Adherence among Orthodontic Patients

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Download date: 27. Jul. 2023
Adherence among Orthodontic Patients

This thesis is submitted as partial fulfilment for the degree of Doctor of Philosophy

(PhD)

Aljazi Aljabaa

King’s College London, Dental Institute

2015
DEDICATION

This thesis is for you, Mom, because without your support and endless love, I would not have been able to accomplish this. Also, I dedicate this thesis to my loving Aunt for her advice, encouragement and emotional support.
ACKNOWLEDGEMENT

First, I would like to thank God for giving me strength to complete this work.

Second, I would like to thank my mom, the best mother in the word, who dedicated her life to raising me and taught me the importance of education. Thanks, Mom, for all your prayers for me and for supporting me throughout this journey, even when you were suffering from the pain when you were sick. You were always there for me, hiding your pain and pretending that you were better just to help me complete my PhD. Also, I would like to thank my lovely Auntie for her love and support. Thank you for always treating me like your daughter. I am truly lucky to have two moms.

I would not have been able to complete this work without the help of my supervisors. My first supervisor, Prof. Tim Newton, is a great supervisor who always encouraged me, supported me and was generous with his time and information. Also, Tim is a great person who is genuinely kind. He supported me during my mother’s sickness and has always made me laugh, even during the worst times in my life. I was honoured to work under his supervision. To Prof. Fraser McDonald, my second supervisor, thank you so much for making my dream become true when I contacted you and you accepted me as a PhD student. Thank you, Professor, for your help, suggestions and constructive criticism throughout my thesis work. Also, thank you for your helpful advice regarding my career; you are a very warm-hearted person. I was lucky to work with both of you.

I wish to thank Prof. Lucy Di-Silvio, my coordinator, for her advice and support.

My warm thanks go out to Dr. Mark Ide for his help and advice in the periodontology section of my thesis.
My deep thanks go out to Dr. Khalid Al-Moammar for sharing his experience with me during the PhD program, as well as for his advice, help and support.

I would also like to thank the many other people who helped me throughout this project. To the orthodontic postgraduate students, thank you for giving me time to examine your patients and for your support. My sincere thanks are extended to all the members of the Department of Orthodontics at Guy’s Hospital. I was lucky to work in such an organized setting with professionals.

I would like to thank all the members of the Dental Public Health Department. A special thanks to Natalie John for her help and support throughout my PhD, especially during the ethical approval paperwork. Thank you, Natalie. You are a wonderful person.

I am highly indebted to the Saudi Arabian government and King Saud University’s College of Dentistry for their higher education scholarship, and I would like to thank the Saudi Cultural Bureau for its support.

I would like to thank my friends Rasha Al-Dabaan and Hassana Al-Fayez for their support during my PhD program. Also, I would like to thank Ghada Al-Kharboush for her support since I began my masters degree. Thank you for always being there for me. Finally, My warm thanks to my lovely friend Hanan Al-Fayez, who was always with me. Thank you for all the great times we spent together. Thank you for tolerating me, even during my worst times; answering my late calls and listening to my endless and illogical complains. Thank you for being a like a family member to me here in London when I was lonely. I am profoundly lucky to have a friend like you in my life.
ABSTRACT

Objectives: A patient’s adherence is an important factor for successful orthodontic treatment. This adherence can take the form of maintaining good oral hygiene, appliance maintenance, observing dietary recommendations, and appointment keeping. This thesis consisted of three studies. A systematic review was conducted to investigate the effectiveness of interventions to enhance adherence among orthodontic patients aged 12 to 18. Specific adherence outcomes included: recall of information given by the orthodontic team; attendance at orthodontic appointments; self-reported oral hygiene behaviour; and clinical indices of oral hygiene. A survey was undertaken to explore predictors of adherence amongst patients 12–18 years of age receiving orthodontic treatment with fixed appliances at the initial follow-up appointment 6 weeks post bracket placement. Finally, a randomised controlled trial compared three methods designed to enhance adherence to oral hygiene instructions in orthodontic patients aged 12–18 years: mind map, if-then plan, and leaflet.

Materials and Methods: Systematic review: Electronic searches of Medline via OVID (1966– March 2012), EMBASE, and the Cochrane central register of control trials from its inception to March 2012, as well as a hand search were undertaken to identify relevant studies.

The longitudinal study: Measured adherence to orthodontic treatment in terms of self-reported oral hygiene-related behaviour, oral hygiene maintenance, knowledge of oral health-related behaviour, appliance breakages, and appointment attendance among 200 individuals undergoing maxillary and mandibular fixed orthodontic appliances with an age range of 12 to 18 years. Oral health-related behaviour and clinical indicators of oral health
were assessed at bond-up appointment (T1) and at 6 weeks follow up appointment (T2) to
determine their relationship to adherence.

**Randomised controlled trial:** Orthodontic patients from Guy’s and St Thomas’ NHS Trust
were drawn as potential participants; patients were randomly allocated to one of the
three interventions used. **Eligibility criteria:** patients aged 12–18 years undergoing
maxillary and mandibular fixed orthodontic treatment. Individuals with systemic disease,
craniofacial development disorders including cleft lip and palate, individuals with previous
history of orthodontic treatment, patients attending the specialist hypodontia clinic and
individuals who declined to participate were excluded. **Outcomes:** Primary outcomes:
plaque levels. Secondary outcomes: bleeding on probing, patient’s knowledge about
adherence in orthodontic treatment, and self-reported behaviours. **Randomisation:**
patients were randomly allocated to one of three conditions. The three groups were: mind
mapping, if-then planning group, and patient information tools (leaflet). Allocation was
concealed using sealed envelopes. **Blinding:** the participant and their parents as well as
the researcher undertaking the intervention and assessing the outcomes were not
blinded. The statistician undertaking the statistical analysis was blinded. Participants were
assessed at four time points: at the fitting of the fixed appliance (T1); at initial follow-up 6
weeks later, at which time after the assessment of their oral hygiene and completion of
the questionnaire (T2), they were randomly allocated to the three groups of intervention;
6 weeks after the intervention (T3); and 18 weeks after the intervention (T4).

**Results: Systematic Review:** A total of 381 articles were identified through the electronic
searches. Initial screening of the abstracts and titles by all review authors identified 7
articles that met the inclusion criteria for this review. The full articles were then retrieved.
Four randomised controlled trials were found; all used different methods of intervention, including: a system of rewards or awards; the Hawthorne effect; written information; and demonstration of the microbiology of plaque.

The longitudinal study: Significant changes in lingual plaque ($P=0.026$), bleeding on probing ($P=0.006$), and knowledge ($P<0.001$) were found between bond-up and at initial follow-up. There were no relationships between age and gender of the patients and adherence. Clinical status at bond-up was the only significant predictor of clinical status at initial follow-up.

Randomised Controlled Trial: Total sample of 90 participants were randomised in a 1:1:1 ratio. No statistical differences were found in adherence among the three methods used.

Conclusion: The literature advocates the use of several methods to improve compliance/adherence among orthodontic patients. While there is insufficient evidence to allow clinicians to choose a single method, the results demonstrate the value of spending time with patients to illustrate the importance of adherence. Future studies should develop multiple methods of assessing patient adherence including self-report, behavioural observation and recording, as well as change in clinical indices, with different types of interventions to be included and tested for effectiveness. The survey demonstrated that the oral hygiene of patients worsens following the start of orthodontic treatment. Age, gender, and knowledge are not good predictors of adherence. However, initial clinical status predicts subsequent adherence. The randomised controlled trial revealed no differences in adherence among the three methods used.
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<td>Plaque Index</td>
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<tr>
<td>BBI</td>
<td>Bonded Bracket Index</td>
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<tr>
<td>IOTN</td>
<td>Index of Orthodontic Treatment Need</td>
</tr>
<tr>
<td>TAU</td>
<td>Treat As Usual</td>
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<tr>
<td>P</td>
<td>Probability Value</td>
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<tr>
<td>$R^2$</td>
<td>Regression Coefficient</td>
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<tr>
<td>SD</td>
<td>Standard Deviation</td>
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<td>S.E</td>
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<td>MANOVA</td>
<td>Multivariate Analysis Of Variance</td>
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<td>SPSS</td>
<td>Statistical Product and Service Solutions</td>
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1. **INTRODUCTION**

Successful orthodontic treatment depends on different factors. Although the knowledge and skills of the treating orthodontist are important, patient adherence remains a significant factor for successful orthodontic treatment outcomes. Instructions given to the patients undergoing orthodontic treatment regarding oral hygiene, diet, maintaining the appliances, and appointment keeping should be fully understood and followed by the patients. For orthodontists, a patient’s adherence is a challenging and complex phenomenon that substantially influences the outcome of treatment and the duration over which active treatment is carried out. Good patient adherence to the treatment regimen is important to reduce the duration of treatment, maintain good oral health, and increase the clinical efficacy for the orthodontist (Skidmore et al., 2006; Mandall et al., 2008). In contrast, patient non-adherence is a major problem which can increase treatment time and cause more damage to the teeth and periodontium, affect the overall treatment plan and lead to, for example, extraction of additional teeth, relapse of the original condition, disappointment to the patient, and extra stress for the treating orthodontist (Southard et al., 1991). Poor patient adherence is a major problem that affects most orthodontic clinics. Previous studies suggested that the rate of poor adherence is 50% (Feil et al., 2002; Larsson and Bergstrom, 2005).

This work aimed to:

a) Carry out a systematic review of studies which have sought to explore interventions to enhance adherence to appointment keeping and oral hygiene amongst patients undergoing orthodontic treatment.
b) Undertake a longitudinal study of predictors of orthodontic patients’ adherence to appointment keeping and advice concerning oral hygiene.

c) Conduct a randomised controlled trial to compare three different interventions to improve adherence in orthodontics among patients undergoing fixed appliance therapy.
1.1 ADHERENCE

1.1.1 Definitions of Compliance, Adherence, and Motivation

- **Compliance**

In healthcare, *compliance* has been defined as “the extent to which a person’s behaviour coincides with medical or health advice” (Haynes, 1979). However, in the 1950s, the term *compliance* was used in the medical literature. Due to its judgmental overtones, it became unpopular and *adherence* was then introduced. Both terminologies are now used interchangeably (Nowicki & Strickland, 1973).

- **Adherence**

*Adherence* is defined as “the extent to which a person’s behaviour such as taking medication, following a diet, and/or executing lifestyle changes, corresponds with recommendations the person has agreed upon with a healthcare provider” (WHO, 2003) cited by Asimakopoulou and Daly (2009).

- **Motivation**

*Motivation* is a psychological force that pushes a person toward a positive or negative action (Haggard, 1989). Additionally, it can be seen as a willingness of the learner to adopt learning reflected by such force (Redman, 2007).

In this thesis, the terms *compliance* and *adherence* will be used interchangeably.
1.1.2 Five interacting dimensions affecting adherence

The World Health Organization (2003) identified five factors that affect patients’ adherence.

1. **Social and economic factors**

Socioeconomic status has not been found to be an independent predictor of adherence; some factors have been reported to be of significance in terms of effect on adherence including: poor socioeconomic status, poverty and low education level. Age was found to have an effect on patients’ adherence but it should be evaluated separately for each condition.

2. **Health care team and system-related factors**

Good patient-provider relationships may improve adherence. Some factors such as poor medication, distribution, lack of knowledge and training for health care, overworked health care providers, lack of incentives and feedback on performance, short consultations, weak capacity of the system to educate patients and provide follow-up, lack of knowledge on adherence and of effective interventions for improving it may compromise care delivery.

3. **Condition-related factors**

Severity of the symptoms, level of disability, and severity of the disease and availability of effective treatment are strong determinants of adherence.
4. **Therapy-related factors**

Adherence is affected by many therapy-related factors that affect adherence. Most important are those related to the complexity of the medical regimen, duration of treatment, previous treatment failures, frequent changes in treatment, the immediacy of beneficial effects, side-effects, and the availability of medical support to deal with them.

5. **Patient-related factors**

Which include the patient's knowledge, attitude, beliefs, perceptions and expectations (WHO, 2003).

### 1.1.3 Models of Health-Related Behaviour

A patient’s behaviour is critically important for oral health. Therefore, it is important for orthodontists to target the patient’s behaviour to maximise treatment outcomes. In order to predict the likelihood of an individual engaging in behavioural change, psychologists have devised many different methods in order to predict behaviours:

#### 1.1.3.1 Health Belief Model (Rosenstock, 1966)

This model consists of two elements: threat perception and behavioural evaluation.

1. Threat perception is composed of two parts:
   
   a) Perceived susceptibility (the person perceives the risk of the disease subjectively).
   
   b) Perceived seriousness (a subjective assessment of the impact of the disease by the individual).

2. Behavioural evaluation has two parts:
a) Perceived benefits (evaluation of the efficacy of different methods used in reducing the threat).

b) Perceived barriers (person’s own prediction of negative aspects of a specific behaviour).

Previous studies have suggested that the health belief model plays a small role in predicting patients’ behaviours in oral health (Kegeles, 1963; Kegeles, 1963; Rayant & Sheiham, 1980; Kuhner & Raetzke, 1989; Barker, 1994; Renz & Newton, 2009).

1.1.3.2 Protection Motivation Theory (Rogers, 1975)

Rogers (1975) proposed that fear is the driving force for any behavioural change. Later, he added other cognitive mediators for behavioural change to his theory. A model of the protection motivation theory was organised into two parallel cognitive processes:

1. Threat appraisal: This includes the individual identification of an event as unsafe with the belief that the recommended behaviour is effective in preventing this harmful event.

2. Coping appraisal: In order for an individual to engage in behaviour, he/she should believe in the efficacy of that behaviour to reduce the threat (response efficacy) and believe in his/her ability to carry out the recommended action (self-efficacy); when these conditions are met, the recommended behaviour is most likely to occur.

No published studies on the effect of protection motivation theory in relation to oral health were found (Renz & Newton, 2009).
1.1.3.3 Locus of Control (Rotter, 1966)

This model assumes that behaviour is a function of:

1. The degree to which an individual believes that performing the behaviour will lead to a reward.
2. The value of the reward.

Different scales have been developed to measure locus of control:

- Rotter (1966) developed “the internal-external scale (internal or external locus of control)”. This is the standard scale that evaluates the general beliefs related to locus of control.
- Levenson (1974) developed the “I, P, and C scale”. This scale divided people into one of the following three orientations: internal, powerful others, and chance.
- Wallston et al. (1978) established the Multidimensional Health Locus of Control (MHLC) scale. This scale is the most widely used measure of locus of control as applied to health behaviours.

Several studies have investigated the locus of control scale in relation to prediction of patients’ adherence in orthodontics; they found that the locus of control theory does not identify all personality characteristics that are essential for creating a clear picture of orthodontic patients’ behaviours (El-Mangoury, 1981; Egolf et al., 1990; Albino et al., 1991; Lee et al., 2008). In relation to oral health, several studies reported that locus of control is not a good predictor of oral health behaviours (Scuruggs et al., 1989; Wolfe et al., 1991; Bagley & Low, 1992; Bajwa et al., 2007; Renz & Newton, 2009).
1.1.3.4 Social Learning Theory (Bandura, 1977)

Social learning theory was proposed by Bandura (1977), who states that self-monitoring, skill training, modelling, and visualisation are important to learning behaviour. Based on that theory, two factors can determine behaviour: a) incentives (personal values which an individual attaches to an outcome), and b) expectancies: situation outcome, action outcome, and perceived self-efficacy.

Several studies indicated that social learning theory is a good predictor of oral health-related behaviours (Stewart et al., 1991; Little et al., 1997; Wewers et al., 2003; Renz & Newton, 2009).

1.1.3.5 Theory of Planned Behaviour (Ajzen, 1991)

This theory, proposed by Ajzen (1991), stated that the immediate predictor of behaviour is the intention to perform an action. The intention is determined by:

- The subject’s attitudes towards the behaviour
- Perceptions of personal control over the behaviour
- Social norms and beliefs

When applied to the study of oral hygiene behaviour, the theory of planned behaviour seems to produce better results when compared with other types of behavioural theories (McCaul et al., 1992; Lavin & Groarke, 2005; Renz & Newton, 2009; Newton & Asimakopoulou, 2015).
1.1.3.6 Implementation Intentions (Gollwitzer & Sheeran, 2006)

Gollwitzer and Sheeran (2006) suggested that motivation may be necessary for behaviour, but by itself it is not enough for behavioural change. Accordingly, Gollwitzer and Sheeran distinguished between goal intentions and implementation intentions. Goal intentions are commitments to engage in certain behaviour and are formed in the motivational phase, while implementation intentions are plans that are used to help individuals commit to the behaviour in terms of when, where, and how the behaviour is to be implemented.

In relation to oral health studies, a previous study indicated that implementation intention was the only significant predictor of adherence (Schuz et al., 2006). Other studies used implementation intention as an intervention to enhance flossing behaviour among participants; results showed that it was a good intervention to enhance oral health behaviours (flossing) (Sniehotta et al., 2007; Suresh et al., 2012).

In orthodontics, Veeroo et al. used the if-then plan to improve patients’ compliance with intraoral elastics; they found no significant difference between the if-then plan group and the group that received routine clinical instructions, although there was a tendency for better wear of intraoral elastics among the if-then plan group (Veeroo et al., 2014).

1.1.3.7 Stages of Change Model (Prochaska & DiClemente, 1984)

This theory contains five stages of change:

1. Pre-contemplation (no intention to take an action in the future is planned by the individuals)
2. Contemplation (the individuals are planning to take an action within the next six months after becoming aware of the problem)
3. **Preparation** (they either plan to take action within the next 30 days and/or have performed an action unsuccessfully in the past year)

4. **Action** (changed behaviour for less than six months)

5. **Maintenance** (people work to avoid relapse and maintain the results achieved during action)

Transitions between the stages affected by processes of change are divided into two broad categories:

a) **Experimental processes**: which is thinking about changing behaviour.

b) ** Behavioural processes**: behaviours which are helpful in behaviour change.

Stewart et al. (1996) tested the effect of the stages of change model on improving oral hygiene among patients with periodontitis, and the results revealed the group that received the stages of change model had higher scores in self-efficacy for flossing compared to the other two groups (control group and group who received educational presentation on the causes of dental diseases).
1.2 ORTHODONTIC TREATMENT AND ADHERENCE

1.2.1 Adherence in Orthodontics

Adherence in orthodontics is defined in terms of maintaining good oral hygiene, appointment attendance, appliance wear, following the recommended diet, and appliance maintenance (Fleming et al., 2007). Patients can be treated in orthodontic clinics using the following types of appliances:

1.2.1.1 Fixed Appliances

This is the most common type of orthodontic appliances currently in use, as they provide controlled three-dimensional tooth movements and consequently address different types of malocclusion (Cobourne & DiBiase, 2010). Adherence during fixed treatment includes: performing good oral hygiene, avoiding bracket/archwire breakages, following the recommended dietary advice, and attending appointments (Fleming et al., 2007).

1.2.1.2 Removable Appliances

In Europe, removable appliances are used primarily during active orthodontic treatment (Miethke & Wronski, 2009; Krey & Hirsch, 2012). They are used mainly for retention in the USA (Valiathan & Hughes, 2010). Removable appliances are usually used for simple tooth movement or in combination with fixed appliances. In order to achieve the best treatment results or avoid relapse of the corrected malocclusion, patients’ adherence is mandatory; they should wear the removable appliances as prescribed by the treating clinician (Schafer
et al., 2015), as well as avoid breakages of the appliance, regularly attend appointments, and maintain good oral hygiene (Fleming et al., 2007).

1.2.1.3 Functional Appliances

Functional appliances can be either removable or fixed. These appliances are designed mainly to treat patients with skeletal Class II malocclusion (Baccetti et al., 2000). Patients’ adherence is required during treatment to achieve good treatment results; adherence includes wearing the appliance as instructed, appointment attendance, regular maintenance of the appliance, and maintaining good oral hygiene (Fleming et al., 2007).

1.2.1.4 Headgear

Headgear is an extra-oral orthodontic appliance which is used in growth modification or anchorage reinforcement (Cureton et al., 1993). Adherence to the scheduled hours is important for treatment progress using headgear; also, adherence entails following dietary and oral hygiene instructions and appointment attendance (Allan & Hodgson, 1968; Gabriel, 1968; Kreit et al., 1968; Starnbach & Kaplan, 1975; Clemmer & Hayes, 1979; Gross et al., 1985).

1.2.2. Adverse Consequence of Non-adherence

Successful orthodontic treatment results depend mainly on patients’ adherence. In orthodontics, non-compliance is a major problem which can increase treatment time and cause more damage to the teeth and periodontium, affecting the overall treatment plan and lead to, for example, extraction of additional teeth, relapse of the original condition,
disappointment to the patient, and extra stress for the treating orthodontist (Southard et al., 1991). A commonly reported adverse consequence for lack of adherence is failure to complete orthodontic treatment (Brattstrom et al., 1991; Fleming et al., 2007).

Good oral hygiene is vitally important for a successful orthodontic treatment. Fixed orthodontic appliances provide additional surfaces for plaque retention, which might increase the patients’ susceptibility to caries, gingival inflammation, and periodontal disease. During orthodontic treatment, poor oral hygiene may affect the treatment outcomes (Gwinnett & Ceen, 1979). As a result, it was estimated that 5% to 10% of orthodontic patients are unable to complete their treatment (Mehra et al., 1998). Moreover, poor compliance during orthodontic treatment significantly increases the length of the treatment (Beckwith et al., 1999; Skidmore et al., 2006), which in turn is associated with the risk of root resorption (Brezniek & Wasserstein, 1993; Baumrind, 1996; Krishnan, 2004).

Lack of adherence with removable appliances may result in slower results or no results at all (Allan & Hadgson, 1968; Gross et al., 1985).

Adherence during headgear treatment is important, as a non-cooperative patient might not achieve satisfactory results and will require additional treatment time and effort (Rubin, 1980; Trakyali et al., 2008). Furthermore, poor compliance with growth modification appliances will necessitate a more invasive treatment plan, which might include extraction or surgery (Cureton et al., 1993).
1.2.3 Previous Studies of Adherence in Orthodontics

Several studies have investigated orthodontic patients’ adherence, most commonly in relation to oral hygiene, appliance breakages, appliance wear, self-reported oral hygiene, and appointment attendance.

There have been numerous studies describing the level of compliance and adherence among orthodontic patients, and exploring the factors that relate to compliance. These studies can be categorized by the type of compliance assessed (typically a range of measures are adopted, from self-reported behaviour to oral hygiene and automated measures of appliance wear) as well as by the variables used to predict adherence. Table 1-1 summarises studies exploring compliance/adherence among orthodontic patients. The individual studies are discussed in detail in the following sections, which are categorized according to the putative factors predicting adherence: Demographic Factors, Psychological Factors, and Structural Factors.

1.2.3.1 Demographic Factors

Age has been reported as one of the most important factors predicting compliance. A study reported that patients who were 12 years of age and younger showed a better level of adherence than older patients (Weiss & Eiser, 1977). However, some studies reported that age was not a good predictor of adherence (Albino et al., 1991; Richter et al., 1998).

Other investigators evaluated the role of gender on adherence, revealing that females were more cooperative during orthodontic treatment than males (Starnbach & Kaplan, 1975; Clemmer & Hayes, 1979). This might be related to females’ attentiveness towards their appearance (Bos et al., 2005). Nevertheless, this had an adverse effect on their
compliance in wearing removable appliances and headgear (Sergl et al., 1992). However, some studies showed moderate or no gender difference in the level of compliance (Nanda & Kierl, 1992; Bartsch et al., 1993; Richter et al., 1998).

Socioeconomic status of the patient may also play a role in compliance. Some studies found that patients from a high socioeconomic status were more cooperative than patients from a lower socioeconomic status (Graber, 1975; Cucalon & Smith, 1990). In contrast, other studies reported that patients from middle and low socioeconomic classes showed more compliance, as they appreciate the orthodontic treatment more, recognized the necessity of the treatment, and have better relationships with their parents (Dorsey & Karen, 1977).

No relationship was found between parental occupation and patients’ compliance with orthodontic treatment (Sergl et al., 1992). However, a study found no relationship between the baseline data (e.g., age, gender, socioeconomic status, index of orthodontic treatment need “IOTN”, type of appliances) and compliance results (Mandall et al., 2008).

To examine patient’s compliance with oral hygiene instructions (OHI), Al-Jewair et al. (2011) carried out a longitudinal study of 41 adolescent patients (17 males, 24 females, age range = 12–16 years) receiving two-arch multi-bracket fixed appliances. Oral hygiene of the participants was assessed using plaque and gingival indices before bonding, 4 weeks later, and 5 months after bonding. In addition, patients and their parents were given a questionnaire, and the patients’ charts were used to identify predictors of compliance. The results showed that after an initial worsening, there was an improvement in compliance with OHI 5 months after bonding. On the other hand, the patients who lived with married parents and patients with good grades at school had better compliance with
OHI provided at baseline and toward maintaining better oral hygiene. The results of this study cannot be generalised to all orthodontic patients, as the sample includes only patients 12–16 years of age with fixed orthodontic appliances.

Microsensors were used to measure adherence among patients wearing removable appliances in the first 3 months of follow-up; results showed that, among the 141 patients who were 7–15 years of age, the females were more adherent to the appliance wear. Also, the younger age group (7–9 years old) were better at wearing the appliances consistently than older patients. Lastly, the study stressed the importance of the orthodontist relationship in maintaining patients’ adherence (Schafer et al., 2015).

1.2.3.2 Psychological Factors

1.2.3.2.1 General Psychological Factors

Extensive evaluations of patients’ psychology and its effect on compliance have been performed. Some studies evaluated the patients’ psychological characteristics during orthodontic treatment and its effect on compliance. One study identified high compliers as: having high self-esteem, optimistic, and deriving self-satisfaction from their achievements (Cucalon & Smith, 1990). Sergl et al. found that uncooperative patients are usually aggressive and active (Sergl et al., 1992). Other studies reported more characteristics of uncooperative patients: individualistic, irritated, intolerant, reckless, negligent, contentious, and egotistical. Cooperative patients, on the other hand, are extroverted, enthusiastic, energetic, self-controlled, accountable, trusting, diligent, and committed (Allan & Hodgson, 1968; Sergl & Zentner, 2000).
Several studies have utilized psychological instruments to measure effective behavioural and motivational variables and their relation to patients’ adherence. For example, El-Mangoury (1981) performed a double-blind quasi-experimental study using instruments aiming to measure achievement, affiliation, and attribution motivation. The sample consisted of 70 orthodontic patients (14 years of age or older) with Angle Class II malocclusion. Patients should have undergone fixed appliance orthodontic treatment for at least 6 months. Psychological tests were administered to the patients, followed by orthodontic and periodontal examination. The psychological tests include, El-Mangoury psychological test which composed of 1) naïve attribution, 2) orthodontic treatment success probability 3) oral hygiene and aesthetic components of orthodontic success, 3) achievement and affiliation motivation test, to measure achievement and affiliation tendencies. Other psychological tests include achievement and affiliation motivation tests and attribution and motivation tests (Rotter’s locus of control scale). The dependent variables were: headgear and elastic wear, appliance maintenance, no broken appointments, oral hygiene, and plaque index. The results indicated that high-need achievers and high-need affiliators cooperate better during orthodontic treatment ($P=0.001$). Affiliation motivation was found to be the first predictor for headgear and elastic wear, appliance maintenance, and punctuality in appointments. The first predictor for oral hygiene was achievement motivation test.

Another study used the Million Adolescent Personality Inventory (MAPI) to predict orthodontic patient compliance. Researchers tested 104 orthodontic patients who were 13 to 18 years of age. Results revealed that seven of the 20 modified test scales plus
gender were good predictors of patients’ compliance (Southard et al., 1991). However, there was no clear description of how compliance was measured.

The relationships between patients’ attitude, treatment experience, appliance acceptance, and compliance were investigated among 67 patients. The sample consisted of 31 males and 36 females with an average age of 12.6 +/- 4.1 years, who were treated with fixed, removable, or functional appliances. A psychological questionnaire was answered by the patients at the beginning of the treatment and 6 months later. The questionnaire covered the following topics: perceived severity of orthodontic malocclusion, expectation of treatment, dental aesthetics, attribution of causes for a successful dental treatment, and appliance acceptance. Patient compliance was assessed by the orthodontist. Other measurements included a self-observation log and appliance characteristics. The results revealed that the greater the patients’ understanding of their own role in treatment success at the beginning of treatment, the more this attitude improved 6 months later. They also found that acceptance of the appliance depends on patients’ attitude and discomfort; this acceptance in turn will affect compliance (Doll et al., 2000).

Daniels et al. evaluated the effect of patients’ and parents’ motivation on predicting patients’ compliance among 227 orthodontic patients and their parents. The survey included 144 patients who had already started the treatment and 83 who were recruited during the orthodontic screening appointment. A questionnaire was distributed to patients and their parents. Two items were used to assess patients’ motivation for treatment: “How much would you like/did you want to have braces?” and “It is very important for me to have braces”. The parents’ motivation was evaluated by two items:
“How much would you like/did you want to have braces for your child?” and “It is very important for my child to have braces”. The results revealed that the patients’ initial motivation was a good predictor for future patient compliance, while the parents’ motivation was not correlated with the patients’ compliance (Daniels et al., 2009). The study did not mention clearly how compliance was measured, which might affect the results of the study.

Previous studies found that patients’ personality, school performance, and relationships with family, friends, and the orthodontist can provide a general prediction of compliance in the orthodontic treatment later (Allan & Hodgson, 1968; Nanda & Kierl, 1992; Sergl & Zentner, 2000). In other studies, patients’ school performance had been used to predict patients’ compliance in orthodontic treatment. The studies found that compliant patients tend to have higher grades at school (Clemmer & Hayes, 1979; Richter et al., 1998); also, high compliers tend to have lower absence rates and their teachers reported that they are academically bright (Woolass, 1988; Sergl & Zentner, 2000).

