across the two trials. The overall strength of evidence for the effectiveness of mobile phones in reducing plaque score was rated as moderate using GRADE, the effectiveness in reducing bleeding scores was considered to be high. **Conclusion:** There is some evidence that mobile phones are effective in improving adherence to oral hygiene advice in orthodontic patients. The generalisability of this review is limited due to the small number of trials and the unclear risk of bias of included studies.

In brief:

- The available evidence suggests that mobile phones may be effective in improving adherence to oral hygiene advice.
- There is a need to design mobile phone interventions that are grounded in behaviour change theory to explore this concept further.
- Given the rapid proliferation of apps and other online information targeted at patients there is a need to assess quality and effectiveness of these resources and navigate patients towards the most appropriate ones.

INTRODUCTION:

Dental caries is almost entirely preventable, however, globally it affects 60-90% of school-aged children⁽¹⁾. In 2013, a national survey (England, Wales and Northern Ireland) reported a 28% prevalence of dental caries among 5-year old children.⁽²⁾

The management of extensive decay in young children is often under general anaesthesia and dental caries is now the most common reason for admission to NHS hospitals in England for 5-9 year olds⁽³⁾. Repeat episodes of dental general anaesthetic are reported to be between 4.2% and 17.0%^(4, 5). Furthermore, general anaesthesia carries risks to health and is costly, often necessitating time off school for children and time away from work for their parents. Recent research has shown that children who have received a dental general anaesthetic are over 2.5 times more likely to be dentally anxious in their late teens than those who have not⁽⁶⁾. There are then implications associated with this in that dental anxiety often leads to avoidance of dental care and allows for dental disease to progress, causing irreversible damage.

The Royal College of Surgeons of England has identified dental caries and dental general anaesthesia as major healthcare challenges. The need for Public Health England to invest in programmes to improve children's oral health was also at the forefront of recommendations made by the college to the Chief Dental Officer.⁽⁷⁾ Given that diet and oral hygiene are key components in the aetiology of dental caries, approaches to affect a change in diet and oral hygiene related behaviours are essential to address this global challenge. Traditionally, approaches to improve oral health behaviour have aimed to increase patient knowledge, however, at present there is weak evidence that improvements in knowledge lead to improved oral health behaviour.⁽⁸⁾ Conversely, there is evidence supporting the use of interventions developed using psychological behaviour change models to improve oral health.⁽⁸⁾ Although

many models of behaviour change exist, a contemporary and widely accepted framework is the Behaviour Change Wheel (BCW). Developed by Michie et al⁽⁹⁾, the BCW is a theoretical framework based on multiple models of behaviour change. The COM-B model forms the core of this and proposes that individuals require capability (C), opportunity (O) and motivation (M) to perform or adapt a particular behaviour (B). Available evidence shows that interventions based on behaviour change theory and those with more behaviour change techniques (BCTs) are more effective than those that are not based on theory and with fewer BCTs.⁽¹⁰⁾ BCTs are defined as ‘the smallest identifiable components that in themselves have the potential to change behaviour’⁽¹¹⁾; 93 BCTs have been identified and categorised in the BCT taxonomy V1⁽¹²⁾.

Mobile phones may be invaluable tools in delivering interventions developed using behaviour change theory. This technology allows for several approaches to be utilised simultaneously in order to address an individual’s capability, opportunity and motivation in a cost-effective manner. Mobile phones are readily available, with some sources reporting 100% penetrance in Western Europe⁽¹³⁾. Moreover, they are very versatile, for example, they can also be utilised to provide personalised treatment information, such as appointment and toothbrushing reminders at times which are convenient to the patient. A scoping review of the literature revealed that a number of randomised controlled trials assessing the effectiveness of mobile phones in improving adherence to treatment advice had been reported. Notably, evidence is emerging to suggest that apps and mobile phone-based reminders are effective in improving oral health.^{(14,}

15)

The aim of this systematic review was therefore to assess the effectiveness of interventions delivered by mobile phones in improving adherence to oral hygiene advice for children and adolescents.

Objective:

A systematic review of randomised controlled trials to determine the effectiveness of interventions delivered by mobile phones *versus* other interventions not using mobile phones in improving adherence to oral hygiene advice for children and/or adolescents.

Methods

The methodology for this systematic review including, criteria for considering studies eligible for inclusion, the outcomes assessed, settings, information sources, data management, analysis and proposed synthesis was registered online on the PROSPERO database in November 2017: CRD42017078414.

