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University  
Of  
Sheffield.

**From Compliance to Concordance in  
Orthodontic Treatment - Development of a  
Patient Decision Aid for Children considering  
Fixed Orthodontic Appliance Treatment**

**A thesis submitted in fulfilment of the requirement for the Degree of  
Doctor of Philosophy**

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## DEDICATION

*I dedicate this thesis to*

*My great father, my beloved mother, my dear wife Najla, and  
my sons Ahmed and Aws for their encouragement, support and  
patience.*

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## ABSTRACT

**Background:** Concordance involves a process of agreement or shared decision-making between patients and healthcare providers. Concordance was introduced to replace the term compliance, which has connotations of a paternalistic doctor-patient relationship. Previous systematic reviews in healthcare have identified the importance of the patient-clinician relationship to achieve concordance. They have also suggested the use of patient decision aids (PDAs) to improve involvement of patients in their own healthcare choices. Patients and parents need sufficient information and discussion before they decide whether to proceed with orthodontic treatment which can last up to 2 years. Recent studies in orthodontics have noted that enhancing the relationship between the orthodontist and patient through effective communication and encouraging patient participation in choosing the best treatment alternative is essential for successful orthodontic treatment.

**Aim:** The aim of the study was to investigate any shifts in emphasis from compliance to concordance within the orthodontic literature, then develop and carry out an initial evaluation of a decision aid for young people and parents considering whether to have fixed orthodontic appliance treatment or not.

### **Objectives:**

1. To conduct a systematic review of the orthodontic literature to identify the factors associated with concordance and compliance with orthodontic treatment and to establish the degree to which the shift has been reflected in the literature. This review will inform the development of the PDA.
2. To use a child-centred approach to develop a Patient Decision Aid for children and parents considering fixed orthodontic appliance treatment to facilitate shared decision-making and improve patient-clinician interaction.
3. To undertake an initial evaluation of the PDA in reducing decisional conflict, increasing knowledge and meeting expectations.

**Methods:** A systematic review of the literature involving different databases was carried out to investigate factors that are important to patients for inclusion in the PDA. The PDA was developed based on the Ottawa Decision Support Framework (ODSF) through the workbook produced by O'Connor and Jacobsen (2003). This involves two separate steps; qualitative interviews and formation of expert groups. The qualitative

study involved interviews with orthodontic patients aged 12 to 16 years old and their parents attending the Orthodontic Department of Charles Clifford Dental Hospital, and formation of expert groups of patients and clinicians to develop and review the PDA. Finally, a pilot evaluation study was conducted to investigate the impact of the PDA on decisional conflict, knowledge and expectations of orthodontic treatment. Thirty young people aged 12-16 years and 30 parents participated in this pre- post-PDA evaluation study.

**Results:** No studies of concordance with orthodontic treatment were found, however, the factor that appeared to be most important to patients was the orthodontist-patient interaction and comprehensive discussions about treatment options and outcomes. A PDA was then developed based on the ODSF. The pilot evaluation of the PDA revealed that the decisional conflict of young people and their parents reduced by nearly 50% after exposure to the PDA. Participants felt more informed, clearer in their values, and more certain about their choice. In addition, the PDA increased participants' knowledge regarding duration of the treatment and the frequency of orthodontic appointments. However, the current PDA showed a limited effect on patients' and parents' expectations about orthodontic treatment.

**Conclusions:** Orthodontic research has failed to embrace the shift from compliance to concordance. The systematic review revealed the importance of the orthodontist-patient relationship for patients. The developed PDA was found to have a significant effect in reducing decisional conflict, increasing knowledge, although it has a limited effect on expectations about orthodontic treatment. The use of the PDA with patients and parents considering orthodontic treatment has the potential to facilitate shared decision-making, although, further research is needed on its effect on patients' persistence with choice. Also, further research on orthodontists' views about PDAs and its influence on orthodontist-patient interaction is required.

# **1 CHAPTER ONE: BACKGROUND**

## **1.1 Introduction**

This chapter discusses the background to concordance and compliance in healthcare and orthodontics. It critiques the concept of compliance and how the shift to concordance has been embraced in healthcare. The shared decision-making model, the theoretical model that underpins concordance, together with the interventions used to improve patients' involvement in decision-making, patient decision aids are all described in this chapter before the rationale for the project is reviewed.

## **1.2 Terminology of concordance and compliance**

### **1.2.1 Concordance**

Concordance has been defined as “the state or condition of agreement or harmony” (TheFreeDictionary, 2011). The word ‘concordance’ comes from the Latin word *concordantia* which means “fact of agreeing”.

Concordance was defined by a multidisciplinary group of health professionals and members of the Pharmaceutical Society in the UK Marinker and Sharp (1997) as follows: “Concordance is based on the notion that the work of the prescriber and patient in the consultation is a negotiation between equals and the aim is therefore a therapeutic alliance between them. This alliance, may, in the end, include an agreement to differ. Its strength lies in a new assumption of respect for the patient’s agenda and the creation of openness in the relationship, so that both doctor and patient together can proceed on the basis of reality and not of misunderstanding, distrust and concealment”. The concept of concordance is based on shared decision-making and consensual agreement between patient and healthcare provider as equal parties (Marinker and Sharp, 1997).

### **1.2.2 Adherence**

In the Oxford English Dictionary (2011) adherence has been defined as “persistence in a practice or tenet; steady observance or maintenance”. The word ‘adherence’ comes from the Latin word *adhaerere*, which means ‘to cling to’ or ‘remain constant’.

The term ‘adherence’ has been used, as an alternative to compliance. Various definitions of adherence have been quoted. For example, “the process in which a person

follows rules, guidelines, or prescription and recommendations for a regimen of care” and “the patients’ ability to choose treatments or accept their doctors’ suggestions” (Bajramovic *et al.*, 2004). It has also been defined as “the ability and willingness to abide by a prescribed therapeutic regimen” (Inkster *et al.*, 2006). While the term was introduced to imply that patients have freedom to choose whether to adhere to clinicians’ recommendations (Barofsky, 1978), these definitions, again, suggest patients should follow clinicians’ instructions.

### **1.2.3 Compliance**

In general, compliance has been defined as “the practice of obeying rules or requests made by people in authority” (Oxford Dictionary, 2005). The word ‘compliance’ comes from the Latin word *complier* which means to fill up or complete an action.

In the medical literature the term ‘compliance’ usually means the following of treatment instructions. The most commonly used definition of compliance in healthcare was presented by Haynes and Sackett (1976) who defined it as when “patient’s behaviors (in terms of taking medication, following diets, or executing life style changes) coincide with healthcare providers’ recommendations for health and medical advice”.

Many other definitions of compliance have been cited, examples include: “the extent to which the patient’s behaviour matches the prescriber’s recommendations” (Haynes *et al.*, 1979), and “the extent to which patients follow the regimens recommended by their doctors” (Pollock, 2005). While these definitions differ in wording, they share the need for patients to accept and accede to clinicians orders.

Kyngäs *et al.* (2000) stated that the definition of compliance is problematic. It refers implicitly to the authority of healthcare personnel over patients, thus denying patient’s the right to take part in decision-making regarding their health condition. The concept of compliance has been rejected because of its paternalism and its implication that healthcare personnel have the right to authority over the patient's behaviours and actions (Dracup and Meleis, 1982; Kontz, 1989; Kim, 2010). Patients are not passive and they no longer accept the care that is recommended to them without question and demonstrate assertiveness in their interactions with health care providers (Donovan and Blake, 1992). In a comprehensive review of the literature Vermeire and colleagues stated that the term compliance should no longer be routinely used (Vermeire *et al.*, 2001). They suggested that this paternalistic approach should be avoided because the

doctor-patient relationship, communication and shared decision-making are the most important considerations and that patients' perspectives should be incorporated into clinical encounters.

The next section of this chapter will review, in more detail, the concept of concordance and how emphasis has shifted more recently away from compliance towards concordance.

### **1.3 Concordance**

In an attempt to clarify the meaning of concordance, Elwyn and colleagues wrote that “Concordance describes the process whereby the patient and doctor reach an agreement on how a drug will be used, if at all. In this process doctors identify and understand patients' views and explain the importance of treatment, while patients gain an understanding of the consequences of keeping (or not keeping) to treatment.” (Elwyn *et al.*, 2003).

Concordance was subsequently defined by the National Co-ordinating Centre for NHS Service Delivery and Organisation (NCCSDO) as “an agreement reached after negotiation between a patient and a healthcare professional that respects the beliefs and wishes of the patient in determining whether, when and how medicines are to be taken” (Horne *et al.*, 2005).

In 1997 the Royal Pharmaceutical Society of Great Britain published a report named ‘*From Compliance to Concordance*’ which was the first formal report describing the concept of concordance (Marinker and Sharp, 1997). It acknowledged that patient preferences regarding treatment should be given priority, because it is the patient who finally decides whether to comply with treatment or not (Pollock, 2005). In support of this concept, Marinker (1997) published a paper “Writing prescriptions is easy” and argued that compliance “may have been appropriate within a welfare state rooted in the values and thinking of society in the 1930s, when services were driven by benign paternalism and the practice of medicine was based on patients trusting their doctors.” According to Marinker, the concept of concordance expresses mutual respect for perspectives of doctor and patient which is crucial in contemporary clinical encounters. After two years, in 1999, three members of the Royal Pharmaceutical Society Group (Dickinson, Wilkie, and Harris) attempted to clarify the meaning of “concordance” and

published a paper “Taking Medicines: Concordance is not Compliance” (Dickinson *et al.*, 1999). They stated that concordance is not a new term for compliance, and they wrote that “If concordance is successful some patients will decide not to take their medicine and some may decide to alter their treatment, and the outcome may not be what the clinician thinks is best.” The term ‘concordance’ was therefore introduced to replace ‘compliance’ and ‘adherence’ in an attempt to emphasize the need for prescriber-patient collaboration in achieving the desired outcome from the treatment by making an agreement about the regimen the patient will undertake (Marinker, 1997; Segal, 2007).

‘Concordance’ therefore is a relatively recent term adopted over the past 15 years and predominantly used in the UK. It has been recommended to replace compliance, as compliance has the connotation of forcing the patient to follow the regime, whereas concordance makes the patient the decision-maker in the process and refers to patient-doctor agreement (Vermeire *et al.*, 2001). Recently, this term has been applied in the medical field to indicate the doctor-patient relationship in shared decision-making about treatment and reinforces the importance of agreement and harmony between patients and healthcare providers (Bridges *et al.*, 2011). In his letter “Compliance becomes concordance; Making a change in terminology produce a change in behaviour” Mullen (1997) suggested that agreement in decision-making regarding treatment is best described by using the notion of concordance, because concordance reinforces the importance of agreement between patient and clinician. In order to achieve this, Mullen recommended that clinicians should not spend as much time on assessing the best treatment for a particular condition, instead more time should be spent assessing the best approach for a particular individual with certain lifestyles and preferences (Mullen, 1997).

Concordance has featured in UK healthcare policy with regard to the importance of involving patients in courses of treatment to inform them about their condition and treatment options (Marinker and Shaw, 2003). In 2002 the Department of Health recommended and approved the principles of concordance and created the Medicines Partnership Task Force group which comprises representatives from different healthcare fields. Its responsibility lay in finding ways to implement concordance in the NHS in order to improve health outcomes and satisfaction with care (Marinker and Shaw, 2003).

In the medical field it has been suggested that accepting the patient's treatment preference, even though it may not be the clinician's first choice, might result in a better therapeutic gain if treatment is being completed rather than abandoned (Pollock, 2005), whereas, ignoring patient values and the matter of concordance can negatively affect subsequent treatment results (Hamann *et al.*, 2003; Kikkert *et al.*, 2006).

The terms compliance, adherence, cooperation and concordance are usually used interchangeably in the literature and in clinical practice (Jin *et al.*, 2008), although, from the review of their definitions in this chapter it becomes evident that they have different meanings. It is inappropriate to use the term concordance as a synonym for compliance or adherence, because the latter terms describe the behaviour of the patient in following doctor's recommendation, while concordance deals with the nature of the interaction between clinician and patient (Bell *et al.*, 2007). Concordance (as mentioned above) is not a one-way communication; it requires the agreement of two parties, it is more complex and reflects the process of agreement or shared decision-making between the patient and the healthcare provider (Martin, 2002; Horne *et al.*, 2005). Similarly, Britten (2001) acknowledged that the notions of compliance and adherence present obvious justifications for blaming patients who are not completely following the instructions of their healthcare providers. According to a review by Carter and Taylor (2005) many studies used the term compliance because it is a more straightforward term and it remains the most commonly cited term in the medical literature.

### **1.3.1 A critical view of concordance**

While the need to shift thinking from compliance to concordance has been repeatedly called for (Mullen, 1997; Marinker and Sharp, 1997; Blenkinsopp, 2001), there are also criticisms levelled at this movement. Segal discussed these criticisms and highlighted the apparent lack of improvements in health outcomes that have resulted from this shift despite the passing of a decade since the Royal Pharmaceutical Society's original report. She suggested that the lack of progress has occurred for several reasons. Firstly she stated that clinicians have failed to embrace the concept possibly because they do not believe patients should actually be involved in decision-making for paternalistic reasons or medical reasons such as the spread of infectious diseases (Milburn and Cochrane, 1997). Second she suggested that even when clinicians tried to involve patients in decision-making they failed to provide them with sufficient information and to acknowledge that not all patients were equally able to participate in decision-making

without intensive support (Segal, 2007). She proposed that further discussion is needed about the concept of concordance.

## **1.4 Compliance**

The terms ‘compliance and non-compliance’ were first used in the 1960s, and became more established with the classic reviews of Sackett and Haynes in the 1970s (Haynes and Sackett, 1976; Haynes *et al.*, 1979). These authors became interested in compliance after they noticed that patients with hypertension had unpredictable or inadequate responses to treatment, which were most likely due to patients’ not taking medications as recommended. They reported up to half of patients failing to comply (Haynes and Sackett, 1976). However, the use of the term ‘compliance’ has been criticised as it implies that a patient must take orders from a health professional and implies a lack of patient contribution (Stimson, 1974). A short review of the literature on compliance will now be described to provide the context for the shift in thinking from compliance to concordance.

### **1.4.1 Background to compliance**

The issue of non-compliance with regimens of care became important for several reasons (Rodin and Janis, 1982; Tedesco, 1997) namely the consequences for the clinical effectiveness of treatments, the financial implications and the potential impact on patients quality of life (Vermeire *et al.*, 2001; Burke and Ockene, 2001; Elwyn *et al.*, 2003).

Non-compliance constitutes a major challenge to the effectiveness of treatment regimens especially for patients with chronic diseases (Cochrane *et al.*, 1999; Vermeire *et al.*, 2001; Sabaté, 2003; van Dulmen *et al.*, 2007). As a result of non-compliance, substantial numbers of patients do not achieve the maximum potential benefit of the prescribed treatment and poor treatment outcomes result (Burke and Ockene, 2001; Elwyn *et al.*, 2003). In addition, non-compliance was judged to be the cause of 69% of the adverse drug events leading to hospital admission in the United States, and most of these admissions were judged to be preventable if patients had adheres to the recommended doses of the prescribed treatment (Senst *et al.*, 2001).