A study was done by Woolass et al. (1988) to measure the predictors of compliance based on psychological assessment, school performance, and parents’ evaluation of their children’s behaviour. Questionnaires to predict compliance were given to 219 children. The children’s Piers-Harris questionnaire was used to investigate self-concepts of the children. The children’s Olweus questionnaire examined children’s attitude towards and experience of aggression. A children’s general questionnaire consisted of general dental health questions and attitudes towards malocclusion and orthodontic treatment. The parents were given a Rutter questionnaire to assess if the child has emotional or behavioural disturbances. A general parental questionnaire covered general questions
about dental health and attitudes towards malocclusion and orthodontic treatment. The teachers filled out a Rutter questionnaire to assess if the child has any emotional or behavioural disturbances. The patients’ compliance was assessed by the orthodontist and by one of the researchers; they were divided into 1) discontinued prematurely 2) poor cooperation 3) fairly good cooperation 4) very good cooperation. The results showed that the best-cooperation group reported increased self-concept of behaviour (P<0.01), good anger control (P<0.001), and they found it difficult to speak up in class (P<0.05). The teachers reported that the more compliant children were brighter (P<0.001). In the parental Rutter questionnaire, the parents of cooperative children reported that the children were less likely to tell lies (P<0.05), be absent from school (P<0.05), steal (P<0.05), and be disobedient (P<0.05).

Eighty patients (4%) had early orthodontic treatment termination during 10 years at the School of Dentistry, Huddinge, Sweden. The patients were interviewed about their reasons for termination, and the results revealed that the most common reason was lack of motivation. Other reasons were: inadequate orthodontic treatment information and communication problems between the orthodontist and patient (Brattstrom et al., 1991). Johnson et al. (1998) studied patients’ and their parents’ attitudes towards treatment with bionators and headgear; also, they investigated the factors associated with compliance among 168 parents and their children at the end of mixed dentition treatment for Class II malocclusion. The patients were treated by either bionators or cervical pull headgear. Patients and their parents were asked to complete a questionnaire which included questions about their attitude toward the appliances, compliance level, and factors affecting compliance. Patients treated with headgear experienced more pain than
patients treated with bionators, but were no less compliant. Pain, speech, and chewing difficulties were the main reasons given for not wearing the appliance. The relationships between the patients and their treating orthodontists and giving the patients information about the goal of the treatment and their role in the treatment were identified as important in improving patients’ compliance.

1.2.3.2 Social Cognition

Behavioural variables and their relation to headgear wearing compliance were tested among 20 adolescent patients (Clemmer & Hayes, 1979). The variables that were tested included: age, gender, recorded hours of headgear wear by the patient, compliance with headgear wear by timers, patient’s malocclusion, patient dental attitudes, and locus of control. A greater probability for difficult attitudes was found among patients who most needed to wear headgear. Females were more cooperative in wearing headgear. The authors suggest that in order for orthodontists to improve headgear wear by the patients, they should consider gender differences, alerting patients to their malocclusions, and by increasing the patients’ appreciation for treatment. The study did not find any relation between general locus of control and compliance in headgear wear. The sample size used in this study was small (20 patients), and there was no information on the follow-up period.

Albino et al. (1991) investigated compliance by distributing a questionnaire to 39 adolescents and parents; they found that parents’ positive attitudes toward orthodontic treatment predicted only short-term compliance, but external chance, attribution of control and initial assessment of cooperation predicted longer-term compliance. In the
study, they did not mention the type of orthodontic treatment, and the sample size was
also small.

Other studies investigated the theory of reasoned action (TRA) in terms of predicting and
understanding patients’ compliance during orthodontic treatment. For example, Bos et al.
(2005) analysed the effect of two additional variables (perceived control and anticipated
regret) in the TRA model. A 40-item questionnaire was distributed to patients and their
parents following the treatment plan discussion, at the Department of Orthodontics of the
Academic Centre of Dentistry in Amsterdam from 2003 to 2004. It was found that
patients’ intentions to comply during orthodontic treatment were significantly correlated
with the above additional variables, their attitudes and motivation to comply, and their
normative and subjective norms.

The relationship of locus of control (LOC) and orthodontic patient compliance was
investigated in a recent study. Two types of LOC questionnaires: the Rotter Internal
Control Scale (RICS; Rotter, 1966) and the Nowicki-Strickland External Control Scale
(NSECS; Nowicki & Strickland, 1973) were given to 561 patients (195 males, 366 females,
mean age =16.4 years) in a private orthodontic clinic in Seoul, South Korea from 1997 to
2002 before treatment. After receiving their orthodontic treatment, the patients were re-
administered the same two questionnaires. An orthodontist and three dental hygienists
assessed patients’ compliance. It was found that patient compliance was a multi-
dimensional component that cannot be predicted by LOC evaluation before orthodontic
treatment (Lee et al., 2008). Although patient compliance was assessed by an orthodontist
and three hygienists, no information was reported in the study regarding an intra-
examiner reliability test.
1.2.3 Structural Factors

Patient–orthodontist relationship plays an important role in compliance. Some studies found that a good relationship between the orthodontist and the patient has an influence on patient adherence (Nanda & Kierl, 1992; Sinha et al., 1996; Sergl & Zentner, 2000).

A study of 199 orthodontic patients explored the effect of orthodontists’ behaviour on patients’ adherence to orthodontic treatment. The age range of the participants was 8–17 years, and they were asked to complete a questionnaire at 8–12 months into treatment. The orthodontists treating the patients assessed patients’ adherence using an orthodontic patient cooperation scale. The results revealed that a good relationship between the orthodontist and the patient led to improved patient adherence (Sinha et al., 1996). The results of this study might be applicable to patients with this age group (mean age 14.4 years).

The effect of the funding of treatments was explored in two studies that compared Medicaid and non-Medicaid patients. As a main indicator of patients’ compliance, appointment keeping was measured in Medicaid (people with low incomes who cannot pay for treatment) and non-Medicaid orthodontic patients retrospectively. A higher rate of appointment failures was found among Medicaid compared to the non-Medicaid patients. However, authors (Horsley et al., 2007) did not mention the age of the patients, what type, and their stage of orthodontic treatment.

The differences in appointment attendance, maintenance of the appliances, and oral hygiene were examined between Medicaid and non-Medicaid patients. Results showed no differences between the two categories in compliance. However, there was a difference in the age between Medicaid (13.6 years) and non-Medicaid (15 years) patients at the start
of treatment, which might affect the results (Dickens et al., 2008). A drawback of the study was that the data were gathered from different private clinics and by different clinicians, and the study did not mention an inter-examiner reliability test. Also, there was no clear explanation of how oral hygiene was examined and scored.

There have also been a limited number of studies that have tested interventions designed to increase adherence or compliance in orthodontic patients. These studies are summarised in Table 1-2.

A clinical trial was conducted on 59 orthodontic patients who were selected from the Graduate Orthodontic Program at the University of Florida College of Dentistry. They received full banded orthodontic treatment. The mean age of the sample was 16.3 years. Subjects were divided into new orthodontic patients (31 subjects had been wearing appliances for 1 to 6 months) and experienced orthodontic patients (28 subjects had been wearing appliances for 1 to 2 years). Twenty-nine of the patients were assigned to a behavioural self-management (SM) arm (self-management manual and oral hygiene packet) and 30 to an instructions-plus-persuasion (IP) intervention (packet containing the first four pages of the self-management manual, three premeasured tubes of toothpaste with fluoride, two toothbrushes, three premeasured bottles of fluoride mouth rinse, and a measuring cap); also, the orthodontist introduced the instructions plus-persuasion (IP) program to each subject. Patients were followed up at 2, 5, and 8 weeks. Plaque and gingival indices and cariogenic bacterial activity were recorded at each visit. The results showed that oral health was improved among all four groups (McGlynn et al., 1987).

Gross et al. evaluated the effectiveness of a behavioural programme (lottery programme) to improve orthodontic patients’ appointment attendance. The patients’ age range was 8–
46 years (mean age: 12 years) with different dentofacial disorders. The lottery program was in the form of a poster in the waiting area with the names of patients who attended on time. A large gift box was placed near the receptionist, and the names of the patients who arrived on time were marked by the receptionist on the appointment card and placed in the box. The winner of the lottery program received a 15$ gift certificate. The baseline data stated that 69% of the patients arrived on time, while after the lottery program this was increased to 79% (Gross et al., 1988). The study did not mention the sample size that was included.

Another clinical trial was conducted to evaluate the effect of an oral hygiene program before the beginning of orthodontic treatment. Sixty-two new orthodontic patients were divided into experimental and control groups. The experimental group received an oral hygiene program which consists of four sessions weekly before starting orthodontic treatment. The sessions include a description of the relationship between plaque and gingival inflammation, a discussion of dietary habits and nutrition, plaque removal technique, and an evaluation of the effectiveness of using disclosing solutions on plaque control. The control group did not receive the oral hygiene program. Bleeding, plaque, and gingival indices were used, together with periodontal pocket depth and gingival fluids. These measurements were recorded at the beginning of the first session and at the end of the orthodontic treatment. The results showed an improvement in the bleeding (P<0.001), gingival fluid (P= 0.01), and gingival indices (P= 0.032) among the experimental group (Yeung et al., 1989). Although the study had a long follow-up duration (almost 4 years), no information was reported regarding the type of orthodontic appliances used, and they did
not mention if the intervention and measurements of compliance were assessed by one or more investigators.

Regarding the effects of reward systems on improving patients’ compliance in orthodontic treatment, Richter et al. (1998) adopted the orthodontic patient cooperation scale (OPCS) to assess adherence in 144 orthodontic patients (average age 12.8 years), who were scheduled to receive treatment over 6 to 12 months. The sample was divided into above-average and below-average compliers. Based on their scores, each group was further divided into three subgroups (control group, an award group, and a reward group). They found that above-average and below-average compliers did not significantly improve with rewards. Finally, the scores on oral hygiene in the reward group with low compliance were higher than in the control group with low compliance. The study mentioned that the patients were divided into high and low compliers using the orthodontic patient cooperation scale, but it did not indicate if calibration was considered based on an inter-examiner reliability measurement. Furthermore, appliance wear was measured on a 9-point scale by nine supervising faculty members; however, inter-examiner reliability was not considered. Although the results indicated gender differences among the groups, detailed descriptions of the actual male/female participants in each group were not clearly provided.

In relation to the use of the Hawthorne effect (Parsons, 1991) to improve compliance, Feil et al. (2002) found that the use of a deception strategy, which aimed to activate the Hawthorne effect, improved the home care of 20 non-compliant adolescent orthodontic patients with “poor” oral hygiene. The intervention group showed a greater reduction in
plaque scores at 3 and 6 months of 54% and 52%, respectively. The results of this study were based on assessing compliance by measuring the plaque index only.

The effect of conscious hypnosis on patient compliance was assessed in one study (Trakyali et al., 2008). Thirty patients (14 females and 16 males), with a skeletal Class II division 1 malocclusion, were divided randomly into two equal groups, an experimental group (mean age =10.78 years) for the hypnosis, and a control group (mean age=10.07 years). All subjects were treated by the same orthodontist, and they wore cervical headgear with timer to record the wear time, and patients were asked to record their actual wear time on the scheduled timetables. Motivation of the experimental (hypnosis) group was done through conscious hypnosis, whereas the control group received verbal praise from their orthodontist. A reduction in headgear wear among the control group was noted from the first to the sixth month (P<0.05), and the differences in the hypnosis group were not significant. There was a significant difference in headgear wear between the two groups at the third month (P<0.01) and the fifth month (P<0.05). The results indicated that conscious hypnosis is a good method to improve orthodontic patient compliance. It was also noted that timetables are not effective and reliable tools for assessing patient compliance since the correlation was significantly low between the actual wear time and the time recorded by the timing module.

Wright et al. (2010) investigated the relationship between information retention and compliance. The study compared an intervention group who had been given a leaflet about fixed appliances and a control group that had been given verbal information about fixed appliances. It was found that there were no significant differences between the two groups regarding their levels of compliance after 12 weeks of treatment.
Acharya et al. (2011) studied the oral hygiene of 62 adolescent patients (age range = 12–18 years) undergoing orthodontic treatment. The patients were divided into three groups. Group I received conventional plaque control, Group II received a chairside motivational intervention together with conventional plaque control, and Group III were treated the same as Group II but had an additional microscope demonstration. It was found that Group III plaque scores were better than I and II at 3 and 6 months, although there was no clear description of how the plaque and gingival scores were assessed.

After our extensive literature review, we found that a number of studies had identified several factors that predicted adherence among orthodontic patients. However, no single factor was identified as a good predictor of adherence. Also some studies sought to improve adherence among orthodontic patients using different interventions, but no method was found to be better at improving adherence. This guided us to conduct a longitudinal study on the predictors of adherence followed by a randomized control trial using methods that were not used previously (mind map and if-then plan) to enhance adherence among orthodontic patients.
Table 1-1: Summary of Previous Studies on Adherence among Orthodontic Patients.

<table>
<thead>
<tr>
<th>Author</th>
<th>Year</th>
<th>Sample Size</th>
<th>Age</th>
<th>Ortho Status</th>
<th>Gender</th>
<th>Measures of adherence</th>
<th>Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allan and Hodgson</td>
<td>1968</td>
<td>30 Patients</td>
<td>12-18 years</td>
<td>No information</td>
<td>17 Females 13 Males</td>
<td>Measures of adherence: - Patients were evaluated according to their orthodontists.</td>
<td>- Age was a good predictor, as younger patients were more cooperative (P&lt;0.01).</td>
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<tr>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>Predictors: - Age. - Gender. - Maryland parent attitude survey; to measure parents’ attitudes toward child rearing. - The adjective check list: patients’ were asked to check the words that best describe them. It is used for self-evaluation.</td>
<td>- Good predictors of patients’ compliance were: the total number of adjectives checked (P&lt;0.01), dominance (P&lt;0.01), autonomy (P&lt;0.01), and achievement (P&lt;0.001).</td>
</tr>
<tr>
<td>Starnbach and Kaplan</td>
<td>1975</td>
<td>362 Patients and parents</td>
<td>No information</td>
<td>No information</td>
<td>153 Females 101 Males</td>
<td>Measures of adherence: - Oral hygiene. - Appointment attendance. - Appliance maintenance.</td>
<td>- Gender was a good predictor of patient compliance, as 71% of cooperative patients were females.</td>
</tr>
<tr>
<td></td>
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<td></td>
<td></td>
<td>Predictors: - Questionnaire mailed to parents, which gathered information about family unit.</td>
<td>- Results revealed that father’s occupation was a good predictor of patient’s compliance.</td>
</tr>
<tr>
<td>Weiss and Eiser</td>
<td>1977</td>
<td>274 Patients</td>
<td>- Group I: prepubescent up to 12 years - Group II: adolescent 12 to 17 years - Group III: adults 17 and over</td>
<td>No information</td>
<td>No information</td>
<td>Measures of adherence: Questionnaires answered by the treating orthodontists including questions about: - Appliances/elastics wear. - Appointment attendance. - Oral hygiene. - Breakages of appliances.</td>
<td>- Group I were good wearers of extraoral appliances (P&lt;0.05). - Group II were better in keeping their appointments and maintaining appliances (P&lt;0.05).</td>
</tr>
</tbody>
</table>
### Clemmer and Hayes (1979)

- **Patients:** 20 Patients
  - 13.8 years (Females 11-17 years; Males 11-15 years)
- **Treatment:** Edgewise treatment and cervical headgear
- **Adherence Measures:**
  - Hours suggested wearing headgear.
  - Reported headgear wear.
  - Headgear timer.
- **Predictors:**
  - Age and Gender.
  - School cooperation.
  - Malocclusion.
  - Perceived severity of malocclusion.
  - Patients and mother locus of control.
- **Findings:**
  - Gender was a good predictor of adherence, compliance in headgear wear was better in females compared to males.
  - Perceived severity of malocclusion was good for predicting compliance.

### El-Mangoury (1981)

- **Patients:** 70 Patients
  - 14 years or older
- **Treatment:** Class II malocclusion under treatment with edgewise for minimum 6 months and were asked to wear headgear and elastics
- **Adherence Measures:**
  - Appliance maintenance.
  - Headgear wear.
  - Elastic wear.
  - Missing or being late for appointments.
  - Plaque index and oral hygiene.
- **Predictors:**
  - El-Mangoury psychological test.
  - Achievement and affiliation motivation test.
  - Attribution motivation test.
- **Findings:**
  - Psychological tests are a good method to predict patients’ compliance.
  - High-need achiever and high-need affiliators cooperate better during orthodontic treatment ($P=0.001$).
  - Affiliation motivation was the best predictor for headgear and elastic wear, appliance care, and appointment attendance.
  - The first predictor for oral hygiene was achievement motivation test.
<table>
<thead>
<tr>
<th>Study</th>
<th>Year</th>
<th>Patients</th>
<th>Age</th>
<th>Gender</th>
<th>Measured Adherence</th>
<th>Predictors</th>
</tr>
</thead>
</table>
| Woolass et al.     | 1988 | 219      | No information | No information | Measures of Adherence:  
  - Appointment attendance.  
  - Appliance maintenance.  
  - Oral hygiene care.  

Predictors:  
- Children’s Piers-Harris questionnaire and Children’s Olweus questionnaire and Children’s general questionnaire.  
- Parents (Parental Rutter questionnaire) a child has emotional or behavioural disturbances.  
- Parental general questionnaire (general questions about oral health and patient perception and attitudes towards malocclusion and orthodontic treatment).  
- Teachers (Teacher’s Rutter questionnaire) to assess if the child has any emotional or behavioural disturbances.  

Best-cooperation group reported increased self-concept of behaviour (P<0.01), a greater extent that they not show their anger (P<0.001) and they do not talk in the class (P<0.05).  
- The teacher reported that the more compliant children were brighter (P<0.001).  
- In the parental Rutter questionnaire, the parents of cooperative children reported that the children were less likely to tell lies (P<0.05), be absent from school (P<0.05), steal (P<0.05), and be disobedient (P<0.05). |
| Cucalon and Smith  | 1990 | 252      | 11-17 years   | 136 Females, 116 Males | Measures of Adherence:  
  - Oral hygiene.  
  - Appliance maintenance.  
  - Headgear wear.  
  - Missing or being late for appointments.  

Predictors:  
- Comprehensive Personal Assessment System: Self-Report Inventory.  
- The adolescent Alienation Index.  
- Home Index.  

Females were more compliant than males.  
- Compliant patients have high scores on self-esteem and more positive toward the future. Also cooperative patients had a better socioeconomic status. |
<table>
<thead>
<tr>
<th>Albino et al.</th>
<th>1991</th>
<th>39 Patients and parents</th>
<th>11-14 years</th>
<th>Fixed appliances</th>
<th>Patients: 21 Females 18 Males</th>
<th>Parents: 35 Females 4 Males</th>
<th>Measures of Adherence:</th>
<th>Predictors:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>- There was a decrease in compliance between T1 and T2, (P&lt;0.001).</td>
<td>- Parents’ positive attitudes toward orthodontic treatment predict only short-term compliance.</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>- Initial compliance predicts future compliance.</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Southard et al.</td>
<td>1991</td>
<td>104 Patients</td>
<td>13-18 years</td>
<td>No information</td>
<td>No information</td>
<td>Measures of Adherence:</td>
<td>Predictors:</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>- Wearing headgear. Maintaining oral hygiene. Appointment attendance. Appliance maintenance. Cooperation during appliance placement. Overall attitude and parent attitude.</td>
<td>The Million Adolescent Personality Inventory (MAPI), which is a behavioural test used to measure person’s characters and attitudes.</td>
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<td></td>
<td></td>
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<td></td>
<td></td>
<td>- Gender is positively correlated with patients’ compliance, the female more cooperative than males.</td>
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<tr>
<td></td>
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<td></td>
<td>- Of the scale, four of the scales positively correlate with compliance: scholastic achievement, sociable, forceful, and peer security.</td>
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<tr>
<td></td>
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<td></td>
<td>- Three of the scales were negatively correlated with compliance: societal conformity, sensitive, and confident.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
**Nanda and Kierl**

<table>
<thead>
<tr>
<th>Year</th>
<th>Patients and Parents</th>
<th>Age</th>
<th>Measure of Adherence</th>
<th>Predictors</th>
<th>Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>1992</td>
<td>100 Patients and 131 parents</td>
<td>9-16 years</td>
<td>No information</td>
<td>- Modified questionnaire of the Orthodontic Patient Cooperation Scale, answered by treating orthodontic postgraduate residents. Postgraduates were asked to fill out follow-up questionnaires.</td>
<td>- Age, gender, family income, single-parent versus two-parents had no significant relationship with patients’ compliance. - Doctor-patient relationship had a positive impact on patients’ compliance.</td>
</tr>
</tbody>
</table>

**Patients**
- 57 Females
- 43 Males

**Parents**
- 97 Females
- 32 Males
- 2 stepparents

**Predictors:**
1. Age and gender.
2. Crowne and Marlowe’s Social Desirability Scale for parents.
3. Jackson’s Personality Research Form for child’s need for approval and need for achievement.
4. Patients’ relation with their parents and peers.
6. Relationship with the orthodontist.

Questionnaires were given to the patients and their parents before starting the treatment and then every 6 months for two successive 6 months. The questionnaire that was given at the 6-month follow-up appointment only contained questions about:
- The need for orthodontic treatment.
- Relationship with the orthodontist.
<table>
<thead>
<tr>
<th>Study</th>
<th>Year</th>
<th>Patients</th>
<th>Age (years)</th>
<th>Gender</th>
<th>Measures of Adherence:</th>
<th>Predictors:</th>
<th>Predictors Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sergl et al.</td>
<td>1992</td>
<td>94</td>
<td>8-16</td>
<td>No info</td>
<td>Patient cooperation scale done by the treating orthodontists.</td>
<td>- Age.</td>
<td>- Gender, age, and parent occupation did not predict compliance.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Patients</td>
<td></td>
<td></td>
<td></td>
<td>- Gender.</td>
<td>- After 3 months of treatment, orthodontic attitudes (P&lt;0.008), and impulsiveness (P&lt;0.02) had a statistically significant correlation with compliance.</td>
</tr>
<tr>
<td></td>
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<td></td>
<td>- Occupation of the parents.</td>
<td>- After 6 months, dominance and impulsiveness (P&lt;0.001) as well as orthodontic attitudes (P&lt;0.002) had a statistically significant correlation with compliance.</td>
</tr>
<tr>
<td></td>
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<td></td>
<td></td>
<td>Questionnaire that involved the following:</td>
<td>- Patients who don’t have siblings were more compliant in wearing the appliance.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>- The scale “impulsiveness/self-control”.</td>
<td>- Patients who were initially motivated for treatment were better compliers.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>- The scale “tendency for dominance”.</td>
<td>- The more parental interest in treatment, the more cooperative patients.</td>
</tr>
<tr>
<td></td>
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<td></td>
<td></td>
<td>- The scale “anxiety”.</td>
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<tr>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>- The “orthodontic attitude scale”.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Evaluation was done at 3 and 6 months after starting the treatment.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bartsch et al.</td>
<td>1993</td>
<td>77</td>
<td>9-15</td>
<td>Bionators</td>
<td>Appliance wear hours measured by built-in timing devices.</td>
<td>- Questionnaires include the general inventory, general parents’ inventory, also items from mutual personality assessment and items from locus-of-control scale.</td>
<td>- Results revealed a complex non-linear relationship between age and compliance.</td>
</tr>
<tr>
<td>Sinha et al.</td>
<td>1996</td>
<td>199</td>
<td>8-17</td>
<td>No info</td>
<td>Orthodontic patient cooperation scale done by orthodontic residents.</td>
<td>- Questionnaire after 8-12 months into treatment filled out by patients which include:</td>
<td>- There was a statistically significant relationship between total orthodontists’ behaviour score and total patient cooperation score (P&lt;0.05).</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Patients</td>
<td></td>
<td></td>
<td>- Orthodontist behaviour questionnaire.</td>
<td>- Orthodontic visit satisfaction scale.</td>
<td>- Patient adherence is influenced by their relationship with their orthodontists.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>- Orthodontist-patient relationship.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| Johnson et al. | 1998 | 168 Patients and parents | No information (only stated that patients with mixed dentition) | Bionator or cervical headgear | No information | Measures of Adherence:  
- Self-reported compliance.  
Predictors:  
- Questionnaire contains questions on attitudes toward the appliances, factors affecting compliance. |
| Doll et al. | 2000 | 67 Patients | 9-32 years | 15 patients, one jaw removable appliance  
31 patients, both jaws removable appliance  
12 patients, functional appliance  
9 patients, fixed appliance  
(27 patients were treated by their first appliances and 40 with a second appliance) | 36 Females  
31 Males | Measures of Adherence:  
- Orthodontic patient cooperation scale done by orthodontists.  
Predictors:  
- Psychological Scales: questionnaire on the attitudes toward orthodontic therapy consisted of the following items:  
  - perceived severity of orthodontic malocclusion,  
  - expectation of treatment,  
  - dental aesthetics,  
  - attribution of causes for a successful dental treatment,  
  - appliance acceptance.  
- Self-observation log.  
- Appliance characteristics.  
- List of retrospective assessment of discomfort and appliance acceptance scale  
The questionnaire on the attitudes toward orthodontic therapy was given to patients at the session before appliance insertion and 6 months later. At the insertion of the appliance the patients were given self-observation logs to record any discomfort for 7 days and they were collected at 2 weeks following the insertion.  
- After 6 months, compliance was assessed by the orthodontists using patient cooperation scale. | - Pain, chew, and speak difficulties reduce compliance.  
- Bionator, more speech problems and associated non-compliance than headgear.  
- Headgear causes more pain but does not cause less compliance. |
- Patients’ compliance couldn’t be predicted from treatment expectations and appliance acceptance at the beginning of treatment.  
- Compliance was related to disliking wearing the appliance in public (10.5%) and feeling of tension (7.0%) after 6 months of treatment.  
- The greater the patients’ understanding of their important role in treatment success in the beginning of treatment, the more this attitude improved 6 months later.  
- Acceptance of appliance depends on patients’ attitude and discomfort; this acceptance in turn will affect compliance. |
### Chapter 1

#### Introduction

**Bos et al.** (2005)  
- 157 Patients and 155 parents  
  - Patients:  
    - Mean age for females 12 years  
    - Mean age for males 12.44 years  
  - Parents:  
    - Mean age for females 41.60 years  
    - Mean age for males 45.68 years  
  - No information  
  - Patients:  
    - 91 Females  
    - 66 Males  
  - Parents:  
    - 115 Females  
    - 40 Males  

**Measures of Adherence:**  
- Patients’ intention to adhere to treatment.  
- Parents’ intention to encourage their child to comply during orthodontic treatment.  

**Predictors:**  
- Questionnaires based on theory of reasoned action (TRA) model were distributed to the patients and their parents after treatment plan discussion which includes the following predictors:  
  - Attitudes towards compliance.  
  - Behavioural and normative beliefs.  
  - Subjective norms.  
  - Motivation to comply.  
  - Perceived control scale.  
  - Anticipated regret.  

- The most significant predictors for patients’ compliance were anticipated regret, attitude, and motivation to comply (P<0.001).  
- 20% of patients’ compliance can be estimated by the (TRA) model, while it estimated 16% of parents’ intention to encourage their child’s motivation during treatment.

**Horsley et al.** (2007)  
- 185 Medicaid  
  - 522 Non-Medicaid  
  - No information  
  - Medicaid:  
    - 106 Females  
    - 79 Males  
  - Non-Medicaid:  
    - 306 Females  
    - 216 Males  

**Measures of Adherence:**  
- Appointment keeping behaviour during 12-month period.  

**Predictors:**  
- Medicaid status.  

- Compliance with appointment attendance indicated that Medicaid patients broke more appointments than non-Medicaid (P<0.0001).

**Dickens et al.** (2008)  
- 43 Medicaid  
  - 42 Non-Medicaid  
  - Mean age for Medicaid patients 13.6 years  
  - Mean age for Non-Medicaid patients 15 years  
  - Fixed orthodontic treatment  
  - No information  

**Measures of Adherence:**  
- Broken appointments.  
- Broken appliances.  
- Comments about poor oral hygiene.  

**Predictors:**  
- Medicaid status.  

- No difference between Medicaid and non-Medicaid in compliance.
<table>
<thead>
<tr>
<th></th>
<th>Year</th>
<th>Patients</th>
<th>Age</th>
<th>No information</th>
<th>Females</th>
<th>Males</th>
<th>Measures of Adherence:</th>
<th>Predictors:</th>
<th>Predictors:</th>
<th>Measures of Adherence:</th>
<th>Predictors:</th>
</tr>
</thead>
</table>
| Mandall et al. | 2008 | 144      | 10-19 years | No information | 79 | 65 | - Treatment completion.  
- Failed appointments. 
- Breakage of appliances. 
- Oral hygiene. | - Age. 
- Gender. 
- Socioeconomic status. 
- Index of Orthodontic Treatment Need (IOTN). 
- Quality of life including orthodontic utility values and oral aesthetic subjective impact score (OASIS); which evaluate the child’s concern about his teeth. | | | - No statistical differences were found between relation between age, gender, socioeconomic status, Index of Orthodontic Treatment Need (IOTN), quality of life, and compliance (P>0.05). |
| Lee et al. | 2008 | 561      | 16.4 ± 6.5 years | No information | 366 | 195 | - Oral hygiene. 
- Attending the scheduled appointments. 
- Appliance wear. 
Measured by the orthodontist and 3 hygienists. | Two types of locus of control (LOS) questionnaires: 
- The first questionnaire measured attitude characteristics for internal control orientation based on the Rotter internal control scale (RICS). 
- The second questionnaire designed to measure the magnitude of external control based on Nowicki-Strickland external control scale (NSECS). 
The questionnaires were given at the beginning and at the end of the treatment. | | - No statistical significant difference between good and poor compliance group in either Rotter internal control scale (RICS) or Nowicki-Strickland external control scale (NSECS) profile. 
- After starting orthodontic treatment, the Nowicki-Strickland external control scale (NSECS) score was lower (P<0.001), while the Rotter internal control scale (RICS) score was unchanged. |
<table>
<thead>
<tr>
<th>Study</th>
<th>Year</th>
<th>Participants</th>
<th>Age</th>
<th>Treatment</th>
<th>Patients</th>
<th>Parents</th>
<th>Measures of Adherence</th>
<th>Predictors</th>
</tr>
</thead>
</table>
| Daniels et al.  | 2009 | 227 Patients | 7.11-16.11 years | Fixed appliances on the anterior maxillary teeth | 113 Females 114 Males | 172 Females 55 Males | - Treatment cooperation reported by the patients and their parents using questionnaires. | - Patients who had braces already are given another survey called Survey for Current Orthodontic Patients and their parents were given Survey for Parents of Orthodontic Patients.  
- All surveys included the following groups of questions:  
  1. Demographic data (age, gender, ethnicity, grade in school).  
  2. Previous orthodontic and dental history.  
- Patients’ motivation for treatment is positively associated with patients’ compliance during treatment.  
- The male patients were less cooperative with treatment than female patients ($P=0.008$).  
- The female parents reported greater perceived patient compliance than male parents ($P=0.018$). |
| Aljewair et al. | 2011 | 41 Patients | 12-16 years | Maxillary and mandibular fixed orthodontic treatment | 24 Females 17 Males | - Plaque and gingival indices  
- Appointment attendance  
- Appliance maintenance | Measures of Adherence | - First questionnaire which was given to the patients before bonding asked about patients’ demographics, attitudes toward oral health, and current and past dental behaviour.  
- Second questionnaire which was given to the patients after 150 days of bonding included questions about attitudes towards treatment, beliefs, psychological, and psychosocial factors.  
- Parents were asked to provide family demographic information.  
- After initial worsening, the subjects’ compliance with OHI improved at 5 months after bonding.  
- Results revealed that a good predictor of compliance was patients who live with married parents ($P=0.001$) and those reporting good academic performance in school ($P=0.013$), also patients who perceived severity of malocclusion ($P=0.043$). |
### Schafer et al. 2015

| Patients | Functional or active removable orthodontic appliances | Measures of adherence: 
| Microsensors incorporated into the appliances. |
| Predictors: 
| - Age. 
| - Gender. 
| - Type of device. 
| - Location of treatment. 
| - Health insurance status. |

<table>
<thead>
<tr>
<th>Year</th>
<th>141 Patients</th>
<th>7 to 15 years</th>
<th>53 Females 88 Males</th>
</tr>
</thead>
</table>

- Results revealed that female patients wore their devices longer than males (P = 0.017).
- Wear time decrease with increasing age (P < 0.0001).
- Patients treated in private practice wore their appliances more than patients treated in University Hospital (P < 0.0001)
- Patients with health insurance had a higher wear time (P = 0.033).
- There was a significant difference in wear time according to the type of appliance only in the first month (P = 0.04) but no difference was found over the 3-month period.