Protocol changes:

The registered protocol initially included ‘children aged 10 to 17 years (inclusive)’, however, an initial screening of the results highlighted that a number of studies included patients up to the age of 18 years. To maximise the potential studies for inclusion it was decided to amend the inclusion criteria to allow inclusion of individuals aged 10 to 18 years (inclusive).

Results:

The search of databases (up to 18th January 2018) retrieved 524 titles and abstracts and, after removing duplicates, 516 were eligible for screening. The titles and abstracts were screened independently by MOS and SJC and categorised as: ‘include’, ‘exclude’ or ‘uncertain’. A weighted Kappa score demonstrated the overall level of agreement to be ‘good’ ($K = 0.664$). There was 100% agreement for the records for ‘inclusion’, the full texts of these studies and those studies categorised as ‘uncertain’ were obtained for further assessment. After assessing nine full texts, two studies were eligible for inclusion and seven were excluded.

No additional studies were identified on the ClinicalTrials.gov or the World Health Organization International Clinical Trials Registry Platform, the reference list screening of

included studies, communication with experts in the field or communication with contact authors. Figure 1 presents a flow diagram for the review.

The searches were updated on 18th December 2018, no additional studies were identified.

Included studies

Two studies were included in this review^(16, 17), one study explored the use of text messages⁽¹⁶⁾ and the other explored the use of an App⁽¹⁷⁾. Both of these studies exclusively recruited orthodontic treatment patients. Table 1 presents characteristics of the included studies and summarises details of the design, methods, participants, interventions, comparisons and outcome measures.

Characteristics of the trial settings and investigators

The Bowen et al. trial⁽¹⁶⁾ was conducted in the Seton Hill University Centre for Orthodontics, USA but the providers of care were not stated. The contact author was contacted by email to obtain clarification, but no response has been received to date.

The setting and care providers were not stated in the Zotti et al. paper⁽¹⁷⁾, however, communication with the contact author confirmed that the study was performed in a dental hospital setting with second and third-year orthodontic postgraduates, supervised by clinical instructors, providing patient care.

Characteristics of trial participants

The total number of participants across the included studies was 130. One hundred and twenty participants completed all follow-up assessments. The mean age of participants in the Bowen et al.⁽¹⁶⁾ and Zotti et al.⁽¹⁷⁾ trials was 15.1 and 13.9 years respectively. More females were recruited in each of the studies, both study samples comprised 58% females and 42% males.

There was some heterogeneity between the included trials, Bowen et al.⁽¹⁶⁾ included participants aged 10-18 years of age whereas Zotti et al.⁽¹⁷⁾ included participants aged 12-17 years of age. Bowen et al.⁽¹⁶⁾ stated that participants were included if they had maxillary fixed appliances and had at least six months of treatment remaining which suggests that participants were in active treatment prior to enrolment in the study. However, Zotti et al.⁽¹⁷⁾ recruited participants prior to commencing treatment.

Characteristics of interventions

The interventions and follow-up periods varied between the two included studies. Bowen et al.⁽¹⁶⁾ provided participants in the intervention group with automated text messages two to three times a week for 4 weeks and followed participants up for 3 months. Zotti et al.⁽¹⁷⁾ provided participants in the intervention group with access to smartphone-specific video tutorials and a chat room as outlined in Table 1 and participants were followed up for 12 months.

In the Bowen et al. trial⁽¹⁶⁾ all participants watched an audio-visual presentation on how to brush with a conventional toothbrush (using the Bass technique). In the Zotti et al.⁽¹⁷⁾ trial all participants received standardized oral hygiene instructions along with toothpaste, toothbrush, mouthwash, interdental brush, dental floss, and plaque-disclosing tablets.

None of the interventions were reported to have been developed based on a specific theory of behaviour change.

Characteristics of outcome measures

Both studies reported plaque scores, however, there was heterogeneity as the method of plaque assessment differed. Bowen et al.⁽¹⁶⁾ utilised planimetry which provides the percentage of plaque coverage on each tooth, whereas Zotti et al.⁽¹⁷⁾ utilised the plaque index, scoring 0 to 3 for each surface, and subsequently calculated the overall mean. It was therefore not possible to combine the data in a meta-analysis.

Zotti et al.⁽¹⁷⁾ also reported bleeding scores and caries. Neither of the included studies reported adverse events, cost effectiveness or patient preferences.