The economic impacts include wasted medicines, resources and the ‘knock-on costs’ due to the increased demands for healthcare (Nunes *et al.*, 2009). In the USA and

Canada it is estimated to annually cost the healthcare systems around 100 billion US dollars (Donovan and Blake, 1992) and 7 to 9 billion dollars respectively (Coombs *et al.*, 1995). In the UK, concerns about waste and its financial consequences have led to increasing interest in the issue of patient compliance (Donovan and Blake, 1992). In 2006-2007, the NHS in England spent £10.6 billion on drugs, with around three quarters of this spend being in primary care. It has been estimated that between a half and third of all medicines prescribed for long term conditions were not taken as recommended (Horne *et al.*, 2005). The cost of unused or unwanted medicines in the NHS was estimated at around £100 million a year (Department of Health, 2008).

The third main impact of non-compliance is reduction in patient quality of life due to increased morbidity and side effects (Nunes *et al.*, 2009). Poor compliance was found to be associated with poorer quality of life (Rivett *et al.*, 2009), for example, it has been reported that approximately 20 per cent of patients with respiratory diseases have disturbed sleep at least once a week due to the symptoms of their disease, which also interfered with daily activities for about 50 per cent of patients, and results in lost work days for 20 per cent of sufferers (Carter and Taylor, 2005). Also, compliance with dietary control and drug intake was found to be significantly associated with good quality of life in patients with type 2 diabetes (Honish *et al.*, 2006; Huang and Hung, 2007; Chaveepojnkamjorn *et al.*, 2008).

The prevalence of non-compliance described in the literature has been estimated to be approximately 30 to 50% of patients (Haynes *et al.*, 1979). However, prevalence varies between patient groups and disease types (Vermeire *et al.*, 2001). For example the prevalence of non-compliance in chronic conditions that require long term treatment has been estimated to be 50% (Haynes, 2001) with rates increasing dramatically after six months of starting treatment (Jackevicius *et al.*, 2002; Cramer *et al.*, 2003).

#### **1.4.2 Factors associated with non-compliance with medical care**

There have been two systematic reviews conducted of factors associated with non-compliance with medical care. These reviews will now be briefly described.

Vermeire and colleagues (2001) carried out a systematic review, using different electronic databases to find studies investigating patient adherence to treatment published between 1975 until 1999. The aim of their review was to examine the extent of compliance or non-compliance, factors that affect compliance rates, methods of

measuring compliance and interventions to improve patient compliance. Included studies had compliance as a key word and they included review articles or studies of good methodological quality. They reported that more than 200 variables had been studied and none of these factors were consistently related to compliance. They found that demographic variables and disease factors were poor indicators of compliance. The authors noticed that the patient's perspective were often absent in research on compliance and stressed the importance of the doctor-patient relationship in compliance, including the prescribing process, by inviting patients to participate in decision-making. Again, this review highlighted the importance of involving patients in decisions about their care to ensure that they follow instructions from healthcare professionals. However, the quality of this review was found to be poor for a number of reasons; it did not describe the total number of studies screened and included, and the exclusion criteria were not specified. Also no details were given about the assessment of the methodological quality of the included studies.

A second qualitative systematic review was carried out by Jin and colleagues (2008) to explore and evaluate the most common factors affecting compliance. A total of 2095 studies were retrieved, published from 1970 to 2005, 102 articles met the inclusion criteria. Studies with small numbers of participants (less than 50 patients) were excluded because of inadequate sample size. Studies that included a very specific sample population, such as involving only males or females, or patients from one specific class (e.g. the homeless or prisoners) were eliminated from the review as the results cannot be generalized. Furthermore, all studies that focused on interventions to improve compliance, methods to measure compliance or clinical trials were excluded, as they were performed with patients under close supervision and the reported rates of compliance therefore cannot be generalized.

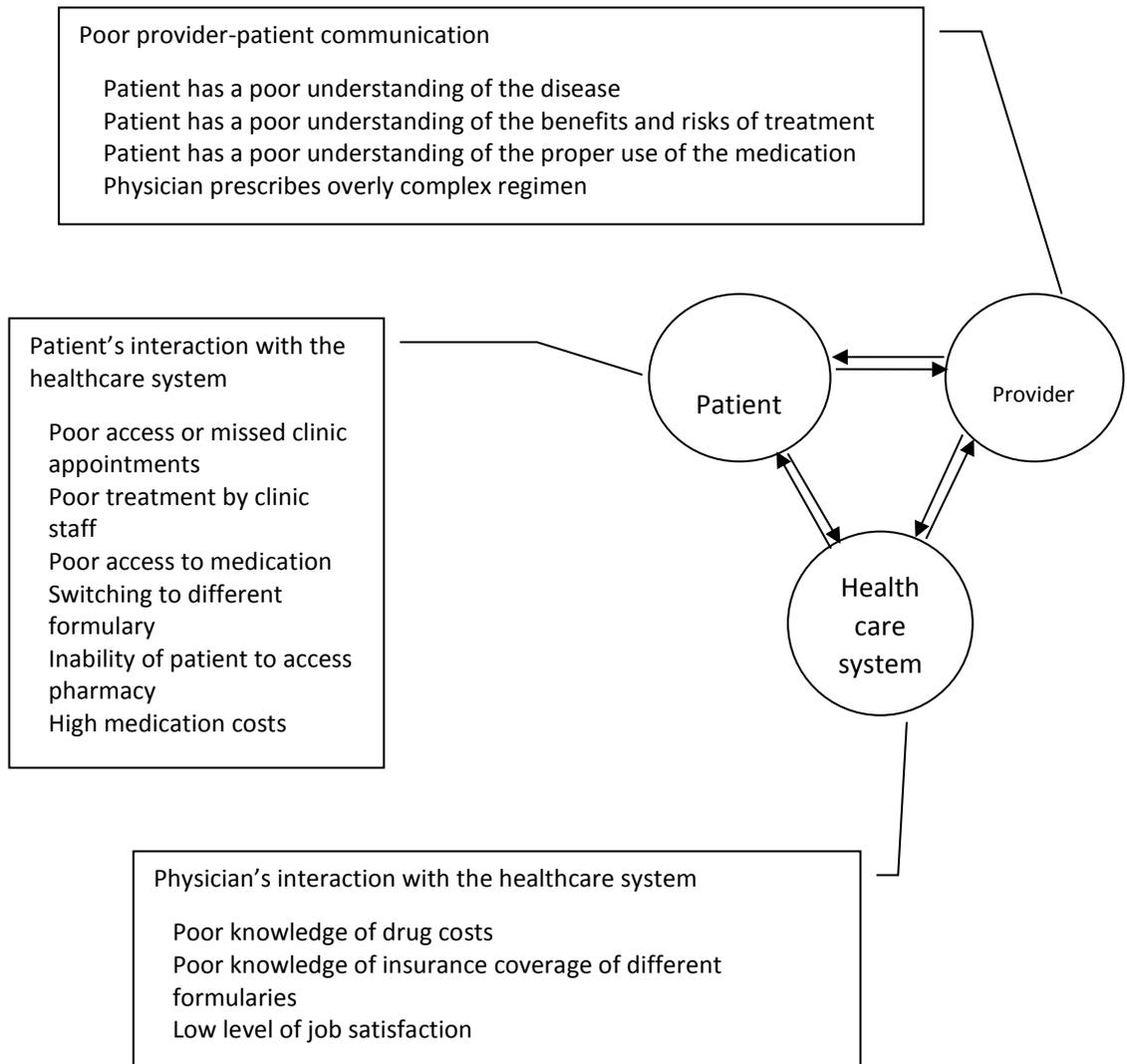
The authors of this review classified the factors associated with compliance into five broad categories including; patient-centred; therapy-related; social and economic; healthcare system; and disease factors. They found that therapy-related problems, such as the route of administration, treatment duration and possible side effects of therapy were associated with the compliance levels of patients. In addition, factors related to the healthcare system including accessibility, patient satisfaction, and type of disease (acute or chronic) are all found to be important factors. Patient-centred factors, such as their

demographic and psychological make-up were found to be complex and the findings in the literature were inconsistent.

Jin and colleagues (2008) discussed how compliance was related to other patient-centred factors, namely patients' beliefs and motivation to follow treatment. From the studies included in their review, they reported higher levels of compliance if patients feel that they are susceptible to disease or its complications and believe that the treatment will be beneficial for their conditions; however, they also found that erroneous beliefs, such as fear of dependence on long-term drugs, and some cultural and religious beliefs, may negatively affect compliance. The nature of the factors identified as being important, particularly around patients understanding the need for and consequences of treatment, resonates with the key principles of concordance. One limitation of this review was that they only searched one electronic database (Medline), so other relevant studies may have been omitted.

In general, the common reasons for non-compliance with medical treatment are summarised by Osterberg and Blaschke (2005) under three main types of factors including; patient centred factors, interaction between doctor and patient, and interaction between patient and healthcare system (Figure 1).

The interactions among the patient, healthcare provider, and healthcare system depicted are those that can have a negative effect on the patient's ability to follow a medication regimen. It seems that the relationship between the patient and the healthcare provider is one of the most important factors in patients' compliance.



**Figure 1: Barriers to adherence adapted from Osterberg and Blaschke, 2005.**

## **1.5 Interventions to improve compliance**

Several interventions have been attempted to improve patients' levels of compliance with taking medication, including short-term treatment regimens, fewer daily doses, easy to use packaging, reminders, and patient education. None of these methods have been found to be effective in enhancing compliance with treatment (Vermeire *et al.*, 2001).

Haynes and colleagues (2008) carried out a Cochrane systematic review of randomized controlled trials of interventions to help patients follow prescribed treatment. From a total of 18,867 citations, 78 trials were included in the review. Interventional studies were included if they measured both medication adherence and treatment outcome, with at least 80 per cent follow-up of each group studied, and at least six months follow-up for studies of long-term treatments with positive initial findings. The authors found that simple interventions, such as informing patients to consume all prescribed medication, can improve compliance with short-term treatments. On the other hand more complex strategies, including simplifying the dose regimen, reminders, and close follow-up, were not very effective in improving compliance and treatment outcomes with long-term treatment. Haynes and colleagues suggested that future studies on improving compliance with treatment should include patients in the development of new interventions, rather than relying on paternalistic approaches.

## **1.6 Problems with the concept of compliance**

Compliance is a concept widely studied in many areas of healthcare. The Cochrane review described above (Haynes *et al.*, 2008) suggested that improving medicine taking may have a far greater impact on clinical outcomes than improvements in treatments; however, attempts to improve compliance have often been ineffective (van Dulmen *et al.*, 2007). Despite five decades of research on this issue very few consistent findings about what factors may lead to poor compliance have been identified (Morris and Schulz, 1992; Vermeire *et al.*, 2001), making compliance still poorly understood and a source of frustration for healthcare practitioners (Tebbi, 1993).

It has been suggested that the interaction between healthcare professionals and their patients should not be simply focused on reinforcing instructions around treatment, but should be viewed in a wider concept of how to obtain mutually agreed goals (Blenkinsopp, 2001). Furthermore, healthcare providers should seek to develop

‘concordance’ with their patients if treatment outcomes are to be improved (Marinker and Sharp, 1997; Chatterjee, 2006).

In the next section, the literature on orthodontic treatment and compliance will be briefly outlined.

## **1.7 Orthodontic treatment and compliance**

The British Orthodontic Society (2008) defined orthodontic treatment as ‘a specialized branch of dentistry concerned with development and management of deviations from the normal position of the teeth, jaws and face (malocclusions)’. Vast majority of orthodontic treatment is carried out on children, and according to the report produced by the Clinical Standards Committee of the British Orthodontic Society (2008), each year more than 130,000 patients (most of them are children under 18 years old) have orthodontic appliances fitted under the NHS in England and Wales. A recent survey revealed that 44% of 12 year olds and 29% of 15 year olds examined perceived a need to have their teeth straightened. Clinicians determined that 45% of 12 years old and 33% of 15 years old examined had a clinical orthodontic treatment need (HSCIC Children’s Dental Health Survey, 2013). The survey also reported that 9% of 12 year olds and 18% of 15 year-olds examined were undergoing orthodontic treatment in England, Wales and Northern Ireland.

In orthodontic practice, as well as in all dental specialties, successful outcomes of treatment depend on a variety of factors. Compliance with orthodontic treatment was mentioned over 2000 years ago by Hippocrates. He advised patients to use continuous finger pressure to move their teeth to a more desirable position, but noted that patients who did not comply with the doctor’s instruction failed to achieve successful results (Graber, 1972).

The rate of non-completion of orthodontic treatment has been suggested to range between 10-20 per cent (Murray, 1989; Roberts *et al.*, 1994). In a study investigating discontinuation of orthodontic treatment, Haynes (1974) found that the discontinuation rate increased from 10%, in 5 to 9 years old patients, to 33% in patients aged 15 years and above.

Although the proficiency of the orthodontist is important, for a successful end result to be obtained, patient and parent involvement are essential (Nanda and Kierl, 1992;

Albino, 2000), bringing them to commit to treatment in order to secure the best cooperation (Nel and Dawjee, 2012). It has been suggested that a satisfactory level of conformity might be obtained by establishing agreement between the expectations of the patients, parents, and orthodontist (Robertson and Maddux, 1986).

Brattström and colleagues (1991) interviewed 80 patients concerning the reasons why they had discontinued orthodontic treatment and lack of motivation was the most common reason. Patients expressed the feeling that they had not been sufficiently well informed about their orthodontic treatment before they started. The authors noted that insufficient information and lack of communication between the orthodontist and patient were the basis for many of reasons for non-completion of treatment given. They proposed that information provided to patients should be tailored to their age and level of appreciation (Brattström *et al.*, 1991).

Barbour and Callender (1981) classified the issue of patient compliance with orthodontic treatment into two types; the *physiological-mechanical* by using treatment modalities that reduce the need for patient compliance, and the *psychological-educational*, which deals with the prediction and alteration of patient behaviour, as well as including the patient in the treatment process.

In the physiological-mechanical area, significant improvements have been made through the development of ‘non-compliance therapy’. This involves the use of appliances such as the Herbst appliance and mini implants, which reduce the need for patient compliance in wearing of headgear, elastics, and removable appliances (McSherry and Bradley, 2000; Keim, 2003). While these approaches may result in more predictable treatment outcomes they still have some disadvantages, such as appliance breakage and high cost (McSherry and Bradley, 2000).

In his model “a new paradigm of motivation” White (1997) reported that the patient compliance with orthodontic treatment is closely related to the individual’s level of sensitivity, i.e. a ‘comfortable’ patient is more likely to be a ‘compliant’ patient. He recommended the use of the simplest mechanics possible and reducing discomfort by using bonded brackets rather than bands whenever possible. The other equally important aspect of the psychological-educational model is involving patients in the treatment process to attain optimal results (Keim, 2003). Sondhi (2003) stated that “instead of trying to ‘sell’ treatment to children and parents...a lot of the time spent

tearing our hair out over problems with patient compliance could be saved if the children were made partners in the consultation process.”

### **1.7.1 Consequences of non-compliance with orthodontics**

Non-compliance with orthodontics has traditionally been described in terms of failure to follow recommendations, such as the care of appliances, maintaining good oral hygiene, keeping appointments and the use of elastics or headgear appliances. The consequences of this include possible enamel demineralization and dental caries (Zachrisson, 1976), lengthened treatment time, compromised treatment results, and in some cases, early termination of treatment becomes necessary. This, in turn, can lead to frustration for patients, parents and clinicians (Allan and Hodgson, 1968; Clark, 1976; Oliver and Knapman, 1985; Cucalon and Smith, 1990; McSherry and Bradley, 2000; Southard *et al.*, 1991).