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### Table 1-2: Summary of Previous Randomized Controlled Trials on Adherence among Orthodontic Patients.

<table>
<thead>
<tr>
<th>Author</th>
<th>Sample Size</th>
<th>Age</th>
<th>Intervention</th>
<th>Outcome</th>
<th>Baseline T1</th>
<th>Follow-up T2</th>
<th>Follow-up T3</th>
<th>Follow-up T4</th>
<th>Follow-up T5</th>
<th>Follow-up T6</th>
</tr>
</thead>
</table>
| McGlynn et al. (1987) | 59 Patients | 12-31 years | - Behavioural self-management (SM) received self-management manual and oral hygiene packet, 29 patients 15 new patients (1-6 months treatment) and 14 experienced patients (1-2 years treatment) and - Instructions-plus-persuasion (IP) received oral hygiene packet and the first four pages of the self-management manual, 30 patients 15 new (1-6 months treatment) and 15 experienced patients (1-2 years treatment) | - Plaque index  
Self-management  
New patients 15  
Experienced patients 14  
Instructions-persuasion  
New patients 16  
Experienced patients 14 | Mean ± SD  
2 weeks   | 5 weeks   | 8 weeks   | - No T5 follow-up  
- No T6 follow-up |
|                 |             |           | - Gingival index  
Self-management  
New patients 15  
Experienced patients 14  
Instructions-persuasion  
New patients 16  
Experienced patients 14 |             | 1.61 (0.58) | -29.6 (32.3) | -21.7 (23.0) | -42.7 (31.0) | -34.8 (21.0) | -50.5 (26.9) | 32.0 (22.0) |
|                 |             |           | - Cariogenic bacterial activity  
Self-management  
New patients 15  
Experienced patients 14  
Instructions-persuasion  
New patients 16  
Experienced patients 14 |             | 1.2x10^6 (1.2x10^5) | 79.6 (439.6) | 210.5 (715.5) | -59.5 (74.4) | -83.2 (35.3) | -96.7 (3.0) | 94.4 (7.2) |
### Gross et al. (1988)

<table>
<thead>
<tr>
<th>Year</th>
<th>No. of Patients</th>
<th>Age</th>
<th>Description of Intervention</th>
<th>Attendance</th>
<th>5 Weeks Later</th>
</tr>
</thead>
<tbody>
<tr>
<td>1988</td>
<td>No information</td>
<td>8-46 years</td>
<td>Lottery program (patients who attended their appointments and arrived on time would be entered into a lottery program and receive a 15$ gift certificate)</td>
<td>69% 7% 4%</td>
<td>79% 4% 1%</td>
</tr>
</tbody>
</table>

### Yeung et al. (1989)

<table>
<thead>
<tr>
<th>Year</th>
<th>No. of Patients</th>
<th>Age</th>
<th>Description of Intervention</th>
<th>Bleeding Index</th>
<th>Gingival Index</th>
<th>Plaque Index</th>
<th>Periodontal pocket depth</th>
<th>Gingival fluid</th>
<th>End of Treatment</th>
<th>Follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>1989</td>
<td>62 Patients</td>
<td>14.7 years</td>
<td>Intervention group: Oral hygiene program consisted of: 1- explanation of relation between dental plaque and gingival inflammation 2- dietary counselling 3- training on plaque removal 4- evaluation of plaque removal using disclosing solutions 5- Control group: received standard care</td>
<td>Mean ± SD</td>
<td>Mean ± SD</td>
<td>Mean ± SD</td>
<td>Mean ± SD</td>
<td>Mean ± SD</td>
<td>Mean ± SD</td>
<td>No T3 follow-up</td>
</tr>
<tr>
<td></td>
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<td></td>
<td>4.30 (0.46) 2.31 (0.50)</td>
<td>6.69 (0.52) 6.10 (0.54)</td>
<td>7.27 (0.70) 6.41 (0.59)</td>
<td>14.18 (0.58) 15.31 (0.55)</td>
<td>11.75 (0.41) 11.55 (0.54)</td>
<td>1.39 (0.25) 3.24 (0.43)</td>
<td>3.94 (0.48) 5.45 (0.43)</td>
</tr>
</tbody>
</table>
### Chapter 1

**Introduction**

- **Richter et al. (1998)**
  - 144 Patients
  - 9.6-17.6 years
  - **-Control**
    - Award for compliance
    - Reward for compliance
    (all participants were divided into high and low compliers before assigning them to a specific group)
  - **-Oral hygiene**
    - High Control
    - High Award
    - High Reward
    - Low Control
    - Low Award
    - Low Reward
    - Mean ± SD
      - 19.6 ± 5.6
      - 16.6 ± 4.3
      - 19.2 ± 6.8
      - 14.4 ± 7.1
      - 14.1 ± 4.7
      - 16.2 ± 5.9
      - 18.3 ± 6.7
      - 15.6 ± 8.1
      - 17.7 ± 5.4
      - 11.6 ± 7.9
      - 14.5 ± 6.6
      - 17.4 ± 4.8
      - Mean ± SD
      - 19.6 ± 5.6
      - 16.6 ± 4.3
      - 19.2 ± 6.8
      - 14.4 ± 7.1
      - 14.1 ± 4.7
      - 16.2 ± 5.9
      - 18.3 ± 6.7
      - 15.6 ± 8.1
      - 17.7 ± 5.4
      - 11.6 ± 7.9
      - 14.5 ± 6.6
      - 17.4 ± 4.8
  - **6 Months**
    - No T3 follow-up
    - No T4 follow-up
    - No T5 follow-up
    - No T6 follow-up
  - **-Appointment attendance**
    - High Control
    - High Award
    - High Reward
    - Low Control
    - Low Award
    - Low Reward
    - Mean ± SD
      - 25.0 ± 8.3
      - 21.4 ± 8.1
      - 24.3 ± 2.4
      - 22.5 ± 6.2
      - 20.0 ± 9.8
      - 24.5 ± 2.2
      - 25.6 ± 6.7
      - 20.5 ± 7.5
      - 24.5 ± 2.2
      - 23.7 ± 3.1
      - 22.9 ± 5.8
      - 23.7 ± 5.6
  - **-Appliance wear**
    - High Control
    - High Award
    - High Reward
    - Low Control
    - Low Award
    - Low Reward
    - Mean ± SD
      - 25.4 ± 22.4
      - 19.1 ± 5.2
      - 19.6 ± 4.9
      - 10.5 ± 9.1
      - 10.7 ± 10.2
      - 13.6 ± 8.1
      - 23.1 ± 10.4
      - 18.9 ± 6.5
      - 16.9 ± 9.6
      - 9.9 ± 7.6
      - 15.7 ± 6.9
      - 18.6 ± 3.5
  - **-Appliance maintenance**
    - High Control
    - High Award
    - High Reward
    - Low Control
    - Low Award
    - Low Reward
    - Mean ± SD
      - 26.8 ± 7.8
      - 22.9 ± 6.3
      - 22.9 ± 6.8
      - 24.4 ± 2.4
      - 23.7 ± 5.2
      - 22.5 ± 5.5
      - 25.7 ± 9.2
      - 20.8 ± 5.5
      - 20.5 ± 2.2
      - 21.7 ± 7.6
      - 20.8 ± 9.6
      - 24.5 ± 2.3
<table>
<thead>
<tr>
<th>Study</th>
<th>Patients</th>
<th>Age Range</th>
<th>Controls</th>
<th>Intervention</th>
<th>Measures</th>
<th>Mean ± SD</th>
<th>3 Months</th>
<th>6 Months</th>
<th>Follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feil et al. (2002)</td>
<td>38</td>
<td>14-18 years</td>
<td>- Control</td>
<td>- Plaque Index</td>
<td>Mean ± SD</td>
<td>74 (±11.46)</td>
<td>78 (±12.18)</td>
<td>79 (±10.76)</td>
<td>- No T4 follow-up</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>- Hawthorne effect</td>
<td>Control</td>
<td></td>
<td>71 (±11.52)</td>
<td>54 (±13.79)</td>
<td>52 (±13.04)</td>
<td>- No T5 follow-up</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>3 Months</td>
<td></td>
<td></td>
<td></td>
<td>- No T6 follow-up</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>6 Months</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trakyali et al. (2008)</td>
<td>30</td>
<td>10.07-10.91 years</td>
<td>- Control</td>
<td>- Timer module</td>
<td>Mean ± SD</td>
<td>12.97 ± 5.18</td>
<td>12.98 ± 3.97</td>
<td>15.45 ± 4.32</td>
<td>- No T4 follow-up</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>- Conscious hypnosis</td>
<td>Control</td>
<td></td>
<td>11.69 ± 4.98</td>
<td>12.98 ± 3.97</td>
<td>18.04 ± 2.72</td>
<td>- No T5 follow-up</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>- Timer module</td>
<td>Hypnosis</td>
<td></td>
<td>15.53 ± 4.11</td>
<td>15.45 ± 4.32</td>
<td>14.55 ± 3.69</td>
<td>- No T6 follow-up</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Month 2</td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>Month 3</td>
<td></td>
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<td></td>
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<td></td>
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<td>Month 4</td>
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<td>Month 5</td>
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<td></td>
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<td></td>
<td>Month 6</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wright et al. (2010)</td>
<td>60</td>
<td>12-16 years</td>
<td>- Control (verbal information only)</td>
<td>- Anxiety</td>
<td>Mean</td>
<td>30.37</td>
<td>28.73</td>
<td>28.31</td>
<td>- No T4 follow-up</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>- Intervention (verbal and written information)</td>
<td>Control</td>
<td></td>
<td>30.64</td>
<td>32.40</td>
<td>32.84</td>
<td>- No T5 follow-up</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>- Motivation</td>
<td></td>
<td></td>
<td></td>
<td>- No T6 follow-up</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
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<td></td>
<td>Control</td>
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<tr>
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<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
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<td></td>
<td>- Apprehension</td>
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<td>Intervention</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>- Periodontal examination</td>
<td></td>
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</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Intervention</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acharya et al. (2011)</td>
<td>62 Patients</td>
<td>12-18 years</td>
<td>- Conventional plaque control</td>
<td>- Chairside motivational tests with conventional plaque control</td>
<td>- Microscope demonstration</td>
<td>Plaque Score</td>
<td>Mean ± SD</td>
<td>3 Months</td>
<td>6 Months</td>
</tr>
<tr>
<td>----------------------</td>
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<td>---------------------------------------------------------------</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Group I</td>
<td>1.1071 ±0.3327</td>
<td>1.0139 ±0.3755</td>
<td>1.0720 ±0.0647</td>
</tr>
<tr>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>Group II</td>
<td>1.1250 ±0.3352</td>
<td>0.9457 ±0.3525</td>
<td>1.0455 ±0.3915</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Group III</td>
<td>1.1343 ±0.4211</td>
<td>0.9514 ±0.2786</td>
<td>0.6410 ±0.3984</td>
</tr>
</tbody>
</table>
2. A SYSTEMATIC REVIEW OF RANDOMISED CONTROLLED TRIALS OF INTERVENTIONS TO IMPROVE ADHERENCE AMONG ORTHODONTIC PATIENTS AGED 12 TO 18

2.1 AIM

The aim of this systematic review was to investigate the effectiveness of interventions to enhance adherence among orthodontic patients aged 12 to 18 years. Specific adherence outcomes included were: recall of information given by the orthodontic team, attendance at orthodontic appointments, self-reported oral hygiene behaviour, and clinical indices of oral hygiene.

2.2 MATERIALS AND METHODS

A systematic review of interventions aimed to improve adherence to advice given to orthodontic patients aged 12 to 18 years regarding key behaviours (appointment attendance, oral hygiene-related behaviours) was conducted.

2.2.1 Inclusion Criteria

2.2.1.1 Type of Studies

Randomised controlled studies with a before and after design were included.

2.2.1.2 Participants

Participants were 12 to 18 years undergoing upper and lower fixed orthodontic appliances treatment.
2.2.1.3 Types of Interventions

These included:

- Verbal advice.
- Written advice.
- Interventions based on psychological theories.
- Educational intervention.

2.2.1.4 Comparisons

These included:

- Intervention versus no intervention.
- Comparison of two or more interventions.

2.2.1.5 Outcomes

The following primary outcomes were examined:

- Recall of information as measured by a validated questionnaire.
- Attendance at orthodontic appointments as recorded in the dental and medical notes.
- Self-reported behaviour as related to oral health.
- Clinical indices, such as plaque and gingival indices.
- Orthodontic patient cooperation scale (OPCS)

The following secondary outcomes were examined:

- Motivation to orthodontic treatment, as assessed by any validated questionnaire.
o Expectation of orthodontic treatment, as assessed by any validated questionnaire.

o Apprehension and worries about orthodontic treatment, as assessed by any validated questionnaire.

### 2.2.2 Information Sources

All studies were identified through electronic and hand searches. All relevant studies were identified irrespective of the language, that is, non-English articles were considered for inclusion after an accurate translation.

#### 2.2.2.1 Electronic Search

An electronic search was conducted using a number of platforms.

These are:

- Medline via OVID (January 1, 1966 through March 1, 2012).
- EMBASE.
- Cochrane central register of control trials until March 2012.

The search strategy is listed in Table 2-1.

### Table 2-1: Search Methodology for Electronic Systematic Review

<table>
<thead>
<tr>
<th>Section</th>
<th>Number of Studies</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Section A: Adherence</strong></td>
<td></td>
</tr>
<tr>
<td>1. Adherence .exp</td>
<td>69,846</td>
</tr>
<tr>
<td>2. Compliance .exp</td>
<td>102,181</td>
</tr>
<tr>
<td>3. Concordance .mp</td>
<td>21,510</td>
</tr>
<tr>
<td>4. 1 OR 2 OR 3</td>
<td>179,151</td>
</tr>
<tr>
<td><strong>Section B: Orthodontics</strong></td>
<td></td>
</tr>
<tr>
<td>1. &quot;orthodontics&quot;.exp</td>
<td>21,664</td>
</tr>
</tbody>
</table>
Combine A and B

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. 4 and 5</td>
<td>390</td>
</tr>
<tr>
<td>Limit to human</td>
<td>381</td>
</tr>
</tbody>
</table>

2.2.2.2 Hand Search

A hand search was also undertaken to identify relevant studies from the following journals: American Journal of Orthodontics and Dentofacial Orthopedics, The Angle Orthodontist, European Journal of Orthodontics, and The Journal of Orthodontics from 1990-2012. No articles (including non-English) were identified and so nothing was retrieved.

2.2.2.3 Personal Contact

In cases where any further information about additional or unpublished studies that were eligible for inclusion in the review was required, authors of the included studies were contacted by the review authors.

2.2.2.4 Language

Non-English articles were considered for inclusion after translation.

2.2.3 Study Selection and Data Extraction

The titles and abstracts resulting from the searches were independently screened by two of the review authors to select potentially relevant studies (AA, JTN). The full text of each study was obtained, and inclusion was assessed independently and in duplicate. Any disagreement regarding the inclusion or exclusion of a study was resolved by discussion or referred to a third reviewer (FMcD) for a third opinion in the inclusion process. The third
assessor was only approached for one study; for all other studies there was complete agreement between the two reviewers in screening for inclusion. The full data extraction and quality assessment were conducted by three reviewers using a specifically designed data extraction form. Independent checks for data extraction were undertaken by all three reviewers for all included papers and agreement was 100%. The variables for which data were sought are summarized in Table 2-3.

2.2.4 Risk of Bias Analysis

Each of the randomised controlled trials found in the search was reviewed using the Consolidated Standards Of Reporting Trials (CONSORT, http://www.consort-statement.org/consort-2010, Accessed July 4 2014) criteria for risk of bias. For each of the CONSORT criteria a Yes/No dichotomous judgment was made. All identified studies were reviewed for risk of bias by two independent raters (AA, JTN) and where disagreements were found these were resolved by discussion. Given that the reviews were based on published studies, there is a risk of publication bias in the findings.

2.2.5 Data Analysis

A meta-analysis was planned combining data across studies to test the efficacy of interventions, provided that the data were sufficiently homogeneous and there was sufficient homogeneity in the types of intervention reported.
2.3 RESULTS

As a result of the electronic searches, 381 articles were identified. From these, 374 proved not to be of direct relevance to the systematic review we were conducting, typically because they were addressing a different orthodontic topic (though they mentioned the importance of compliance in orthodontic treatment) or were not trials. Four randomised controlled trials were included (See Figure 2-1). Three trials were excluded as listed in Table 2-2 with the reason for exclusion.

Table 2-2: Summary of the Studies that Were Excluded

<table>
<thead>
<tr>
<th>Author</th>
<th>Year</th>
<th>Reason for exclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>McGlynn et al.</td>
<td>1987</td>
<td>Age range was between 12 to 31 years</td>
</tr>
<tr>
<td>Gross et al.</td>
<td>1988</td>
<td>Age range was between 8 and 46 years, and no information on the type of orthodontic treatment used</td>
</tr>
<tr>
<td>Trakyali et al.</td>
<td>2008</td>
<td>Age range was 10.78 +/- 1.06 and 10.07 +/-1.09, and patients were treated using headgear</td>
</tr>
</tbody>
</table>
Figure 2-1: PRISMA Flow Diagram

- **Identification**
  - 381 Records identified through database searching

- **Screening**
  - 381 Records screened
    - 7 Full-text articles assessed for eligibility
      - 3 Full-text articles excluded, with reasons
  - 374 Records excluded

- **Eligibility**
  - 4 Studies included in qualitative synthesis
  - 0 Studies included in quantitative synthesis

51
Table 2-3: Summary of Data Extraction

<table>
<thead>
<tr>
<th>Author</th>
<th>Year</th>
<th>Nature of Intervention</th>
<th>Sample Size</th>
<th>Age</th>
<th>Orthodontic Status</th>
<th>Gender</th>
<th>Outcomes Measures</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Richter et al.</strong></td>
<td>1998</td>
<td>Control Group: received standard instructions</td>
<td>48</td>
<td>9.6-17.6 years</td>
<td>Fixed and extra oral orthodontic appliances</td>
<td>81 Females, 63 Males</td>
<td>Orthodontic Patients Compliance Scale to compare compliance before and after the 6-month experimental period</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Award group: received compliance instructions and a written evaluation of compliance</td>
<td>48</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Reward group: received compliance instructions, a report card, and eligibility to receive rewards for adherent behaviour</td>
<td>48</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Feil et al.</strong></td>
<td>2002</td>
<td>Intervention group: oral hygiene instructions &quot;Hawthorne effect&quot;</td>
<td>19</td>
<td>14-18 years</td>
<td>Fixed orthodontic appliance</td>
<td>10 Females, 10 Males</td>
<td>Plaque score: - Immediate - 3 months - 6 months</td>
</tr>
<tr>
<td>(n = 40) (2 dropouts of unknown gender)</td>
<td></td>
<td>Control Group: no intervention</td>
<td>19</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Wright et al.</strong></td>
<td>2010</td>
<td>Intervention group: leaflet about fixed appliances</td>
<td>29</td>
<td>12-16 years</td>
<td>Upper and lower fixed appliances</td>
<td>No information</td>
<td>Motivation - Apprehension - Anxiety - Appointment attendance - Periodontal status - Appliance breakages</td>
</tr>
<tr>
<td>(n = 60)</td>
<td></td>
<td>Control group: verbal information about fixed appliances</td>
<td>31</td>
<td></td>
<td></td>
<td></td>
<td>T1: the beginning of treatment T2: 4 weeks T3: 12 weeks</td>
</tr>
<tr>
<td><strong>Acharya et al.</strong></td>
<td>2011</td>
<td>Group I: conventional plaque control</td>
<td>21</td>
<td>12-18 years</td>
<td>Fixed appliances No further information</td>
<td>No information</td>
<td>Plaque score: - Immediate - 3 months - 6 months</td>
</tr>
<tr>
<td>(n = 62)</td>
<td></td>
<td>Group II: chairside motivational tests with conventional plaque control</td>
<td>23</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Group III: microscope demonstration</td>
<td>18</td>
<td></td>
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</tbody>
</table>
Meta-analysis was not performed because of methodological heterogeneity among the selected trials. The outcome measures chosen were different for each paper. Each study was viewed and appraised separately. Table 2-4 shows the characteristics of the included randomised controlled trials.

In the first randomised controlled trial identified, Richter et al. evaluated the effect of a reward system on improving compliance among orthodontic patients. The participants consisted of 144 patients (63 males, 81 females) with an age range of 9.6 to 17.6 years who underwent orthodontic treatment. The patients were divided into three groups: a control group who received standard instructions; an award group who received compliance instruction and a written evaluation of compliance; and a reward group who received compliance instructions, a report card, and eligibility to receive rewards for adherent behaviour. The patients in each group were divided into two main categories—high compliers and low compliers—using the Orthodontic Patient Cooperation Scale, which is used to evaluate patients’ compliance at the initiation of the investigation and after 6 months of treatment. Outcomes assessed were oral hygiene, appointment attendance, appliance wear, and appliance maintenance. The researchers compared compliance before and after 6 months in treatment. The results showed that there was no significant improvement of the above-average compliers who received rewards. Below average compliers did not improve significantly either. However, the oral hygiene scores for the low compliers in the reward group were better than the low compliers’ scores in the control group (Richter et al., 1998).
Table 2-4: Characteristics of the Included Randomised Clinical Trials.

<table>
<thead>
<tr>
<th>Author</th>
<th>Sample Size</th>
<th>Age</th>
<th>Intervention</th>
<th>Outcome</th>
<th>Baseline</th>
<th>T1</th>
<th>Follow-Up</th>
<th>T2</th>
<th>Follow-Up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Richter et al. (1998)</td>
<td>144</td>
<td>9.6-17.6 years</td>
<td>1- Control</td>
<td>Oral hygiene</td>
<td>Mean</td>
<td>S.D.</td>
<td>Mean</td>
<td>S.D.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>2- Award for compliance</td>
<td>High control</td>
<td>19.6</td>
<td>5.6</td>
<td>18.3</td>
<td>6.7</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>High Award</td>
<td>16.6</td>
<td>4.3</td>
<td>15.6</td>
<td>8.1</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>High Reward</td>
<td>19.2</td>
<td>6.8</td>
<td>17.7</td>
<td>5.4</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Low control</td>
<td>19.6</td>
<td>5.6</td>
<td>11.6</td>
<td>7.9</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Low Award</td>
<td>16.6</td>
<td>4.3</td>
<td>14.5</td>
<td>6.6</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Low Reward</td>
<td>19.2</td>
<td>6.8</td>
<td>17.4</td>
<td>4.8</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>(all participants were divided into high and low compliers before assigning them to a specific group)</td>
<td>Appointment attendance</td>
<td>Mean</td>
<td>S.D.</td>
<td>Mean</td>
<td>S.D.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>High control</td>
<td>25</td>
<td>8.3</td>
<td>25.6</td>
<td>6.7</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>High Award</td>
<td>21.4</td>
<td>8.1</td>
<td>20.5</td>
<td>7.5</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>High Reward</td>
<td>24.3</td>
<td>2.4</td>
<td>24.5</td>
<td>2.2</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Low control</td>
<td>22.5</td>
<td>6.2</td>
<td>23.7</td>
<td>3.1</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Low Award</td>
<td>20</td>
<td>9.8</td>
<td>22.9</td>
<td>5.8</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>Low Reward</td>
<td>24.5</td>
<td>2.2</td>
<td>23.7</td>
<td>5.6</td>
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</tr>
<tr>
<td></td>
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<td></td>
<td></td>
<td>Appliance wear</td>
<td>Mean</td>
<td>S.D.</td>
<td>Mean</td>
<td>S.D.</td>
<td></td>
</tr>
<tr>
<td></td>
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<td></td>
<td></td>
<td>High control</td>
<td>25.4</td>
<td>22.4</td>
<td>23.1</td>
<td>10.4</td>
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<td></td>
<td></td>
<td>High Award</td>
<td>19.1</td>
<td>5.2</td>
<td>18.9</td>
<td>6.5</td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>High Reward</td>
<td>19.6</td>
<td>4.9</td>
<td>16.9</td>
<td>9.6</td>
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<td></td>
<td></td>
<td>Low control</td>
<td>10.5</td>
<td>9.1</td>
<td>9.9</td>
<td>7.6</td>
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<td></td>
<td>Low Award</td>
<td>10.7</td>
<td>10.2</td>
<td>15.7</td>
<td>6.9</td>
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<tr>
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<td>Low Reward</td>
<td>13.6</td>
<td>8.1</td>
<td>18.6</td>
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</tr>
<tr>
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<td>Appliance maintenance</td>
<td>Mean</td>
<td>S.D.</td>
<td>Mean</td>
<td>S.D.</td>
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<td>High control</td>
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<td>High Award</td>
<td>22.9</td>
<td>6.3</td>
<td>20.8</td>
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<td></td>
<td></td>
<td></td>
<td>High Reward</td>
<td>22.9</td>
<td>6.8</td>
<td>20.5</td>
<td>2.2</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Low control</td>
<td>24.4</td>
<td>2.4</td>
<td>21.7</td>
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<td></td>
<td></td>
<td>Low Award</td>
<td>23.7</td>
<td>5.2</td>
<td>20.8</td>
<td>9.6</td>
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<td></td>
<td></td>
<td>Low Reward</td>
<td>22.5</td>
<td>5.5</td>
<td>24.5</td>
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<td></td>
</tr>
<tr>
<td>Feil et al. (2002)</td>
<td>38</td>
<td>14-18 years</td>
<td>1- Control</td>
<td>Plaque Index</td>
<td>Mean</td>
<td>S.D.</td>
<td>Mean 3 Months</td>
<td>S.D. 6 Months</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>2- Hawthorne effect</td>
<td>74%</td>
<td>11.5</td>
<td>78%</td>
<td>12.2</td>
<td>79%</td>
<td>10.8</td>
</tr>
<tr>
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<td></td>
<td></td>
<td>71%</td>
<td>11.5</td>
<td>54%</td>
<td>13.8</td>
<td>52%</td>
<td>13.0</td>
</tr>
<tr>
<td>Wright et al. (2010)</td>
<td>60</td>
<td>12-16 years</td>
<td>1- Control (Verbal Information)</td>
<td>Anxiety score</td>
<td>Mean</td>
<td>4 Weeks</td>
<td>12 Week</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>2- Intervention (Verbal and written information)</td>
<td>Control</td>
<td>30.4</td>
<td>28.7</td>
<td>28.3</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Intervention</td>
<td>30.6</td>
<td>32.4</td>
<td>32.8</td>
<td></td>
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<tr>
<td></td>
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<td>Motivation score</td>
<td>Control</td>
<td>32.4</td>
<td>34.8</td>
<td>29.8</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Intervention</td>
<td>28.4</td>
<td>26.0</td>
<td>31.2</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Apprehension score</td>
<td>Control</td>
<td>31.3</td>
<td>29.2</td>
<td>29.2</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Intervention</td>
<td>29.6</td>
<td>32.0</td>
<td>31.8</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Periodontal examination (BPE)</td>
<td>Control</td>
<td>30.8</td>
<td>30.9</td>
<td>36.5</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Intervention</td>
<td>30.2</td>
<td>30.1</td>
<td>34.8</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Feil et al. used a single-blind, quasi-random assignment, with 40 patients ranging in age from 14 to 18 years with poor oral hygiene and who were undergoing fixed orthodontic treatment. Only 38 participants who continued the study were randomly assigned to two groups of 19 participants. In the intervention group, the Hawthorne effect (Parsons, 1991) was induced by approaching the participants during a regular appointment and telling them that they were participating in an experiment evaluating the effectiveness of a new orthodontic toothpaste (in reality, regular Crest with fluoride, Proctor & Gamble) that would improve the oral health for orthodontic patients specifically. All toothpaste was provided in an unmarked tube except for patient identifier number. The 19 participants in the control group were not asked to participate in any activity not usually practiced during their orthodontic treatment. The outcome measured was the plaque index. Results showed that there was no plaque score difference between groups at baseline (P > 0.05). Means and standard deviations for tooth surface covered with disclosed plaque for the study and control groups, respectively, were 71% (SD 11.52) and 74% (SD 11.46) at baseline; 54% (SD 13.79) and 78% (SD 12.18) at 3 months; and 52% (SD 13.04) and 79% (SD 10.76) at 6 months. Finally, the intervention group showed better reduction in plaque scores at 3 and 6 months (Feil et al., 2002).