Excluded studies

Seven studies were excluded and the reasons for exclusion are as follows:

- Patients were not the focus of the intervention⁽¹⁸⁻²⁰⁾
- Mobile phones were not used to deliver the intervention^(21, 22)
- Patients over the age of 18 years were included⁽²³⁾, the authors were contacted to determine whether data was available for adolescents only but to date no response has been received

- Inadequate follow up period⁽²⁴⁾

Ongoing studies

Two potentially relevant studies are currently ongoing and were identified by contact with experts in the field. However, no data is available as yet. The protocol for one of these studies has been published⁽²⁵⁾, the results of this study may be appropriate for inclusion when they become available.

Risk of bias in included studies (Cochrane risk of bias tool)⁽²⁶⁾:

Review Manager 5.3 was used to aid with presentation of the risk of bias. The risk of bias assessment for each of the included studies is included in Table 2 and Table 3. The risk of bias graph and summary are presented in Figures 2 and 3.

Allocation:

Sequence Generation and allocation concealment:

Random sequence generation and allocation concealment were assessed to be at unclear risk for Bowen et al.⁽¹⁶⁾ as insufficient detail was present to make a clear judgement and it has not been possible to obtain further information. The Zotti et al.⁽¹⁷⁾ study was considered to be at low risk of bias, the authors reported using a stratified randomisation list produced by an external office which was contacted by the researchers to determine patient allocation.

Blinding:

Blinding of participants was judged to be a low risk for Bowen et al.⁽¹⁶⁾, the authors reported that patients were not aware that messages were part of the study. The Zotti et al.⁽¹⁷⁾ study was deemed to be at unclear risk of bias, however, it is appreciated that given the nature of the study it was not possible to blind subjects.

Blinding of outcome assessment was considered to be an unclear risk for Bowen et al.⁽¹⁶⁾ as the authors did not specify any measures taken to allow for this. The Zotti et al.⁽¹⁷⁾ study was deemed to be at low risk of bias in this domain, the authors reported blinding.

Incomplete outcome data:

This domain was judged as an unclear risk for the Bowen et al.⁽¹⁶⁾ study as there were some inconsistencies regarding the flow of patients through this trial (detailed in Table 1). There

were no drop outs reported in the Zotti et al.⁽¹⁷⁾ study and therefore this was deemed to be at low risk of bias.

Selective reporting:

Selective reporting was considered to be at unclear risk for both Bowen et al.⁽¹⁶⁾ and Zotti et al.⁽¹⁷⁾.

Other sources of bias:

Bias from other sources was deemed to be an unclear risk for Bowen et al.⁽¹⁶⁾ and as low risk for Zotti et al.⁽¹⁷⁾.

Overall assessment of bias:

All domains had to be assessed as being at low risk of bias for the study to be considered low risk of bias overall, both studies were therefore considered as being at unclear risk of bias overall.

The COM-B components and behaviour change techniques in included studies

In both studies, capability, opportunity and motivation were addressed to some degree and the BCTs used for this varied between studies. The results are summarised in Table 4 and some examples are provided to support the judgements made in the review.

Effects of interventions:

Plaque scores

For both studies, plaque scores were statistically significantly lower in the intervention group when compared with the control group at the final follow-up, however, the final follow-up time point differed between studies. Bowen et al.⁽¹⁶⁾ followed patients up for a maximum of 3 months (T0: baseline, T1: 1 month and T2: 3 months) and Zotti et al.⁽¹⁷⁾ followed patients up for 12 months (T0: baseline, T1: 3 months, T2: 6 months, T3: 9 months and T4: 12 months).

Bowen et al.⁽¹⁶⁾ reported significantly less plaque accumulation in the intervention group at one month and three months. Interestingly, Zotti et al.⁽¹⁷⁾ reported no statistically significant difference in plaque scores between the intervention and control groups at 3 months, the difference was evident only from 6 months onwards ($p < 0.01$).

Gingival bleeding scores

Only the Zotti et al.⁽¹⁷⁾ study reported gingival bleeding scores. There was no significant difference at baseline or 3 months between the intervention and control groups, however, at 6, 9 and 12 months there was significantly less gingival bleeding in the intervention group ($p < 0.05$ for all three timepoints).

Caries

Only the Zotti et al.⁽¹⁷⁾ study reported caries and there was no statistically significant difference in white spot lesions at baseline, 3 months or 6 months. However, at 9 and 12 months, patients in the intervention group were significantly less likely to have white spots than the control group ($p < 0.05$ for both time points).