Loss of compliance can therefore result in considerable wastage of workforce and financial resources that could be more profitably utilized in treating other patients (Woollass *et al.*, 1988). According to the Annual Reports of the Dental Estimate Boards, the rate of active orthodontic treatment discontinuation in the period of 1967-1971 was 17 per cent, and increased to 20 per cent in the period of 1972-1979, with a total cost to the National Health Service estimated to be over one million pounds per year (i.e. more than twelve million pounds a year in today's money). It has been suggested that discontinuation might be reduced by using fixed rather than removable appliances (Murray, 1989).

Previous researchers proposed that improving patient compliance could reduce treatment time, ensure optimum treatment outcomes, and reduce the incidence of dental diseases, such as caries (Årtun and Brobakken, 1986; Øgaard *et al.*, 1988; Kazmierski-Furno, 2005; Al-Shamsi, 2007). Punctuality in keeping appointments allows the orthodontic practitioner to observe the treatment progress and make the required adjustments in a proper time (Kazmierski-Furno, 2005). Lastly, if the patient is careful and does not persistently damage their appliance it might permit treatment to progress with fewer interruptions (Harmen, 2008).

### **1.7.2 Interventions to improve compliance with orthodontic treatment**

Many interventions have been attempted to improve compliance with orthodontic treatment including; patient and parent education about the consequences of poor

compliance, discussing treatment goals, patient support at home, and continuous encouragement and feedback (such as rewarding and verbal praise) from the orthodontic clinic (Mehra *et al.*, 1998; Sinha and Nanda, 2000).

Recently, Aljabaa and colleagues (2014) conducted a systematic review of randomized controlled trials investigating the effectiveness of interventions to improve adherence among patients undergoing fixed orthodontic appliance treatment aged 12 to 18 years old. The search involved different electronic databases as well as a hand search in order to capture all relevant trials. Studies with a before and after design to compare interventions such as verbal advice, written advice, interventions based on psychological theories, and educational interventions to no intervention or studies comparing different interventions were included in the review. The primary outcomes included recall of information, appointment attendance, self-reported behaviour, and clinical indexes (including the plaque index). The secondary outcomes were assessed through validated questionnaires and included; motivation for orthodontic treatment, expectation of orthodontic treatment, and apprehension and worries about orthodontic treatment.

Of the 381 articles identified, four RCTs of moderate quality involving 304 participants were included in the review. Trials examined different methods of interventions including (awards/rewards system, the Hawthorne effect, written information, and demonstration of the plaque microbiology). The results showed that all interventions, except the use of awards/rewards system, were associated with improvements in adherence. Authors used the CONSORT checklist to identify bias in the included studies. The main concerns as noted by Aljabaa and colleagues (2014) and regarded as shortcomings of the included trials were related to the appropriateness of the sample size, as none of these trials identified the basis on which the sample size was determined, as well as limitations regarding allocation and blinding procedure for the studies. Due to the variation in methodologies in these studies, the authors were unable to perform a meta-analysis, and although the included studies were considered to be of moderate quality, the authors indicated that more high quality studies were needed in order to investigate the effectiveness of interventions on patients' compliance with orthodontic treatment (Aljabaa *et al.*, 2014).

The relationship between orthodontist and patient seems to play a key role in patient compliance (Schäfer *et al.*, 2014). It has been suggested that successful orthodontic treatment outcomes require the establishment of a good patient-orthodontist relationship (Klages *et al.*, 1992; Nanda and Kierl, 1992), and the lack of communication between the orthodontist and the patient as well as insufficient information about orthodontic treatment can lead to premature termination of the treatment (Nel and Dawjee, 2012). However, there has not previously been a systematic review of factors associated with compliance or concordance with orthodontic treatment. Sinha and Nanda (2000) carried out a narrative review of studies using interventions to improve compliance with orthodontic treatment and stated that “the doctor-patient-parent rapport is critical in establishing a win-win situation. In this way, patients feel that they have participated in the treatment decisions and would be responsible for the achievement of commonly accepted goals.” However, the review did not include details of interventions to improve orthodontist-patient-parent relationships. The next section will highlight the importance of the relationship between patient and clinician.

## **1.8 Clinician-patient relationship**

### **1.8.1 Background**

Talcott Parsons (1951) was the first social scientist to examine and theorise the doctor-patient relationship. Many authors have since attempted to describe the different types of doctor-patient relationship. For example, Morgan (2003) described the four main types as follows;

*‘Paternalism’* - the doctor is dominant and the patients are passive. This is typified by doctors asking patients closed questions, such as ‘was the pain you had sharp or dull?’ Such questions aim to help doctors reach a diagnosis, rather than obtaining the patient’s unique experience of illness. The paternalistic relationship is where the doctor acts as a ‘parent’ figure who decides what he or she thinks to be in the patient’s best interest.

*‘Mutuality’* - based on shared decision-making. It has been described as a ‘meeting between experts’. In this approach the clinician uses open questions such as ‘tell me about the pain’, ‘how do you feel?’ and ‘what do you think is the cause of the problem?’ to encourage the patients to talk about their complaint.

*'Consumerism'* - focuses on patients' rights and doctors' obligations. In this relationship the patient knows what they want and forces the doctor into a patient-centred approach, i.e. the patient takes the active role and the clinician adopts a fairly passive role.

*'Default relationships'* – occurs when the patient-centred style does not work. The doctor is trying to relinquish control, but the patient is unwilling to accept it. It happens when patients are not aware of alternatives to remaining passive, resulting in a lack of control both by patients and providers.

Historically, a paternalistic approach to medical decision-making has been prominently adopted in healthcare. In this approach the patient usually remains passive in the decision-making process and it is the doctor's responsibility to choose the appropriate treatment for the patient (Roberts and Krouse, 1990; Parsons, 1991; Emanuel and Emanuel, 1992). Ethical strategies of the time put forward the principle that it is a doctor's responsibility to always act in the best interests of the patient (Lomas and Contandriopoulos, 1994). This would appear to imply that the patient's involvement and participation in the decision-making processes is not required.

In more recent years, because attitudes to 'doctor knows best' have changed, a shift in thinking away from a paternalistic approach in medical care has developed, and the implementation of the concept of shared decision-making has become more evident (Kasper *et al.*, 1992). The mutualistic relationship is usually considered as the best type of doctor-patient rapport, and as stated by Edwards and Elwyn "it is characterized by a broad balance in power and symbolic resources for each participant; the agenda is negotiated; the patient's values are explored, and the doctor takes an advisory role regarding the patient's goals and decisions" (Edwards and Elwyn, 2009).

While the paternalistic and consumerism models have been seen to predominate, the shared decision-making of the mutualistic relationship has been suggested to represent a promising template for the doctor-patient relationship in the 21st century (Hamann *et al.*, 2003).

Federman and colleagues (2001) carried out a cross sectional survey which examined the influence of doctor-patient relationships on treatment discontinuation in primary care patients, using telephone interview with 2782 patients aged 20 to 75 years old, randomly selected from 11 general medical practices. Patients were asked to rate several

aspects of their healthcare and the outcome of interest was ‘unwilling to return’ when the patient was asked ‘Do you plan to come back to this practice’. The authors reported that 6% of patients did not want to return to their usual primary care site. Patients’ unwillingness to return to their physicians was mainly due to dissatisfaction with the length of time spent with the physician (OR 3.2; 95% CI, 1.4 to 7.4, multivariate analysis), and perceptions that doctor’s attention to their concerns was inadequate (OR 8.8; 95% CI, 2.5 to 30.7, multivariate analysis). The authors suggested that doctor-patient relationship can influence patients’ decisions not to seek care (Federman *et al.*, 2001). The authors reported some limitations, for instance, the study did not include the type of health insurance the patient had in the analysis as the insurance type may effect patient satisfaction. Second, the study did not considered the post-survey follow-up rates as some patients may return for care even after reporting their intention not to do so.

### **1.8.2 Models of decision-making**

In general, there are three models of decision-making regarding treatment, namely; paternalistic decision-making, shared decision-making and informed decision-making (Table 1).

From the perspectives of patients, these models differ according to the degree to which they are able to participate in the choice of their treatment. In the paternalistic model, the healthcare provider usually selects the treatment based on a patient examination and potential clinician-based outcomes. While in the shared decision-making model, both parties (doctors and patients) are involved in treatment decisions by sharing information about the disease and treatment options (Charles *et al.*, 1997). However, in the informed decision-making model, usually the patient is the decision-maker, and the physician informs the patient about the risks, benefits and other treatment options.

Wirtz and colleagues (2006) state that these models do not have universally agreed definitions, and there is an enormous amount of debate and confusion about what application of these models would involve. Indeed these models are very similar to those described in the literature on clinician-patient relationship (section 1.8.1) as decision-making about treatment is often a significant component of interactions between patient and health professionals. The next section of this chapter will describe the shared decision-making model in more details.

**Table 1: Decision-making models of treatment** (Adapted from Morgan, 2003).

Analytical stage		Paternalistic	Shared	Informed
<b>Information exchange</b>	<i>Flow</i>	One way	Two way	One way
	<i>Direction</i>	Doctor → patient	Doctor ↔ patient	Doctor → patient
	<i>Type</i>	Medical	Medical and personal	Medical
	<i>Amount</i>	Minimum legally required	All relevant for decision-making	All relevant for decision-making
<b>Deliberation</b>		Doctor alone or with other doctors	Doctor and patient (plus potential others)	Patient (plus potential others)
<b>Deciding on treatment to implement</b>		Doctor	Doctor and patient	patient

## 1.9 The Shared Decision-Making model

### 1.9.1 Shared decision-making in adults

Shared decision-making (SDM) has been defined in a number of different ways. The President’s Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioural Research in its report ‘Making Health Care Decisions’ (1982) defined it as follows: “shared decision-making requires that a practitioner seeks not only to understand each patient’s needs and develop reasonable alternatives to meet those needs, but also to present the alternatives in a way that enables patients to choose the one they prefer. To participate in this process, patients must engage in a dialogue with the practitioner and make their views on well-being clear” (Donovan, 1995).

The most widely accepted and commonly cited definition of shared decision-making was created by Charles and colleagues (1997) who described the process of shared decision-making as “involvement of both the patient and the doctor, a sharing of

information by both parties, both parties taking steps to build a consensus about the preferred treatment, and reaching an agreement about which treatment to implement”.

Makoul and colleagues (2006) described the process of shared decision-making, as beginning with an explanation of the problem by the patients and healthcare providers. Physicians should present the options, if they exist, and patients should be free to discuss other options of which they may be aware. Doctors and patients then need to discuss the advantages and disadvantages of the selected options (as they may have different perspectives on the benefits, risks, and costs) with clarification of patient values and preferences together with the doctor’s knowledge and recommendations. Research on health literacy (Donnan *et al.*, 2002; Wolf *et al.*, 2004) has emphasised the importance of maintaining regular checks of understanding of perspectives and providing further clarification when required.

Subsequently, Coulter and Collins (2011) define it as “a process in which clinicians and patients work together to select tests, treatments, management or support packages, based on clinical evidence and the patient’s informed preferences”.

In policy terms, the rights of patients to be involved in informed decision-making about their healthcare was described in the NHS reforms of 1991 (Morgan, 2003), and supported by the National Institute for Health and Clinical Excellence (NICE) guidelines “good communication between healthcare professionals and patients is essential” (NICE, 2010).

Internationally, shared decision-making has also gained a high level of policy support (Coulter and Ellins, 2006) and it is regarded as a promising method of improving the quality of care (Minnesota Shared Decision Making Collaborative, 2009). It has been deemed appropriate for many types of healthcare decisions, including medical or surgical treatment, screening tests, taking medication, and lifestyle changing regimens (Coulter and Collins, 2011). To date, the prescription of drug treatment in relation to shared decision-making has received the highest level of attention in the literature. Studies reported that in chronic conditions, approximately 50 per cent of patients did not take their treatment as prescribed because they did not share the clinicians’ opinion about the suitability of the prescribed treatment or were worried about the side effects of the drugs (Morgan, 2003).

However, the lack of a consensus definition of shared decision-making complicates its employment in clinical situations, and more research is required to develop the successful integration of the model beyond a research setting (Minnesota Department of Human Services, 2010). Furthermore, the concept of shared decision-making may not suit all types of patients (Edwards *et al.*, 2005; Deber *et al.*, 2007), and is difficult to achieve in practice (Towle *et al.*, 2006).

The Cochrane systematic review by Haynes and colleagues (2008) suggested that investigators should include patients in the development of future interventional studies designed to improve compliance with treatment. Patient decision aids (PDAs) have been suggested as ways to implement shared decision-making as they increase patient involvement and produce beneficial results (Sowden *et al.*, 2001; Estabrooks *et al.*, 2001; Dolan and Frisina, 2002). Studies have shown that higher levels of patients' involvement in decision-making through the use of specific interventions that help patients address their information needs, such as decision aids resulted in better behavioural and health status benefits (O'Connor *et al.*, 2003a; Kinnersley *et al.*, 2007). O'Connor and colleagues (2003b) found that programmes of shared decision making, including PDAs, resulted in improved knowledge and expectation, and increased the proportions of patients active in decision-making. A recent update of this review (Stacey *et al.*, 2014) will be described in more detail in section 1.10.2.

### **1.9.2 Shared decision-making in children**

Involvement of children in decision-making has been acknowledged in recent years (Stacey *et al.*, 2011). It has been stated that “children should be encouraged to be active partners in decisions about their health and care, and, where possible, be able to exercise choice” (Department of Health, 2003). Healthcare professionals must take into account the values and thinking of their patients, in 2004, the National Service Framework for Children approved the involvement of children by discussing the risks and benefits of medication through shared decision-making between doctors, patients, and parents (Department of Health, 2004b).

More recently, the Department of Health published ‘*Liberating the NHS: Greater Choice and control*’ stated that “Children and young people should be involved in decisions and choices about their healthcare as much as possible, even when they are unable to make decisions and choices by themselves. The level of involvement that they

are able to have will depend on their individual circumstances and ability and how information is presented to them and it may often be in partnership with their parents, family and other representatives as appropriate” (Department of Health, 2010).

In 2013, the Department of Health published ‘Liberating the NHS: No decision about me, without me’ stated that “treating all patients and the public as grown-ups – by giving them more opportunities to be involved in decisions about their care and treatment” (Department of Health, 2013).

Previous findings suggested that children prefer to be involved in decision-making processes and are willing to participate in a wide range of medical decisions relating to conditions such as cystic fibrosis (Angst and Deatrck, 1996), diabetes (Dovey-Pearce *et al.*, 2005), and cancer (Quinn *et al.*, 2011). In contrast, some researchers found that children may desire a more passive role in decision-making process (Knopf *et al.*, 2008).

Despite the support for the use of shared decision-making and decision aids in children and young people, the amount of research investigating their impact is very limited compared to adults. For instance, only 35 out of the 652 PDAs available in the Decision Aid Library Inventory focused mainly on decisions involving children, with the majority of these decisions focused toward the parents and their role in the decision-making process (Ottawa Hospital Research Institute, 2014). Therefore, further research is needed to investigate the impact of shared decision-making and PDAs on decisions involving children and young people.