<table>
<thead>
<tr>
<th>Acharya et al. (2011)</th>
<th>62</th>
<th>12-18 years</th>
<th>1- Conventional plaque control</th>
<th>Plaque Score</th>
<th>Mean</th>
<th>S.D.</th>
<th>3 months Mean</th>
<th>S.D.</th>
<th>6 months Mean</th>
<th>S.D.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>2- Chairside motivational tests with conventional plaque control</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
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<td>3- Microscope demonstration</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Group I</td>
<td>1.1</td>
<td>0.3</td>
<td>1.0</td>
<td>0.4</td>
<td>1.1</td>
<td>0.1</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Group II</td>
<td>1.1</td>
<td>0.3</td>
<td>0.9</td>
<td>0.4</td>
<td>1.0</td>
<td>0.4</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Group III</td>
<td>1.1</td>
<td>0.4</td>
<td>1.0</td>
<td>0.3</td>
<td>0.6410</td>
<td>0.4</td>
<td></td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

\(^1\text{CAE} \) Clinical Adherence Evaluation.
Wright et al. evaluated the effect of written information on adolescent anxiety, motivation, and compliance on 60 patients (age range 12–16 years) who did not undergo previous orthodontic treatment and required dual-arch appliance therapy. Randomisation was done using a computer-generated unstratified allocation sequence in two groups. The intervention group received verbal and written information while the control group received verbal instructions only. The outcomes measured were motivation, apprehension, anxiety, and compliance with emphasis on appointment attendance, periodontal status, and appliance breakages at the of beginning of treatment (T1), after 4 weeks of treatment (T2), and at 12 weeks of treatment (T3). Results showed that there was no mean change in anxiety scores for either group between T1 and T2. There was a statistically significant difference in motivation scores between the groups after consent to orthodontic treatment, that is, the intervention group showed a smaller decline/reduction in motivation. Although a generalized reduction in anxiety, motivation, and apprehension as treatment progressed was demonstrated by the negative differences between T1 and T3 for both groups, these differences were not significant. The intervention group’s periodontal condition improved between T1 and T3, in contrast to the control group’s periodontal condition. At T3, both groups showed similar levels of motivation, apprehension, and anxiety, but the intervention group was better in terms of appointment attendance, periodontal status, and appliance breakages (Wright et al., 2010).

Acharya et al. (2011) randomly allocated 62 orthodontic patients (age range 12–18 years) to three types of intervention. Randomization was performed using a systematic random sampling technique. Group I consisted of 21 patients who were motivated through
conventional plaque control measures (for example, plaque was disclosed with 2% mercurochrome). The composition of plaque, its effects on oral health, and the importance of its removal were stressed, and a horizontal scrubbing technique of brushing was demonstrated to the patients. Group II consisted of 23 patients who were motivated for the dental plaque removal using chairside motivational techniques. As in Group I, conventional plaque control measures were also demonstrated to the patients. Group III consisted of 18 patients who were motivated by showing them live motile bacteria in their own plaque under a phase contrast microscope. This study measured the plaque and gingival indices at the baseline, 1 month, 3 months, and 6 months. Results for Group III were better than those for Group I and II at 3 and 6 months.

Table 2-5 summarizes the risk of bias for randomised controlled trials as judged by the CONSORT criteria.
## Table 2-5: Risk of Bias for the Four Randomised Controlled Trials as Judged by CONSORT Criteria

<table>
<thead>
<tr>
<th>Consort Checklist</th>
<th>Richter et. al.</th>
<th>Feil et. al</th>
<th>WRIGHT et. al</th>
<th>Acharya et. al</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Title and abstract</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>a Identification as a randomised trial in the title</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>b Structured summary of trial design, methods, results, and conclusions (for specific guidance, see CONSORT for abstract)</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Introduction</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Background and objectives</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>a Scientific background and explanation of rationale</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>b Specific objectives or hypotheses</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Methods</strong></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td><strong>Trial design</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>a Description of trial design (such as parallel, factorial) including allocation ratio</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>b Important changes to methods after trial commencement (such as eligibility criteria), with reasons</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td><strong>Participants</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>a Eligibility criteria for participants</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>b Settings and locations where the data were collected</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Interventions</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The interventions for each group with sufficient details to allow replication, including how and when they were actually administered</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Outcomes</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>a Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>b Any changes to trial outcomes after the trial commenced, with reasons</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Sample size</td>
<td>a How sample size was determined</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
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<td>---------------------------------</td>
<td>----</td>
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<td>----</td>
</tr>
<tr>
<td></td>
<td>b When applicable, explanation of any interim analyses and stopping guidelines</td>
<td>No</td>
<td>No</td>
<td>No</td>
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<tr>
<td>Randomisation:</td>
<td>Sequence</td>
<td>a Method used to generate the random allocation sequence generation</td>
<td>No</td>
<td>Yes</td>
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<tr>
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<td></td>
<td>b Type of randomisation; details of any restriction (such as blocking and block size)</td>
<td>No</td>
<td>Yes</td>
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<tr>
<td>Allocation</td>
<td>Concealment mechanism</td>
<td>Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned</td>
<td>No</td>
<td>Yes</td>
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<tr>
<td>Implementation</td>
<td>Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Blinding</td>
<td>a If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>b If relevant, description of the similarity of interventions</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
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<tr>
<td>Statistical methods</td>
<td>a Statistical methods used to compare groups for primary and secondary outcomes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>b Methods for additional analyses, such as subgroup analyses and adjusted analyses</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
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<tr>
<td>Results</td>
<td>Participant flow (a diagram is strongly recommended)</td>
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<tr>
<td>---------</td>
<td>------------------------------------------------------</td>
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</tr>
<tr>
<td></td>
<td>a For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>b For each group, losses and exclusions after randomisation, together with reasons</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
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<tr>
<td>Recruitment</td>
<td>a Dates defining the periods of recruitment and follow-up</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
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<tr>
<td></td>
<td>b Why the trial ended or was stopped</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
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<tr>
<td>Baseline data</td>
<td>a table showing baseline demographic and clinical characteristics for each group</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
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<tr>
<td>Numbers analysed</td>
<td>For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Outcomes and estimation</td>
<td>a For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
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<tr>
<td></td>
<td>b For binary outcomes, presentation of both absolute and relative effect sizes is recommended</td>
<td>No</td>
<td>No</td>
<td>No</td>
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<tr>
<td>Ancillary analyses</td>
<td>Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
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<td>Harms</td>
<td>All important harms or unintended effects in each group (for specific guidance, see CONSORT for harms)</td>
<td>No</td>
<td>No</td>
<td>No</td>
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<td>Chapter 2</td>
<td>Systematic Review</td>
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</tr>
<tr>
<td><strong>Discussion</strong></td>
<td><strong>Limitations</strong></td>
<td>Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Generalisability</strong></td>
<td>Generalisability (external validity, applicability) of the trial finding</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Interpretation</strong></td>
<td>Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Other information</strong></td>
<td><strong>Registration</strong></td>
<td>Registration number and name of trial registry</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td><strong>Protocol</strong></td>
<td>Where the full trial protocol can be accessed, if available</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Funding</strong></td>
<td>Sources of funding and other support (such as supply of drugs), role of funders</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>
2.4 DISCUSSION

A number of interventions are advocated in the literature to improve patients’ adherence during orthodontic treatment. The report card and reward system was evaluated by Richter and colleagues on 144 orthodontic patients. The results indicated that only oral hygiene improvement was found among the low compliance reward group compared with the low compliance award group. However, the finding of this study did not support the hypothesis that the award/reward intervention might improve compliance. A possible reason is the lack of attractiveness in the rewards that were used in the study, which might have influenced the results. The study mentioned that the patients were divided into high and low compliers using the Orthodontic Patient Cooperation Scale but did not indicate if calibration was considered by inter-examiner reliability measurement. Furthermore, the study included patients with banding/bonding of the entire arch and some patients who were using headgear and other appliances. Appliance wear was measured on a 9-point scale by nine supervising faculty members; however, inter-examiner reliability was not considered. Although the results indicated gender differences among the groups, a detailed description of the actual male/female participants in each group were not clearly provided (Richter et al., 1998).

In another study, the Hawthorne effect was evaluated in improving patients’ compliance. The strength in the study lies in the randomization of two equal groups as well as the explicit and concise selection criteria. In the experimental group, the patients were asked to return the experimental toothpaste at the end of the study, which would indicate whether they complied with the instruction. The outcome revealed a reduction in plaque
score in the experimental group. The Hawthorne effect might be an asset in improving compliance in orthodontic patients (Feil et al., 2002). However, compliance in this study was measured by oral hygiene improvement using Plaque Score Index only. The study did not investigate whether the Hawthorne effect influences compliance in terms of appointment attendance and appliance wear.

Wright et al. studied how written and verbal information affected anxiety, motivation, and compliance among 60 orthodontic patients. The results showed that there was improvement in appointment attendance, appliance breakage, and periodontal condition in the intervention group, but this improvement was not statistically significant. The sample size was relatively small; a larger sample might have provided more convincing evidence. This study highlighted the importance of information retention in orthodontic treatment as they found that the initial positive effect of written information was not maintained throughout the treatment (Wright et al., 2010).

In the fourth study, the effect of three interventions to improve oral hygiene among 62 patients undergoing fixed orthodontic treatment was investigated (Acharya et al., 2011). The researchers found that plaque and gingival scores were reduced in Group III patients, who were motivated by showing live motile bacteria in their own plaque under a phase contrast microscope. One drawback to the study was the lack of clear description of how the plaque and gingival scores were measured. Further, no information was provided on the number of examiners undertaking the assessment of plaque and gingival scores. Lastly, inter-examiner and reliability tests were not preformed or at least reported.
Subsequently, while searching the literature for a different aspect of the thesis, a fifth RCT was found (Yeung et al., 1989). This study described a trial in which 62 adolescent orthodontic patients participated in a 4-week oral health education intervention. A special intensive oral hygiene program was given to the experimental group which consists of: an explanation of the relationship of plaque and gingival inflammation, dietary advice, plaque removal technique description, and assessment of the efficiency of using disclosing solutions to remove plaque. No intervention was given to the control group. Oral hygiene was assessed using bleeding index, gingival index, and plaque index, periodontal pocket depth, and gingival fluid. Patients were assessed at the beginning and the end of orthodontic treatment. The results showed an improvement in the bleeding (P<0.001), gingival fluid (P= 0.01), and gingival indices (P= 0.032) among the experimental group.

The quality of the randomised controlled trials located for this review was moderate, since at least 30% of all responses to the CONSORT criteria were negative. The CONSORT criteria are an assessment of reporting not directly risk of bias so may not be an accurate measure of bias. Particular concerns related to determination of an appropriate sample size as none of the four trials identified the basis on which the sample size was determined. There were also issues concerning allocation concealment and blinding for the studies.

This review has not been updated as we took the decision to keep it as a record of the literature which informed the next 2 studies in the thesis.
2.5 CONCLUSIONS

- The literature advocates the use of several methods to improve compliance/adherence among orthodontic patients. Although there is no evidence to support one particular intervention over another, the results do demonstrate the value of spending time with patients to illustrate the importance of adherence.

- Future studies should develop multiple methods of assessing patient adherence, including self-report, behavioural observation and recording, and change in clinical indices. Different types of interventions should be included and tested for effectiveness.
3. PREDICTORS OF ADHERENCE AMONG ORTHODONTIC PATIENTS: A LONGITUDINAL STUDY

3.1 INTRODUCTION

The literature review in Chapter 1 established that several studies have investigated levels of adherence among orthodontic patients in an attempt to explore predictors of compliance. Cucalon and Smith suggested that females are more cooperative in orthodontic treatment than males (Kreit et al., 1968; Cucalon & Smith, 1990), and studies have reported that patients’ age is a good predictor of patients’ adherence (Allan & Hodgson, 1968; Colenaty & Gabriel, 1977; Weiss & Eiser, 1977). Allan and Hodgson (1968) found that while personality was a poor predictor of adherence, the best distinct predictor for compliance among orthodontic patients was age, since better compliance was found among younger patients. Weiss and Eiser (1977) found that regarding headgear and removable appliance wear, 12 year-old and younger patients were more cooperative than older patients; but that younger patients were less cooperative in appointment attendance and in appliance maintenance. Patients’ awareness of their own dental problems was investigated in relation to compliance. El-Mangoury (1981) reported that patients with a greater need for orthodontic treatment cooperate better; also, she reported that psychological tests are a good predictor for orthodontic patients’ compliance.

The aim of the present study was to explore predictors of adherence amongst patients receiving orthodontic treatment with fixed appliances at the initial follow-up appointment 6 weeks after fixed appliance placement. Adherence is assessed through self-reported
behaviour, knowledge of oral health-related behaviour, appointment keeping and appliance breakages, as well as proxies of behaviour—plaque levels and periodontal bleeding. The objectives of the present study are to explain the relationship between:

- Plaque accumulation among orthodontic patients and demographic characteristics.
- Plaque accumulation among orthodontic patients and teeth alignment.
- Plaque accumulation among orthodontic patients and initial oral hygiene.
- Plaque accumulation among orthodontic patients and Knowledge about important oral health information and self-reported behaviours.

3.2 PARTICIPANTS AND METHODS

A longitudinal study design was adopted with participants assessed at initial placement of their fixed appliances and at their follow-up appointment typically 6 weeks later; this will be termed the index appointment. The outcomes were plaque status, bleeding on probing, and self-reported oral hygiene behaviours at the index appointment. The relationship between gender, age, teeth alignment, initial clinical status (plaque score or bleeding on probing at placement of appliances), and knowledge of oral hygiene are used as predictors of adherence.

Ethical approval for the study was granted by the City and East, National Research Health Service Committee, London, UK. (See Appendix 7.1)
3.2.1 Participants

A consecutive series of 200 individuals attending for orthodontic treatment at Guy’s and St Thomas’ NHS Foundation Trust who met the following criteria were invited to participate:

**Inclusion criteria:** individuals aged 12 to 18 years undergoing treatment with upper and lower fixed orthodontic appliances.

**Exclusion criteria:** individuals with systemic diseases and craniofacial development disorders including cleft lip and palate, patients attending the specialist hypodontia clinic, patients with previous history of orthodontic treatment were excluded, as well as those who declined to participate.

A sample size of 200 was selected as this will give a power of 80% to detect medium-size effects (approximately 0.5) in the primary outcomes, while allowing the proposed regression analyses to be adjusted for approximately five covariates simultaneously.

3.2.2 Measures

3.2.2.1 Demographic and orthodontic information

Participants’ age and gender were recorded. The following clinical variables indicating the nature of their orthodontic status were collected through clinical examination at the initial bond-up appointment:

a. **Skeletal pattern:** This was assessed using the ANB angle. The skeletal pattern is often determined cephalometrically by comparing the relationship of the maxilla and
mandible with the cranial base by means of angles SNA and SNB; the difference between these two measurements is the ANB angle (Steiner, 1953). Since our sample consisted of patients from different ethnic groups, different ANB norms were used to classify patients as skeletal Class I, Class II, or Class III depending on the patient ethnic group (Ballard, 1956; Miyajima et al., 1996; Hamdan & Rock, 2001; Beane et al., 2003).

b. IOTN (Index of Orthodontic Treatment Need): the dental health component was recorded by a trained and calibrated examiner using the IOTN.

*Dental health component:* contains five grades

Grade 1: no need, Grade 2: little need, Grade 3: moderate need, Grade 4: great need,

Grade 5: very great need (Brook & Shaw, 1989).

c. Spacing: “The width of the interdental space, for example, the distance between the mesial and distal crown convexities of adjacent teeth” (Lavelle, 1973). Spacing might be localized or generalized. Spacing was categorized into three groupings: patients with 1-3 mm spacing, patients with 3.1-5 mm spacing, and patients with +5 mm spacing.

d. Crowding: “The disparity in the relationship between tooth size and jaw size which results in imbrication and rotation of teeth” (Howe et al., 1983). Crowding was categorized into four groupings: None, Mild: less than or equal to 4 mm, Moderate: 5-9 mm, and Severe: 10 mm or more (Proffit et al., 2012).

IOTN index, spacing, crowding, and skeletal pattern were all assessed by a single rater (AA). Spacing and crowding were assessed from study models.
3.2.2.2 Self-reported adherence

Self-reported brushing and flossing was assessed by questionnaire at the index appointment. The questionnaire included questions taken from the UK Adult Dental Health Survey about the frequency of tooth brushing, flossing, and consumption of sugary snacks (the questions are listed in Appendix 7.13).

3.2.2.3 Knowledge of appropriate oral health-related behaviours during orthodontic treatment

Patients’ knowledge of important information during orthodontic treatment was assessed at both the initial appointment and the index appointment using a questionnaire taken from previously published data (Thickett & Newton, 2006); the questionnaire contains nine questions with a closed response format. The questions allowed subjects to choose from a fixed number of choices. The minimum score on the questionnaire was 0 and maximum score was 25. For some questions it was possible to obtain a score greater than 1, so that the maximum score for knowledge was 25. The participants were accompanied at all times to ensure that no external help was provided (the questions are listed in Appendix 7.14).

3.2.2.4 Clinical indicators of adherence

Levels of plaque and bleeding on probing were assessed both at the initial bond-up visit and at the index visit (6 weeks later) in order to assess the relationship between baseline clinical indices and adherence.
Buccal Plaque: Buccal plaque was scored differently at Time 1 and at Time 2 because of the presence of brackets after Time 1. At Time 1, the Buccal Plaque Index was used. This index scores plaque on the buccal surfaces of the teeth at the bond-up appointment (T1). A disclosing bud (PLAQSEARCH disclosing buds by MOLAR Ltd) was used, and the patient was asked to rinse; then the principal investigator used the probe to examine the presence of plaque at the dentogingival junction; once plaque was seen on a surface, it was marked and then plaque was measured by dividing the number of surfaces with plaque by the total number of surfaces examined (O’Leary et al., 1972). Thus the plaque index measures the proportion (expressed as a percentage) of examined surfaces with plaque. At T2, the Bonded Bracket Index was used. This index scores plaque on the buccal surfaces of the teeth after bonding. A disclosing bud (PLAQSEARCH disclosing buds by MOLAR Ltd) was used, and the patient was asked to rinse; then the principal investigator used a probe to examine the presence of plaque accumulation. Plaque for each buccal surface was scored as follows.

Grade I: Plaque present on the bracket only.

Grade II: Plaque present on the bracket and the immediate adjacent tooth surface.

Grade III: Plaque present on the bracket and continuous to the interproximal surface.

Grade IV: A continuous layer of plaque extending from the bracket to the gingival margin.

The average rating across all 8 teeth was calculated for each patient by summing the ratings and dividing by 8. The Bonded Bracket Index was developed as part of a study...
exploring plaque accumulation during orthodontic treatment (Aloufi et al., 2010). The authors did not present data on the reliability or validity of the index. A single rater judged the Bonded Bracket Index on all patients; the rater was calibrated by using a standard set of photographs showing the different levels of the Bonded Bracket Index, calibration was conducted using a set of 20 photos of different grades of Bonded Bracket Index which were presented to the principal investigator on two occasions 2 weeks apart. The order of presentation was randomised on each separate occasion in order to minimise memory effects. Intra-rater reliability was assessed using the same photographs as in calibration and was in 100% agreement.

b. **Lingual Plaque Index**: This index scores plaque on the lingual surfaces of the teeth at T1 and T2. A disclosing bud (PLAQSEARCH disclosing buds by MOLAR Ltd) was used and the patient were asked to rinse; then the principal investigator used the probe to examine the presence of plaque at the dentogingival junction; once plaque was seen on a surface, it was marked and then lingual plaque index was calculated by dividing the number of surfaces with plaque by the total number of surfaces examined (O’Leary et al., 1972).

c. **Bleeding on Probing**: This measure determines the presence or absence of gingival bleeding inter-proximally and on the facial and lingual surfaces of each tooth. A periodontal probe was used to probe the gingival crevice at four sites per tooth, and the presence or absence of bleeding was recorded.

The plaque and bleeding scores of the mesiobuccal, mid-buccal, mesiolingual, and mid-lingual surfaces of upper centrals, lower centrals, upper right, and left first or second
Premolars and lower right and left first or second premolars was assessed at the bond-up appointment and at the follow-up appointment (6 weeks after bonding).

d. Appointment attendance and breakages of appliances were taken from the patients’ records and covered the period between initial appointment and the index appointment. Patients were considered to have not attended their appointment if they did not attend, arrived late (more than 20 minutes after the appointment time), or cancelled less than 24 hours before the appointment date. Appliance breakages were considered if the patients had one or more broken bracket and/or had a broken archwire.

Figure 3-1: Flow Diagram
3.2.3 Statistical Analysis

The statistical analysis comprised three steps. First, the demographic and orthodontic characteristics of the participants were described. Second, summary descriptive statistics were calculated for the measures of adherence. Finally, three linear regression models were calculated in SPSS V.19 with the following outcomes: plaque score and bleeding score. The following predictor variables were included: gender, age, teeth alignment, initial clinical status (plaque score or bleeding on probing at placement of appliances), and knowledge of oral hygiene. A further two binary logistic regressions were calculated with outcomes: self-reported frequency of flossing, self-reported frequency of sugary snacks, and predictors: gender, age, teeth alignment, initial clinical status (plaque score, bleeding on probing at placement of appliances), and knowledge of oral hygiene.
3.3 RESULTS

3.3.1 Demographic and orthodontic characteristics of the participants

The sample consisted of 115 (57.5%) females and 85 (42.5%) males. The demographic characteristics of the sample are presented in Table 3-1. There were no differences between the male and female participants in age or any of the orthodontic variables.

Table 3-1: Demographic and orthodontic characteristics of the sample.

<table>
<thead>
<tr>
<th></th>
<th>Female n= 115</th>
<th>Male n= 85</th>
<th>Total n= 200</th>
<th>Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>14.31</td>
<td>14.65</td>
<td>14.45</td>
<td>t= 1.09</td>
</tr>
<tr>
<td>S.D</td>
<td>2.15</td>
<td>2.14</td>
<td>2.14</td>
<td>P= 0.28</td>
</tr>
<tr>
<td>Skeletal Pattern</td>
<td></td>
<td></td>
<td></td>
<td>X²= 3.22</td>
</tr>
<tr>
<td>Class I</td>
<td>29 (25.2%)</td>
<td>31 (36.5%)</td>
<td>60 (30.0%)</td>
<td>P= 0.20</td>
</tr>
<tr>
<td>Class II</td>
<td>73 (63.5%)</td>
<td>44 (51.8%)</td>
<td>117 (58.5%)</td>
<td></td>
</tr>
<tr>
<td>Class III</td>
<td>13 (11.3%)</td>
<td>10 (11.8%)</td>
<td>23 (11.5%)</td>
<td></td>
</tr>
<tr>
<td>Dental IOTN</td>
<td></td>
<td></td>
<td></td>
<td>X²= 3.18</td>
</tr>
<tr>
<td>3</td>
<td>15 (13.0%)</td>
<td>7 (8.24%)</td>
<td>22 (11%)</td>
<td>P= 0.37</td>
</tr>
<tr>
<td>4</td>
<td>78 (67.8%)</td>
<td>60 (70.6%)</td>
<td>138 (69%)</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>22 (19.1%)</td>
<td>18 (21.2%)</td>
<td>40 (20%)</td>
<td></td>
</tr>
<tr>
<td>Space Analysis</td>
<td></td>
<td></td>
<td></td>
<td>X²= 10.94</td>
</tr>
<tr>
<td>Well Aligned</td>
<td>33 (28.7%)</td>
<td>20 (23.5%)</td>
<td>53 (26.5%)</td>
<td>P= 0.21</td>
</tr>
<tr>
<td>Lower Spacing only</td>
<td>1 (0.9%)</td>
<td>1 (1.2%)</td>
<td>2 (1.1%)</td>
<td></td>
</tr>
<tr>
<td>Upper Spacing only</td>
<td>11 (9.6%)</td>
<td>3 (3.5%)</td>
<td>14 (7.0%)</td>
<td></td>
</tr>
<tr>
<td>Upper and Lower Spacing</td>
<td>3 (2.6%)</td>
<td>10 (11.8%)</td>
<td>13 (6.5%)</td>
<td></td>
</tr>
<tr>
<td>Lower Crowding only</td>
<td>12 (10.4%)</td>
<td>10 (11.8%)</td>
<td>22 (11%)</td>
<td></td>
</tr>
<tr>
<td>Upper Crowding only</td>
<td>27 (23.5%)</td>
<td>16 (18.8%)</td>
<td>43 (21.5%)</td>
<td></td>
</tr>
<tr>
<td>Upper and Lower Crowding</td>
<td>26 (22.6%)</td>
<td>22 (25.9%)</td>
<td>48 (24%)</td>
<td></td>
</tr>
<tr>
<td>Lower Spacing and Upper Crowding</td>
<td>1 (0.9%)</td>
<td>1 (1.2%)</td>
<td>2 (1%)</td>
<td></td>
</tr>
<tr>
<td>Lower Crowding and Upper Spacing</td>
<td>1 (0.9%)</td>
<td>2 (2.4%)</td>
<td>3 (1.5%)</td>
<td></td>
</tr>
</tbody>
</table>
The average age of the participants was 14.45 years, and there was no significant difference between males and females in age (P= 0.28). Most of the sample had a skeletal Class II (58.5%), followed by a skeletal Class I (25.2%), and less common was a skeletal Class III (11.5%). There was no significant difference between males and females (P= 0.20).

The majority of the sample was categorized as Dental IOTN 4 (69%), followed by Dental IOTN 5 (20%), and only (11%) had Dental IOTN 3. No significant difference in Dental IOTN was found between males and females (P= 0.37).

Regarding space analysis, no statistical difference was found between males and females (P= 0.21). The most common types of categories of space analysis among our sample were well aligned (26.5%), upper and lower crowding (24%), and upper crowding only (21.5%).

Patients’ knowledge at the bond-up appointment and the index appointment is shown in Table 3-2. Knowledge scores improved between the two appointments (P<0.001).

**Table 3-2:** Mean, Standard Deviation, Minimum, and Maximum Values of Knowledge of Oral Hygiene at Bond-up Appointment and the Index Appointment.

<table>
<thead>
<tr>
<th>Knowledge</th>
<th>Bond-up Appointment Knowledge</th>
<th>Index Appointment Knowledge</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean</td>
<td>19.40</td>
<td>20.2</td>
</tr>
<tr>
<td>S.D</td>
<td>2.26</td>
<td>2.13</td>
</tr>
<tr>
<td>Min.</td>
<td>11</td>
<td>12</td>
</tr>
<tr>
<td>Max.</td>
<td>25</td>
<td>24</td>
</tr>
<tr>
<td>Significance</td>
<td>t= 4.85</td>
<td>P&lt;0.001</td>
</tr>
</tbody>
</table>

There were no significant differences between males and females in knowledge scores at the initial bond-up appointment (t= 1.48, P= 0.14) and at the 6-week follow-up (t=0.63, P= 0.53).
3.3.2 Descriptive analysis of measures of adherence

3.3.2.1 Self-reported oral hygiene behaviour

Table 3-3 shows the self-reported behaviour of participants at the bond-up appointment and the index appointment. The proportion of participants brushing their teeth twice a day or more increased significantly; however, the frequency of floss use decreased. Participants reported eating sugary snacks less frequently at the follow-up appointment.

<table>
<thead>
<tr>
<th></th>
<th>Bond-up Appointment</th>
<th>Index Appointment</th>
<th>Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Teeth Brushing</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Once/day</td>
<td>23</td>
<td>9</td>
<td>$X^2 = 6.66$</td>
</tr>
<tr>
<td>Twice/day or more</td>
<td>177</td>
<td>191</td>
<td>$P = 0.009$</td>
</tr>
<tr>
<td><strong>Flossing</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Never</td>
<td>129</td>
<td>104</td>
<td>$X^2 = 10.69$</td>
</tr>
<tr>
<td>Once/week at most</td>
<td>47</td>
<td>48</td>
<td>$P = 0.004$</td>
</tr>
<tr>
<td>More than once/week</td>
<td>24</td>
<td>48</td>
<td></td>
</tr>
<tr>
<td><strong>Sugary Snacks</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Never</td>
<td>25</td>
<td>48</td>
<td>$X^2 = 10.81$</td>
</tr>
<tr>
<td>Once/day</td>
<td>102</td>
<td>100</td>
<td>$P = 0.01$</td>
</tr>
<tr>
<td>Twice/day</td>
<td>54</td>
<td>38</td>
<td></td>
</tr>
<tr>
<td>More than twice/day</td>
<td>19</td>
<td>14</td>
<td></td>
</tr>
</tbody>
</table>

3.3.2.2 Clinical indicators of adherence

A comparison between the patients’ oral hygiene at bond-up appointment and at the index appointment is presented in Table 3-4. The table displays the differences in the lingual plaque and the bleeding on probing at bond-up appointment and follow-up appointment (6 weeks later). Buccal plaque was not compared because, at the bond-up appointment, the teeth did not yet have brackets, and at the follow-up appointment,
teeth were bonded, which requires the use of different indices to measure the buccal plaque.

The presence of buccal plaque as assessed by the plaque index at bond-up correlated significantly (Spearman’s rho = 0.16, P= 0.024) with the presence of buccal plaque as assessed by the Bonded Bracket Index at initial follow-up. Similarly, the presence of lingual plaque at bond-up correlated significantly with the presence of plaque at initial follow-up (rho=0.202, P= 0.004).

Table 3-4: The Mean, Standard Deviation, Minimum, and Maximum Values of Lingual Plaque and Bleeding on Probing at Bond-up Appointment and (6 Weeks) Follow-up Appointment

<table>
<thead>
<tr>
<th></th>
<th>Lingual Plaque</th>
<th>Bleeding on Probing</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Bond-up</td>
<td>Index</td>
</tr>
<tr>
<td></td>
<td>Appointment</td>
<td>Appointment</td>
</tr>
<tr>
<td></td>
<td>Lingual Plaque</td>
<td>Plaque Index</td>
</tr>
<tr>
<td></td>
<td>Mean</td>
<td>S.D</td>
</tr>
<tr>
<td></td>
<td>24.66</td>
<td>25.50</td>
</tr>
<tr>
<td></td>
<td>30.25</td>
<td>29.08</td>
</tr>
<tr>
<td></td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td></td>
<td>Significance</td>
<td>t= 2.24</td>
</tr>
<tr>
<td></td>
<td></td>
<td>P= 0.026</td>
</tr>
</tbody>
</table>

3.3.2.3 Appliances and appointment attendance at 6-week follow-up appointment

Appliance breakages were as follows: 63% (n=126) had no appliance breakages, 18% (n=36) had a single broken bracket, 8% (n=16) had a broken archwire, 10% (n=20) had multiple broken brackets, and 1% (n=2) had broken bracket/brackets and archwire. The results showed that 78.5% (n=157) never missed an appointment at T2, 15.5% (n= 31) had one instance of missing, cancelling, or arriving too late to their appointment, 2.5% (n=12)
had more than two instances of missing, cancelling or arriving too late to their appointment. No statistical differences in appliance breakages ($P= 0.96$) and appointment attendance ($P= 0.97$) were found between males and females ($P>0.05$). Participants attended the index appointment on average 6.6 weeks after the bond up appointment (Median= 6 weeks) (Range= 6 to 12 weeks).