Summary

The results of the studies were not pooled as the content and delivery of interventions was different. Both studies reported plaque scores, however, the method of plaque assessment differed and therefore it was not possible to combine these scores in a meta-analysis.

Overall strength of evidence:

The overall strength of evidence for the effectiveness of mobile phones in reducing plaque scores as rated by GRADE⁽²⁷⁾ was considered to be moderate and the effectiveness of mobile phones in reducing bleeding scores was considered to be high. The results of the GRADE assessment are summarized in Figure 4.

Discussion

The studies included in this review were exclusively aimed at supporting orthodontic patients, because excellent oral hygiene is a pre-requisite for orthodontic treatment the results obtained cannot necessarily be generalised to the dental population as a whole. Although the interventions in both studies were delivered via a mobile phone, the content varied with one trial providing text messages⁽¹⁶⁾ and the other utilising video tutorials and a chatroom. Both studies were deemed to be at 'unclear risk of bias' overall.

The results indicated that there is some evidence to suggest that the use of mobile phones is effective in improving adherence to oral hygiene advice. These findings are consistent with recently published systematic reviews assessing the effectiveness of reminders (including the use of mobile phones to deliver these) in improving the oral hygiene of orthodontic patients.^(15, 28)

Overall completeness, quality and applicability of evidence

The overall strength of evidence for the effectiveness of mobile phones in reducing plaque scores, as rated by GRADE⁽²⁷⁾, was considered to be moderate. The effectiveness of mobile phones in reducing bleeding scores was considered to be high. However, the generalisability of this review is limited due to the inclusion of only two trials which were focused solely on orthodontic patients and their unclear risk of bias. Only one of the outcomes assessed was the same in both studies (plaque score) and the method of outcome assessment differed, therefore meta-analysis was not appropriate. In addition, the duration of follow-up differed in the two studies and neither study followed patients up for the whole duration of their orthodontic treatment.

Behaviour change techniques utilised

Neither of the interventions were reported to have been developed based on a specific theory of behaviour change. This highlights a significant area for future research given that the available evidence suggests interventions based on behaviour change theory and those with more BCTs are more effective than those that are not based on theory and have fewer BCTs.^(10, 27) Interestingly from the 93 BCTs available, only six were utilised across the two trials to address psychological capability, physical and social opportunity, and automatic and reflective motivation to some degree.

Implications for practice and future research:

Neither of the included studies reported utilising digital interventions that were designed using a ‘ground up’ approach with patient and professional engagement. However, given that there is now some evidence in support of digital interventions the next stage should be to develop comprehensive behaviour change interventions based on behaviour change theory. In addition to the BCTs identified in this review, incorporation of others such as ‘feedback on outcomes

of behaviour' (2.7) and 'self-monitoring' (2.3) would seem logical given their potential role for influencing adherence.

The maximum follow-up period identified in this review was 12 months, however, the aim of an intervention designed to improve adherence to oral hygiene advice would be to sustain change over much longer periods, preferably a lifetime. Therefore, future research also has a role in exploring the impact of digital interventions in terms of prolonged behaviour change.

This review has highlighted that there is significant heterogeneity in regards to outcome measures and interventions utilised in the current literature, additionally there the risk of bias in the included studies is unclear. There is an increasing trend in the use of mobile phone technology, more specifically Apps in supporting patients with healthcare. In July 2018 a screening search of apps relating to oral hygiene on the Apple App store and Google Play store retrieved 1,075 potential apps for inclusion.²⁹ A detailed assessment of 20 apps for each search term utilised in this screening search revealed that the majority were developed after 2015, focused on the provision of oral hygiene information and were frequently free of charge. There was no indication of independent dental or oral health organisation approval or testing of effectiveness and acceptability for any of the apps. Given this availability there is a need for practitioners to assess the quality and content of information available to patients and to navigate patients towards high quality, effective apps/resources to support them with their oral hygiene practices. A judgement must then be made in regards to recommending or guiding patients towards appropriate information resources to support their oral health. Furthermore, there is a need to assess mobile interventions utilising robust randomised controlled trial methodology including a core outcome set related to oral hygiene. This will help to ensure that results of future studies may be synthesised in future systematic reviews.

Conclusions:

There is some evidence to suggest that mobile phones are effective in improving adherence to oral hygiene advice in orthodontic patients. However, the generalisability of this review is limited as the included studies were exclusively aimed at supporting orthodontic patients and were associated with an unclear risk of bias.