### **1.10 Patient decision aids**

Various decision aids and tools have been developed to encourage patients’ participation in the process of decision-making (Levine *et al.*, 1992; Deber, 1996; Gafni *et al.*, 1998; Martin, 2002). Decision aids are defined as ‘interventions designed to help people make specific and deliberative choices among options by providing (at the minimum) information on the options and outcomes relevant to the person’s health status’ (O’Connor *et al.*, 1999). PDA or “shared decision-making programmes” are tools that have been developed to make it easier for people to discuss treatment options and participate in making health decisions with healthcare professionals (Gafni *et al.*, 1998; Martin, 2002; Stacey *et al.*, 2011).

In the UK policy, it has been stated that “improving information for patients can empower them to take a more active role in their healthcare, improve relationships and communication with healthcare professionals, and increase their ability to take control of their health and participate more fully in decisions about their care and treatment” (Department of Health, 2004a).

Patient decision aids (PDAs) have become increasingly popular, particularly in the USA and Canada. Currently, there are over five hundred PDAs that have been developed worldwide (Ng *et al.*, 2014) for different conditions including breast cancer, diabetes, acne, allergy, arthritis, back pain, prostate cancer, and heart diseases. Few PDAs about dental care decisions have been developed: a PDA has been developed for endodontics ‘the Endodontic Decision Board’ (EndoDB) (Johnson *et al.*, 2006), and for restorative dentistry (Kupke *et al.*, 2013). These two PDAs are included as Appendices A1 and A2. More details on dental PDAs are described in section 1.11.

PDAs are available in various formats including; leaflets, decision boards, audiotapes, audio-guided workbooks, computer programmes, DVDs, group presentations, and internet-based resources (O’Connor and Jacobsen, 2003; Stacey *et al.*, 2008). Decision aids, as described by O’Connor and Edwards (2001) are different from general health education materials or interventions to recommend specific options. Such health education materials are designed to help people understand their disease and treatment plan in general terms, and negate their participation in decision-making (Stacey *et al.*, 2011). Decision aids are intended to complement and support, rather than replace, the doctor-patient interaction by allowing patients to work with the healthcare provider to make an informed choice (Elwyn *et al.*, 2006).

The International Patient Decision Aids Standards (IPDAS) collaboration described the three specific features of the PDAs that encourage patients’ involvement in decision-making as; firstly, they provide facts about health condition, the options for treatment and the related costs, benefits and uncertainties. Secondly, they help patients in recognising their values and outcomes. And finally, they help people in communicating their values with the healthcare professionals (IPDAS, 2005a).

Recently, Coulter and Collins illustrated the content of the PDAs in more details. They proposed that PDAs should contain the following: clear description of the disease and its symptoms, the likely prognosis with and without treatment, the treatment options and

outcome probabilities, what is known from the evidence and not known (uncertainties), illustrations to help patients understand what are the most frequent side-effects or complications of the treatment options, means of helping people clarify their preferences, and sources of further information (Coulter and Collins, 2011).

### **1.10.1 Development of PDAs**

The IPDAS collaboration was established to propose standards for the development of PDAs. The quality criteria framework was achieved through inviting 212 participants from 14 different countries to serve on a voter panel. A total of 122 individuals agreed to participate; including 21 patients, 10 health professionals, 14 policy makers and 77 researchers (IPDAS, 2005b). The IPDAS produced a set of quality criteria (Elwyn *et al.*, 2006) which included the following requirements:

- A systematic development process
- The provision of information about options and probabilities
- Clarification of values
- Disclosure of conflicts of interest
- A balanced presentation of options
- Use of plain language
- Information based on up to date scientific evidence
- Establishing effectiveness

The full IPDAS criteria checklist has been included as Appendix S.

O'Connor and Jacobsen (2003) summarised the process of developing and evaluating PDAs into seven steps:

1. *Assessment of need:* this should be defined from the perspective of both patients and clinicians. It involves the collection of evidence regarding the difficulty in the decision, variation in practice and preference, and the demand for developing a decision aid.
2. *Assessment of feasibility:* to determine the availability of evidence and resources that can be used to develop a regularly updated and accessible decision aid. Evidence is usually retrieved from recent clinical trials, systematic reviews, and discussion with clinical experts.

3. *Objectives*: the objectives of the decision aid should be specific, measurable and clearly explain what will be achieved. This is important because it influences the selection of the framework, methods of decision support, and how aids will be evaluated.
4. *Selection of framework*: based on the objectives, several frameworks are available to guide the development of the PDA. For example;
  - The *Healthwise* approach used mainly in developing decision aids for commercial use (Coulter *et al.*, 2013). The Healthwise PDAs have not been formally evaluated in any trial, and the developers do not provided explicit details of their development process.
  - The *Informed Medical Decisions Foundation* (IMDF) develops DAs for both research and commercial use. However, the development process of IMDF decision aids is complex and lengthy in time (Coulter *et al.*, 2013).
  - The *Ottawa Decision Support Framework* (ODSF) originates from the Ottawa Health Research Institute Patient Decision Aids Group. The ODSF is particularly suitable for preference-sensitive decisions in which a considerable amount of information on potential treatment risks and benefits is involved (Coulter *et al.*, 2013). The ODSF decision aids are designed to address the problematic determinants of decision-making including inadequate knowledge, unrealistic expectations and decisional conflicts by providing accurate, balanced, and clear information. This approach will be utilised in the development and evaluation of the PDA in this thesis. The selection of the ODSF for the development of the current PDA was based on several factors: First, ODSF workbook provides a detailed description of the method (O'Connor and Jacobsen, 2003) which is presented in a systematic process. Second, the workbook is specifically targeted for PDA use in an actual physician-patient consultation. The ODSF and the Ottawa Personal Decision Guide are included as Appendices B1 and B2.
5. *Selection of the methods of decision support*: the content, methods and delivery depends on the nature and the objectives of the decision aid. Although, the essential content of PDAs is still a matter of debate, it usually consists of the following:

#### 5.1 Information about clinical situations, options and outcomes

In general, PDAs start with a description of the information that patients need regarding their clinical condition and its options and outcomes, followed by the method and the duration of delivery of each option. Next, the outcomes of all options are described in sufficient details for patients to understand.

### 5.2 Presenting probabilities of outcomes

Providing patients with information regarding benefits and risks is crucial in creating patients with realistic expectation of outcomes. Using numbers in presenting risk information is better than using words, such as ‘high probability’. Also graphic illustrations with numbers such as 100 faces were found helpful in creating realistic expectation (O’Connor and Jacobsen, 2003).

### 5.3 Value clarification

Value clarification can be done through the use of a personal worksheet in which the benefits and risks are placed on a balance scale. In this way, patients can add other perceived potential benefits and risks and communicate their values efficiently to their healthcare providers.

### 5.4 Information about other opinions

Although some developers of PDAs prefer to remain neutral by avoiding using any examples, others prefer to provide balanced information on different points of view. Providing information about others opinions may reinforce the concept that decision-making is variable and depends on individual’s own values.

6. *Selection of the design and measures to develop the decision aid:* based on the objectives of the PDA, decisions about the sampling, design, evaluation criteria and measurement tools need to be made. The usual standard method to develop a PDA may involve drafting and redrafting by health service expert inter-disciplinary panel; assessment and revision by panels of practitioners and patients; pilot testing with practitioners and patients; and evaluative studies using randomised trials.

7. *Dissemination of the decision aid:* this involves the distribution and the promotion of the use of the PDA.

## **1.10.2 Evaluation and effectiveness of PDAs**

A wide range of measures has been used to evaluate the effectiveness of the decision aids, however, PDAs are commonly evaluated on domains such as decisional conflict,

risk perception, realistic expectations and knowledge (Kennedy, 2003). Results from a Cochrane systematic review of RCTs of decision aids found reliable and positive effects of PDAs on these domains (O'Connor *et al.*, 2003). Other domains, for instance quality of life, satisfaction with care, and adherence to treatment have also been used in the evaluation of some PDAs (Stalmeier and Roosmalen, 2009).

Although, multiple measures and scales are available for each domain, it is appropriate to have questionnaires that are concise and responsive in detecting any important changes as they reduce burden on the patient as well as increase response rates (Deyo *et al.*, 1991; Stalmeier and Roosmalen, 2009).

Numerous studies and reports examining the effectiveness of decision aids have been published. Recently, a Cochrane systematic review of randomised controlled trials was conducted to evaluate the effectiveness of PDAs for patients facing treatment or screening decisions (Stacey *et al.*, 2014), which was an update of their previous review (Stacey *et al.*, 2011). The review focused on two main attributes as primary outcomes, the attributes of 'choice' and the 'decision-making process'. In this instance, the choice attributes were related to evidence suggesting that the use of PDAs increases agreement between the chosen treatment option and features that are most valued by the informed patient. The attributes of decision-making process relate to evidence that use of a PDAs assist patients to; recognise that a decision needs to be made; understand options and their features; understand that values impact upon the decision; and clarify option features that matter most to patients. In addition, the effect of using PDAs on decisional conflict, patient-practitioner communication, satisfaction, the proportions of undecided patients, and participation in decision-making were examined. The secondary outcomes in this review included anxiety; health status and quality of life; depression; adherence to the chosen option; healthcare costs; and consultation length.

The authors searched several databases and included work published up to June 2012. All randomised controlled trials (RCTs) of decision aids compared to usual care and alternative interventions were included in their review. Studies in which patients were not active in taking decisions about their treatment and studies of participants making hypothetical decisions were excluded. Researchers identified 115 RCTs, comprising 34,444 participants from nine different countries including; Australia, Canada, China, Finland, Germany, Netherlands, Sweden, the UK, and the USA.

In relation to the attributes of the choice, the results indicated that one of the largest effects of using a PDA was the impact on the patient's knowledge of the options available and associated outcomes. Of the 115 trials included in the review, 76 evaluated the effect of PDAs on knowledge and suggested that patients who used PDAs had significantly higher average knowledge scores than those receiving usual care (mean differences 13.34%; 95% CI 11.17 to 15.51).

Another outcome, related to the attributes of choice, investigated by this review (Stacey et al., 2014) was the effect of the use of a PDA on the accuracy of patients' perceptions of risk (the primary outcome in 25 out of the 115 included studies). The reviewers concluded that, when compared to usual care, people gained a more accurate perception of risk when exposed to a PDA in which the probability of an adverse event was expressed (RR 1.82; 95% CI 1.52 to 2.16), especially when probabilities were written in numbers (RR 2.00; 95% CI 1.65 to 2.43) rather than words (RR 1.31; 95% CI 1.13 to 1.52).

In relation to the characteristics of the decision process, Stacey and colleagues (2014) reported that the use of PDAs can help reduce patient's decisional conflict. In this review the use of PDAs resulted in reduced decisional conflict related to feeling uninformed (MD -7.26%; 95% CI -9.73 to -4.78) evaluated in 34 studies, and feeling unclear about personal values (MD -6.09%; 95% CI -8.50 to -3.67) assessed in 29 studies. In addition they found that the use of decision aids reduced the proportion of patients who were passive in decision-making (RR 0.66; 95% CI 0.53 to 0.81), and reduced the proportion of patients who remained undecided (RR 0.59; 95% CI 0.47 to 0.72). These results relate to lower scores on two sub-scales of the Decisional Conflict Scale (DCS) by O'Connor (1995) which suggest that use of PDAs leave patients feeling more informed and clearer about their personal values. DCS measures uncertainty and factors contributing to it, including feeling uninformed, unclear about values, and unsupported in decision-making. The scale responses range between 0 - 100, with a low score indicating less decisional conflict, i.e. score of 0 indicates no decisional conflict and a high score representing a high decisional conflict. For more details about DCS including scoring, reliability and validity see section 4.3.4.1. in Chapter Four.

In addition to the above findings, the authors established that the effect of PDA on the outcome 'patient-practitioner communication' was measured in 9 out of the 115 studies

included. They reported that PDAs appeared to have a positive effect on patient-practitioner communication and can often lead patients to desire a more active role in the decision-making process, and this effect was higher when the decision aid was used within the clinical encounter. Such increased participation being a key in the implementation of shared decision-making throughout healthcare.

Findings relating to patient satisfaction with the chosen treatment option and the process of decision-making were inconclusive. Out of the 115 studies included in the review carried out by Stacey and colleagues (2014), 20 studies measured satisfaction with choice, and 17 studies measured satisfaction with the process of decision-making. Results showed that the use of PDAs has a limited effect on the patient's satisfaction, and it has been assumed that there are several possible explanations for these findings including measurement insensitivity or 'ceiling effects' which occurs when high levels of satisfaction with usual care is already displayed by patients (Stacey *et al.*, 2014). Also, it may be psychologically more comfortable to express satisfaction with chosen treatment, rather than showing uncertainties whether they made the correct choice or not (Gruppen *et al.*, 1994).

The impact of using PDAs on healthcare systems in relation to cost and resource use was investigated in eight studies included in the review by Stacey and colleagues (2014) and the results were inconclusive regarding the health service resource use between the PDA group and the usual care group. However, a significant difference in costs was reported when additional equipment, like the use of interactive video systems, was used in the PDAs (Murray *et al.*, 2001a; Murray *et al.*, 2001b). When considering the impact of using a decision aid on consultation length the findings were inconclusive. This was investigated in nine of the included studies, two of them reported an increase in consultation length when PDA being used, and one study reported that consultations about breast cancer were shorter when a decision aid was used. However, the other six studies were unable to detect any significant difference in the length of consultations. Although, lack of data and conflicting results make it difficult to draw a conclusive overview about the effect of using PDAs on healthcare system and resources, it can be stated that findings advocated that PDAs do not significantly increase costs and consultation length, even when they failed to reduce these factors. Hence, the implementation of PDAs can be justified on benefits that can be gained from their use including enhanced patient's knowledge and reduced decisional conflict.

The review also found that the effect of PDAs on other outcomes such as anxiety, general health outcomes, and condition-specific health outcomes were inconclusive (Stacey *et al.*, 2014).

In summary, based on the quality of the evidence, the authors concluded that, compared to usual care, PDAs improve knowledge about options and outcomes. These effects on knowledge and risk perceptions are clinically important to ensure informed decision-making. In addition, PDAs help in reducing decisional conflicts, as patients who are exposed to PDA felt informed about their options and were clearer about their values, when compared to usual care. Finally, the comparison between usual care and using decision aids revealed that PDAs reduced the proportion of patients who were passive in taking treatment decisions, and significantly improve patient's involvement in decision-making process by positively enhancing the doctor-patient relationship during consultation (Stacey *et al.*, 2014).

### **1.10.3 Limitations of PDAs**

While the use of PDAs is supported by good evidence that they stimulate patients' participation in decision-making, their use requires motivated healthcare professionals, who are willing to embrace shared decision-making in practice (Legare *et al.*, 2008). Their successful implementation in clinical practice depends on several conditions: good quality PDAs; willingness to use these aids by healthcare providers as part of routine clinical practice; effective delivery of PDAs; and supportive clinical culture that facilitates patient engagement in the decision-making process (Elwyn *et al.*, 2010; Stacey *et al.*, 2014). The evidence relating to barriers and facilitators to implementing shared decision-making and PDAs will now be described in more details.

### **1.10.4 Implementation of Shared Decision Making and PDAs in clinical practice**

#### **1.10.4.1 Health professionals' perspectives on SDM**

Legare and colleagues (2008) carried out a systematic review examining the ways of facilitating the implementation of shared decision-making and PDAs in clinical practice from the health professionals' point of view. In total, 38 studies were included, involving 3624 participants and most of these were physicians (n= 3231). Included studies originated from ten different countries including; the UK, the USA, Canada, Netherlands, France, Mexico, Australia, Norway, Germany and China. Studies were of

varying methodological designs; 21 were qualitative, 11 were quantitative, and six studies used mixed methods design. Also, different strategies were used for data collection including; personal interviews, questionnaires, focus groups and observation.