### 3.3.2.4 Predictors of adherence

Three multivariate linear regression analyses and two logistic regression analyses were conducted with the following outcomes: lingual plaque at index appointment, buccal plaque at index appointment, bleeding score at index appointment, self-reported flossing, and self-reported frequency of sugary snacks. These models are summarized in Table 3-5.

**Table 3-5: Regression analyses**

<table>
<thead>
<tr>
<th>Outcome: Index Appointment Lingual Plaque</th>
<th>Predictors</th>
<th>B</th>
<th>S.E.</th>
<th>Beta</th>
<th>Sig.</th>
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<tr>
<td></td>
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<td>0.40</td>
<td>0.96</td>
<td>0.03</td>
<td>0.68</td>
</tr>
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</table>

**Model $R^2= 0.015$**

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<th>S.E.</th>
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<th>Sig.</th>
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<td>-0.09</td>
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</tr>
<tr>
<td></td>
<td>Bond-up Appointment Buccal Plaque Index</td>
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<td>0.003</td>
<td>0.17</td>
<td>0.02</td>
</tr>
<tr>
<td></td>
<td>6-Week Follow-up Appointment Knowledge</td>
<td>-0.02</td>
<td>0.032</td>
<td>-0.05</td>
<td>0.50</td>
</tr>
</tbody>
</table>

**Model $R^2= 0.014$**
For the analysis of flossing frequency, the variable was dichotomised into 0=never floss, 1=floss weekly or more often.

For the analysis of sugary snacks, the variable was dichotomised into 0=once per day or less, 1=twice a day or more frequently.

For the clinical indices (lingual plaque, buccal plaque, and bleeding on probing), the only significant predictor of the clinical status at the index appointment is the corresponding index at the initial appointment. Initial clinical status predicts later clinical status. For the
behavioural measures, similarly, initial self-reported behaviour predicts future behaviour. In addition, there is some relationship between self-reported behaviour and initial clinical status, though the direction of this relationship cannot be determined. Age, gender, teeth alignment and knowledge of oral hygiene procedures consistently fail to predict adherence measures at the index appointment.

3.4 DISCUSSION

The sample in this study included patients who were going to undergo upper and lower fixed orthodontic treatment. The majority of the sample was Skeletal Class II (58.5%). Sixty-nine per cent of the sample was categorized as Dental IOTN 4; this is because our sample was drawn from a public hospital that mainly accepts patients with Dental IOTN 4 or 5.

Patient adherence in the present study was measured in terms of oral hygiene and appliance maintenance, appointment attendance, and knowledge. The results revealed that there was a statistically significant difference in oral hygiene between bond-up appointment and the 6-week follow-up appointment. The patients had a higher score for lingual plaque index and bleeding on probing at the 6-week follow-up appointment, which is in agreement with previous studies (Oliver & Knapman, 1985; Sergl & Zentner, 1998; Acharya et al., 2011; Al-Jewair et al., 2011). This may be due to the discomfort that is caused by initial insertion of the appliances, which worsens the patients’ oral hygiene (White, 1996). Also, it is expected as after bond-up gingival bleeding might increase in crowded dentition (Addy et al., 1988). In the present study, the time between T1 and T2
was 6 weeks; by the time of T2, patients are still not used to brushing with the presence of the new fixed appliances.

There was no relationship between age and the patients’ adherence, in accordance with some previous studies (Cucalon & Smith, 1990; Albino et al., 1991; Richter et al., 1998). Other studies found that patients of 12 years of age and younger are more adherent to orthodontic treatment than adolescent patients (Allan & Hodgson, 1968; Colenaty & Gabriel, 1977; Weiss & Eiser, 1977). This might be due to differences in methods used to measure adherence and sample size differences.

Gender has been suggested to be a good predictor of a composite measure of compliance based on the assessment of the treating clinician, with females being reported to show higher adherence than males (Clemmer & Hayes, 1979; Cucalon & Smith, 1990). Females are more aware of their appearance and dentofacial attractiveness, and as a result, they have greater acceptance to orthodontic treatment (Sergl et al., 2000). In our study, there was no correlation between gender and adherence, which was in agreement with previous research (Nanda & Kierl, 1992; Richter et al., 1998; Mandall et al., 2008).

El-Mangoury (1981) reported that patients with a high clinical need for treatment cooperated better. This differed from our findings, as no relationship was found between dental IOTN index and adherence. The reason for this difference might be that we used clinical tests to evaluate adherence, while in El-Mangoury’s study, she used psychological tests to evaluate compliance. Our findings were in agreement with a study completed by Mandall et. al. (2008), which found no correlation between IOTN and completion of treatment among orthodontic patients.
In our study, we found a statistically significant difference in the patients’ knowledge between the bonding appointment and the next follow-up appointment after 6 weeks (P<0.001). There was an improvement in their self-reported behaviours between bond-up and the index appointment for brushing (P= 0.009), flossing (P= 0.004), and sugary snacks (P= 0.01), which was surprising because they had worse oral hygiene. The explanation may be that they knew what to do but did not do it, they did it incorrectly, or they answered the questionnaire untruthfully. Also, as mentioned earlier, the patients were seen 6 weeks after the bonding visit, and they may still have experienced discomfort, which could interfere with standard oral hygiene.

The results revealed that 63% of our sample did not have any breakages, while 37% had breakages. Seventy-eight per cent of the sample did not miss any appointments, while 21.5% missed one or more appointments. Since appointment attendance is considered a predictor for adherence to treatment, many researchers have argued that appointment attendance among adolescent patients depends mainly on parents’ availability to bring the patients to the orthodontic clinic (Mehra et al., 1998; Richter et al., 1998). No statistical difference was found between males and females in appointment attendance and appliance breakages.

The best predictor of plaque index, bleeding index, or self-reported behaviour is the corresponding index at the initial appointment; this was in agreement with Hardy (2014), who found that initial oral hygiene of the patient is associated with patient compliance during the treatment.
A limitation of our study was that patients were treated by different orthodontic postgraduate students. A recommendation for future studies would be to quantify adherence in patients treated by a single clinician. Also, the patients were assessed after 6 weeks; a longer follow-up period might reveal better results in future studies. This study was limited in that it did not address compliance in adult patients and those treated with other kinds of appliances. However, the patients in the present study represented the typical age group for individuals treated with fixed appliances. Another limitation of the study was the Sugary snack question in the questionnaire which might not have been clear to the participants, since they may not understand about the sugar content of foodstuffs. For all models there was a relatively poor level of model fit as assessed by the R-squared values.

3.5 CONCLUSION

- Patients’ oral hygiene worsens initially after starting orthodontic treatment.

- Sound patient knowledge is not a guarantee of better adherence.

- Age and gender are not good predictors of adherence.

- The presence of plaque at bond-up is correlated with the presence of plaque at follow-up.
4. ENHANCING ADHERENCE AMONG ORTHODONTIC PATIENTS USING A MIND MAP, IF-THEN PLANNING, AND A LEAFLET INTERVENTION: A SINGLE-CENTER, RANDOMISED CONTROLLED TRIAL

4.1 INTRODUCTION

Plaque accumulation increases among patients with fixed orthodontic treatment, as good brushing becomes more difficult, especially between brackets. This might increase the risk of caries and periodontal diseases, and may affect the treatment outcomes (Gwinnett & Ceen, 1979; Feil et al., 2002). A study by Mehra et al. (1998) revealed that 5% to 10% of orthodontic patients terminate the treatment due to poor oral hygiene. Oral hygiene instructions are routinely provided by all orthodontists. Throughout the orthodontic treatment, orthodontists are keen to motivate and improve their patients’ adherence in terms of performing good oral hygiene, appointment attendance, and appliance care. Since patients’ adherence is a challenging problem, one study explored different interventions to improve it, but it provided no conclusions on the best method (Aljabaa et al., 2015).

Recall of the provided instructions is an important factor for good adherence (Kessels, 2003). Ley’s model on effective communication highlights the role of information retention as one of the important factors for patients’ adherence (Ley, 1988). Patients usually do not understand the instructions, or they might misinterpret them (Southard et al., 1991), especially if medical terminologies were used (Boyle, 1970). A group of 51 orthodontists revealed that adequate verbal and nonverbal communication encouraged
compliance (Bos, 2005). Oral, verbal, and visual aids or a combination of all can be used for delivering information (Patel et al., 2008). Thomson et al. compared the retention of information among orthodontic patients using verbal, written, and visual aids. They found that, for better recall, verbal instructions should be accompanied by written instructions (Thomson et al., 2001). Thickett and Newton (2006) tested the effect of three methods: mind map, acronym, and information leaflet on the retention of information among orthodontic patients, and they found that the mind map and acronym methods revealed a small but significant advantage in information retention.

Orthodontists report using different methods to improve compliance, but most of these methods concentrate on patients’ intentions to perform a behaviour. Gollwitzer and Sheeran (2006) distinguish between goal intentions and implementation intentions. Goal intentions are commitments to engage in a certain behaviour (for example, “I intend to do x”), while implementation intentions are if-then plans which commit the individual as to when, where, and how the behaviour is to be implemented (for example, “I intend to do x whenever the situational conditions y are met”). Implementation intention mainly focuses on planning when, where, and how a person will perform a certain behaviour; it also includes what to do if something goes wrong or is forgotten. If-then planning methods were used in some studies in dentistry; Schuz et al. (2006) tested if-then planning among 157 dental students to improve their adherence to daily flossing; results revealed that the planning was the only significant predictor of adherence. Similarly, in a study of implementation intention among a group of university students, participants were asked to plan when and where they would floss their teeth. The results showed an improvement in the proportion of students who reported flossing three times a week or more.
(Sniehotta et al., 2007). Suresh et al. (2012) reported reduced plaque and bleeding scores and increased flossing among patients with periodontal disease who kept a flossing diary. Veeroo et al. (2014) used if-then planning to improve patients’ compliance with intraoral elastics; they found no significant difference between the if-then plan group and the group that received routine clinical instructions, although there was a tendency for better wear of intraoral elastics among the if-then plan group.

No studies to date have used implementation intention to improve adherence among orthodontic patients in terms of oral hygiene, knowledge, appointment attendance, and appliance care.

This study addressed the following research question: In patients receiving fixed orthodontic treatment in a secondary care setting, what is the effect of the use of a mind map or if-then planning compared to treatment as usual (TAU) on plaque levels?

The objectives of the study are to:

- Determine the effect of if-then plan on plaque accumulation, knowledge and self-reported behaviours among orthodontic patients.
- Determine the effect of mind-mapping on plaque accumulation, knowledge and self-reported behaviours among orthodontic patients.

### 4.2 MATERIALS AND METHODS

Ethical approval for the study was obtained from the City and East, National Research Health Service Committee, London, UK (See Appendix 7.1). A letter of invitation to
participate in the study was sent to the patients at least one week before their appointment (See Appendix 7.6). An informed consent was signed by all participants before they took part in the study (See Appendices 7.10, 7.11, 7.12). The recruitment of patients was from 11 March 2013 to 02 October 2013. All patients in the study received upper and lower fixed orthodontic treatment using MBT bracket prescription with a 0.022 inch slot size.

4.2.1 Trial design and any changes after trial commencement

This was a 3-arm parallel-group, randomised controlled trial with a 1:1:1 allocation ratio. There were no changes to the study protocol after trial commencement.

4.2.2 Participants, eligibility criteria, and settings

Ninety individuals from the Orthodontic Department at Guy’s and St Thomas’ NHS Trust were drawn as potential participants; all had previously participated in the cohort study described in Chapter 3. This is a secondary care service; treatment is free at the point of delivery. The inclusion criteria were 1) patients aged 12-18 years, 2) undergoing maxillary and mandibular fixed orthodontic treatment. Exclusion criteria were 1) individuals with serious systemic diseases; 2) craniofacial development disorder including cleft lip and palate; 3) patients attending the specialist hypodontia clinic; 4) individuals with a previous history of orthodontic treatment; 5) individuals who declined to participate.

The 3 arms of the RCT consisted of: mind mapping, an if-then planning group, and a control group employing treatment as usual (TAU), which consisted of giving patients
leaflets from the British Orthodontic Society (Appendix 7.15) and Guys’ and St Thomas’ Hospitals’ (Appendix 7.16) as well as verbal instructions.

Mind map: A single mind map sheet detailing aspects of oral care while wearing braces was given to patients in the mind map group. The mind map employed was the one described by Thickett and Newton (2006) (Appendix 7.17).

If-then planning: This intervention was undertaken by the principal investigator (AA), based on the method of Veeroo et al. (Appendix 7.18). Participants were asked to identify where and when they would engage in oral hygiene-related behaviours (Veeroo et al., 2014).

Participants were assessed at four time points: at the fitting of the fixed appliance (T1); at initial follow-up 6 weeks later (T2), at which time they were randomly allocated to one of the 3 groups; 6 weeks after the intervention (T3); and 18 weeks after the intervention (T4).

A self-reported questionnaire, questionnaire of oral-health related behaviours during orthodontic treatment, records of attendance, and any appliance breakages were recorded at each visit.

4.2.3 Measures

Demographic and orthodontic information
Participants’ age and gender were recorded through a questionnaire. The following clinical variables indicating the nature of their orthodontic status were collected through clinical examination:

a. **Skeletal pattern:** This was assessed using the ANB angle. The skeletal pattern is often determined cephalometrically by comparing the relationship of the maxilla and mandible with the cranial base by means of angles SNA and SNB; the difference between these two measurements is the ANB angle (Steiner, 1953). Since our sample consisted of patients from different ethnic groups, different ANB norms were used to classify patients as skeletal Class I, Class II, or Class III depending on the patient ethnic group (Ballard, 1956; Miyajima et al., 1996; Hamdan & Rock, 2001; Beane et al., 2003).

b. **IOTN (Index of Orthodontic Treatment Need):** the dental health component was recorded by a trained and calibrated examiner using the IOTN index.

*Dental health component:* contains five grades

Grade 1: no need, Grade 2: little need, Grade 3: moderate need, Grade 4: great need, Grade 5: very great need (Brook & Shaw, 1989).

c. **Spacing:** The width of the interdental space, i.e., the distance between the mesial and distal crown convexities of adjacent teeth (Lavelle, 1973). Spacing might be localized or generalized. Spacing was categorized into three groupings: patients with 1-3 mm spacing, patients with 3.1-5 mm spacing, and patients with +5 mm spacing.
d. **Crowding**: The disparity in the relationship between tooth size and jaw size which results in imbrication and rotation of teeth (Howe et al., 1983). Crowding was categorized into four groupings: None, Mild: less than or equal to 4 mm, Moderate: 5-9 mm, Severe: 10 mm or more (Proffit et al., 2012).

IOTN index, spacing, crowding, and skeletal pattern were all assessed by a single rater (AA).

### 4.2.4 Outcome measures

The primary outcome was plaque levels as measured by the Bonded Bracket Index at T2, T3 and T4. Secondary outcomes were buccal and lingual plaque, bleeding on probing, knowledge about adherence in orthodontic treatment, and self-reported behaviours. No changes were made to the outcome measures after the trial commenced.

#### 4.2.4.1 Primary and clinical outcomes

a. **Buccal Plaque**: Buccal plaque was scored differently at Time 1 and at Times 2, 3, and 4 because of the presence of brackets after Time 1. At Time 1, the Buccal Plaque Index was used. This index scores plaque on the buccal surfaces of the teeth at the bond-up appointment (T1). A disclosing bud (PLAQSEARCH disclosing buds by MOLAR Ltd) was used, and the patient was asked to rinse; then the principal investigator used the probe to examine the presence of plaque at the dentogingival junction; once plaque was seen on a surface, it was marked and then plaque was calculated by dividing the number of surfaces with plaque by the total number of surfaces examined (O’Leary et al., 1972). At T2, T3, and T4, the Bonded Bracket Index was used. This index scores plaque on the buccal
surfaces of the teeth after bonding. A disclosing bud (PLAQSEARCH disclosing buds by MOLAR Ltd) was used, and the patient was asked to rinse; then the principal investigator used a probe to examine the presence of plaque accumulation. Plaque for each buccal surface was scored as follows.

**Grade I:** Plaque present on the bracket only.

**Grade II:** Plaque present on the bracket and the immediate adjacent tooth surface.

**Grade III:** Plaque present on the bracket and continuous to the interproximal surface.

**Grade IV:** A continuous layer of plaque extending from the bracket to the gingival margin.

Bonded Bracket Index was developed as part of a study exploring plaque accumulation during orthodontic treatment (Aloufi et al., 2010). The authors did not present data on the reliability or validity of the index. A single rater judged the Bonded Bracket Index on all patients, and the rater was calibrated by using a standard set of photographs showing the different levels of the Bonded Bracket Index. Intra-rater reliability was assessed using the same photographs as in calibration and was in 100% agreement.

**b. Lingual Plaque Index:** This index scores plaque on the lingual surfaces of the teeth at (T1, T2, T3, and T4). A disclosing bud (PLAQSEARCH disclosing buds by MOLAR Ltd) was used, and the patient was asked to rinse; then the principal investigator used the probe to examine the presence of plaque through the gingival crevice; once plaque was seen on a surface, it was marked and then lingual plaque index was calculated by dividing the
number of surfaces with plaque by the total number of surfaces examined (O’Leary et al.,
1972).

c.  **Bleeding on Probing:** This measure determines the presence or absence of gingival
bleeding interproximally and on the facial and lingual surfaces of each tooth. A
periodontal probe was used to probe the gingival crevice at four sites per tooth, and the
presence or absence of bleeding was recorded.

The plaque index, bonded bracket index, and bleeding on probing were measured at the
mesiobuccal, mid-buccal, mesiolingual, and mid-lingual surfaces of upper centrals, lower
centrals, upper right, and left first or second premolars and lower right and left first or
second premolars.

4.2.4.2 Secondary Outcomes

a.  **Self-reported adherence**

Self-reported brushing and flossing was assessed using a questionnaire. The questionnaire
included questions from UK adult dental health survey about how frequently the patients
brush their teeth per day, how frequently they floss their teeth per week, and how many
times they consume sugary snacks per day (the questions are listed in Appendix 7.13).

b.  **Knowledge of appropriate oral health-related behaviours during orthodontic
treatment**

The amount of patients’ knowledge about important information during orthodontic
treatment was assessed using a questionnaire. The questionnaire designed by Thickett
and Newton was used (Thickett & Newton, 2006); the questionnaire contains nine questions with a closed response format. The questions allowed subjects to choose from a fixed number of choices. The minimum score on the questionnaire was 0 and maximum score was 25. For some questions it was possible to obtain a score greater than 1, so that the maximum score for knowledge was 25. The participants were accompanied at all times to ensure that no external help was provided. Questionnaires were completed in person at (T2, T3, and T4) under the same circumstances (the questions are listed in Appendix 7.14).

c. Information about appointment attendance and breakage of appliances

This was extracted from the patients’ records. Patients did not receive credit for attending if they did not show up at all, arrived late (more than 20 minutes after the appointment time), or cancelled less than 24 hours before the appointment date. Appliance breakages were recorded if the patients had one or more broken bracket and/or had a broken archwire. Appointment attendance and breakages of the appliances were recorded at T2, T3, and T4.

4.2.5 Sample size calculation

An a priori sample size calculation was performed. The primary outcome is the change in the plaque levels as measured by bonded bracket plaque index. In the absence of previous information on the effectiveness of the interventions, the sample size was based on a medium effect size (Somer’s delta) of 0.5, with the usual assumptions of power (0.80) and significance level (0.05); with these assumptions, a sample size of 30 in each group (total sample size 90 participants) should be sufficient for a MANOVA. (G* power) (Faul et. al.,
2007). No dropouts were excluded because we were considering the use of intention to treat. Therefore, any dropouts were included in the study.

### 4.2.6 Interim analyses and stopping guidelines

An interim analysis was planned at the point when 50% of the cases were complete. The trial was planned to stop if one or more method(s) emerged as superior at that point, in order to reduce participant burden should one method prove to be better at an early stage.

### 4.2.7 Randomization

Participants were randomly allocated to one of the three methods by a researcher not involved in recording data from patients or delivering the intervention (J.T.N) using a random number generator (www.random.org). Allocation was concealed using sealed envelopes. The allocated intervention was written on a card and sealed in an envelope. The envelopes were opaque and sequentially numbered and opened.

### 4.2.8 Blinding

It was not possible to blind the participants and their parents to the intervention. The statistician undertaking the statistical analysis was blinded to group allocation. Outcome measurements were recorded by the same investigator who delivered the intervention.

### 4.2.9 Statistical Analysis

The final statistical analysis comprised three steps. First, the demographic and orthodontic characteristics of the participants were described. Second, summary descriptive statistics
were calculated for the measures of adherence. For frequencies of categorical variables, confident intervals of the observed frequencies were calculated using an online calculator at `vassarstats.net/prop 1.html` following the method of Newcombe (1998). Finally, the outcome variables were compared across the three interventions for all time points. For continuous variables (all primary outcomes and the knowledge score) repeated measures module of the multivariate analysis of variance (MANOVA) program (SPSS V.19) was used to compare mean values for the three interventions. Post Hoc Tukey B tests were planned if any significant effects were found. For the categorical variables (all secondary outcomes except knowledge score) multiple chi-square analyses were undertaken comparing the three intervention groups at each assessment point. All analyses were undertaken on an intention to treat basis. Missing data were replaced with scores from the previous assessment point. This criterion was adopted as a more conservative measure so as not to overestimate the degree of change, which may have been the case if say the group average was included.

### 4.3 RESULTS

#### 4.3.1 Participant flow

Ninety patients were randomised in a 1:1:1 ratio to mind map, if-then planning, and TAU groups; four patients were lost to follow-up (Figure 4-1). Patient recruitment commenced in March 2013 and ended in October 2013. The average number of weeks between each appointment was as follows: T1 to T2, average= 6.8 weeks, median= 6 weeks and range= 6 to 12 weeks; T2 to T3, average= 6.5 weeks, median= 6 weeks and range= 6 to 10 weeks; T3 to T4, average= 6.8 weeks, median= 6 weeks and range= 6 to 13 weeks.
Figure 4-1: Consort Flow Chart Showing Patient Flow During the Trial.

- **Assessed for eligibility (n=102)**
  - Excluded (n=12)
    - Not meeting inclusion criteria (n=5)
    - Declined to participate (n=7)

- **Participants consented to participate (n=90)**

  **T1: Bond-up (n=90)**
  - Measures:
    - demographic information
    - buccal plaque index
    - lingual plaque index
    - bleeding on probing
    - knowledge
    - self-reported behaviors

  **T2: 6-week follow-up (n=90)**
  - Measures:
    - buccal plaque index
    - lingual plaque index
    - bleeding on probing
    - knowledge
    - self-reported behaviors
    - appointment attendance
    - breakages of appliances

**Allocation**

- Allocated to mind map (n=30)
  - Received allocated intervention (n=30)
- Allocated to (TAU) (n=30)
  - Received allocated intervention (n=30)
- Allocated to if-then planning (n=30)
  - Received allocated intervention (n=30)
Chapter 4

The RCT

T3: 12-week follow-up (n=89)

Measures:
- buccal plaque index
- lingual plaque index
- bleeding on probing
- knowledge
- self-reported behaviors
- appointment attendance
- breakages of appliances

Follow-up

- Follow-up (n=30)
- Discontinued intervention (n=0)

T4: 18-week follow-up (n=86)

Measures:
- buccal plaque index
- lingual plaque index
- bleeding on probing
- knowledge
- self-reported behaviors
- appointment attendance
- breakages of appliances

Follow-up

- Follow-up (n=29)
- Lost follow-up (n=1)
- Discontinued intervention (n=0)

Analysis

- Analysed (n=30)
- Excluded from analysis (n=0)

- Analysed (n=30)
- Excluded from analysis (n=0)

- Analysed (n=30)
- Excluded from analysis (n=0)
4.3.2 Baseline data

At baseline, information regarding age, gender, skeletal classification, IOTN index, and space analysis was collected. The demographic characteristics of the sample are presented in Table 4-1. The mean age of the sample was 14.44 years. The majority had skeletal Class II pattern and were dental IOTN 4. There were no differences between the participants in the 3 arms of the trial in terms of demographic or clinical variables.
### Table 4-1: Demographic characteristics of the sample.

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<td>Leaflet</td>
<td>If-then plan</td>
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<td>Significance</td>
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<tr>
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<td>14.33</td>
<td>15.03</td>
<td>14.44</td>
<td>F= 1.90</td>
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<td>P= 0.15</td>
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</tr>
<tr>
<td>Female</td>
<td>17 (56.7%)</td>
<td>19 (63.3%)</td>
<td>16 (53.3%)</td>
<td>52 (57.8%)</td>
<td>X²= 0.64</td>
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<td>P= 0.73</td>
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<td>±17.25</td>
<td>±17.85</td>
<td>±17.73</td>
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<tr>
<td>Male</td>
<td>13 (43.3%)</td>
<td>11 (36.7%)</td>
<td>14 (46.7%)</td>
<td>38 (42.2%)</td>
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<td>±17.73</td>
<td>±17.25</td>
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<td><strong>Skeletal Pattern</strong></td>
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<td>Class I</td>
<td>10 (33.3%)</td>
<td>2 (6.7%)</td>
<td>7 (23.3%)</td>
<td>19 (21.1%)</td>
<td>X²= 8.28</td>
<td></td>
<td>P= 0.08</td>
</tr>
<tr>
<td>95% CI</td>
<td>±16.86</td>
<td>±8.95</td>
<td>±15.13</td>
<td>±8.43</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Class II</td>
<td>19 (63.3%)</td>
<td>23 (76.7%)</td>
<td>19 (63.3%)</td>
<td>61 (67.8%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>95% CI</td>
<td>±17.25</td>
<td>±15.13</td>
<td>±17.25</td>
<td>±9.65</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Class III</td>
<td>1 (3.3%)</td>
<td>5 (16.7%)</td>
<td>4 (13.3%)</td>
<td>10 (11.1%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>95% CI</td>
<td>±6.39</td>
<td>±13.35</td>
<td>±12.15</td>
<td>±6.49</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Dental IOTN</strong></td>
<td>3</td>
<td>4</td>
<td>5</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>95% CI</td>
<td>±10.74</td>
<td>±12.15</td>
<td>±15.13</td>
<td>±14.4%</td>
<td>X²= 4.62</td>
<td></td>
<td>P= 0.33</td>
</tr>
<tr>
<td>4</td>
<td>21 (70%)</td>
<td>22 (73.3%)</td>
<td>23 (76.7%)</td>
<td>66 (73.3%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>95% CI</td>
<td>±16.4</td>
<td>±15.83</td>
<td>±15.13</td>
<td>±15.13</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>6 (20%)</td>
<td>4 (13.3%)</td>
<td>1 (3.3%)</td>
<td>11 (12.2%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>95% CI</td>
<td>±14.31</td>
<td>±12.15</td>
<td>±6.39</td>
<td>±6.76</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Space Analysis</strong></td>
<td>Well aligned</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>95% CI</td>
<td>±17.24</td>
<td>±13.35</td>
<td>±15.13</td>
<td>±9.02</td>
<td>X²= 20.6</td>
<td></td>
<td>P= 0.11</td>
</tr>
<tr>
<td>Lower Spacing only</td>
<td>0 (0%)</td>
<td>2 (6.7%)</td>
<td>0 (0%)</td>
<td>2 (2.2%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>95% CI</td>
<td>±8.95</td>
<td>±8.95</td>
<td>±12.23</td>
<td>±3.03</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Upper Spacing only</td>
<td>2 (6.7%)</td>
<td>2 (6.7%)</td>
<td>4 (13.3%)</td>
<td>8 (8.9%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>95% CI</td>
<td>±8.95</td>
<td>±8.95</td>
<td>±12.23</td>
<td>±5.88</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Upper and Lower</td>
<td>1 (3.3%)</td>
<td>2 (6.7%)</td>
<td>3 (10%)</td>
<td>6 (6.7%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Spacing</td>
<td>±6.39</td>
<td>±8.95</td>
<td>±10.74</td>
<td>±5.17</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lower Crowding only</td>
<td>2 (6.7%)</td>
<td>4 (13.3%)</td>
<td>4 (13.3%)</td>
<td>10 (11.1%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>95% CI</td>
<td>±8.95</td>
<td>±12.23</td>
<td>±12.23</td>
<td>±6.49</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Upper Crowding only</td>
<td>4 (13.3%)</td>
<td>8 (26.7%)</td>
<td>11 (36.6%)</td>
<td>23 (25.6%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>95% CI</td>
<td>±12.23</td>
<td>±15.83</td>
<td>±17.24</td>
<td>±9.02</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Upper and Lower</td>
<td>9 (30%)</td>
<td>7 (23.3%)</td>
<td>1 (3.3%)</td>
<td>17 (18.9%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Crowding</td>
<td>±16.4</td>
<td>±15.13</td>
<td>±6.39</td>
<td>±8.09</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lower Spacing and</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Upper crowding</td>
<td>95% CI</td>
<td>±6.39</td>
<td>±6.39</td>
<td>±6.39</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lower Crowding and</td>
<td>1 (3.3%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>1 (1.1%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Upper Spacing</td>
<td>95% CI</td>
<td>±6.39</td>
<td>±6.39</td>
<td>±6.39</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
4.3.3 Outcomes

The comparison between the patients’ oral hygiene at T1, T2, T3, and T4 is displayed in Table 4-2, while the difference between the self-reported behaviour at T1, T2, T3, and T4 is displayed in Table 4-3, and the patients’ knowledge is presented in Table 4-4. A comparison of patients’ appointment attendance and breakages of appliances is displayed in Table 4-5 and Table 4-6.

4.3.3.1 Primary and clinical outcomes:

Table 4-2: Mean, Standard Deviation, Minimum and Maximum Values of Buccal Plaque Index, Lingual Plaque Index, and Bleeding on Probing at T1, T2, T3, and T4.