In the short term, given the rapid proliferation of apps and other online information aimed at improving oral hygiene, there is a need to assess quality and effectiveness of these resources as this will help dental professionals navigate patients towards effective resources.

In the medium to long term, this review suggests the need to develop mobile phone interventions grounded in behaviour change theory; using core outcomes to allow for meta-analysis, and assessment of cost effectiveness. Future studies should utilise a core outcome set related to oral hygiene and explore outcomes related to patient satisfaction and engagement with the technologies being tested, this may help to identify features of successful digital interventions.

Declarations:

Ethics approval and consent to participate

Not applicable.

Consent for publication:

Not applicable.

Availability of data and material:

Not applicable.

Competing interests:

The authors declare there are no competing interests.

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Authors contributions:

MOS, TN and SJC conceived the study, assisted in its design and developed the original protocol, conducted the review and developed this manuscript. The Guarantor of the review is MOS.

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	Study 1: Bowen et al.⁽¹⁶⁾	Study 2: Zotti et al.⁽¹⁷⁾
Methods	<p>Study design: A randomised, controlled, parallel-group trial.</p> <p>Sample size calculation: ‘The power analysis showed that our sample size was sufficient enough to achieve a power of 80% and maintain a type I alpha risk of .05’.</p> <p>Setting: Seton Hill University Centre for Orthodontics, Greensburg, Pennsylvania, USA.</p> <p>Number of centres: 1</p> <p>Operators: Not stated</p> <p>Recruitment period: June 2013 – June 2014</p> <p>Maximum follow up: 3 months</p> <p>Funding source: None stated</p> <p>Declarations of interest: None stated</p>	<p>Study design: A randomised, controlled, parallel-group.</p> <p>Sample size calculation: ‘An a priori sample size (n) calculation, with the periodontal indices as the main outcomes, was performed, fixing a power of 90%...α of 5% ($Z_{\alpha/2}$ 5 1.96...’</p> <p>*Setting: School of Dentistry, University of Brescia, Italy.</p> <p>*Number of centres: 1</p> <p>*Operators: Not stated</p> <p>Recruitment period: Not stated</p> <p>Maximum follow up: 12 months</p> <p>Funding source: None stated</p> <p>Declarations of interest: None stated</p>
Participants	<p>Inclusion criteria:</p> <ul style="list-style-type: none"> • 10-18 years • Access to a cellular phone • Orthodontic treatment with a fixed maxillary appliance • At least 6 months of treatment (remaining) <p>Exclusion criteria:</p> <ul style="list-style-type: none"> • Not specified <p>Gender: 29 females, 21 males</p> <p>Mean age: 15.1 years. Intervention group = 15.5 years. Control Group: 14.6 years.</p> <p>Age range: Not stated</p> <p>*Number randomised: Intervention Group: 25. Control Group: 25.</p> <p>*Number analysed: Intervention Group: 19. Control Group: 21</p> <p>*Lost to follow up/dropouts: 10 (reasons not given)</p>	<p>Inclusion criteria:</p> <ul style="list-style-type: none"> • Adolescent patients • Scheduled to start orthodontic multibracket treatment • Own a smartphone • Able to be online daily <p>Exclusion criteria:</p> <ul style="list-style-type: none"> • The presence of a significant medical history • A restrictive dietary regimen • Difficulties in reading or speaking the national language <p>Gender: 46 females, 34 males</p> <p>Mean age: Intervention group = 14.1 years. Control Group: 13.6 years</p> <p>Age range: Not stated</p> <p>Number randomised: Intervention Group: 40. Control Group: 40</p>