Among the 38 studies included, 22 reported that time constraints were the most frequently identified barrier to the implementation of SDM. Recently, these findings have been supported by a qualitative study conducted by Rees *et al.* (2009) who investigated the healthcare professionals' views on two computer-based PDAs for pregnant women facing decisions about ways of delivering their babies. However, a study conducted by (Price and Leaver, 2002) and not included in this systematic review showed that shared decision-making takes no more time than traditional consultations. Although, lack of time in consultations was frequently cited as a barrier, the evidence as to whether PDAs actually increase consultation time compared to usual procedure (i.e. is the lack of time for detailed discussions with patients preventing physicians from engaging in shared decision-making) remains inconclusive (Stacey *et al.*, 2014).

Legare and colleagues (2008) found that the second most frequently cited barrier for health professionals to the application of shared decision-making was the patient characteristics, this was reported in 18 of the 38 included studies. However, the authors of the review did not describe what these patient characteristics might be. The third barrier to the implementation of shared decision-making in clinical practice was the lack of agreement concerning the applicability of shared decision-making to the practice population (16 of the 38 studies included), which might be dependent upon the clinical situation, for example mental health issues. However, this systematic review focused on health professional perceptions and depended solely on clinicians' evaluation of the patient desire for active participation in decision-making. The authors suggested that interventions to increase the education of patients need to be considered in future studies, in order to foster the implementation of shared decision-making in clinical practice.

More recent studies reported that the clinicians' attitude towards the impact of shared decision-making is a crucial factor in the successful implementation of such a practice. Previous studies suggested that clinicians generally have a positive attitude toward involving patients in the decision-making process and reported high levels of comfort in its implementation (Rees *et al.*, 2009; Caldon *et al.*, 2011; Fiks *et al.*, 2011). However,

some healthcare professionals were concerned that the use of decision support may result in what is called “information overload,” which can lead to a negative impact on the decision-making process (Caldon *et al.*, 2011).

Other barriers to the implementation of shared decision-making have been identified in previous research, but were not included in the systematic review described above. These additional barriers include lack of self-efficacy (belief that one cannot perform shared decision-making) and lack of familiarity with the concept of shared decision-making (Gravel *et al.*, 2006). However the lack of familiarity may be overcome through training programmes for healthcare practitioners (Elwyn *et al.*, 2004). Another equally important issue as reported by Graham *et al.* (2003) is the maintenance of PDAs that are up to date. This is important because of the rapid emergence of new evidence and as treatment alternatives become available in healthcare field (O'Donnell *et al.*, 2006). In addition to the above mentioned barriers, the conflicting recommendations from various healthcare practitioners, language barriers, and lack of physician awareness have been reported in the literature as perceived barriers to implement PDAs into clinical practice (Caress *et al.*, 2005; Silvia *et al.*, 2008; van Til *et al.*, 2010). Table 2 present the most common barriers to the implementation of the concept of shared decision-making.

**Table 2: The most commonly identified barriers to implementing shared decision-making as reported in the current literature.** Adapted from Legare *et al.*, 2008 and updated

Barrier and description
<b>Knowledge</b>
<i>Lack of awareness:</i> Inability to correctly acknowledge the existence of shared decision-making (Cabana <i>et al.</i> , 1999)
<i>Lack of familiarity with the concept of shared decision-making:</i> Inability to correctly answer questions about shared decision-making content, as well as self-reported lack of familiarity (Gravel <i>et al.</i> , 2006)
<b>Attitudes</b>
<i>Lack of agreement with specific components of shared decision-making:</i> Not believing that specific elements of shared decision-making are supported by scientific evidence (Gravel <i>et al.</i> , 2006)
<i>Lack of applicability - Characteristics of the patient:</i> Lack of agreement with the applicability of shared decision-making to practice population based on the characteristics of the patient (Cabana <i>et al.</i> , 1999)
<i>Lack of applicability - Clinical situation:</i> Lack of agreement with the applicability of shared decision-making to practice population based on the clinical situation (Cabana <i>et al.</i> , 1999)
<i>Clinician's attitude:</i> May result in patient information overload which can lead to negative impact on decision-making process (Caldon <i>et al.</i> , 2011)
<i>Lack of self-efficacy:</i> Belief that one cannot perform shared decision-making (Cabana <i>et al.</i> , 1999; Gravel <i>et al.</i> , 2006)
<i>Overall lack of agreement with using the model:</i> Lack of agreement with shared decision-making in general (Cabana <i>et al.</i> , 1999)
<b>Environmental factors</b>
<i>Time pressure:</i> Insufficient time to put shared decision-making into practice (Cabana <i>et al.</i> , 1999; Rees <i>et al.</i> , 2009)
<i>Lack of resources:</i> Insufficient materials or staff to put shared decision-making into practice (Espeland and Baerheim, 2003)
<i>Lack of access to services:</i> Inadequate access to actual or alternative health care services to put shared decision-making into practice (Espeland and Baerheim, 2003)
<i>Up to date decision aids:</i> Rapid emergence of new evidence and treatment alternatives (Graham <i>et al.</i> , 2003)
<b>Other barriers</b>
These include; conflicting recommendations from healthcare practitioners, language barriers, patient perspectives towards shared decision-making (Caress <i>et al.</i> , 2005; Silvia <i>et al.</i> , 2008; van Til <i>et al.</i> , 2010)

Motivation of healthcare practitioners was the most commonly reported facilitator of shared decision-making as cited in the systematic review (Legare *et al.*, 2008). This was mentioned in 23 of the 38 studies included. The clinician's positive impression of shared decision-making on both patient outcomes and the clinical encounter itself was mentioned as factors which facilitates shared decision-making in 16 of the 38 studies included. A positive perception regarding the effectiveness of shared decision-making and the compatibility of patient's preferences fitting the shared decision-making process were also reported as important factors which facilitate the implementation of PDAs in clinical practice (Legare *et al.*, 2008).

#### **1.10.4.2 Patients' perspectives on shared decision-making**

Patients' perspectives and reports on shared decision-making is another important issue which needs to be addressed. Previous research studies have investigated patients' attitude toward shared decision-making and have reported that patients do want to be part of the decision-making process, particularly if various treatment options exist (Guadagnoli and Ward, 1998; Davison *et al.*, 2002; Janz *et al.*, 2004; Kremer *et al.*, 2007), and patients are willing to have a comprehensive understanding of their health conditions, the available options and the relative risks and benefits associated with these options (Elwyn *et al.*, 2001; Coulter and Dunn, 2002; Deber *et al.*, 2007). In addition, as mentioned before, a previous systematic review reported that factors, such as side effects of treatment, duration of treatment, benefits and patient satisfaction are all important to patients (Jin *et al.*, 2008). However, some researchers reported that the patients' desired level of involvement may depend on different factors including age, gender, social class and education. It has been found that younger, more educated, female patients of a higher social status prefer a more active role in the decision-making process (Arora and McHorney, 2000; Murray *et al.*, 2007; Brom *et al.*, 2014), but these findings were not supported by other researchers (Stewart *et al.*, 2000; Janz *et al.*, 2004; Kremer *et al.*, 2007; Ernst *et al.*, 2011). This suggests a further investigation is needed into the relationship between socio-demographic factors and the variation in outcomes of decision aids.

### **1.11 PDAs in dentistry**

It seems that there is little attention to the concept of shared decision-making and the use of PDAs in the dental literature. Johnson and colleagues (2006) carried out a study

to develop and test a decision aid (EndoDB) to help patients reaching a decision from available treatment options when endodontic treatment or extraction of a tooth is indicated. The Endodontic Decision Board (EndoDB) was tested in a randomised controlled trial. A patient questionnaire was used to assess the primary outcome variables (knowledge, satisfaction, and anxiety), and the independent variable was the use of EndoDB compared to usual care process (standard discussion and informed consent). Knowledge was represented by the number of correct answers to five questions, whereas satisfaction and anxiety were assessed using a seven-point Likert scale. A higher number on the satisfaction scale indicated a higher level of satisfaction with treatment, the response format were as follows; 1= very dissatisfied, 2= dissatisfied, 3= somewhat dissatisfied, 4= neutral, 5= somewhat satisfied, 6= satisfied, and 7= very satisfied. Whereas a lower number on the anxiety scale indicated less anxiety about the treatment choice, the response format contained; 1= much less anxious, 2= less anxious, 3= slightly less anxious, 4= no difference, 5= slightly more anxious, 6= more anxious, and 7= much more anxious. They found that participants in the EndoDB group (n=32) showed a significant increase in knowledge (P= 0.03, t-test) compared to the control group (standard discussion group) (n=35). No differences were found between groups regarding the measures of satisfaction or anxiety (Mann-Whitney U-test, P =0.82 and P =0.27 respectively). The authors concluded that the decision board was a useful tool in facilitating shared decision-making and evidence-based clinical practice (Johnson *et al.*, 2006), a copy of EndoDB is included as (Appendix A1). Although the study showed improvement in patients' knowledge regarding treatment options, a panel of dental professionals, not patients, determined what information was relevant. Probably, as noted by the authors, it would be better if they interviewed patients to discover the type and amount of information they need. A further limitation is that the questionnaires used had not previously been tested for reliability and validity. No other studies using the EndoDB PDA have been found in the dental literature.

The other study describing the use of a PDA in dentistry was a randomised controlled trial to evaluate the effect of a decision board on patients' knowledge and satisfaction with consultation in treatment of Class-II defects (Kupke *et al.*, 2012), a copy of this DB is included as Appendix A2. Five treatment options were available including; no therapy, amalgam, gold cost, composite, and ceramic restoration. The patient

questionnaire consisted of four questions regarding the patients' knowledge concerning the criteria covered by the DB, two questions concerning the patients' satisfaction with the consultation. The questions about 'survival rate', 'treatment time', 'costs' and 'self-payment' were open questions, whereas the question about 'characteristics' contained three single choice questions. The satisfaction with the consultation during the shared decision-making process was measured with a VAS scale (100-mm line, very unsatisfied – very satisfied). They found significant differences in total knowledge scores with 60% correct answers (mean= 10.04; SD= 3.5) in the DB group (n= 50), compared to 27% correct answers (mean= 4.16; SD= 2.5) in the non-DB group (n= 31) ( $p < 0.0001$ , Mann–Whitney U-test). No difference was found regarding satisfaction with the consultation between the DB group (mean= 91.4; SD= 12.5) and non-DB group (mean= 86.3; SD= 18.6) ( $p = 0.143$ , t-test). The authors concluded that the use of a decision board significantly improves the knowledge of patients about their chosen treatment option. However, this gain in knowledge does not improve their satisfaction with the consultation, and the lack of difference in patients' satisfaction was explained by the fact that the communication skills of dental students are not as distinct as those of more experienced dentists. No further details were provided of the reliability and validity of the measure used in this study. Kupke and colleagues recommended the use of decision boards in clinical practice to enable dentists to better communicate the different treatment options.

### **1.12 Decision-making in orthodontics**

Orthodontic treatment is different from many other healthcare interventions for several reasons; it is largely elective, takes an average of two years to complete, and in some healthcare systems financial contracts are established before starting treatment (Miller *et al.*, 2011). In addition, the success of treatment is highly dependent on patient cooperation, usually from young people aged 12 to 15 years accompanied by their parents (Bekker *et al.*, 2010; Nel and Dawjee, 2012; Naidoo, 2012). For all these reasons, it is vital for patients to have sufficient information about what treatment entails, and whether or not it will meet their expectations before they take the decision to undergo treatment (Bekker *et al.*, 2010).

Previous research has suggested that desirable outcomes of orthodontic treatment such as more satisfied patients, realistic understanding of the problem, and increased

adherence to treatment regimens, are more likely when patients have a good understanding of the treatment, are not anxious and have minimal pain and discomfort (Frost and Peterson, 1991; Bos *et al.*, 2003; Renz *et al.*, 2007; Bellani, 2008; Nel and Dawjee, 2012). While many educational resources are available, including the websites of the British Orthodontic Society and NHS Choice, studies have suggested that the content and form of this information is not sufficient to improve patients' knowledge about orthodontic treatment and conditions (Anderson and Freer, 2005; Patel *et al.*, 2008; Kang *et al.*, 2009). Indeed, in orthodontics, the resources to enable patient decision-making are extremely limited (as can be said for most dental treatments) when compared to other medical treatments (Bekker *et al.*, 2010).

A set of questions have been identified by Bekker and colleagues (2010) to help orthodontists to think about the effectiveness of the information they provide, which include;

1. What is the point of the information? To increase patients' awareness of the condition or treatment, to prepare them for treatment process, to help them making informed decisions about treatment or to improve compliance. The content of information should be suitable for each purpose, i.e. if information is intended to help patients make a choice it should equally present all available treatment options and their consequences. But if it is about the treatment procedure, then it should describe what will happen, when it is going to happen and what to expect.
2. Does your information enable understanding? Effective information should be clear, relevant and accurate. Thus resources need to be understandable and have good readability by orthodontic patients of all age groups. The authors suggested that this can be done by using concise language covering details of all treatment options (including no treatment option; risks and benefits of each option) this can be facilitated through the utilisation of figures, diagrams, photos, models and X-rays.
3. Does your information enable reasoning? Most written information is passive, but some techniques are available to enable patients to 'trade-off' between treatment options during the consultation stage. For example, 'Treatment A is quicker than Treatment B but the appearance will not be as good. Treatment C would give the best result, but would need more compliance than A or B, because you would be required to wear X, Y and Z for longer duration'. A range of simple techniques can be used to help

patients to share their own values and experiences, including rating scales, to allow patients to express the degree to which they want to undergo orthodontic treatment, tick boxes to indicate their feelings toward an option, and free-text space for patients to write what is important for them.

4. Does your information encourage patient involvement? Asking patients about their opinions and preferences should occur frequently in orthodontic practice; however, some patients may not easily interact and express their preferences. Various methods can be used to encourage patients to play a more active role in treatment, such as; promoting patients to address questions before their consultation, and providing cards with points that need to be covered during consultation.

5. Does your information enhance patients' oral hygiene skills? A higher level of oral hygiene is required from orthodontic patients, which can be enhanced through different techniques including practicing skills on models.

In summary, only information resources are currently available for patients considering orthodontic treatment and the development of a PDA would facilitate their involvement in the decision-making process and address some of the above posed questions.

Recently, Nel and Dawjee (2012) carried out a quantitative, exploratory study to determine whether a well-informed patient, who has been actively engaged in the decision-making process about orthodontic treatment, was more cooperative. The study included 13 orthodontic practices in South Africa. Questionnaires were handed to 256 patients undergoing orthodontic treatment for at least 3 months, aged 13 to 18 years old, and their parents, who were asked to complete them independently. However, no further details were mentioned about the questionnaire used, or the type of appliance the participants were wearing. The authors found that only 24% of patients reported that they had made the final decision to have treatment by themselves, whereas 72% of patients stated that they had not made their own final decision and had not taken part in the decision-making process. However, the report did not state the reason for excluding the remaining 4% of the sample from the analysis, which could be considered as another limitation in this study. Only 72% of children considered that they had been informed by their orthodontist about what to expect from treatment, although 94% indicated that they understood their treatment. This study found that patients who do not understand the orthodontic care they received were more dissatisfied with their treatment than

others who understood the treatment (15.4% versus 2.3%), and children who participated in the decision-making process were less discontented than those who had a decision taken for them (0.61% versus 8.45%). Nel and Dawjee (2012) concluded that enhancing cooperation in orthodontic patients can simply be gained through involving patients in the course of treatment. In order to improve doctor-patient communication, they suggested a “Formula for Success”. They recommend using effective communication methods and techniques with children of different stages of emotional development. Moreover, they suggested as a well-informed patient is a happy patient; educating patients using booklets, videos and observational learning was also recommended. Finally, keeping the patient’s discomfort as low as possible for example using low forces, pain killers and topical anaesthesia were also recommended (Nel and Dawjee, 2012).