<table>
<thead>
<tr>
<th></th>
<th>T1 Mean (S.D)</th>
<th>T2 Mean (S.D)</th>
<th>T3 Mean (S.D)</th>
<th>T4 Mean (S.D)</th>
<th>Repeated Measures Analysis of Variance</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Buccal Plaque</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Mind Map</strong></td>
<td>34.58 (33.30)</td>
<td>±11.92</td>
<td>95% CI</td>
<td>39.58 (31.93)</td>
<td>±11.43</td>
</tr>
<tr>
<td><strong>Leaflet</strong></td>
<td>39.58 (31.93)</td>
<td>±11.43</td>
<td>95% CI</td>
<td>23.54 (32.28)</td>
<td>±11.55</td>
</tr>
<tr>
<td><strong>If-Then Plan</strong></td>
<td>23.54 (32.28)</td>
<td>±11.55</td>
<td>95% CI</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Bonded Bracket Index</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Mind Map</strong></td>
<td>0.95 (0.79)</td>
<td>±0.28</td>
<td>1.40 (1.22)</td>
<td>1.36 (0.98)</td>
<td>±0.35</td>
</tr>
<tr>
<td><strong>Leaflet</strong></td>
<td>1.40 (1.22)</td>
<td>±0.44</td>
<td>1.36 (0.98)</td>
<td>±0.35</td>
<td></td>
</tr>
<tr>
<td><strong>If-Then Plan</strong></td>
<td>1.36 (0.98)</td>
<td>±0.35</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Bonded Bracket Index</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Mind Map</strong></td>
<td>0.78 (0.73)</td>
<td>±0.26</td>
<td>0.83 (0.86)</td>
<td>0.75 (1.03)</td>
<td>±0.37</td>
</tr>
<tr>
<td><strong>Leaflet</strong></td>
<td>0.83 (0.86)</td>
<td>±0.31</td>
<td>0.75 (1.03)</td>
<td>±0.37</td>
<td></td>
</tr>
<tr>
<td><strong>If-Then Plan</strong></td>
<td>0.75 (1.03)</td>
<td>±0.37</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Bonded Bracket Index</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Mind Map</strong></td>
<td>0.65 (0.61)</td>
<td>±0.22</td>
<td>0.69 (0.75)</td>
<td>0.53 (0.56)</td>
<td>±0.21</td>
</tr>
<tr>
<td><strong>Leaflet</strong></td>
<td>0.69 (0.75)</td>
<td>±0.27</td>
<td>0.69 (0.75)</td>
<td>±0.27</td>
<td></td>
</tr>
<tr>
<td><strong>If-Then Plan</strong></td>
<td>0.69 (0.75)</td>
<td>±0.27</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Buccal Plaque</strong></td>
<td>34.58 (33.30)</td>
<td>±11.92</td>
<td>95% CI</td>
<td>39.58 (31.93)</td>
<td>±11.43</td>
</tr>
<tr>
<td><strong>Lingual Plaque</strong></td>
<td>30.21 (24.07)</td>
<td>±8.61</td>
<td>95% CI</td>
<td>30.42 (29.03)</td>
<td>±10.39</td>
</tr>
<tr>
<td><strong>If-Then Plan</strong></td>
<td>30.42 (29.03)</td>
<td>±10.39</td>
<td>95% CI</td>
<td>34.17 (27.40)</td>
<td>±9.8</td>
</tr>
<tr>
<td><strong>Bleeding on Probing</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Mind Map</strong></td>
<td>5.10 (9.04)</td>
<td>±3.23</td>
<td>5.31 (6.77)</td>
<td>±2.42</td>
<td></td>
</tr>
<tr>
<td><strong>Leaflet</strong></td>
<td>5.31 (6.77)</td>
<td>±2.42</td>
<td>5.73 (10.70)</td>
<td>±3.83</td>
<td></td>
</tr>
<tr>
<td><strong>If-Then Plan</strong></td>
<td>5.73 (10.70)</td>
<td>±3.83</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Bonded Bracket Index</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Mind Map</strong></td>
<td>6.15 (10.99)</td>
<td>±3.93</td>
<td>7.08 (11.04)</td>
<td>±3.95</td>
<td></td>
</tr>
<tr>
<td><strong>Leaflet</strong></td>
<td>7.08 (11.04)</td>
<td>±3.95</td>
<td>5.73 (10.70)</td>
<td>±3.83</td>
<td></td>
</tr>
<tr>
<td><strong>If-Then Plan</strong></td>
<td>5.73 (10.70)</td>
<td>±3.83</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Bonded Bracket Index</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Mind Map</strong></td>
<td>2.08 (5.08)</td>
<td>±1.82</td>
<td>4.38 (10.07)</td>
<td>±3.6</td>
<td></td>
</tr>
<tr>
<td><strong>Leaflet</strong></td>
<td>4.38 (10.07)</td>
<td>±3.6</td>
<td>4.96 (7.90)</td>
<td>±2.88</td>
<td></td>
</tr>
<tr>
<td><strong>If-Then Plan</strong></td>
<td>4.96 (7.90)</td>
<td>±2.88</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Bonded Bracket Index</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Mind Map</strong></td>
<td>6.47 (13.62)</td>
<td>±4.96</td>
<td>7.22 (13.90)</td>
<td>±5.06</td>
<td></td>
</tr>
<tr>
<td><strong>Leaflet</strong></td>
<td>7.22 (13.90)</td>
<td>±5.06</td>
<td>3.90 (8.22)</td>
<td>±3.04</td>
<td></td>
</tr>
<tr>
<td><strong>If-Then Plan</strong></td>
<td>3.90 (8.22)</td>
<td>±3.04</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

1 Buccal plaque T1 scores are based on the plaque index; for T2, T3, and T4, scores are based on the bonded bracket plaque index. Analysis only compares T2, T3, and T4.
Figure 4-2: Box Plots of Bonded Bracket Index at T2, T3, and T4

Figure 4-2 shows that there is large overlap both over time and between interventions, which supports the finding that there was no statistical difference between the groups.
Figure 4-3: Box Plots of Lingual Plaque Index at T1, T2, T3, and T4

The chart showed that there was a reduction in the Lingual Plaque Index score among the three intervention groups; the if-then plan group had the lowest median and range at T4. Patients in the leaflet and mind map groups had an increase in the lingual plaque index at T4 compared to T3. On average, participants in the if-then plan group had the lower levels of lingual plaque (MANOVA...
F=1.90, P=0.04). However, the interaction term was not significant, suggesting that the degree of decline in lingual plaque over time did not differ between groups.

**Figure 4-4:** Box Plots of Bleeding on Probing at T1, T2, T3, and T4

![Intervention](image)

Figure 4-4 and Table 4-2 show the Bleeding on Probing scores among the three intervention groups.
4.3.3.2 Secondary outcomes:

Table 4-3 shows the proportion of participants within the three groups who reported key oral hygiene-related behaviours at the four time points. There was an overall trend towards improved oral hygiene-related behaviour over time, though all three groups showed similar improvements.
<table>
<thead>
<tr>
<th>Table 4-3: Frequencies of self-Reported Behaviours of Patients within each Intervention and throughout the Four Follow-up Appointments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Self-reported behaviours</strong></td>
</tr>
<tr>
<td><strong>Brushing: Number of patients brush 1/day or less 95% CI</strong></td>
</tr>
<tr>
<td>Mind Map</td>
</tr>
<tr>
<td>3</td>
</tr>
<tr>
<td>(10%)</td>
</tr>
<tr>
<td>±10.74</td>
</tr>
<tr>
<td><strong>Significance</strong></td>
</tr>
<tr>
<td><strong>Flossing: Number of patients floss Never 95% CI</strong></td>
</tr>
<tr>
<td><strong>1/week up to 1/day 95% CI</strong></td>
</tr>
<tr>
<td><strong>1/day or more 95% CI</strong></td>
</tr>
<tr>
<td>Mind Map</td>
</tr>
<tr>
<td>15</td>
</tr>
<tr>
<td>(50%)</td>
</tr>
<tr>
<td>±17.89</td>
</tr>
<tr>
<td>9</td>
</tr>
<tr>
<td>(30%)</td>
</tr>
<tr>
<td>±16.4</td>
</tr>
<tr>
<td><strong>Significance</strong></td>
</tr>
<tr>
<td>Sugary Snacks: Number of patients eat sweets</td>
</tr>
<tr>
<td>---------------------------------------------</td>
</tr>
<tr>
<td>1 (3.3%)  ±6.39</td>
</tr>
<tr>
<td>22 (73.3%)  ±15.83</td>
</tr>
<tr>
<td>6 (20%)  ±14.31</td>
</tr>
<tr>
<td>4 (13.3%)  ±12.15</td>
</tr>
<tr>
<td>1 (3.3%)  ±6.39</td>
</tr>
<tr>
<td>Significance  (X^2 = 9.54)  (P = 0.14)</td>
</tr>
</tbody>
</table>

\(X^2 = 9.54\)  \(P = 0.14\)

\(X^2 = 8.69\)  \(P = 0.19\)

\(X^2 = 9.16\)  \(P = 0.16\)

\(X^2 = 3.73\)  \(P = 0.71\)
The mean knowledge score for all three groups over time is summarized in Table 4-4 and Figure 4-5.

**Table 4-4**: Mean and Standard Values of the Knowledge of the Patients among the Three Interventions at T1, T2, T3, and T4.

<table>
<thead>
<tr>
<th>Knowledge</th>
<th>T1 Mean (S.D)</th>
<th>T2 Mean (S.D)</th>
<th>T3 Mean (S.D)</th>
<th>T4 Mean (S.D)</th>
<th>Repeated Measures Analysis of Variance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mind Map</td>
<td>15.10 (2.20)</td>
<td>16.37 (2.63)</td>
<td>16.33 (1.88)</td>
<td>16.38 (1.59)</td>
<td>F_{Time} = 0.46, P = 0.50</td>
</tr>
<tr>
<td></td>
<td>±0.79</td>
<td>±0.94</td>
<td>±0.67</td>
<td>±0.58</td>
<td></td>
</tr>
<tr>
<td>Leaflet</td>
<td>15.57 (1.94)</td>
<td>15.67 (2.15)</td>
<td>16.30 (2.15)</td>
<td>16.38 (2.09)</td>
<td>F_{INT} = 0.61, P = 0.55</td>
</tr>
<tr>
<td></td>
<td>±0.69</td>
<td>±0.77</td>
<td>±0.77</td>
<td>±0.76</td>
<td></td>
</tr>
<tr>
<td>If-Then Plan</td>
<td>14.83 (2.17)</td>
<td>15.50 (1.81)</td>
<td>16.17 (1.83)</td>
<td>15.82 (1.83)</td>
<td>F_{INT} X F_{Time} = 0.75, P = 0.47</td>
</tr>
<tr>
<td></td>
<td>±0.78</td>
<td>±0.65</td>
<td>±0.67</td>
<td>±0.68</td>
<td></td>
</tr>
</tbody>
</table>
Knowledge scores for all three intervention groups were improved at T3; the results showed that the leaflet group maintained the same level of knowledge at T4, while mind map and if-then plan groups showed a decline in knowledge at T4. No statistically significant difference was found between the three intervention groups.
There were no differences between the three groups in terms of the proportion of individuals who missed appointments (Table 4-5), though there was a trend for participants in the leaflet group to miss more appointments.

**Table 4-5:** The Difference in Patients’ Attendance of Appointments among the Three Interventions between T2 and T4.

<table>
<thead>
<tr>
<th></th>
<th>T2</th>
<th>T4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appointments</td>
<td>Mind Map</td>
<td>Leaflet</td>
</tr>
<tr>
<td>No missing</td>
<td>26 (86.7%) ±12.15</td>
<td>20 (66.7%) ±16.86</td>
</tr>
<tr>
<td>1 or more</td>
<td>4 (13.3%) ±12.15</td>
<td>10 (33.3%) ±16.86</td>
</tr>
<tr>
<td>Significance</td>
<td>X² = 5.00 P = 0.08</td>
<td>X² = 2.4 P = 0.30</td>
</tr>
</tbody>
</table>

The proportion of participants recording breakages of their appliance was highest at Time 2, but there were no significant differences between the three groups in the reporting of breakages (Table 4-6).

**Table 4-6:** Breakages of Appliances among the Interventions in T2, T3, and T4.

<table>
<thead>
<tr>
<th>Appliances</th>
<th>T2</th>
<th>T3</th>
<th>T4</th>
</tr>
</thead>
<tbody>
<tr>
<td>No Breakages</td>
<td>16 (53.3%) ±17.85</td>
<td>16 (53.3%) ±17.85</td>
<td>22 (73.3%) ±15.83</td>
</tr>
<tr>
<td>95% CI</td>
<td>(60%) ±17.53</td>
<td>(53.3%) ±17.85</td>
<td>(66.7%) ±15.83</td>
</tr>
<tr>
<td>Some Breakages</td>
<td>14 (46.7%) ±17.85</td>
<td>14 (46.7%) ±17.85</td>
<td>8 (26.7%) ±15.83</td>
</tr>
<tr>
<td>95% CI</td>
<td>(40%) ±17.53</td>
<td>(46.7%) ±17.85</td>
<td>(33.3%) ±16.86</td>
</tr>
<tr>
<td>Significance</td>
<td>X² = 0.36 P = 0.84</td>
<td>X² = 0.66 P = 0.71</td>
<td>X² = 2.15 P = 0.34</td>
</tr>
</tbody>
</table>

110
4.3.4 Ancillary analysis

No unplanned subgroup analyses or adjusted analyses were performed.

4.3.5 Harms

There were no harmful consequences detected for any of the interventions.

4.4 DISCUSSION

4.4.1 Main findings in the context of the existing evidence, interpretation

This study is the first study to compare the effect of mind map and if-then plan interventions on adherence in terms of maintaining good oral hygiene, knowledge, and self-reported behaviours, as well as appliance maintenance and appointment attendance.

The lack of a significant finding in this study demonstrates the importance of trial registration. Since trials with non-significant findings are less likely to be published, registering trials prior to the findings ensures the results will be publicity available. The majority of the included sample had a skeletal Class II (67.8%) and dental IOTN 4 (73.3%); this is expected as the sample was recruited from a public hospital and the referral criteria acts as a filter for the requirements of the participants.

The interim analysis did not reveal that any intervention was better than the other in improving adherence, and therefore the trial continued to completion.
Randomisation is a fundamental component of any controlled trial, and it is critical to eliminate bias and confirm the outcome’s validity. In the current study, randomisation was done using a random number generator; therefore, there was no significant difference in the sample characteristics between different intervention groups. The allocation is another integral aspect of any trial to avoid bias in assigning participants to a particular intervention. Allocation was concealed using sealed opaque envelopes, which were numbered, and the name of the intervention was written on a card in the sealed envelopes.

Neither mind mapping nor the use of planning interventions conferred any advantage over TAU in terms of: plaque scores, bleeding scores, knowledge, self-reported behaviours, appointment keeping, and appliance breakages. This contrasts with previous research suggesting additional benefit for such an intervention (Thickett & Newton, 2006; Schuz et al., 2006; Sniehotta et al., 2007; Suresh et al., 2012). The reasons for this are unclear. A possible explanation is that patients were treated by different orthodontists, thus the variation due to the interventions may have been hidden by the variance due to different clinicians. Also, the lack of statistical difference in oral hygiene between the three groups might be due to the fact that patients were treated by postgraduate students who may have more time than qualified orthodontists to motivate their patients and give instructions on how to maintain optimum oral hygiene. A multilevel model exploring the effect of the clustering of patients under clinicians was not possible since the number of patients clustered under clinicians was small (Masood et al., 2015).
Furthermore, previous trials of planning have tended to look at volitional behaviours such as flossing whereas behaviours in this trial were habitual. It is also possible that the Hawthorne effect operated in the present study, given that a single individual delivered all three interventions; their approach alone may have been sufficient to produce improvements in adherence, as patients knew that they were involved in the study and that their oral hygiene was going to be examined each visit. They might have shown better performance because they knew they were being watched; this explanation was supported by Feil et al., as their results showed an improvement in the orthodontic plaque scores of orthodontic patients who were in the Hawthorne group compared to the control group at 3 and 6 months follow-up (Parsons, 1991; Feil et al., 2002).

There is some suggestion in the current study that the mind map did produce short-term changes in knowledge which were better than the other two methods (see T2 in Figure 4-5). However, this effect soon faded. This was in agreement with Thickett and Newton (2006) who looked at knowledge over a short period of time (6 weeks) and found that recall among the mind map group was better than that of the other two groups at T2.

Breakages of appliances were measured at T2, T3, and T4. The number of patients with broken appliances in the if-then plan group were 14 patients at T2 while only three patients had broken appliances at T4, but these differences were not statistically significant. Missed appointments were measured at T2 and T4 among the groups, but no significant difference was found. The number of patients missing appointments in the mind map and leaflet groups were greater than in the if-then plan group, although many
researchers argued that appointment attendance among adolescent patients depends mainly on parental availability to bring the patients to the orthodontic clinic (Mehra et al., 1998; Richter et al., 1998).

4.4.2 Limitations

One of the limitations of this study is that patients were treated by different postgraduate students which might have affected compliance. Using a single orthodontist to standardize the clinician’s approach would control for the amount of verbal information given to the patient.

Also, the sample included 90 patients, 30 in each group. At Time 4 the effect size for the effect of mind-map compared to Leaflet on buccal plaque was 0.06 giving a power for the statistical test of 4%. In order to achieve 80% power to detect a difference of this magnitude we would require approximately 5,000 participants in each group. Similarly, at the same time point the effect size for the effect of If-then planning compared to Leaflet on buccal plaque was 0.24, giving a power of 14%. In order to achieve 80% power to detect a difference of this magnitude we would require approximately 300 participants in each group. Further study with a larger sample size would be valuable in the future. In addition the period of follow up could be extended to detect the durability of the changes found. The study was single-centred, taking place at the orthodontic department at Guy’s and St Thomas’ NHS Foundation. A multi-centred study would allow recruiting a wider range and larger number of patients.
4.4.3 Generalizability

The current findings may lack generalizability to primary care settings where individuals pay for their treatment. The effect of direct payment for treatment on adherence is likely to be complex. However, in individuals attending secondary care, these findings are likely to be generalizable since a good range of demographic and clinical cases are included.

4.5 CONCLUSION

- If-then planning and mind maps convey no significant advantage over the use of leaflets to support advice on oral hygiene given by a clinician.
- The three methods convey no harm to participants and all lead to similar improvements in plaque levels, knowledge and self-reported behaviours.
5. DISCUSSION AND CONCLUSIONS

The research described in this thesis sought to explore two related aspects of adherence in orthodontics: firstly, its prediction of adherence, and secondarily, the effectiveness of interventions to enhance adherence. In order to achieve this, a systematic review of interventions used to enhance adherence among orthodontic patients was undertaken which formed the basis of the interventions used in a randomised controlled trial. The randomised clinical trial was conducted to compare the effect of three methods—mind map, if-then plan, and leaflet—to improve adherence in terms of self-reported behaviour, knowledge of oral health-related behaviour, appointment keeping, and appliance breakages, as well as OH among patients undergoing maxillary and mandibular fixed orthodontic treatment. No previous study had assessed the effect of these interventions on orthodontic patients’ adherence.

The predictors of adherence among orthodontic patients attending an orthodontic clinic and being treated with fixed appliances were examined at the initial follow-up appointment 6 weeks post bracket placement. Adherence was assessed through self-reported behaviour, knowledge of oral health-related behaviour, appointment keeping, and appliance breakages, as well as proxies of behaviour: plaque levels and periodontal bleeding. The survey suggests that age and gender are not good predictors for adherence, sound knowledge is not a guarantee for good adherence, and plaque level at bond-up is correlated with the presence of plaque at follow-up.
5.1 SUMMARY OF FINDINGS

5.1.1 Summary of the Systematic Review findings

The aim of the systematic review was to evaluate the effectiveness of interventions used to enhance adherence among orthodontic patients aged 12 to 18 years of age. The review followed the PRISMA rules and checklist. The search revealed 381 articles which were screened independently by two authors using the titles and the abstracts to identify related studies. The full texts of the relevant articles were obtained and full data extraction was done independently by the three authors for inclusion. The results revealed four randomised clinical trials which matched our criteria. Meta-analysis was not performed due to the heterogeneity of the data of the relevant trials. The first trial tested the effect of an award/reward system to improve adherence among 144 patients aged 9.6 to 17.6 years of age after dividing the patients into high compliers and low compliers using the Orthodontic Patient Cooperation Scale. The study indicated that oral hygiene was improved among the low compliers reward group compared to the low compliers of the control group. The findings of the study did not support the hypothesis that the award/reward intervention might improve adherence, which might be due to the lack of attractiveness of the rewards that were used (Richter et al., 1998).

Feil et al. (2002) investigated the ability of the Hawthorne effect to improve adherence among orthodontic patients. The patients were divided into two groups, 20 in each group: control and Hawthorne effect group. The results of this study support the use of the Hawthorne effect, as patients had an improvement in their plaque index compared to the
control group, although the Hawthorne effect was not tested in terms of appointment attendance and appliance breakages.

The effects of written versus verbal information were tested in relation to motivation, anxiety, and compliance among orthodontic patients. They found that there was an improvement in the periodontal condition of the patients who received written information, but no statistically significant difference was found. The study sample size was small, which might have affected the results (Wright et al., 2010).

The last study used three types of educational/motivational intervention to improve oral hygiene among 76 orthodontic patients. The results found that gingival and plaque indices were improved among the third group who were motivated by showing the patients plaque under the microscope, although no clear description of how gingival and plaque scores were measured was provided (Acharya et al., 2011).

In summary, the systematic review revealed that different methods were used to improve patients’ adherence/compliance, but no method was shown to be superior to another. Also, it revealed the need for more interventions to be tested for their effectiveness to improve adherence.

5.1.2 Summary of the Survey Findings

Patients’ adherence during orthodontic treatment is a challenging problem that faces the orthodontist, and it will affect the treatment outcome and duration. The objective of the survey in this dissertation was to investigate the predictors of adherence among orthodontic patients 6 weeks after the insertion of the fixed orthodontic appliances. The
sample consisted of 200 orthodontic patients 12–18 years of age. The results revealed that the lingual plaque index and the bleeding point index were $P = 0.006$ and $P = 0.026$, respectively. This means that it was worse 6 weeks after bond-up, which might be due to pain and discomfort caused by the initial insertion (White, 1996); also, it was mentioned that gingival bleeding might increase after bond-up in patients with crowded dentition (Addy et al., 1988). Another explanation is that we evaluated patients 6 weeks after bond-up, and the patients might not have been used to performing good oral hygiene with the presence of the brackets and the wires. Knowledge was improved at the follow-up appointment: $P < 0.001$. Using the regression analyses, we found that regarding the clinical indices at the follow-up visit, the best predictors were the initial clinical indices; also for behavioural measures, initial reported behaviours were the best predictors for the behaviours at the follow-up appointment, which was in agreement with Hardy (2014). The results revealed that age and gender are not good predictors for adherence, which was in accordance with previous studies (Cucalon & Smith, 1990; Albino et al., 1991; Nanda & Kierl, 1992; Richter et al., 1998). The predictors of adherence remain to be determined.

5.1.3 Summary of the Randomised Controlled Trial

As discussed earlier, the systematic review results did not support the use of one intervention over another to enhance adherence; also, it revealed the need to explore different interventions to improve adherence. The survey stated that the oral hygiene of the orthodontic patients worsened 6 weeks after bond-up although their knowledge was better. This guided us to conduct the randomised controlled trial study which consisted of a mind map group, if-then plan group, and a leaflet group. There was no statistically
significant difference in terms of OH, knowledge, and self-reported behaviour among the three groups, which was not in agreement with previous studies (Thickett & Newton, 2006; Schuz et al., 2006; Sniehotta et al., 2007; Suresh et al., 2012). This might be due to the Hawthorne effect as the patients and their parents knew that they were enrolled in a study designed to improve their adherence. Furthermore, previous studies looked at volitional behaviours while we have looked at habitual behaviours. Another explanation may be that patients in the current study were treated by different orthodontic postgraduates who were motivating the patients throughout the treatment to maintain a high level of oral hygiene. No intervention emerged as superior.
5.2 LIMITATION OF THE STUDIES

5.2.1 Limitations of the Systematic Review

There were some limitations in the systematic review that were not avoidable. First, the number of trials that matched our criteria was very small, only four trials (Richter et al., 1998; Feil et al., 2002; Wright et al., 2010; Acharya et al., 2011). We could not run a meta-analysis due to the heterogeneity of the data. Concerns as to the effectiveness of the search strategy might be revised since one study was found outside the search criteria.

Trials matching our criteria were single centred, which might have affected their sample sizes, as multi-centred trials allow recruiting of larger numbers of patients.

Regarding the outcomes, some studies included in our review measured the effect of adherence in terms of plaque scores only, without considering other outcomes such as appointment attendance, appliance breakages, and knowledge (Feil et al., 2002; Acharya et al., 2011).

Randomization, allocation, concealment, blinding, and withdrawals are important elements in any randomised clinical trial. One of the included trials did not mention the randomization method used (Richter et al., 1998). There was no information about allocation and implementation in two trials (Richter et al., 1998; Wright et al., 2010), and the other two trials did not mention anything about blinding (Wright et al., 2010; Acharya et al., 2011).
5.2.2 Limitations of the Survey

The major limitation was that the orthodontic patients were treated by different postgraduate students, which might affect their adherence. Better results might be achieved if patients were treated by the same orthodontist. Additionally, the patients were assessed after 6 weeks; a longer follow-up period might reveal better results. This study was also limited in that it did not address compliance in adult patients and those treated with other kinds of appliances. However, the patients in the present study represent the typical age group for individuals treated with fixed appliances.

5.2.3 Limitations of the Randomised Controlled Trial

One of the limitations of the RCT was that patients were treated by different postgraduate students, which might have affected compliance. Using a single orthodontist to standardize the clinician’s approach would control for the amount of verbal information given to the patient.

Moreover, the sample included 90 patients, 30 in each group. A larger number might improve the power of the study. This was not possible in our case as it is a PhD project that has a timeline. Also, the patients had to be followed for almost 3 months after recruitment, which made a larger number impossible.

The study was single-centred, taking place at the orthodontic department at Guy’s and St Thomas’ NHS Foundation. A multi-centred study would allow recruiting a wider range and larger number of patients.
Blinding is really important in a randomised controlled trial; however, in our research, that was not an option as it was impossible for the patients and their parents to be blinded, but the statistician who undertook data analysis was blinded.
5.3 DISCUSSION OF FINDINGS IN RELATION TO ADHERENCE

The aim of orthodontic treatment is to move teeth to a more favourable position in the jaws, and improve function and facial aesthetics (Breznik & Ben-Ya’ir, 1989). Orthodontic patients might experience some discomfort due to pain or functional restriction (Serol et al., 1998; Doll et al., 2000).

Orthodontic treatment usually takes two years depending on the severity of malocclusion, patients’ age at the start of the treatment, the treatment regimen, and compliance. Patients’ compliance usually decreases during the treatment regardless of the level of compliance at the beginning of the treatment (Richter et al., 1998).

Patients’ adherence during orthodontic treatment is an important factor that will have an impact on treatment duration and outcome. This dissertation revealed that patients’ adherence in terms of oral hygiene worsened 6 weeks after bond-up, which was in agreement with previous studies (Oliver & Knapman, 1985; Serol & Zentner, 1998; Acharya et al., 2011; Al-Jewair, 2011). In terms of knowledge, patients’ knowledge had improved 6 weeks after bond-up.

The systematic review revealed the effectiveness of some interventions used to improve adherence during orthodontic treatment (Richter et al., 1998; Feil et al., 2002; Wright et al., 2010; Acharya et al., 2011). In addition, it revealed the need for more interventions to be tested for their effectiveness in improving adherence.

Among the three types of interventions used in the RCT, the if-then plan group performed better on the bonded bracket index, lingual plaque index, and bleeding upon probing,
while they showed a drop in their knowledge at T4 compared to the mind map and the leaflet groups, but the differences were not statistically significant.
5.4 RECOMMENDATIONS AND FUTURE IMPLICATIONS

5.4.1 Implications for Practice

Orthodontists should expect patients to exhibit poor oral hygiene initially and therefore should consider intervening to improve it. It was difficult to predict what determines non-adherence. It is therefore important to assess, take action, and treat each person individually. No intervention was clearly better/more effective than another. Consider should be given to adapting different interventions for different people.

5.4.2 Implications for Future Research

There are several implications for researchers. One is to recruit patients treated by the same orthodontist to eliminate inconsistencies among practitioners. Since blinding is difficult in psychological tests, for future research, the person who is providing the intervention should be different from the person who is assessing the outcome. Future researchers might consider a broader range of predictors such as social class, school performance etc. Other interventions might be tested for effectiveness in improving adherence after assessing the patients’ behaviours by using the COM-B model (Asimakopoulou & Newton, 2015).
5.5 CONCLUSION

- The systematic review revealed that the literature advocates the use of several methods to improve compliance/adherence among orthodontic patients. Although there is no evidence to support one particular intervention over another, the results do demonstrate the value of spending time with patients to illustrate the importance of adherence.

- Future studies should develop multiple methods of assessing patient adherence. Different types of interventions should be included and tested for effectiveness.

- Patients’ oral hygiene worsens initially after starting orthodontic treatment.

- Sound patient knowledge may not be a guarantee of better adherence.

- Age and gender may not good predictors of adherence.

- Initial patients’ adherence is the best predictor for future adherence.

- If-then planning and the use of mind maps convey no significant advantage over the use of leaflets to support advice on oral hygiene given by a clinician.
6. REFERENCES


References


7. APPENDICES

7.1 The Study NHS Ethical Approval

Health Research Authority

NRES Committee London - City & East
Bristol Research Ethics Committee Centre

Whitefriars
Level 3, Block B
Lewins Mead
Bristol
BS1 2NT

Telephone: 01173421386
Facsimile: 01173420445

22 January 2013

Dr Aljazi Aljabaa
PHD Student
King’s College London
King’s College London Dental Institute
Floor 18, Tower Wing, Guy’s Hospital
SE1 9RT

Dear Dr Aljabaa,

Study Title: Adherence to oral hygiene related advice in orthodontic patients: A survey and A trial of structured interventions
REC reference: 12/LO/1958
IRAS project ID: 111573

Thank you for your letter of 16 January 2013, responding to the Committee’s request for further information on the above research and submitting revised documentation.

The further information was considered in correspondence by a sub-committee of the REC. A list of the sub-committee members is attached.

We plan to publish your research summary wording for the above study on the NRES website, together with your contact details, unless you expressly withhold permission to do so. Publication will be no earlier than three months from the date of this favourable opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to withhold permission to publish, please contact the Co-ordinator Mr Rajat Khullar, nrescommittee.london-cityandeast@nhs.net.
Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Ethical review of research site

NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see “Conditions of the favourable opinion” below).