		<p>Number analysed: Intervention Group: 40. Control Group: 40</p> <p>Lost to follow up/dropouts: 0</p>
Interventions	<p>Both groups watched an audio-visual presentation on how to brush correctly with a conventional toothbrush (the Bass technique).</p> <p>Intervention group: Received automated text messages two to three times a week for 4 weeks (totalling 12 texts) as a reminder and encouragement to practice good oral hygiene.</p>	<p>Both groups received standardized oral hygiene instructions along with toothpaste, toothbrush, mouthwash, interdental brush, dental floss, and plaque-disclosing tablets.</p> <p>Intervention group:</p> <ul style="list-style-type: none"> • Smartphone-specific video tutorials • Individuals given access to a chat room (“Brush Game”). All participants were instructed to share selfies of their teeth weekly, before and after using the plaque-disclosing tablets • Participants were allowed to share information, pictures, and movies regarding oral hygiene and orthodontic treatment • Each Saturday, the moderator visually assessed the patients’ photographs and level of participation in the chat room and then published a ranking of the five best participants of the week
Outcomes	<p>Primary outcome measures:</p> <ul style="list-style-type: none"> • Plaque score: disclosed using Trace Disclosing Solution. Followed by photographs and plaque analysis of four maxillary and four mandibular teeth using planimetry. <p>Secondary outcome measures: None reported</p> <p>Adverse outcomes: No adverse events reported</p>	<p>Primary outcome measures: Unclear</p> <p>The following outcome measures were reported:</p> <ul style="list-style-type: none"> • Plaque Index: scored by evaluating the presence of plaque at four surfaces (mesial, buccal, distal, and lingual) of tooth 1.6, 1.2, 2.4, 3.6, 3.2, and 4.4, assigning a score from 0 to 3 for each surface, and calculating the mean overall value • Gingival Index: scored by evaluating the presence of inflammation on the same teeth as for PI and assigning a score from 0 to 3 as described • Caries: buccal white spot presence on each bonded tooth, scored after 5 seconds of air drying and

		assigned a score from 0 to 3 and extent visually and radiographically evaluated and recorded Adverse outcomes: No adverse events reported
Notes	<p>*In the materials and methods the authors state ‘The text message group was composed of 15 girls and 10 ... while the control group included 14 girls and 11 boys ...’ However, in the results section, the following was stated ‘Twenty subjects were randomly assigned to the text message or control group. Forty subjects completed all study measurements, as two subjects from the control group and three subjects from the text group did not complete T2 measurements.’</p> <p>This led to some confusion regarding the number of patients randomised, analysed and lost to follow up. The author was contacted by email to clarify this and to obtain further information relating to study settings and operators. To date no response has been received.</p>	*The information relating to these sections was not clear from the manuscript, the contact author was contacted by email and kindly clarified these points.

Table 1: Characteristics of included studies

Bias	Authors' Judgement	Support for Judgement
Random sequence generation (selection bias)	Unclear risk	pg. 544: 'Subject group assignment was done by preassigning the first 20 subjects to either the text message or control group'.
Allocation concealment (selection bias)	Unclear risk	Not specified.
Blinding of participants and personnel (performance bias)	Unclear risk	Pg. 544: 'Subjects were blinded as to group status and were not made aware that text messages were part of the study'.
Blinding of outcome assessment (detection bias)	Unclear risk	Not specified.
Incomplete outcome data (attrition bias)	Unclear risk	Fifty patients were consented, however, only data for 40 participants was available for the final analysis. There is some information on drop-outs (two from the control group and three from the intervention), however, this does not equate to 10.
Selective reporting (reporting bias)	Unclear risk	One outcome was described in the manuscript and reported on. However, the study protocol is not available to allow for complete assessment of this domain.
Other bias	Unclear risk	The contact author was contacted by email to clarify inconsistencies in the manuscript and to obtain further information relating to study settings and operators, to date no response has been received.

Table 2: Risk of bias assessment Bowen et al.⁽³⁾

Bias	Authors' Judgement	Support for Judgement
Random sequence generation (selection bias)	Low risk	Pg. 102: '...a stratified randomization list was produced by an external office, <u>taking into account</u> baseline dental health, gender, age, and socioeconomic status.'
Allocation concealment (selection bias)	Low risk	Pg. 102: 'The external office was then contacted for patient allocation to the control group (CG) or study group (SG).'
Blinding of participants and personnel (performance bias)	Unclear risk	It is not possible to blind participants.
Blinding of outcome assessment (detection bias)	Low risk	Pg. 102: '...all patients were examined, and PI, GI, WS, and caries presence were recorded by the same blinded examiner.'
Incomplete outcome data (attrition bias)	Low risk	There were no dropouts.
Selective reporting (reporting bias)	Unclear risk	All outcomes described in the manuscript were reported on. However, the study protocol is not available to allow for complete assessment of this domain.
Other bias	Low risk	The study authors very kindly clarified any points of concern via email.