### **1.13 Rationale for PhD study**

In the healthcare field ‘concordance’ has been defined as “an agreement reached after negotiation between a patient and a healthcare professional that respects the beliefs and wishes of the patient in determining whether, when and how medicines are to be taken” (Horne *et al.*, 2005). This term has been introduced to replace the term ‘compliance’ which refers to the extent to which patients follow the regimens recommended by their doctors (Pollock, 2005).

Within medical care, there has been a shift in thinking from compliance to concordance which is based on a shared decision-making model. For many medical interventions this has been facilitated by the development and implementation of PDAs. It has been suggested that decision aids facilitate patients involvement in the decision-making by provide them with the information they need and enabling them to consider their own values or preferences for particular treatments or outcomes (Estabrooks *et al.*, 2001; Barry, 2002). Results from a systematic review by Gravel *et al.* (2006) and updated by Legare *et al.* (2008) showed how rapidly the knowledge base of this relatively new research field is growing. Shared decision-making, as a topic of interest, is gaining recognition in more diverse cultures and healthcare systems.

PDAs have been shown to be effective at improving patient-clinician interaction, reducing the number of patients who are uncertain about their decision (decisional conflict), improving patients’ knowledge, creating more realistic expectations about

outcomes, and increasing peoples' participation in decision-making (Stacey *et al.*, 2014).

In order to enhance orthodontist-patient relationship and facilitate involvement of patients contemplating orthodontic treatment in the decision-making process, the development of a PDA for orthodontic therapy is required. The current literature in the field of orthodontics advocates the use of several methods to improve cooperation among orthodontic patients, and spending time with patients to explain its importance during orthodontic treatment (Aljabaa *et al.*, 2014). Recent studies noted that enhancing the relationship between the orthodontist and patient through effective communication and encouraging patient participation in choosing the best treatment alternative is essential for successful orthodontic treatment (Souza *et al.*, 2013; Schäfer *et al.*, 2014). The lack of communication between the orthodontist and the patient, and insufficient information about orthodontic treatment can increase discontinuation rates (Brattström *et al.*, 1991), result in failure or dissatisfaction with the treatment results (Keles and Bos, 2012; Souza *et al.*, 2013), as well as premature termination of the treatment (Nel and Dawjee, 2012). However, there has not been a systematic review looking at the factors associated with concordance with orthodontic treatment.

Orthodontics usually involves long-term care, therefore, prior to the commencement of treatment, particularly for children, orthodontists should outline the various options available, including the benefits and risks, as well as the consequences of no treatment (Mouradian *et al.*, 1999). Hence, it is important to involve the child in the decision-making process, as far as age and abilities allow, because he or she will be more cooperative when informed and in agreement with the treatment (Adewumi *et al.*, 2001; Naidoo, 2012).

Switching from the traditional practitioner-centred care to the patient-centred approach can be done by increased patient involvement in decision-making (Sinha, 2010). Therefore, to move from compliance to concordance in orthodontic treatment, there is a need to improve patient-clinician interaction and the involvement of patients in the decision-making process in order to educate patients and ensure that they achieved full comprehension about what to expect from orthodontic treatment.

The development of a PDA for patients considering orthodontic treatment will facilitate shared decision-making and improve concordance, as decision aids have been shown to

increase patient participation in the decision-making process when compared to usual care (Stacey *et al.*, 2014). Therefore the aim of the study is to investigate any shift in emphasis from compliance to concordance within the orthodontic literature, then develop and carry out an initial evaluation of a patient decision-aid for children considering fixed orthodontic appliance treatment.

The specific objectives of the study:

1. To conduct a systematic review of the orthodontic literature to identify the factors associated with concordance and compliance with orthodontic treatment and to establish the status of the research in this field and the degree to which the shift has been reflected in the literature.
2. To use a child-centred approach to develop a Patient Decision Aid for children considering fixed orthodontic appliance treatment to facilitate shared decision-making and improve patient-clinician interaction.
3. To undertake an initial evaluation of the PDA in reducing decisional conflict, increasing knowledge and meeting expectations in children and parents considering fixed orthodontic appliance treatment.

## **2 CHAPTER TWO: FACTORS ASSOCIATED WITH CONCORDANCE WITH ORTHODONTIC TREATMENT - A SYSTEMATIC REVIEW**

The aim of this systematic review was to identify factors that have been studied in the literature associated with the concept of concordance in its broadest sense with orthodontic treatment of children. From the literature review described in chapter one, few references to concordance were observed. This systematic review was conducted to establish the degree to which the shift in thinking from compliance to concordance has been embraced in the orthodontic literature. The review included factors associated with concordance as well as its defining characteristics including clinician-patient interaction. During the review, aspects of orthodontic treatment found to be relevant to patients were identified to aid the development of the PDA.

### **2.1 Objectives**

- To systematically search for studies that identified factors related to patient concordance and compliance with orthodontic treatment of children
- To critically appraise these studies
- To determine the nature of the association between these factors and concordance and compliance
- To establish the degree to which research in orthodontics has considered the concept of concordance and its defining characteristics
- To investigate factors that are important to patients for inclusion in the PDA

### **2.2 Methods**

#### **2.2.1 Inclusion criteria**

In order to identify all relevant studies in relation to concordance and compliance with orthodontic treatment this review included studies describing primary data on factors influencing concordance and compliance during active orthodontic treatment with patients aged 18 years old or younger. Only English language journal articles were included. Studies that concerned the wearing of retainers or interventions to improve compliance or concordance were excluded. The decision to exclude studies

investigating interventions to improve compliance with orthodontic treatment was based on the rationale described in the systematic review conducted by Jin and colleagues, namely that the interventions were evaluated under close supervision and therefore the findings cannot necessarily be generalised (Jin *et al.*, 2008). However, these studies have been mentioned in section 1.7.2.

In summary, the included studies:

- measured concordance or compliance with orthodontic treatment in humans
- described primary data
- involved participants of 18 years old or younger, or studies where this age group was analysed separately
- were published in English

### **2.2.2 Exclusion criteria**

The following exclusion criteria were applied:

- in vitro studies
- studies using retainers
- studies involving patients wearing headgear
- conference proceedings
- case reports
- studies of orthognathic surgery
- studies involving patients with craniofacial anomalies
- studies describing interventions to improve concordance or compliance

### **2.2.3 Databases**

To find the relevant articles, the search strategy was performed using the following databases: Web of Science 1899-2011, Medline (Ovid) 1948-2011, PsycINFO 1806-2011, The Cochrane Library (Including Cochrane Systematic Reviews and DARE) 1991, Social Sciences Citation Index via Web of Knowledge, SCOPUS 1966, EMBASE, and Index to theses.

### **2.2.4 Search strategy**

As shown in section 1.4.2 previous systematic reviews of factors associated with non-compliance with healthcare regimens identified the importance of the doctor-patient

relationship, involving patients in decisions about their care, and the patients' understanding the need for and consequences of treatment. While the systematic reviews were concerned with compliance, these factors are relevant when considering the defining characteristics of concordance. However, it is important to note that when the decision was made to include search terms related to compliance it was not the intention to endorse the use of this concept.

Therefore, in order to capture all the potentially relevant studies on concordance or compliance the following key words were used: Complian\* OR noncomplian\* OR non-complian\*/ Concordan\* OR nonconcordan\* OR non-concordan\*/ Cooperat\* OR cooperat\*/ Adheren\* OR nonadheren\* OR non-adheren\* and Orthodontic-related words: Orthodont\*.

The search results were downloaded (Endnote Web 3.3) and duplicates removed. Initial screening of titles and abstracts was undertaken independently by two reviewers to identify studies that should be included in the review. Articles that failed to meet the inclusion criteria were excluded. Articles that passed the preliminary screening were retrieved in full and data extracted by two reviewers onto a specially designed spreadsheet (Appendix C1). Articles that failed to meet the inclusion criteria at this stage were excluded. Any disagreement was settled through discussion between reviewers.

### **2.2.5 Data extracted**

The data to be extracted were chosen based on the systematic review conducted in healthcare more generally (Jin *et al.*, 2008) who grouped the factors identified into three main categories; socio-demographic factors, individual characteristics, and therapy-related factors. Data were extracted about the quality of the conduct of the studies, the assessment of the concepts and factors associated with them. The main author (AE) extracted the data from all the included studies. This process was then independently duplicated by the other two members of the research team, with ZM extracting data from one half of the included studies and PB extracting data from the other half of the included studies.

### **2.2.6 Training**

Prior to data extraction the reviewers undertook a training exercise. Ten abstracts were retrieved and all three authors extracted the data and compared their decisions regarding

inclusion and extracted data to assess the level of agreement. The same procedure was then performed with ten full papers.

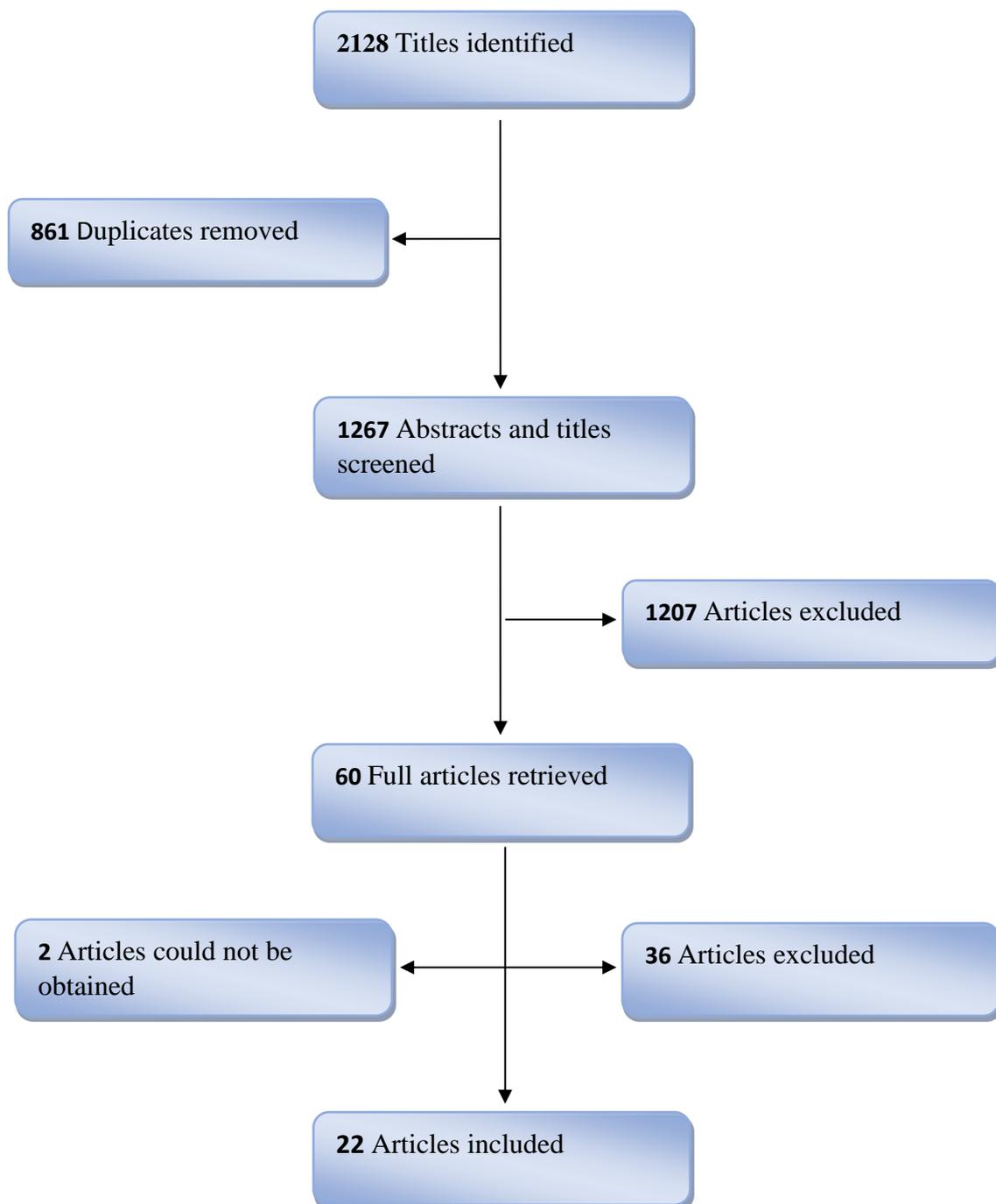
### **2.2.7 Statistical analysis**

Due to the heterogeneity of the methods used to measure concordance and compliance and the large number of potentially influential factors meta-analyses were not undertaken and the analysis is descriptive.

## **2.3 Results**

The level of agreement between reviewers was high, disagreement about the inclusion of papers was found in only 28 articles from the total list of 1267 articles (97.7% agreement). Levels of agreement between pairs of reviewers were 97.5% (617 from 633), and 98.0% (621 from 634).

The flow of articles through the review is shown in Figure 2. The execution of the search strategy performed on November 2011 week 1 produced a total of 2128 papers; Medline Ovid (n= 490), PsycINFO (n= 22), Web of Science (n= 1276), Scopus (n= 158), Social Sciences Citation Index (n= 182). After removing duplicates (n= 861), the number of studies for screening was 1267. Two reviewers screened the titles and abstracts against the criteria and 60 papers resulted. After obtaining these full articles a further 36 papers were excluded, and two papers could not be obtained. The final number of articles included was 22, from which the data were extracted.



**Figure 2: Flowchart outlining the included and excluded articles in the systematic review**

### **2.3.1 Terminology used and methods of measurement**

Three different terms were used in the included studies; compliance, cooperation, and adherence. The term ‘compliance’ was used in 13 out of the 22 included articles (59%), the term ‘cooperation’ was used in 8 articles (36%), and in only one study was the term ‘adherence’ used. No studies used the term concordance. In no studies were the terms compliance, cooperation or adherence defined.

Four types of compliance measures were used; these could be broadly described as orthodontists’ ratings, data from clinical records, patient and parent questionnaires. The orthodontist rating was usually performed through completion of the Orthodontic Patient Cooperation Scale (OPCS) derived by Slakter *et al.* (1980) which was developed specifically to study adolescent cooperation in orthodontic treatment. The OPCS consists of a list of ten patient behaviours that were considered by orthodontists as important variables in evaluating patient’s cooperation. Data from clinical records were used to evaluate patient compliance included punctuality with appointments, numbers of broken appointments, maintenance of good levels of oral hygiene, incidence of broken appliances (including broken arch wires and loose bands), wearing of headgear and elastics, and adherence to dietary recommendations. Various different self-reported patient and parent measures have been developed by different authors to measure compliance during orthodontic treatment. For example, Daniels and colleagues (2009) distributed different questionnaires to patients and their parents undergoing orthodontic treatment compared to those patients at their initial appointments. Similarly, Bartsch and colleagues (1993) utilised several patient and parental psychological inventories that were developed through in-depth interviews and evaluated by pretesting involving clinical and in-practice samples. The different measures used to assess patient’s level of compliance are described in Appendix C2.