Non-NHS sites

The Committee has not yet been notified of the outcome of any site-specific assessment (SSA) for the non-NHS research site(s) taking part in this study. The favourable opinion does not therefore apply to any non-NHS site at present. We will write to you again as soon as one Research Ethics Committee has notified the outcome of a SSA. In the meantime no study procedures should be initiated at non-NHS sites.

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

Where a NHS organisation’s role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Approved documents
The final list of documents reviewed and approved by the Committee is as follows:

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<tr>
<th>Document</th>
<th>Version</th>
<th>Date</th>
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<td>Response to Request for Further Information</td>
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Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document “After ethical review – guidance for researchers” gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

Further information is available at National Research Ethics Service website > After Review

12/LO/1958 Please quote this number on all correspondence

We are pleased to welcome researchers and R & D staff at our NRES committee members’ training days – see details at http://www.hra.nhs.uk/hra-training/

With the Committee’s best wishes for the success of this project.

Yours sincerely,

PP Dr Arthur T. Tucker
Chair
Email:nrescommittee.london-cityandeast@nhs.net

Enclosures: List of names and professions of members who were present at the meeting and those who submitted written comments

“After ethical review – guidance for researchers”

Copy to: Mr Keith Brennan
Dr Karen Ignatian, Guy's & St Thomas' NHS Trust
NRES Committee London - City & East

Attendance at Sub-Committee of the REC meeting on 17 January 2013

Committee Members:

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<tr>
<td>Dr Ayse Baxter</td>
<td>Independent Consultant Pharmaceutical Physician</td>
<td>Yes</td>
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</tr>
<tr>
<td>Dr Arthur T. Tucker</td>
<td>Principal Clinical Scientist &amp; Honorary Reader, (REC Chairman)</td>
<td>Yes</td>
<td></td>
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Also in attendance:

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<tr>
<th>Name</th>
<th>Position (or reason for attending)</th>
</tr>
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<tbody>
<tr>
<td>Mr Rajat Khullar</td>
<td>Committee Coordinator</td>
</tr>
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</table>
7.2 The Study Research and Developmental Approval

Dr Aljazi Aljabaa
Kings College London
Floor 18, Guys Tower
Guys Hospital
London
SE1 9RT

13/03/2013

Dear Dr Aljazi Aljabaa

Title: Adherence to oral hygiene related advice in orthodontic patients: A survey and A trial of structured interventions

In accordance with the Department of Health’s Research Governance Framework for Health and Social Care, all research projects taking place within the Trust must receive a favourable opinion from an ethics committee and approval from the Department of Research and Development (R&D) prior to commencement.

- Ethics Number: 12/LO/1958
- Sponsor: King’s College London
- Funder: No external funding
- End Date: 30/09/2014
- Protocol: 3.5
- Site: GSTFT
- R&D Approval Date: 13/03/2013
- Chief Investigator: Dr Aljazi Aljabaa

NHS permission for the above research has been granted on the basis described in the application form, protocol and supporting documentation as listed in the ethics letter of favourable opinion letter dated 22nd January 2013. I am pleased to inform you that we are approving the work to proceed within Guy’s and St Thomas’ NHS Foundation Trust and that the study has been allocated the Trust R&D registration number RJ113/N059 I can confirm that from the SSI application form you have agreed to recruit 200 within 1 year.

Whilst the Trust takes on non funded research without charge for sponsorship, research management and governance or research costs we encourage all research to be funded and particularly encourage UKCRN portfolio eligible research. Prior to your next research proposal please contact the R&D department about portfolio eligibility and how to gain funding for research so as to ensure that the study can gain appropriate funding prior to your research application.
Conditions of Approval:

- The principal investigator must ensure that the recruitment figures are reported.
- The principal investigator must notify R&D of the actual end date of the project.
- R&D must be notified of any changes to the protocol prior to implementation.
- The project must follow the agreed protocol and be conducted in accordance with all Trust Policies and Procedures especially those relating to research and data management.
- Members of the research team must have appropriate substantive or honorary contracts with the Trust prior to the study commencing. Any additional researchers who join the study at a later stage must also hold a suitable contract.

Data Protection:

Please ensure that you are aware of your responsibilities in relation to The Data Protection Act 1998, NHS Confidentiality Code of Practice, NHS Caldicott Report and Caldicott Guardians, the Human Tissue Act 2004, Good Clinical Practice, the NHS Research Governance Framework for Health and Social Care, Second Edition April 2005 and any further legislation released during the time of this study.

The Principal Investigator is responsible for ensuring that Data Protection procedures are observed throughout the course of the project.

If the project is a clinical trial under the European Union Clinical Trials Directive the following must also be complied with:

3. If a clinical trials team has to keep a subject in a department" out of hours" for whatever reason, the Senior Nurse for the Hospital should be informed of their presence – as should the Resuscitation Team.
4. For CIMP studies hosted by GSTFT, the sponsor is responsible for reporting updates and providing updated documents related SMPC at this site

Amendments:

Please ensure that you submit a copy of any amendments made to this study to the R&D Department.

ISRCTN registration:

If appropriate it is recommended that you register with the Current Controlled Trials website http://isrctn.org/. Find out more about registering for an International Standard Randomised Controlled Trial Number (ISRCTN) as part of the Portfolio application process. Non-commercial studies with an interventional component that are eligible for NIHR CRN support can register for an ISRCTN for free via the Portfolio Database.

Annual Progress Report:

It is obligatory that an annual report is submitted by the Chief Investigator to the research ethics committee, and we ask that a copy is sent to the R&D Department. The yearly period commences from the date of receiving a favourable opinion from the ethics committee.

Please submit a copy of the progress report on the anniversary of the Ethics favourable opinion (January 2014).

Should you require any further information please do not hesitate to contact us.
In line with the Research Governance Framework, your project may be randomly selected for monitoring for compliance against the standards set out in the Framework. For information, the Trust’s process for the monitoring of projects and the associated guidance is available from the Trust’s intranet or on request from the R&D Department. You will be notified by the R&D Department if and when your project has been selected as part of the monitoring process. No action is needed until that time.

Thank you for registering your research project.

Yours sincerely

[Signature]

Elizabeth Bruna
R&D Governance Specialist
7.3 Survey Parents’ Information Sheet

Reference number: 12/LO/1958  
Version number: 3.4  
Date: 20/11/2012

Adherence to oral hygiene related advice in orthodontic patients: A survey  
Parent/Guardian information sheet

Researchers: Tim Newton  
Fraser McDonald  
Aljazi AlJabaa

We are pleased to invite your child to take part in a research project. It is important for you to understand the reason for this work and what will be involved before you decide. Please take your time to read the following information carefully. Ask us if there is anything you need further explanation on and we will be more than happy to assist you.

Thank you for reading this.

1. **What is the purpose of the study?**

   Orthodontic treatment involves wearing braces in order to straighten teeth and improve the appearance of your smile. It also makes it easier for people to eat and speak. During treatment patients are asked to change their diet, attend appointments regularly and take good care of their teeth by brushing and flossing. Our clinical impression is that many orthodontic patients do not follow this advice. We are conducting a survey to find out whether or not people follow the advice that they have been given, so that we can develop new ways to help patients in the future.

2. **Why my child was chosen?**

   We are asking patients who have just started orthodontic treatment to take part in this project. Your child was selected because he/she is a patient who is about to start brace treatment on their teeth.

3. **Does my child have to take part?**

   It is up to him/her and you to decide whether or not to participate. If you decide that your child will help us, he/she will need to complete this questionnaire. If you don’t want them to take part this will not affect the treatment they receive.

4. **What will happen to my child if he/she takes part?**

   We will ask your child to take the time to complete the enclosed questionnaires. We will use the information provided to understand the orthodontic patients' view on cooperation with braces.

5. **What are the possible risks to take part?**

   We believe that there are no risks to taking part in this project.
6. **Will his/her participation in this study be kept confidential?**

All information, which is collected, during the course of the project will be kept strictly confidential. At no point will we ask for their name or any detail that might identify them as an individual.

7. **What will happen to the results of the study?**

The results will be used by Dr Aljabaa as part of her PhD project. The research will be published in academic journals.

8. **Contact for further information?**

If you would like any further information please do not hesitate to contact Dr Aljabaa by phone 02032993481 or by e-mail; (Aljazi.Aljabaa@kcl.ac.uk)

Thank you for taking the time to read this information.
7.4 Children Participants’ Information Sheet

Reference number: 12/LO/1958
Version number: 3.4
Date: 20/11/2012

Adherence to oral hygiene related advice in orthodontic patients: A Survey

Researchers: Tim Newton
Fraser McDonald
Aljazi aljabaa
What is this leaflet/letter about?
Hi, I am Dr. Aljazi Aljabaa. I want to invite you to help me gathering some information which is important in the study.

What is the study about?
You are now visiting the Orthodontist to put braces on your teeth. When you have your braces you should follow your Orthodontist's advice. This will include avoiding some food, brushing your teeth and attending your appointments. In this study you will answer several questions which will help us to find out whether or not you remember and follow the advice that have been given to them.

Why I was invited?
You were invited, because you will start having braces.

What will happen if I take part in the study?
You will answer some questions and also we will examine your teeth to see if you are brushing well.

What if I don't want to participate?
You are totally free to choose to help us or not. Your treatment will go on as normal and nothing will be affected if you do not want to be involved in this study. I would really be happy if you decided to join us. I would really appreciate you help. Even if you decided to join and then change your mind, there will be no problem.

Is there any danger if I participate in the study?
There are no any dangers related with this study. The main advantage for the information you provide is to help us to find out whether or not people remember and follow the advice that they were given, so that we can develop a good method to help orthodontic patients to follow the advice of their dentist/orthodontist. This will mean you will have healthier teeth and an easier orthodontic treatment.

What if I need further information or I want to take more time to think?
Please feel free to contact me, Dr. Aljazi Aljabaa by phone 02032993481 or by e-mail (Aljazi.Aljabaa@kcl.ac.uk)

Thank you for taking the time to read this information.
Adherence to oral hygiene related advice in orthodontic patients: A survey

Participants information sheet (16 years and older)

Researchers: Tim Newton
Fraser McDonald
Aljazi AlJabaa

You are invited to take part in a research project. Before you decide it is important for you to understand why the research is performed and what it will involve. Please take your time to read the following information carefully and discuss it with you friends and relatives if you wish.

Thank you for reading this.

1. **What is the purpose of the study?**

Orthodontic treatment involves wearing braces in order to straighten teeth and improve the appearance of your smile. It also makes it easier for people to eat and speak. During treatment patients are asked to change their diet, attend appointments regularly and take good care of their teeth by brushing and flossing. Our clinical impression is that many orthodontic patients do not following this advice. We are conducting a survey to find out whether or not people remember and follow the advice that they have been given, so that we can develop new ways to give the advice.

2. **Why I have been chosen?**

You have been selected because you are an orthodontic patient about to start treatment.

3. **Do I have to take part?**

It is up to you to decide whether or not to take part. If you decide to take part we hope you will take the time to complete this questionnaire. If you decide not to take part this will not affect the treatment you receive.

4. **What will happen to me if I take part?**

If you decide to take part we will ask you to take the time to complete the enclosed questionnaires. We will use the information you provide to understand your view on adherence with orthodontic treatment.

5. **What are the possible risks to take part?**

We believe that there are no risks to taking part in this project.
6. **Will my taking part in this study be kept confidential?**

   All information, which is collected, about you during the course of the project will be kept strictly confidential. At no point will we release your name or any detail that might identify you as an individual.

7. **What will happen to the results of the study?**

   The results will be used by Dr Aljabaa as part of her PhD project. The research will be published in academic journals.

8. **Contact for further information?**

   If you would like any further information please do not hesitate to contact Dr. Aljabaa by phone 02032993481 or by e-mail; (Aljazi.Aljabaa@kcl.ac.uk)

Thank you for taking the time to read this information.
7.6 Letter to the Participants (RCT)

Reference number: 12/LO/1958
Version number: 3.4
Date: 20/11/2012

LETTER TO PARTICIPANT

Name:
Address:
Postcode:
Date:

Dear

RE: Adherence to oral hygiene related advice in orthodontic patients: A trial of structured interventions

We are writing to ask for your kind help as we would like to invite you to participate in our study, which aims to enhance your adherence during the orthodontic treatment. You will be assigned randomly (this means that you are equally likely to be in any of the three arms, we decide this by selecting an enclosed envelope that even the researcher does not know which method is inside it) to one of the arms of the study. The interventions ask you to do one of three things to help you remember what you have to do and improve your compliance.

At your next visit after the intervention, we will ask you to complete a questionnaire to see how much you have remembered and will examine your teeth to see if you followed the advice. Together the questionnaire and the oral examination should take no more than 10 minutes of your time.

Your responses will be treated with the utmost confidentiality. They will be processed and stored using a unique identifying code. The results will not be reported in any way which allows individual responses to be identified.

Yours Sincerely,

Aljazi Aljabaa
Postgraduate Dental Student
KCL Dental Institute
Floor 18, Guy’s Hospital
London SE1 9RT
7.7 RCT Parents’ information sheet

Reference number: 12/LO/1958
Version number: 3.4
Date: 20/11/2012

Adherence to oral hygiene related advice in orthodontic patients: A trial of structured interventions

Parent/Guardian information sheet

Researchers:  Tim Newton
Fraser McDonald
Aljazi aljabaa

We are pleased to invite your child to take part in a research project. It is important for you to understand the reason for this research and what will be involved before you decide. Please take your time to read the following information carefully. Ask us if there is anything you need to have explained more clearly and we will be more than happy to assist you.

Thank you for reading this.

1. What is the purpose of the study?

Orthodontic treatment involves wearing braces in order to straighten teeth and improve the appearance of your child’s smile. It also makes it easier for people to eat and speak. During treatment patients are asked to change their diet, attend appointments regularly and take good care of their teeth by brushing and flossing. However many orthodontic patients do not follow this advice. We are studying ways to help young people, particularly teenagers to improve their compliance. This study is looking at two ways to enhance the cooperation during orthodontic treatment.

2. Why my child was chosen?

We are asking patients who have just started orthodontic treatment to take part in this project. Your child was selected because he/she is an orthodontic patient about to start treatment.

3. Does my child have to take part?

It is up to him/her and to you to decide whether or not to participate. If you decide that your child will participate, he/she will be asked to sign a consent form. We will also ask you to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. If you don’t want him/her to take part this will not affect the treatment he/she receive. This will not affect your treatment in any way.

4. What will happen to my child if he/she takes part?

We will put him/her into one of three parts of the study. This will be done at random (this means that he/she are equally likely to be in any of the three parts of the study. We decide this by selecting a sealed envelope, that even the researcher is unaware of its contents, like drawing names from a hat). The
interventions will ask him/her to do one of three things to help him/her to remember what he/she have to do and improve his/her compliance. At his/her next visit we will ask him/her to complete a questionnaire to see how much he/she have remembered. We will also examine his/her teeth to see if he/she followed the advice. Together the questionnaire and the oral examination should take no more than 10 minutes of your time.

5. **What are the possible disadvantages and risks of taking part?**

We believe that there are no risks or disadvantages to taking part.

6. **Will his/her participation in this study be kept confidential?**

Absolutely, all information which is collected about you during the course of the research will be kept strictly confidential.

7. **What will happen to the results of the research study?**

The results will be used by Dr Aljabaa as part of her PhD studies. We also hope to publish the research in academic journals. It will not be possible for any individual participant to be identified in any publication that is produces from the information we produce.

8. **Contact for further information**

If you would like any further information please feel free to contact Dr.Aljazi AlJabaa by phone 02032993481 or by e-mail (Aljazi.Aljabaa@kcl.ac.uk)

Thank you for taking the time to read this information.
7.8 RCT Children participants’ Information Sheet

Reference number: 12/LO/1958
Version number: 3.4
Date: 20/11/2012

Adherence to oral hygiene related advice in orthodontic patients: A trial of structured interventions

Researchers:  Tim Newton
              Fraser McDonald
              Aljazi Aljabaa
What is this paper?
Hi, I am Dr. Aljazi Aljabaa. I want to invite you to help me gathering some information which is important.

What is the study about?
You are now visiting the Orthodontist to put braces on your teeth. When you have your braces you should listen to you’re the Orthodontist’s advice. Some of this advice is to avoid some types of food, brushing your teeth and attending your appointments. This study is to improve your help with this advice.

Why I was invited?
You were invited, because you will start having braces.

What will happen if I take part in the study?
Since the study is aimed to improve your help with orthodontic treatment, you will be picked randomly (this means that you are equally likely to be given any of three possible ways to help you. We decide this without even ourselves knowing what is in some sealed envelopes. Any one of these three things will help you remember the advice. The next visit you will answer some questions and we will quickly examine your teeth. This will help us to see how much you followed the advice. It won’t take more than 10 minutes of your time.

What if I don’t want to participate?
You are free to choose to participate or not. Your treatment will go on as normal and nothing will be affected. I would really be happy if you decided to join and I would appreciate you help in this study. Even if you decided to join and then change your mind, there will be no problem.

Is there any danger if I participate in the study?
There is no danger related with this study.
The main advantage for the information you provide is to help us to find the best method that will help other patients who wear braces. This will allow you to have healthier teeth and an easier treatment.

If I need further information or if I need more time to think?
Please feel free to contact me, Dr. Aljazi Aljabaa, by phone 02032993481 or by e-mail (Aljazi.Aljabaa@kcl.ac.uk)
Thank you for taking the time to read this information.
7.9 RCT Participants’ Information Sheet (16 years and older)

Reference number: 12/LO/1958
Version number: 3.4
Date: 20/11/2012

Adherence to oral hygiene related advice in orthodontic patients: A trial of structured interventions

Participants information sheet (16 years and older)

Researchers:  Tim Newton
             Fraser McDonald
             Aljazi Aljabaa

You are being invited to take part in a research study at King’s College London Dental Institute at Guy’s Hospital. Before you decide it is important for you to understand why the research is being carried out and what it will involve. Please take time to read the following information carefully. Ask us if there is anything that is not clear or if you would like more information. Take the time to decide whether or not you wish to take part.

Thank you for reading this.

9. What is the purpose of the study?

Orthodontic treatment involves wearing braces in order to straighten teeth and improve the appearance of yours smile. It also makes it easier for people to eat and speak. During treatment patients are asked to change their diet, attend appointments regularly and take good care of their teeth by brushing and flossing. However many orthodontic patients do not follow this advice. We are studying ways to help young people such as yourself, to improve their compliance. We are especially interested in people such as yourself. This study is looking at ways to help your cooperation during orthodontic treatment.

10. Why have I been chosen?

You have been selected because you are an orthodontic patient.

11. Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. We will also ask your parent or guardian to sign a form to indicate that they are willing to allow you to take part. If you decide to take part you are still free to withdraw at any time and without giving a reason. This will not affect the treatment you receive.

12. What will happen to me if I take part?

If you decide to take part we will put you into one of three groups. You will not meet the other members of the group but you will be given a specific technique to help you remember what you have to do to help with your brace treatment. At your next visit we will ask you to complete a questionnaire to see how much you
have remembered and we will examine your teeth to see how well you followed the advice. Together the questionnaire and the oral examination should take no more than 10 minutes of your time.

13. **What are the possible disadvantages and risks of taking part?**

We believe that there are no risks or disadvantages in taking part in this study.

14. **Will my taking part in this study be kept confidential?**

Absolutely. All information which is collected about you during the course of the research will be kept strictly confidential.

15. **What will happen to the results of the research study?**

The results will be used by Dr Aljabaa as part of her PhD studies. We also hope to publish the research in academic journals. It will not be possible for any individual participant to be identified in any of the publications.

16. **Contact for further information**

If you would like any further information please feel free to contact Dr. Aljazi Aljabaa by phone 02032993481 or by e-mail (Aljazi.Aljabaa@kcl.ac.uk)

Thank you for taking the time to read this information.
7.10 RCT Parents’ Consent Form

Reference number: 12/LO/1958
Version number: 3.4
Date: 20/11/2012

CONSENT FORM FOR PARENT/GUARDIAN

Centre number:.....................
Study number:.....................
Participant Identifier number for this trial: .............

NB Three copies should be made, for
(1) child, (2) researcher, (3) hospital notes

Title of Project:
Adherence to oral hygiene related advice in orthodontic patients: A trial of structured interventions

Name of Researchers: Tim Newton, Fraser McDonald and Aljazi Aljabaa

1. I confirm that I have read and understand the information sheet for the above study and have had the opportunity to ask questions.

2. I understand that my child’s participation is voluntary and that he/she is free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.

3. I agree to my child’s participation in the above study.

Name of Parent/Guardian ___________________________ Date ____________ Signature ___________________________

Aljazi Aljabaa ___________________________ Date ____________ Signature ___________________________

Name of Person taking consent

Aljazi Aljabaa ___________________________ Date ____________ Signature ___________________________

Researcher

Aljazi Aljabaa ___________________________ Date ____________ Signature ___________________________
7.11 RCT Children Participants’ Assent Form

Reference number: 12/LO/1958
Version number: 3.4
Date: 20/11/2012

ASSENT FORM FOR CHILD

Study number: ..................
Participant Identifier number for this trial: .............

NB Three copies should be made, for
(1) child, (2) researcher, (3) hospital notes

Title of Project:
Adherence to oral hygiene related advice in orthodontic patients: A trial of structured interventions

Name of Researchers: Tim Newton, Fraser McDonald and Aljazi Aljabaa

1. I have read the information sheet for this study and have had the opportunity to ask questions.

2. I understand that I only need to take part if I want to and that I can stop being in the study at any time, and this will have no effect on me.

3. I agree to take part in the above study.

Name of Participant ___________________________ Date ___________________________ Signature ___________________________

Aljazi Aljabaa
Name of Person taking consent ___________________________ Date ___________________________ Signature ___________________________

Aljazi Aljabaa
Researcher ___________________________ Date ___________________________ Signature ___________________________
7.12 RCT participants’ Consent Form (16 years and older)

Reference number: 12/LO/1958
Version number: 3.4
Date: 20/11/2012

CONSENT FORM FOR PARTICIPANTS (16 years and older)

Study number: ........................
Participant Identifier number for this trial: ..............

NB Three copies should be made, for
(1) child, (2) researcher, (3) hospital notes

Title of Project:
Adherence to oral hygiene related advice in orthodontic patients: A trial of structured interventions

Name of Researchers: Tim Newton, Fraser McDonald and Aljazi Aljabaa

4. I have read the information sheet for this study and have had the opportunity to ask questions.

5. I understand that I only need to take part if I want to and that I can stop being in the study at any time, and this will have no effect on me.

6. I agree to take part in the above study.

________________________________  ___________________  ___________________
Name of Participant  Date  Signature

______________________________  ___________________  ___________________
Aljazi Aljabaa  Date  Signature

Name of Person taking consent

________________________________  ___________________  ___________________
Name of Person taking consent  Date  Signature

Aljazi Aljabaa

________________________________  ___________________  ___________________
Researcher  Date  Signature
7.13 Self-reported Behaviours Questionnaire

Reference number: 12/LO/1958
Version number: 3.4
Date: 20/11/2012

Self-reported dental health behaviours

We would like to ask you about your dental health behaviours (brushing and flossing). Please read the questions below and tick the answer that best describes your behaviour over the past 7 days. There are no right or wrong answers.

1. During the past week, how often did you brush your teeth?
   - Not at all,
   - Once a week
   - Every second day
   - Once a day
   - Twice a day
   - Other (please specify)_______________________________________

2. During the past week, how often did you floss your teeth?
   - Not at all
   - Once a week
   - Every second day
   - Once a day
   - Twice a day
   - Other (please specify)_______________________________________

3. How often each day do you eat sugary snacks or drink sugary drinks?
   - Not at all
   - Once a day
   - Twice a day
   - Three times a day
   - Four times a day
   - Five or more times a day
### 7.14 Questionnaire on Important Information during Orthodontic Treatment

**Reference number:** 12/LO/1958  
**Version number:** 3.4  
**Date:** 20/11/2012

**Questionnaire to test the amount of patient’s knowledge about important information during orthodontic treatment**

1. Which food and drinks should you avoid?  
   Yes | No  
   --- | ---  
   FRUIT |  
   CHEWING GUM |  
   CRUSTY BREAD |  
   STILL WATER |  
   SWEETS |  
   HARD FOODS |  
   FIZZY DRINKS |  
   DIET FIZZY DRINKS |  

2. How often should you visit your High Street dentist while wearing braces?  
   Yes | No  
   --- | ---  
   Never |  
   Every 3–4 months |  
   Every 6 months |  
   Every year |  

3. Should you use a fluoride mouthwash?  
   Yes | No  
   --- | ---  
   |  

4. How often should you brush?  
   Once a day  
   |  
   Twice a day  
   |  
   Three times  
   |  

5. It is important to brush after a meal?  
   Yes | No  
   --- | ---  
   |  

6. How long will treatment take?

- 6 months to 1 year □
- 1-2 years □
- Over 3 years □

7. If the brace makes your teeth or cheeks ache what should you do?

- Yes □
- No □

- Just put up with it □
- Use some wax □
- Do take painkillers □

8. What do you do if you damage your brace?

- Yes □
- No □

- Do nothing & wait until you next appointment □
- Phone your own dentist for an appointment □
- Come into the hospital as an emergency □

9. Can poor brushing lead to the following?

- Yes □
- No □

- Healthy gums □
- Decayed teeth □
- No staining □
7.15 BOS Orthodontic Patients' Leaflet

**Fixed Appliances**

A fixed brace can be used to straighten crooked teeth like these.

Now that you have a fixed brace (appliance) you may have some questions you would like answered. For more information about Orthodontics, please visit: www.bos.org.uk

**Will it be painful?**

It is likely to be sore for about 3 - 5 days each time the brace is adjusted. If necessary, simple painkillers such as the ones you would normally take for a headache should help - please read the instructions on the packet. If the brace rubs your lips or cheeks, you can use some wax to help with this. Your orthodontist can give you further advice.

**Can I remove the brace?**

The brace you are now wearing is fixed to the teeth for the whole of your treatment. You should not try to remove it, as you may damage your teeth and the treatment will not work.
Can I eat normally?
Yes, you should be able to eat normally. However, for your orthodontic treatment to work well and in the shortest possible time, it is important that you take care of your teeth and brace. In order to prevent damage to both, you should:

- Avoid sugary snacks/drinks between meals and at bedtime.
- Avoid sticky, chewy or hard sweets, mints and sugared chewing gum.
- Avoid fizzy drinks (including diet drinks) and large amounts of fruit juice.
- Hard or chewy foods - such as apples, carrots and crusty bread - can damage your brace. Avoid them or cut them up first!

Brushing may take a little longer when you have a fixed brace so take your time. Pay particular attention to brush where the gums meet the teeth. Inter-dental brushes may help you to clean around the brace and in between the teeth.

An alcohol-free fluoride mouthrinse should also be used daily. Use it at a different time of the day to when you brush your teeth. This helps maintain the fluoride protection to your teeth. Avoid eating or rinsing for 20 minutes after use. Sugary snacks/drinks and poor cleaning of your teeth and brace will lead to permanent damage to your teeth as shown in the picture opposite.

How long will treatment take?
Usually about 12 - 30 months but this will vary according to how severe your tooth problem is. Missed appointments or repeated breakages of the brace will add to your overall treatment time.

Will I need to wear anything in addition to the fixed brace?
It may be necessary for you to wear elastics and/or headgear at some stage during your treatment. Headgear is usually worn in the evenings and at night. Elastics are worn inside the mouth during the day and night, including at mealtimes.

This picture shows the permanent, unsightly marks on teeth caused by poor tooth brushing and eating/drinking habits.

What about tooth brushing?
It is important that you brush your teeth well for at least 3 minutes, twice a day. Use a fluoride toothpaste. If possible, carry a brush with you for use after lunch.
Will I need to wear another brace once my treatment has finished?
Once the active phase of your treatment has been finished, it will be necessary to wear a retaining brace. This may be removable or it may be fixed behind your front teeth. The length of time this has to be worn can vary. Your orthodontist will advise you.

How often will I need an appointment?
You will need regular appointments (usually every 5-8 weeks) during treatment for the brace to be adjusted.

Do I still need to see my regular dentist?
Yes. It will be important you still have check-ups with your regular dentist throughout orthodontic treatment so that your teeth can be checked for decay.

What if I play contact sports?
It is recommended that you wear a gumshield. This will also be the case if you take part in activities requiring a protective helmet e.g. roller-blading, skateboarding and horse riding. Ask your orthodontist about this.

What if I play a musical instrument?
A fixed brace may make it more difficult for you to play your wind or brass instrument. You will need to discuss this with your music teacher and orthodontist. Download the advice sheet on this subject from the BOS website (www.bos.org.uk).

REMEMBER
- Brush your teeth for 3 minutes at least twice each day.
- Use an alcohol-free fluoride mouthrinse once every day.
- Avoid sugary snacks & drinks between meals and at bedtime.
- Avoid fizzy drinks.
- Avoid hard, sticky and chewy sweets and foods.
- Continue to visit your dentist regularly.
- Treatment will usually take 12 - 30 months.
- You will need to wear retainers for some time after your treatment finishes.

What do I do if my brace breaks?
Ring up for an appointment as soon as is reasonably possible. Do not wait for your next routine appointment as the breakage may slow your treatment, or may result in damage to your teeth. If you repeatedly break your brace, your treatment may be stopped early.

The daytime telephone number you should contact if a breakage occurs is:

Tel.................................

This leaflet has been produced with guidance from the Plain English Campaign and British Dyslexia Association to make it easier for you to read.

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Instructions for Patients wearing a Fixed Appliance

You have been fitted with a fixed appliance. Initially there may be some difficulty in eating and speaking but this will soon improve.

The appliance will at first feel rather rough on your lips, cheeks and tongue and so you will be provided with some wax. The wax can be placed on the part of the appliance that feels rough and will provide some temporary protection. If the problem persists, please contact the department.

Do not play with the appliance with your fingers, tongue or cheeks. This may cause breakage of the appliance and cause discomfort.

Initially after fitting and each time the brace has been adjusted, you may experience some discomfort for a day or two. This may be eased with a mild analgesic (paracetamol by example).

Fixed appliance treatment usually involves the use of the elastic bands. Please wear them exactly as prescribed to complete treatment successfully.

Please take great care of your appliance and teeth.