Table 3: Risk of bias assessment Zotti et al.⁽⁴⁾

<u>Study 1: Bowen et al.⁽¹⁶⁾</u>			
Group	COM-B component	Behaviour change technique	Support for judgement
Control and intervention	Psychological capability	4.1: Instruction on how to perform the behaviour	Pg. 544: ‘Both groups watched an audio-visual presentation on how to properly brush with a conventional toothbrush, using the Bass technique.’
Intervention	Physical opportunity	7.1: Prompts and Cues	Pg. 544: ‘...received automated text messages two to three times a week for 4 weeks (totalling 12 texts) as a reminder and encouragement to practice good oral hygiene.’
	Psychological capability	4.2: Information about Antecedents	Pg. 545, Table 1: ‘Brush & floss? We want no white spots or cavities. Remember 2 brush after every meal & your results will B fantastic. C U soon!’
	Reflective and automatic motivation	5.3: Information about social and environmental consequences	Pg. 545, Table 1: ‘Your smile is the first thing people see!! keep those teeth clean and shu Orthodontics will get them straight.’
<u>Study 2: Zotti 2016⁽¹⁷⁾</u>			
Group	COM-B component	Behaviour change technique	Support for judgement
Control and intervention	Psychological capability	4.1: Instruction on how to perform the behaviour	Pg. 102: ‘...patients were instructed to download smartphone-specific video tutorials regarding oral hygiene maintenance during their orthodontic treatment’

Intervention	Reflective and automatic motivation	2.5: Monitoring of outcome(s) of behaviour without feedback	Pg. 102: ‘...all participants were instructed to share two selfies of their teeth weekly, before and after using the plaque-disclosing tablets, to show their ability in maintaining oral hygiene.’
	Social opportunity	3.1: Social support (unspecified)	Pg. 102: ‘...The patients were also allowed to use this chat room to share information, pictures, and movies regarding oral hygiene and orthodontic treatment.’

Table 4: The COM-B component and behaviour change techniques addressed in the studies