In 19 out of 22 studies (86%) orthodontists rated the patients’ level of compliance. Data from clinical records were used in 6 articles (27%) (two as the main compliance measure, and in four articles it was used together with an orthodontist’s rating). Patient and parent questionnaires were used together in only two studies (9%) (one of them in addition to an orthodontist rating).

Only two studies used theoretical models to inform the choice of factors to be included in the data collection. El-Mangoury (1981) used the ‘El-Mangoury psychological test’,

and Lee *et al.* (2008) used the 'Locus of Control theory'. In no studies was concordance measured.

### **2.3.2 Assessment of the quality of the included studies**

The research methods used and methodological quality assessments are shown in Table 3. No suitable tool was found to assess the quality of studies with different methodological designs; therefore we developed a simple tool through discussion and consensus. The most frequent research design was a cross-sectional study (n= 15, 68%). One study used case note review, and 6 studies (27%) used a longitudinal design. Of the 22 papers, 12 studies were conducted in the USA, 6 in Germany, 2 in the UK, 1 in Korea, and 1 in Egypt. The mean number of participants was 147, but ranged from 30 to 561 orthodontic patients. Only one study was informed by a sample size calculation.

The type of appliance worn by participants was not specified in 12 studies (54.5%). Participants were wearing fixed orthodontic appliances only in five studies (22.7%) and removable appliances only in two studies. In three of the included studies (13.6%) all three types of appliances (fixed, removable and functional) were worn by participants.

Eight studies (36%) used bivariate analyses and 13 studies (59%) used multivariate analyses, one study used both bivariate and multivariate analyses.

**Table 3: Research design and methodological quality of each of the included studies**

Study	Country	Research Design	Participants	Theoretical model	Type of appliance worn by participant	Sample size calculation	Statistical analysis
(Albino <i>et al.</i> , 1991)	USA	Longitudinal	39	No	Fixed	No	Multivariate
(Allan and Hodgson, 1968)	USA	Cross sectional	30	No	Not specified	No	Multivariate
(Amado <i>et al.</i> , 2008)	USA	Cross sectional	70	No	Not specified	No	Bivariate
(Bartsch <i>et al.</i> , 1997)	Germany	Cross sectional	210	No	Removable	No	Multivariate
(Bartsch <i>et al.</i> , 1993)	Germany	Cross sectional	77	No	Removable	No	Multivariate
(Cucalon and Smith, 1990)	USA	Cross sectional	252	No	Not specified	No	Multivariate
(Daniels <i>et al.</i> , 2009)	USA	Cross sectional	227	No	Fixed	No	Both
(Dickens <i>et al.</i> , 2008)	USA	Case note review	85	No	Fixed	No	Bivariate

Study	Country	Research Design	Participants	Theoretical model	Type of appliance worn by participant	Sample size calculation	Statistical analysis
(Doll <i>et al.</i> , 2000)	Germany	Cross sectional	67	No	Removable, fixed, functional	No	Multivariate
(El-Mangoury, 1981)	Egypt	Longitudinal	70	Yes	Fixed	No	Multivariate
(Lee <i>et al.</i> , 2008)	Korea	Longitudinal	561	Yes	Not specified	No	Bivariate
(Mandall <i>et al.</i> , 2008)	UK	Longitudinal	144	No	Not specified	Yes	Multivariate
(Miller and Larson, 1979)	USA	Cross sectional	90	No	Not specified	No	Bivariate
(Sergl <i>et al.</i> , 1992)	Germany	Cross sectional	94	No	Not specified	No	Multivariate
(Sergl <i>et al.</i> , 1998)	Germany	Longitudinal	84	No	Removable, fixed, functional	No	Bivariate
(Sergl <i>et al.</i> , 2000)	Germany	Cross sectional	84	No	Removable, fixed, functional	No	Bivariate

Study	Country	Research Design	Participants	Theoretical model	Type of appliance worn by participant	Sample size calculation	Statistical analysis
(Sinha <i>et al.</i> , 1996)	USA	Cross sectional	199	No	Not specified	No	Multivariate
(Southard <i>et al.</i> , 1991)	USA	Cross sectional	104	No	Not specified	No	Multivariate
(Starnbach and Kaplan, 1975)	USA	Cross sectional	362	No	Not specified	No	Bivariate
(Woollass <i>et al.</i> , 1988)	UK	Longitudinal	219	No	Not specified	No	Bivariate
(Gross <i>et al.</i> , 1988)	USA	Cross sectional	75	No	Fixed	No	Multivariate
(Nanda and Kierl, 1992)	USA	Cross sectional	100	No	Not specified	No	Multivariate

### **2.3.3 Factors associated with compliance**

As no studies were identified regarding concordance, the factors associated with compliance will now be described.

The significant factors associated with compliance will be summarised according to whether bivariate or multivariate analyses were undertaken. Where both types of analyses were undertaken the results from the multivariate analysis are quoted. The separation of studies according to type of analysis was chosen because studies that undertook a multivariate analysis were generally considered to be of higher quality than studies undertaking a bivariate analysis, as they attempted to account for confounding factors. For each study, P-values are given where these were quoted in the papers. In describing the included studies, the main term employed by the authors to describe compliance will be used.

#### ***2.3.3.1 Factors identified from bivariate analyses***

Eight of the included studies used bivariate analyses alone. The factors identified have been grouped into three broad categories: socio-demographic, individual characteristics and treatment factors.

##### **2.3.3.1.1 Socio-demographic factors**

The socio-demographic factors identified from the included studies are shown in Table 4.

###### ***2.3.3.1.1.1 Age***

Amado and colleagues (2008) conducted a prospective study to investigate patient cooperation in a sample of 70 adolescents (age range between 12 and 16 years) receiving active orthodontic treatment. The main outcome measure was the Orthodontic Patient Cooperation Scale (OPCS), as determined by their clinician. No significant relationship was found between the patient's age and cooperation with treatment according to the OPCS scores ( $P = 0.800$ , chi-squared test).

###### ***2.3.3.1.1.2 Gender***

Results from two studies regarding gender were contradictory. In a cross sectional study ( $n = 362$ ), Starnbach and Kaplan (1975) found a significant relationship between gender of the patient and cooperation ( $P = 0.01$ , chi-squared test). Female participants were found to be better 'cooperators' than males, with 71% of cooperative patients being females. However, a more recent but smaller study ( $n = 70$ ) by Amado and colleagues

(2008) failed to confirm the influence of patient's gender on compliance with orthodontic treatment ( $P = 0.09$ , chi-squared test).

#### *2.3.3.1.1.3 Socio-economic status*

Starnbach and Kaplan (1975) found a significant relationship between father's occupation and patient cooperation ( $n = 362$ ,  $P = 0.01$ , chi-squared test). They concluded that children of non-self-employed fathers, and fathers in farming and labourers tended to be more cooperative patients. They also reported that patients from rural and industrial areas cooperated better than patients from high socioeconomic areas. No significant associations were found between family income and patient cooperation.

#### *2.3.3.1.1.4 Medicaid vs non-medicaid*

One study found no significant differences between the compliance of those patients whose orthodontic treatment was funded by private insurance (Medicaid) versus publicly funded treatment ( $n = 85$ ) (Dickens *et al.*, 2008). However, only descriptive information was available with no details of any statistical tests performed.

#### *2.3.3.1.1.5 Religion*

Starnbach and Kaplan (1975) found a significant relationship between orthodontic patient cooperation and type of religion. Patients whose religion was Protestant or Catholic were found to be 'excellent' cooperative patients ( $n = 362$ ,  $P = 0.01$ , chi-squared test). However, no further explanation was given by authors regarding the mechanism of the effect of religion on levels of compliance.

#### *2.3.3.1.2 Individual characteristics*

Several individual characteristics of patients were investigated namely personality traits and locus of control (Table 5).

##### *2.3.3.1.2.1 General personality factors*

Amado and colleagues (2008) studied the relationship between personality traits such as 'introversion', 'extroversion', 'adjustment', 'anxiety', 'receptiveness', 'hard mentality', 'uninhibited', 'self-controlled', 'accommodating' and 'independent' and cooperation of adolescent orthodontic patients ( $n = 70$ ). They concluded that none of these personality traits were associated with patient cooperation during orthodontic treatment as measured using OPCS ( $P < 0.05$ , chi-squared test).

#### 2.3.3.1.2.2 *Locus of control (LOC)*

Locus of control refers to the individual's perception of reinforcement; either internal due to their own behaviour or outside of their control. In a prospective study, Lee and colleagues examined the relationship between compliance and locus of control using the LOC- Rotter Internal Control Scale (RICS) and Nowicki Strickland External Control Scale (NSECS), in a group of 561 orthodontic patients before and after treatment. No significant differences were found between those classified as good and poorly compliant patients and LOC orientation (RICS,  $P = 0.822$  and NSECS,  $P = 0.438$ , independent  $t$  test). They concluded that patient compliance as measured using orthodontist and hygienists rating cannot be predicted by LOC (Lee *et al.*, 2008).

Woollass and colleagues (1988) investigated whether several individual characteristics were predictors of cooperation with orthodontic treatment in children ( $n = 219$ ). The characteristics included were child self-concept, child attitude towards aggression, and parents and teachers assessment of emotional or behavioural problems exhibited by the child. They reported that of the 147 variables examined, significant differences were found in only ten variables ( $P < 0.05$ ). They concluded that predictors of cooperation included increased self-concept and specific patient characteristics, such as ability to hide anger, difficulty speaking up in class, and those who did not want to run away from home. Other predictors included teacher's rating of how academically bright the child is and parents assessments of the child's tendency to tell lies, truancy from school, likelihood to steal, and level of disobedience (Woollass *et al.*, 1988). However, the reporting of this study made meaningful interpretation difficult.

#### 2.3.3.1.3 Treatment factors

The third category of factors was those factors relating to the orthodontic treatment itself (Table 6).

##### 2.3.3.1.3.1 *Motivation towards treatment*

Daniels and colleagues (2009) performed a cross-sectional questionnaire survey examining orthodontic treatment motivation and cooperation among 227 child and adolescent patients treated with fixed orthodontic appliances. They found that those with higher patient treatment motivation had higher levels of patient perceived cooperation during the course of treatment ( $P < 0.001$ , MANOVA).

#### *2.3.3.1.3.2 Attitude towards malocclusion*

Woolass and colleagues (1988) found that a child's attitudes towards dental health and malocclusion did not show an important influence on their compliance during orthodontic treatment, however, the authors of this study did not explain this finding in sufficient details for it to be meaningful.

Miller and Larson (1979) developed the Orthodontic Attitudinal Test Survey, to investigate the relationship between compliance and attitude towards orthodontics including, alteration of appearance due to the visibility of the appliance, the willingness of the child to undergo orthodontic treatment (named 'authority') and the discomfort or pain produced by the orthodontic appliances. The OATS was administered to 30 noncompliant children, 30 compliant children, and another 30 unclassified patients. They found no significant relationship between compliance and appearance of the orthodontic appliance, or with the compliant and noncompliant patients with regard to attitude to 'authority' confirming the hypothesis that, patients who are willing to undergo orthodontic treatment show more compliance than those who are not willing to undergo treatment.

#### *2.3.3.1.3.3 Patient perceptions of discomfort*

Sergl and colleagues (2000) studied the effect of functional and social discomfort on patient's compliance during orthodontic treatment in 84 orthodontic patients treated with removable, functional, or fixed appliances. The Orthodontic Patient Cooperation Scale (OPCS) was used by clinicians to rate the patient's level of compliance. They found a significant correlation ( $r = -0.27$ ,  $P < 0.05$ , Spearman correlations) between social discomfort (lack of confidence in public) and compliance. However, no significant association was found between functional discomfort (impaired speech, impaired swallowing, and oral constraints) from orthodontic appliances and level of patient compliance, indicating that impaired oral function is less likely to have an influence on compliance. However, in a previous study Sergl and colleagues (1998) explored the effect of pain and discomfort from the orthodontic appliances on patients' compliance during orthodontic treatment, and reported a significant negative correlation ( $n = 84$ ,  $r = -0.27$ ,  $P < 0.05$ , Pearson correlation coefficient) between compliance and long term complaints. They concluded that the level of compliance improved with decreasing intensity of complaints.

**Table 4: Results of socio-demographic factors from bivariate analyses**

Variable	Significant	Non-significant
Age		Amado <i>et al.</i> 2008
Gender	Starnbach and Kaplan, 1975	Amado <i>et al.</i> 2008
Socio-economic status		
Income		Starnbach and Kaplan, 1975
Occupation of father	Starnbach and Kaplan, 1975	
Neighbourhood	Starnbach and Kaplan, 1975	
Medicaid vs non-medicaid		Dickens <i>et al.</i> 2008
Religion	Starnbach and Kaplan, 1975	

**Table 5: Results of individual characteristics from bivariate analyses**

Variable	Significant	Non-significant	Inconsistent
Personality traits			
Introverted		Amado <i>et al.</i> 2008	
Extroverted		Amado <i>et al.</i> 2008	
Adjustment		Amado <i>et al.</i> 2008	
Anxious		Amado <i>et al.</i> 2008	
Receptiveness		Amado <i>et al.</i> 2008	
Hard mentality		Amado <i>et al.</i> 2008	
Uninhibited		Amado <i>et al.</i> 2008	
Self-controlled		Amado <i>et al.</i> 2008	
Accommodating		Amado <i>et al.</i> 2008	
Independent		Amado <i>et al.</i> 2008	
Locus of control			
LOC-Rotter internal control scale (RICS)		Lee <i>et al.</i> 2008	
LOC-Nowicki Strickland external control scale (NSECS)		Lee <i>et al.</i> 2008	
Child behaviour as judged by parent or teacher			Woolass <i>et al.</i> 1988
Child Self-concept	Woolass <i>et al.</i> 1988		
Attitude towards aggression			Woolass <i>et al.</i> 1988

**Table 6: Results of treatment factors from bivariate analyses**

Variable	Significant	Non-significant
Motivation toward treatment	Daniels <i>et al.</i> 2009	
Attitude towards malocclusion		Woolass <i>et al.</i> 1988
Attitude (authority)	Miller and Larson, 1979	
Attitude (appearance)		Miller and Larson, 1979
Attitude (invasion)		Miller and Larson, 1979
Long term complaints	Sergl <i>et al.</i> 1998	
Impaired speech		Sergl <i>et al.</i> 2000
Impaired chewing and swallowing		Sergl <i>et al.</i> 2000
Oral constraints		Sergl <i>et al.</i> 2000
Lack of confidence in public	Sergl <i>et al.</i> 2000	

### **2.3.3.2 Factors identified from studies using multivariate analyses**

Fourteen of the 22 included articles used multivariate analyses to explore the association between compliance and factors that are proposed to have a potential influence during orthodontic treatment.

#### **2.3.3.2.1 Socio-demographic factors of patients**

The socio-demographic factors identified from the included studies are shown in Table 7.