You must:

1. Clean your teeth with a toothbrush and toothpaste after every meal and before you go to bed. It takes about four minutes of continuous brushing to clean the teeth and gums adequately. If your teeth are not kept clean, damage to teeth and gums will occur. Since it will be necessary to use a toothbrush after eating, most patients find it best to avoid snacks taken between main meals;

2. Hard food (such as crusty bread, apples and pears) should be cut into small pieces first;

3. Avoid eating sticky food (such as toffee and nougat) and chewing-gum;

4. Stay away from carbonated (fizzy) drinks. The best time for consumption of fruit juices is around mealtimes;
Use a daily fluoride mouth rinse;

Contact the department if the appliance hurts, becomes loose, or if any part, however small, is broken. Check each day that your appliance is not broken or damaged. (Sometimes metal ligatures are used to keep the arch wires in place. The 'ends' of the ligatures may become dislodged and cause discomfort. 'Loose ends' can be tucked under the arch wire with a blunt wooden instrument such as an orange stick; match or a toothpick cut in half). Although breakages can occur occasionally frequent damage is uncommon and is usual due to nail biting and pencil chewing etc.... Repeated bracket - failure will prolong your treatment unnecessarily.

Continue with your routine dental visits
7.17 Mind-Map Intervention

Reference number: 12/LO/1958
Version number: 3.4
Date: 20/11/2012
7.18 Implementation Intention Intervention (If-then plan)

- When would be a good time for you to brush each day?
- How many times do you brush each day?
- Where would be a good place for you to brush each day?
- What will you need to have to make sure you remember?
- What will you do if you forget one day?
- When would be a good time for you to floss each day?
- How many times do you floss each day?
- Where would be a good place for you to floss each day?
- What will you need to have to make sure you remember?
- What will you do if you forget one day?
- How will you make sure you remember your appointment?
- What will you need to help you remember?
- What will you do if you forget an appointment?
• What do you do if a bracket falls off?

• What do you need to help you with that?

• What foods do you need to be careful about?

• Who do you need to tell help you with that?

• What is the length of your treatment?

• What will you do if the length of treatment goes beyond what you thought?
Systematic Review Article

A systematic review of randomized controlled trials of interventions to improve adherence among orthodontic patients aged 12 to 18

AliJazi Aljabaa; Fraser McDonald; Jonathon Timothy Newton

ABSTRACT

Objective: To investigate the effectiveness of interventions to enhance adherence among orthodontic patients aged 12 to 18 years. Specific adherence outcomes included were recall of information given by the orthodontic team, attendance at orthodontic appointments, self-reported oral hygiene behavior, and clinical indexes of oral hygiene.

Materials and Methods: Electronic searches of Medline via OVID (January 1, 1966 through March 1, 2012), EMBASE, and the Cochrane central register of control trials from its inception through March 2012, as well as a hand search, were undertaken to identify relevant studies.

Results: Through the electronic searches, 381 article were identified. Initial screening of the abstracts and titles by all review authors identified 21 articles that met the inclusion criteria for this review. The full articles were then retrieved. Four randomized controlled trials were found, all of which used different methods of intervention: a system of rewards or awards, the Hawthorne effect, written information, and demonstration of the microbiology of plaque. All the interventions, except the use of award/reward, were associated with improvements in adherence.

Conclusion: The literature advocates the use of several methods to improve compliance/adherence among orthodontic patients. Although there is insufficient evidence to allow clinicians to choose a single method, the results demonstrate the value of spending time with patients to illustrate the importance of adherence. Future studies should develop multiple methods of assessing patient adherence, including self-report, behavioral observation and recording, and change in clinical indexes. Such studies should test different types of interventions for effectiveness. (Angle Orthod. 2015;85:305–313.)

KEY WORDS: Adherence; Compliance; Systematic review; Orthodontics; Randomized controlled trial

INTRODUCTION

Compliance, as it relates to health care, is the extent to which a person’s behavior coincides with medical or health advice. A physician-led approach to prescribing treatment came to be described as “compliance” in the medical literature of the 1950s. This word quickly became unpopular for its judgmental overtones, and alternatives were sought. “Adherence” was then introduced and used interchangeably with compliance.

Adherence is defined as the extent to which a person’s behavior, such as taking medication, following a diet, and/or executing lifestyle changes, corresponds with recommendations the person has agreed to with a healthcare provider. It also implies that people freely choose to undertake behavioral plans, have input to them, and have collaborative involvement in developing and adjusting their treatment strategy. One of the most difficult challenges that face a dental team is supporting patients in changing and sustaining change in their oral health behaviors.

In orthodontics, adherence relates to keeping appointments, maintaining good oral hygiene, wearing elastics, wearing functional appliances or headgear as
Instructed, and avoiding foods that can debond the brackets.

Interventions aimed at enhancing health-related behaviors typically target three aspects of the behavior: capability, opportunity, and motivation. Capability (C) refers to the physical and psychological skills to perform the behavior (B). Opportunity (O) has physical components (e.g., access to resources) and social environment aspects (e.g., exposure to ideas) such that the person feels able to undertake the new behavior. Finally, motivation (M) refers to the person’s conscious (e.g., planning and decision making) and automatic (e.g., innate drives, emotional reactions, habits) processes said to underlie any behavior. Michie and West describe a “behavior change wheel” to demonstrate how existing behavioral change interventions map to this COM-B model.

Traditionally, many interventions in the dental field have focused on providing patients with improved knowledge of their disease. Patients who have a good knowledge of their disease or procedures have a better outcome than those who do not. Furthermore, Ley stated that providing the patient with greater information generally leads to increased compliance with treatment recommendations. Good communication is also associated with improved clinical outcomes. In order for a communication to be effective, it must be both remembered and understood. Patients often do not understand or misinterpret the information given to them. Frequently, this is because the information is given in an inappropriate form. Material written by clinicians may be too technical or difficult for the patients to understand or ambiguous. In the same context, Thickett and Newton assessed how three different methods of presenting information affected recall of information in orthodontic patients in the short and long term. They found that mind mapping and acronyms convey a significant advantage in patient recall of information.

The aim of this article is to investigate the effectiveness of interventions to enhance adherence among orthodontic patients aged 12 to 18 years. Specific adherence outcomes included were recall of information given by the orthodontic team, attendance at orthodontic appointments, self-reported oral hygiene behavior, and clinical indexes of oral hygiene.

MATERIALS AND METHODS

A systematic review of interventions aimed at improving adherence to advice given to orthodontic patients aged 12 to 18 years regarding key behaviors (appointment attendance, oral hygiene-related behaviors) was conducted.

Inclusion Criteria

The following inclusion criteria were used:

- Type of studies: Randomized controlled studies with a before and after design were included.
- Participants: Participants were 12- to 18-year-olds undergoing upper and lower fixed orthodontic appliances treatment.
- Types of interventions: These included verbal advice, written advice, interventions based on psychological theories, and educational interventions.
- Comparisons: These included intervention vs no intervention or comparisons of two or more interventions.

Outcomes

The following primary outcomes were examined:

- Recall of information as measured by a validated questionnaire.
- Attendance at orthodontic appointments as recorded in the dental and medical notes.
- Self-reported behavior.
- Clinical indexes, such as the Plaque Index.

The following secondary outcomes were examined:

- Motivation for orthodontic treatment, as assessed by any validated questionnaire.
- Expectation of orthodontic treatment, as assessed by any validated questionnaire.
- Apprehension and worries about orthodontic treatment, as assessed by any validated questionnaire.

Information Sources

All studies were identified through electronic and hand searches. All relevant studies were identified without regard for language, that is, non-English articles were considered for inclusion after an accurate translation.

An electronic search was conducted using Medline via OVID (January 1, 1966 through March 1, 2012), EMBASE, and the Cochrane central register of control trials until March 2012. The search strategy is listed in Table 1.

A hand search was also undertaken to identify relevant studies from the following journals: American Journal of Orthodontics and Dentofacial Orthopedics, The Angle Orthodontist, European Journal of Orthodontics, and The Journal of Orthodontics.

Authors of the included studies were contacted by the review authors, when needed, to obtain any further information about additional or unpublished studies that were eligible for inclusion in the review.
ADHERENCE AMONG ORTHODONTIC PATIENTS

Table 1. Search Methodology for Electronic Systematic Review

<table>
<thead>
<tr>
<th>Section</th>
<th>No. of Studies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Section A: adherence</td>
<td></td>
</tr>
<tr>
<td>1. Adherence .exp</td>
<td>69,646</td>
</tr>
<tr>
<td>2. Compliance .exp</td>
<td>102,181</td>
</tr>
<tr>
<td>3. Concordance .exp</td>
<td>21,510</td>
</tr>
<tr>
<td>4. 1 OR 2 OR 3</td>
<td>179,151</td>
</tr>
<tr>
<td>Section B: orthodontics</td>
<td></td>
</tr>
<tr>
<td>1. &quot;Orthodontics&quot;.exp</td>
<td>21,664</td>
</tr>
<tr>
<td>Combine A and B</td>
<td></td>
</tr>
<tr>
<td>1, 4 and 5</td>
<td>390</td>
</tr>
<tr>
<td>Limit to human</td>
<td>381</td>
</tr>
</tbody>
</table>

Study Selection and Data Extraction

The titles and abstracts resulting from the searches were independently screened by two of the review authors to select potentially relevant studies (AA, JTN). The full text of each study was obtained, and inclusion was assessed independently and in duplicate. Any disagreement regarding the inclusion or exclusion of a study was resolved by discussion or referred to a third reviewer. The full data extraction and quality assessment were conducted by three reviewers using a specifically designed data extraction form. The variables for which data were sought are summarized in Table 2.

Risk of Bias Analysis

Each of the randomized controlled trials found in the search was reviewed using the CONsolidated Standards Of Reporting Trials (CONSORT, http://www.consort-statement.org/consort-2010, Accessed July 4 2014) criteria for risk of bias. Given that the reviews

Table 2. Summary of Data Extraction

<table>
<thead>
<tr>
<th>Author</th>
<th>Year</th>
<th>Nature of Intervention</th>
<th>Sample Size</th>
<th>Age</th>
<th>Orthodontic Status</th>
<th>Gender</th>
<th>Outcomes Measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acharya et al.</td>
<td>2011</td>
<td>Group 1: conventional plaque control</td>
<td>21</td>
<td>12-18 years</td>
<td>Fixed appliances</td>
<td>No information</td>
<td>Plaque score: Immediate, 1 month, 3 months, 6 months</td>
</tr>
<tr>
<td>(N = 62)</td>
<td></td>
<td>Group 2: chair-side motivational tests with conventional</td>
<td></td>
<td></td>
<td>No further info</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>plaque control</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Group 3: microscope demonstration of plaque</td>
<td>18</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wright et al.</td>
<td>2010</td>
<td>Intervention group: fixed appliances and leaflet about</td>
<td>29</td>
<td>12-16 years</td>
<td>Upper and lower</td>
<td>No information</td>
<td>Motivation: Apprehension, Anxiety, Periodontal status,</td>
</tr>
<tr>
<td>(N = 60)</td>
<td></td>
<td>fixed appliances</td>
<td></td>
<td></td>
<td>fixed ortho</td>
<td></td>
<td>Appliance breakages T1: the beginning of treatment,</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Control group: Verbal information about fixed appliances</td>
<td>31</td>
<td></td>
<td></td>
<td></td>
<td>T2: 4 weeks, T3: 12 weeks</td>
</tr>
<tr>
<td>Fell et al.</td>
<td>2002</td>
<td>Intervention group: oral hygiene instructions and the</td>
<td>20</td>
<td>14-18 years</td>
<td>Fixed orthodontic</td>
<td>10 boys, 10 girls</td>
<td>Plaque score: Immediate, 3 months, 6 months</td>
</tr>
<tr>
<td>(N = 40)</td>
<td></td>
<td>Hawthorne effect</td>
<td></td>
<td></td>
<td>appliance</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Control group: no intervention</td>
<td>20</td>
<td></td>
<td></td>
<td>4 boys, 16 girls</td>
<td></td>
</tr>
<tr>
<td>Richer et al.</td>
<td>1998</td>
<td>Control group: received standard instructions</td>
<td>144</td>
<td>9.6-17.6 years</td>
<td>No information</td>
<td>No information</td>
<td>Orthodontic Patient Compliance Scale to compare</td>
</tr>
<tr>
<td>(N = 144)</td>
<td></td>
<td>Award group: received compliance instructions and a written</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>compliance before and after the 6-month experimental</td>
</tr>
<tr>
<td></td>
<td></td>
<td>evaluation of compliance</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>period. Clinical evaluation of compliance that was</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Reward group: received compliance instructions, a report</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>based on oral hygiene, appointment punctuality,</td>
</tr>
<tr>
<td></td>
<td></td>
<td>card, and eligibility to receive rewards for adherent</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>appliance wear, and appliance maintenance.</td>
</tr>
</tbody>
</table>

Angles Orthodontist, Vol 65, No 2, 2015
were based on published studies; there is a risk of publication bias in the findings.

**Data Analysis**

A meta-analysis was planned combining data across studies to test the efficacy of interventions, provided that the data were sufficiently homogeneous and there was sufficient homogeneity in the types of intervention reported.

**RESULTS**

Through the electronic searches, 381 articles were identified. Of these, 376 proved to not be of direct relevance to the two systematic reviews we were conducting, typically because they were addressing a different orthodontic topic (though they mentioned the importance of compliance in orthodontic treatment) or were not trials. Four randomized controlled trials were included (See Figure 1).

Meta-analysis was not performed because of methodologic heterogeneity among the selected trials. The outcome measures chosen were different for each article. Each study will be viewed and appraised separately. Table 3 displays the characteristics of the included randomized clinical trials.

In the first randomized controlled trial identified Richter et al., evaluated the effect of a reward system on improving compliance among orthodontic patients. Participants were 144 patients (63 boys, 81 girls) with an age range of 9.6 to 17.6 years who underwent orthodontic treatment. The patients were divided into three groups: a control group who received standard instructions; an award group who received compliance instruction and completed a written evaluation of compliance; and a reward group who received compliance...
### Table 3. Characteristics of the Included Randomized Clinical Trials

<table>
<thead>
<tr>
<th>Author</th>
<th>Sample Size</th>
<th>Age</th>
<th>Intervention</th>
<th>Outcome</th>
<th>Baseline T1</th>
<th>Follow-up T2</th>
<th>Follow-up T3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Richter et al.</td>
<td>N = 144</td>
<td>0.6–17.6 years</td>
<td>Control 1: Oral hygiene</td>
<td></td>
<td>Mean ± SD</td>
<td>6 Months</td>
<td>No T3</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>2: Award for compliance High control</td>
<td></td>
<td>19.6 ± 5.6</td>
<td>18.3 ± 6.7</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>High award</td>
<td></td>
<td>16.6 ± 4.3</td>
<td>15.6 ± 8.1</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>High reward</td>
<td></td>
<td>19.2 ± 6.8</td>
<td>17.7 ± 5.4</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Low control</td>
<td></td>
<td>14.4 ± 7.1</td>
<td>11.6 ± 7.9</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Low reward Low reward</td>
<td></td>
<td>14.1 ± 4.7</td>
<td>14.5 ± 6.6</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>2: Appointment attendance High control</td>
<td></td>
<td>25.0 ± 8.3</td>
<td>25.6 ± 6.7</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>High award</td>
<td></td>
<td>21.4 ± 8.1</td>
<td>20.5 ± 7.5</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>High reward</td>
<td></td>
<td>24.3 ± 2.4</td>
<td>24.5 ± 2.2</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Low Control</td>
<td></td>
<td>22.5 ± 6.2</td>
<td>23.7 ± 3.1</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Low reward Low reward</td>
<td></td>
<td>20.0 ± 9.8</td>
<td>22.6 ± 5.8</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>3: Appliance wear</td>
<td></td>
<td>24.5 ± 2.2</td>
<td>23.7 ± 5.6</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>High control</td>
<td></td>
<td>25.4 ± 2.4</td>
<td>23.1 ± 10.4</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>High award</td>
<td></td>
<td>19.1 ± 5.2</td>
<td>18.9 ± 6.5</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>High reward</td>
<td></td>
<td>18.6 ± 4.9</td>
<td>16.9 ± 9.5</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Low control</td>
<td></td>
<td>10.5 ± 9.1</td>
<td>9.9 ± 7.6</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Low reward Low reward</td>
<td></td>
<td>10.7 ± 10.2</td>
<td>15.7 ± 6.9</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>4: Office maintenance</td>
<td></td>
<td>13.6 ± 8.1</td>
<td>18.6 ± 3.5</td>
<td></td>
</tr>
<tr>
<td>Feil et al.*</td>
<td>N = 38</td>
<td>14–18 years</td>
<td>1: Control Plaque Index Mean ± SD</td>
<td></td>
<td>74 ± 11.46</td>
<td>78 ± 12.18</td>
<td>79 ± 10.76</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>2: Hawthorne effect</td>
<td></td>
<td>71 ± 11.52</td>
<td>54 ± 13.79</td>
<td>52 ± 13.04</td>
</tr>
<tr>
<td>Wright et al.</td>
<td>N = 60</td>
<td>12–16 years</td>
<td>1: Control (verbal information only) Intervention</td>
<td></td>
<td>Mean</td>
<td>4 Weeks</td>
<td>12 Weeks</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>2: Anxiety Control</td>
<td></td>
<td>30.37</td>
<td>23.73</td>
<td>28.21</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>2: Motivation Control</td>
<td></td>
<td>30.64</td>
<td>32.40</td>
<td>32.84</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>2: Motivation Control</td>
<td></td>
<td>32.44</td>
<td>34.79</td>
<td>29.82</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>2: Motivation Control</td>
<td></td>
<td>28.43</td>
<td>25.91</td>
<td>31.62</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>4: Perioral examination</td>
<td></td>
<td>31.32</td>
<td>29.15</td>
<td>29.24</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>4: Perioral examination</td>
<td></td>
<td>25.62</td>
<td>31.95</td>
<td>31.84</td>
</tr>
<tr>
<td>Acharya et al.</td>
<td>N = 62</td>
<td>12–16 years</td>
<td>1: Conventional plaque control Group 1 Plaque Score Group 1</td>
<td></td>
<td>1.1071 ± 0.3287</td>
<td>1.0159 ± 0.3755</td>
<td>1.0720 ± 0.0647</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>2: Chair-side motivational tests with conventional plaque control Group 2</td>
<td></td>
<td>1.1200 ± 0.3352</td>
<td>0.9457 ± 0.3525</td>
<td>1.0456 ± 0.3915</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>3: Microscope demonstration</td>
<td></td>
<td>1.1343 ± 0.4211</td>
<td>0.9514 ± 0.2786</td>
<td>0.6410 ± 0.3984</td>
</tr>
</tbody>
</table>

* Feil et al. (2002) study, two individuals dropped out at the 6 months follow up. In the manuscript, data was reported only for participants with complete data at all points, lowering the sample size from 40 to 38.
### Table 4. Risk of Bias for the Four Randomized Controlled Trials as Judged by CONSORT* Criteria

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Title and abstract</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>a. Identification as a randomized trial in the title</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>b. Structured summary of trial design, methods, results, and conclusions</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>(for specific guidance see CONSORT for abstracts)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Introduction</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Background and objectives</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>a. Scientific background and explanation of rationale</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>b. Specific objectives or hypothesis</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Methods</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trial design</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>a. Description of trial design (eg, parallel, factorial), including allocation ratio</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>b. Important changes to methods after trial commencement (eg, eligibility criteria) with reasons</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Participants</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>a. Eligibility criteria for participants</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
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<tr>
<td>b. Settings and locations where the data were collected</td>
<td>Yes</td>
<td>Yes</td>
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<tr>
<td>Interventions</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>The interventions for each group with sufficient detail to allow replication,</td>
<td></td>
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<tr>
<td>Including how and when the interventions were actually administered</td>
<td></td>
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<tr>
<td>Outcomes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>a. Completely defined prespecified primary and secondary outcome</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
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<tr>
<td>measures, including how and when they were assessed</td>
<td>No</td>
<td>No</td>
<td>No</td>
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<tr>
<td>b. Any changes to outcomes after the trial commenced with reasons</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
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<td>Sample size</td>
<td>No</td>
<td>No</td>
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<td>No</td>
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<tr>
<td>a. How the sample size was determined</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
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<tr>
<td>b. When applicable, explanation of any interim analyses and stopping guidelines</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
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<td>Randomization:</td>
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<td>Sequence</td>
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<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
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<tr>
<td>a. Method used to generate the random allocation sequence</td>
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<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
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<tr>
<td>generation</td>
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<tr>
<td>b. Type of randomization; details of any restriction (eg, blocking and block size)</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
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<tr>
<td>Allocation</td>
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<td>Concealment mechanism</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
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<tr>
<td>Mechanism used to implement the random allocation sequence (eg, sequentially</td>
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<tr>
<td>numbered containers), describing any steps taken to conceal the sequence until</td>
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<td>interventions were assigned</td>
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<td>Implementation</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
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<tr>
<td>Who generated the random allocation sequence, who enrolled participants,</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
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<tr>
<td>and who assigned participants to interventions</td>
<td></td>
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<tr>
<td>Blinding</td>
<td></td>
<td></td>
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<tr>
<td>a. If done, who was blinded after assignment to interventions (eg, participants,</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
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<td>care providers, those assessing outcomes) and how</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
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<tr>
<td>b. If relevant, description of the similarity of interventions</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
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<td>Statistical methods</td>
<td></td>
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<tr>
<td>a. Statistical methods used to compare groups for primary and secondary outcomes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
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<tr>
<td>b. Methods for additional analyses (eg, subgroup analyses and adjusted analyses)</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
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<tr>
<td>Results</td>
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<tr>
<td>Participant flow (a diagram is strongly recommended)</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
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<tr>
<td>a. For each group, the numbers of participants who were randomly assigned,</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
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<tr>
<td>received intended treatment, and were analyzed for the primary outcome</td>
<td></td>
<td></td>
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<tr>
<td>b. For each group, losses and exclusions after randomization, together with reasons</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
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Table 4. Continued

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<td><strong>Recruitment</strong></td>
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<td>a. Dates defining the periods of recruitment and follow-up</td>
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<td>Yes</td>
<td>Yes</td>
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<td>b. Why the trial ended or was stopped</td>
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<td><strong>Baseline data</strong></td>
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<tr>
<td>a. Table showing baseline demographic and clinical characteristics for each group</td>
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<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
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<tr>
<td><strong>Numbers analyzed</strong></td>
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<tr>
<td>For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups</td>
<td>Yes</td>
<td>Yes</td>
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<td>Yes</td>
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<tr>
<td><strong>Outcomes and estimation</strong></td>
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<tr>
<td>a. For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
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<td>b. For binary outcomes, presentation of both absolute and relative effect sizes is recommended</td>
<td>No</td>
<td>No</td>
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<td><strong>Ancillary analyses</strong></td>
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<td>Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing prospective from exploratory</td>
<td>Yes</td>
<td>Yes</td>
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<td><strong>Harms</strong></td>
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<td>All important harms or unintended effects in each group</td>
<td>No</td>
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<td>No</td>
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<td>(for specific guidance see CONSORT for harms)</td>
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<td><strong>Discussion</strong></td>
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<td><strong>Limitations</strong></td>
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<td>Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
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<td><strong>Generalizability</strong></td>
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<td>Generalizability (external validity, applicability) of the trial finding</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
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<td><strong>Interpretation</strong></td>
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<td>Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
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<td><strong>Other information</strong></td>
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<td>Registration</td>
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<td>Registration number and name of trial registry</td>
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<td>No</td>
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<td>Protocol</td>
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<td>Where the full trial protocol can be accessed, if available</td>
<td>Yes</td>
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<td><strong>Funding</strong></td>
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<td>Sources of funding and other support (eg, supply of drugs), role of funders</td>
<td>No</td>
<td>Yes</td>
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</tr>
</tbody>
</table>

* CONSORT is defined as CONsolidated Standards of Reporting Trials.

instructions, a report card, and eligibility to receive rewards for adherent behavior. The patients in each group were divided into two main categories—high compliers and low compliers—using the Orthodontic Patient Cooperation Scale, which is used to evaluate patients' compliance at the initiation of investigation and after 6 months of treatment. Outcomes assessed were oral hygiene, appointment attendance, appliance wear, and appliance maintenance. The researchers compared compliance before and after 6 months of treatment. The results showed that there was no significant improvement for above-average compliers who received rewards. Below-average compliers did not improve significantly either. However, the oral hygiene scores for the low compliers in the reward group were better than scores for the low compliers in the control group.

Feil et al.12 used a single-blind, quasi-random assignment of 40 patients ranging in age from 14 to 18 years old with poor oral hygiene and who were undergoing fixed orthodontic treatment. The patients were randomly assigned to two groups of 20 patients. In the intervention group, the Hawthorne effect15 was induced by approaching the subjects during a regular

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appointment and telling them that they were participating in an experiment evaluating the effectiveness of a new orthodontic toothpaste (in reality, regular Crest with fluoride, Procter & Gamble) that would improve the oral health of orthodontic patients specifically. All toothpaste was provided in an unmarked tube except for patient identifier number. The 20 patients in the control group were not asked to participate in any activity not usually practiced during their orthodontic treatment. The outcome measured was the plaque index. Results showed that there was no plaque score difference between groups at baseline ($P > .05$). Means and standard deviations for tooth surface covered with disclosed plaque for the study and control groups, respectively, were 71% ($\pm 11.52$) and 74% ($\pm 11.46$) at baseline; 54% ($\pm 13.79$) and 78% ($\pm 12.18$) at 3 months; and 52% ($\pm 13.04$) and 79% ($\pm 10.76$) at 6 months. Finally, the intervention group showed better reduction in plaque scores at 3 and 6 months.

Wright et al. measured the influence of supplemental written information on adolescent anxiety, motivation, and compliance on 60 patients (age range 12–18 years) who did not undergo previous orthodontic treatment and required dual-screw appliance therapy. Randomization was done using computer-generated unstratified allocation sequence in two groups. The intervention group received verbal and written information while the control group received verbal instructions only. Outcomes measured were motivation, apprehension, anxiety, and compliance (i.e., appointment attendance, periodontal status, and appliance breakages) at the beginning of treatment (T1), after 4 weeks of treatment (T2), and after 12 weeks of treatment (T3). Results showed that there was no median change in group scores for either group between T1 and T2. There was a statistically significant difference in motivation scores between the groups after consent to orthodontic treatment, that is, the intervention group became more motivated. Although a generalized reduction in anxiety, motivation, and apprehension as treatment progressed was demonstrated by the negative differences between T1 and T3 for both groups, these differences were not significant. The intervention group’s periodontal condition improved between T1 and T3, in contrast to the control group’s periodontal condition. At T3 both groups showed similar levels of motivation, apprehension, and anxiety but the intervention group was better in appointment attendance, periodontal status, and appliance breakage.

Acharya et al. randomly allocated 62 orthodontic patients (age range 12–18 years) to three types of intervention. Randomization was performed using a systematic random sampling technique. Group 1 consisted of 21 patients who were motivated through conventional plaque-control measures (i.e., plaque was disclosed with 2% mercurochrome). The composition of plaque, its effects on oral health, and the importance of its removal were stressed, and a horizontal scrubbing technique of brushing was demonstrated to the patients. Group 2 consisted of 23 patients who were motivated for dental plaque removal using chair-side motivational techniques. As in group 1, conventional plaque control measures were also demonstrated to the patients. Group 3 consisted of 18 patients who were motivated by showing them live motile bacteria in their own plaque under a phase contrast microscope. This study measured the plaque and gingival indexes at baseline, 1 month, 3 months, and 6 months. Results showed that plaque scores for group 3 were better than those for groups 1 and 2 at 3 months and 6 months.

Table 4 summarizes the risk of bias for the four randomized controlled trials as judged by the CONSORT criteria.

**DISCUSSION**

A number of interventions are advocated in the literature to improve patients’ adherence during orthodontic treatment. Richter et al. used the report card and reward system in an attempt to improve adherence among 144 orthodontic patients. The results indicated that only oral hygiene improvement was found among the low compliance reward group compared with the low compliance award group. The finding of this study did not support the hypothesis that the award/reward intervention might improve compliance. A possible reason is the lack of attractiveness in the rewards that were used in the study, which might have influenced the results. The study mentioned that the patients were divided into high and low compliers using the Orthodontic Patient Cooperation Scale but did not indicate if calibration was considered by interexaminer reliability measurement. Furthermore, the study included patients with banding/bonding of the entire arch and some patients who were using headgear and other appliances. Appliance wear was measured on a nine-point scale by nine supervising faculty members; however, interexaminer reliability was not considered. Although the results indicated gender differences among the groups, a detailed description of the actual male/female participants in each group was not clearly provided.

In another study, the Hawthorne effect was evaluated in improving patients’ compliance. The strength of the study lies in the randomization of two equal groups as well as the explicit and concise selection criteria. In the experimental group, the patients were asked to return the experimental toothpaste at the end of the study, which would indicate whether they
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complied with the instructions. The outcome revealed a reduction in plaque score in the experimental group. The Hawthorne effect might be an asset in improving compliance in orthodontic patients. However, compliance in this study was measured by oral hygiene improvement using the Plaque Score Index only. The study did not investigate whether the Hawthorne effect influences compliance in terms of appointment attendance and appliance wear.

Wright et al. studied how written and verbal information affected anxiety, motivation, and compliance among 76 orthodontic patients. Results showed improvement in appointment attendance, appliance breakage, and periodontal condition in the intervention group, but this improvement was not statistically significant. The sample size was relatively small; a larger sample might have provided more convincing evidence. This study highlighted the importance of information retention in orthodontic treatment as they found that the initial positive effect of written information was not maintained throughout the treatment.

In the fourth study, the effect of three interventions to improve oral hygiene among 78 patients undergoing fixed orthodontic treatment was investigated. The researchers found that plaque and gingival scores reduced in group 3 patients, who were motivated by being shown live mobile bacteria in their own plaque under a phase contrast microscope. One drawback to the study was the lack of a clear description on how the plaque and gingival scores were measured. Also, no information was provided on the number of examiners undertaking the assessment of plaque and gingival scores. Lastly, interexaminer and intraexaminer reliability were not reported.

The quality of the randomized controlled trials located for this review was moderate. Particular concerns related to determination of an appropriate sample size as none of the four trials identified the basis on which the sample size was determined. There were also issues concerning allocation concealment and blinding for the studies.

CONCLUSIONS

- The literature advocates the use of several methods to improve compliance/adherence among orthodontic patients. Although there is no evidence to support one particular intervention over another, the results demonstrate the value of spending time with patients to illustrate the importance of adherence.

- Future studies should develop multiple methods of assessing patient adherence, including self-report, behavioral observation and recording, and change in clinical indexes. Different types of interventions should be included and tested for effectiveness.

ACKNOWLEDGMENT

The work undertaken for this research was part of the first author’s PhD studies, generously funded through the Saudi Cultural Bureau.

REFERENCES