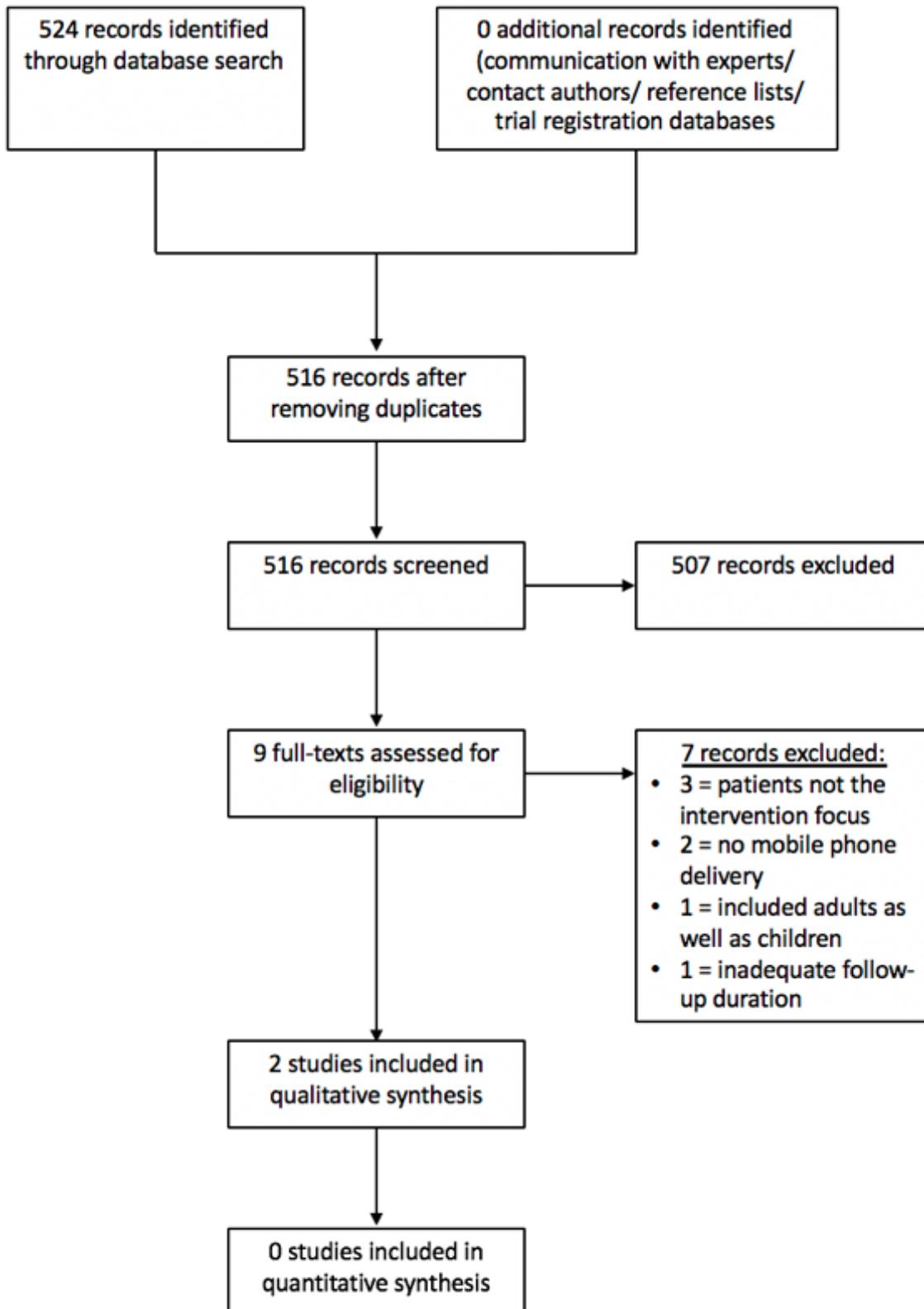


Figure 1: Study flow diagram

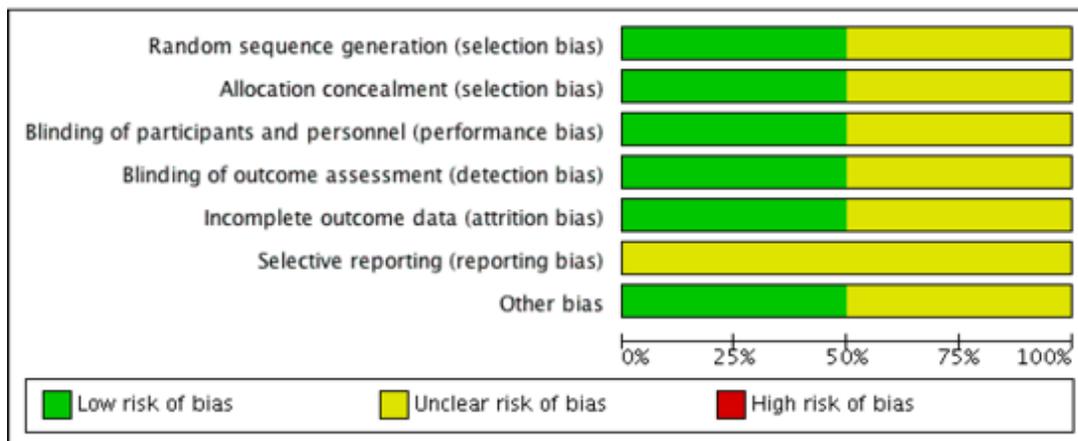


Figure 2: Risk of bias graph - judgements about each risk of bias item presented as percentages across all included studies

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Bowen 2015	?	?	+	?	?	?	?
Zotti 2016	+	+	?	+	+	?	+

Figure 3: Risk of bias summary - judgements about each risk of bias item for each included study

Certainty assessment							Summary of findings	
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Impact	Certainty
Plaque score (follow up: range 3 months to 12 months; assessed with: Planimetry and Plaque Index)								
2	randomised trials	serious ^a	not serious	not serious	not serious	none	Bowen et al. reported no difference in plaque score at baseline (T0), however, at the 4 week (T1) and 12 week (T2 - final) follow up there was statistically significantly less plaque accumulation in the intervention group (p<0.05). Zotti et al. reported no difference in plaque scores at baseline (T0) or 3 months (T1), however, at 6 months (T2), 9 months (T3) and 12 months (T4 - final) there was statistically significantly less plaque accumulation in the intervention group (p<0.01 for all three timepoints).	⊕⊕⊕⊕ MODERATE
Gingival bleeding scores (follow up: 12 months; assessed with: Gingival index)								
1	randomised trials	not serious	not serious	not serious	not serious	none	Zotti et al. reported no difference in bleeding scores at baseline (T0) or 3 months (T1). At 6 months (T2), 9 months (T3) and 12 months (T4 - final) there was statistically significantly less gingival bleeding in the intervention group (p<0.05). ¹	⊕⊕⊕⊕ HIGH

Figure 4: GRADE assessment summary table