##### **2.3.3.2.1.1 Age**

A cross sectional questionnaire survey (n= 30) was conducted of orthodontic patients (aged 12 to 18 years) from middle-class families undergoing orthodontic treatment for at least one year (Allan and Hodgson, 1968). They found that age was significantly and negatively related with cooperation level ( $r = -0.51$  and  $p = 0.01$ , regression analyses) with younger patients being more cooperative than older ones. Bartsch and colleagues investigated patient compliance in a cross sectional study (n= 77) of patients treated with bionators with built-in timing devices to measure wearing time. Partial correlation analysis revealed a complex relationship between patient's age and cooperation (regression coefficient =  $-0.172$ ) and they concluded that age was significantly correlated with cooperation in the wearing of removable appliances (Bartsch *et al.*, 1993).

Southard and colleagues (1991) evaluated orthodontic patient compliance in 13 to 18 year olds (n= 104) and found that age was not a statistically significant predictor of compliance; however, the authors did not provide details of the statistical methods used or quote any P values. Nanda and Kierl (1992) studied patient cooperation in 100 adolescent orthodontic patients (age ranged from 9 to 16 years). They found no significant relationship between cooperation and age. More recently, Mandall and colleagues (2008) conducted a survey (n= 144) to explore the association between compliance with orthodontic therapy and quality of life and included age. Age was not significantly correlated with patient compliance ( $P > 0.05$ , multiple linear regression analysis). However, quality of life was measured using the oral aesthetic subjective impact score rather than using a measure developed based on a theoretical model of health.

#### 2.3.3.2.1.2 Gender

In the five studies retrieved concerning gender, the results were contradictory. Some investigators found that the gender of the patient was influential on compliance during treatment, with females being more cooperative than males. Cucalon and Smith (1990) conducted a prospective survey (n= 252, 11 to 17 year olds) using clinical records to categorize patients according to their compliance level. They found that the gender of the patient was an important factor in predicting compliance with orthodontic treatment ( $P < 0.002$ , chi-squared test), girls showed better levels of compliance than boys. This was consistent with the results of other studies including Southard *et al.* (1991) (n= 104, no P value quoted, backward elimination procedure) and Daniels *et al.* (2009) (n= 227) who found gender to be significantly associated ( $P = 0.008$ , MANOVA) with orthodontic compliance (girls more cooperative than boys).

In contrast, Mandall and colleagues (2008) (n= 144), found that the gender of the patient was not a significant factor in predicting patient compliance with orthodontic treatment ( $P > 0.05$ , multiple linear regression analysis). Nanda and Kierl (1992) (n= 100) suggested that females may be slightly more cooperative than males; however there was a low moderate association with cooperation (-0.26, stepwise regression analysis), and they concluded that gender did not have a significant relationship with cooperation of the patient.

#### 2.3.3.2.1.3 Socioeconomic status

Results regarding socioeconomic status were also inconsistent. Cucalon and Smith (1990) used the Home Index to evaluate the socioeconomic status of the patients (n= 252). They found that patients with higher scores indicating higher socioeconomic status showed better compliance levels ( $P < 0.002$ , chi-squared test). They concluded that females of high socioeconomic status showed highest compliance levels, whereas, males of low socioeconomic status exhibited poor levels of compliance during orthodontic treatment. Conversely, Mandall *et al.* (2008) used Townsend deprivation scores based on patient's postcodes and found no significant association between socioeconomic status and patient's compliance ( $P > 0.05$ , multiple linear regression). Similar finding were previously reported by Nanda and Kierl (1992) who concluded that socioeconomic background cannot be used to predict patient cooperation during orthodontic treatment.

#### *2.3.3.2.1.4 Parents' marital status*

According to Nanda and Kierl (1992), no significant relationship was identified between the marital status of parents and patient cooperation with orthodontic therapy. However, only descriptive information was available with no details of the P value or statistical test cited regarding the influence of parental marital status and patient's cooperation.

#### *2.3.3.2.1.5 Family rapport*

Southard and colleagues (1991) evaluated the influence of family rapport on compliance with orthodontic treatment through measuring the feelings of conflict in the family setting, and they found that patient-parent relationship was not a statistically significant predictor of patient compliance. However, Bartsch and colleagues (1993) found from a regression analysis that compliance with the wearing of a removable appliance was significantly associated with patient's perception of both parental supervision and parental interest in treatment, (beta weight = 0.168 and 0.479 respectively).

#### 2.3.3.2.2 Individual characteristics

The individual characteristics of patients identified from the included studies are shown in Table 8.

##### *2.3.3.2.2.1 General personality factors*

Although Allan and Hodgson (1968) reported that patient cooperation was significantly associated with dominance, autonomy, and achievement (P = 0.01, 0.01, and 0.001 respectively, stepwise regression analysis), Nanda and Kierl (1992) investigated the correlations between psychosocial factors including attitude toward treatment, social desirability, need for approval, and need for achievement and patient's compliance, they concluded that personality characteristics did not prove to be significant predictors of cooperation during treatment. Similarly, Sergl and colleagues (1992) carried out a prospective study to determine to what extent social and psychological characteristics of patients (dominance, impulsiveness, general anxiety, and orthodontic attitude) can be used to predict their level of compliance during orthodontic treatment in a sample of 94 orthodontic patients. Orthodontists used the OPCS to assess participants' level of compliance. They found that general anxiety significantly predicts patient cooperation during first three months of treatment (P < 0.05, stepwise regression analysis) with more anxious patients being less cooperative, but has no significant association with compliance level after six months of treatment. In addition, 'impulsiveness' (i.e. being more impulsive) was shown to be a non-significant predictor of cooperation in the first

three months of wearing an appliance, but it can significantly predict compliance after six months of treatment ( $P < 0.01$ , stepwise regression analysis). However, the results of a previous study by Southard *et al.* (1991) revealed that impulse control was not a statistically significant predictor of compliance. Finally, 'dominance' (i.e. being more dominant) did not show a significant correlation with cooperation in 6 months treatment duration.

Southard and colleagues (1991) used the Millon Adolescent Personality Inventory (MAPI) by Millon *et al.* (1982) to measure three categories of personality namely; personality style, expressed concern, and behavioural correlate and their relation with compliance. Among the 20 variables measured, they found a significant association with being sensitive, being sociable, being forceful, and confidence from the personality styles category, two variables from behavioural correlates category (social conformity and scholastic achievement), and peer security from the expressed concern category. They also found that scholastic achievement was a significant and positive predictor of compliance. Whereas, academic confidence which is part of the expressed concern scale that measures feelings of inadequate scholastic performance, as well as school attendance consistency (behavioural correlate) which measures absence from school because of psychosocial reasons, were found to be non-significant predictors of patient compliance.

Southard and colleagues (1991) also stated that other variables including; introversion, inhibition, cooperation, respectfulness (personality styles category), self-concept, personal esteem, body comfort, sexual acceptance, social tolerance, family rapport, academic confidence (expressed concern category), impulse control, and attendance consistency (behavioural correlate category) were found to be non-significant predictors of compliance with orthodontic treatment.

Gross and colleagues (1988) measured self-esteem and its relationship with compliance during treatment with fixed and functional orthodontic appliances in a group of 75 children aged 8 to 14 years, using the Perceived Competence Scale for Children by Harter (1982), which measures 4 subscales of global self-worth, cognitive competence, social competence, and physical competence. Among the four subscales measured, Gross and colleagues found that only the cognitive competence was significantly related to patient's level of compliance ( $P < 0.02$ , ANOVA). Compliant patients scored higher on self-perceived cognitive competence.

#### 2.3.3.2.2.2 *Peer influences*

Southard and colleagues (1991) studied peer influences on a patient's compliance (n=104) aged 13-18 years old and stated that peer security (concerns about peer group affiliation) is an important indicator of compliance in adolescent patients, probably because adolescents usually see orthodontic treatment as a badge of social acceptance, (no P value quoted, multiple regression analysis). Conversely, Nanda and Kierl (1992) reported that patient's orientation toward peers is not proved to be a significant predictor of patient cooperation (correlation coefficient less than 0.1).

#### 2.3.3.2.2.3 *Locus of control*

Albino and colleagues (1991) investigated locus of control and cooperation. They found that two sources of perceived control namely external-chance and external powerful others (professionals) were negatively correlated with longer term cooperation (P < 0.01, multiple regression analysis) suggesting that patients who are influenced by others (rather than those with internal control orientation) are less likely to cooperate with treatment. These findings are also supported by Bartsch *et al.* (1993) who reported that there is a close relationship between external locus of control and adherence in wearing of removable orthodontic appliances (B-weight = 0.209, multiple regression analysis).

#### 2.3.3.2.2.4 *Perceived self-image*

No significant relationship was found between cooperation and self-image by Albino *et al.* (1991). They also looked at several specific aspects of self-concept (self-consciousness, stability of self-evaluation, self-esteem, perceived self-image, and depressive affect) which were not good predictors of cooperation of adolescent patient with orthodontic treatment.

#### 2.3.3.2.2.5 *Sensory perception of colour*

Bartsch and colleagues (1997) explored the significance of predicting cooperation through a Luscher colour test, a psychological test based on colour preferences by patients to reflect different aspects of personality. The theory behind this test, as explained by Luscher (1971), is that the selection of preferred colours is guided in an unconscious manner and so present individuals as they really are, not as they would like to be perceived. The sample studied comprised of 210 orthodontic patients aged 9 to 16 years and treated with a removable appliance for minimum of six months. Patient's cooperation prognosis was derived and compared with clinician's assessment of compliance. No significant association was found between colour preferences and

patient compliance ( $P = 0.10$ , multiple regression analysis). Bartsch and colleagues concluded that the Luscher colour test cannot be used to rate patient's level of compliance in clinical orthodontic practice.

Other scales such as Self Report Inventory, Adolescent Alienation Index, and Home Index were used by Cucalon and Smith (1990) to test their association with orthodontic patient compliance, and no significant relationship were identified.

#### 2.3.3.2.3 Treatment factors

Treatment factors identified from the included studies are shown in Table 9.

##### 2.3.3.2.3.1 *Orthodontist-patient relationship*

Nanda and Kierl (1992) found the perceptions of patients and parents of the orthodontist-patient relationship to be significant predictors of cooperative behaviour ( $R^2$  ranged between 0.1129 and 0.2039). These results are also supported by Bartsch and colleagues (1993) who found a significant correlation between provider role pattern (high dominance and verbal activity) and compliance with wearing of removable orthodontic appliances in 77 orthodontic patients aged 9 to 15 years old treated with a functional appliance (bionators) ( $B\text{-weight} = 0.234$ , multiple regression analysis). They concluded that better compliance was found in patients who felt comfortable during the session of treatment and who are not treated by a hurried orthodontist. Also, Sinha *et al.* (1996) evaluated the effect of patient perceived orthodontist behaviours on orthodontist-patient relationship and adherence in orthodontic treatment. A sample of 199 orthodontic patients aged 8 to 17 years were asked to assess orthodontists behaviour including politeness, friendliness, communicativeness, and empathy. Similarly, the levels of patient cooperation were assessed by treating orthodontists using OPCS. They found that politeness toward the patient can significantly predict their cooperation level ( $P < 0.05$ ), and doctor's criticisms of patient's teeth and how he/she has been taking care of them was significantly and negatively correlated with patient adherence ( $P < 0.05$ ). They concluded that establishing a good rapport with the patient will influence patient cooperation.

##### 2.3.3.2.3.2 *Type of appliance*

In their study, Mandall and colleagues (2008) reported that the type of appliance did not show a significant association with compliance during orthodontic therapy ( $n = 144$ ,  $p > 0.05$ , multiple linear regression analysis).

#### 2.3.3.2.3.3 *Duration of treatment*

There was a clear association between duration of treatment and compliance as described by Bartsch and colleagues (1993), who found that the level of compliance decreased as treatment duration increased (*B-weight* = -0.141, multiple regression analysis). They also found that uniform and regular patterns of wearing orthodontic appliances (hours of daily wear as recommended by orthodontist and the regularity of wear according to patient and parent) may increase the total wearing time, therefore as expected the regularity of wear was found to be significantly correlated with patient's compliance (*B-weight* = 0.344, multiple regression analysis).

#### 2.3.3.2.3.4 *Patients discomfort from wearing appliances*

The psychogenic dimensions of patient discomfort and its relationship with compliance were examined by Doll *et al.* (2000), using scales to assess discomfort and appliance acceptance retrospectively in a sample of 67 orthodontic patients treated with removable, fixed, and functional appliances. Patient's level of compliance was rated by their clinician using the Orthodontic Patient Cooperation Scale. They found a significant relationship between compliance and aversion to wearing the appliance in public, feelings of tension, and appliance acceptance after six months of treatment ( $P \leq 0.01$ ,  $P \leq 0.05$ , and  $P \leq 0.001$  respectively, multiple regression analysis).

#### 2.3.3.2.3.5 *Orthodontic attitude*

The contribution of child and parental attitude and opinions about orthodontic therapy were investigated by Nanda and Kierl (1992) through the Orthodontic Attitude Survey devised by Fox *et al.* (1982). They found that attitude toward orthodontic treatment was not a significant predictor of future patient cooperation ( $P < 0.1$ , stepwise regression analysis). Whereas, Sergl and colleagues (1992) found a significant relationship between compliance and orthodontic attitude during the first three months of treatment ( $P = 0.008$ , Pearson correlation coefficient), however, after six months of treatment orthodontic attitude did not predict cooperation behaviour (*B-weight* = -0.15, regression analysis).

#### 2.3.3.2.3.6 *Parental attitude to orthodontic treatment*

In a longitudinal study to examine adolescent cooperation during orthodontic treatment, Albino and colleagues (1991) measured the cooperation of 39 patients (11 to 14 years old) treated using fixed appliances, with a set of psychological and orthodontic specific measures. They found that a positive parental attitude toward orthodontic treatment was

a significant predictor of patient cooperation early in treatment ( $P < 0.01$ , multiple regression analysis), it was the strongest predictor of cooperation and accounted for 19% of the variance, indicating that parental support and belief regarding the need for their children to have braces is associated with increased compliance level.

#### *2.3.3.2.3.7 Motivation to orthodontic treatment*

El-Mangoury (1981) performed a longitudinal survey to determine the relationship between motivation and cooperation during orthodontic treatment in a sample consisting of 70 patients receiving treatment with fixed orthodontic appliances. She used clinical records to measure patient's cooperation, and psychological measures (achievement, affiliation, and attribution motivation) to assess the level of motivation. She demonstrated a significant relationship between cooperation and motivation (affiliation, achievement, attribution). That is, high need achievers cooperate better than low need achievers, and high need affiliators cooperate better than low need affiliators. She also concluded that orthodontic cooperation does not involve a single general dimension, and patients who are good at maintaining oral hygiene are not necessarily good at wearing headgear, and vice versa. However, the quality of the reporting of this study was poor. Albino *et al.* (1991) were not able to confirm the findings of El-Mangoury, as their data showed no correlation between the need for affiliation and patient's cooperation.

#### *2.3.3.2.3.8 Importance of child's occlusion*

The importance of a child's own occlusion (measured using a subscale of orthodontic attitude survey) was found by Albino *et al.* (1991) to be a strong predictor of long term cooperation ( $P < 0.05$ , correlation analysis), however, it appeared not to be related to cooperation with orthodontic treatment in the short term.

#### *2.3.3.2.3.9 Impact of malocclusion on patients*

Mandall and colleagues (2008) studied the relationship between the Index of Orthodontic Treatment Need (IOTN) scores and Oral Aesthetic Subjective Impact Scores (OASIS) and patient compliance during orthodontic treatment ( $n = 144$ ), and found that neither factor was a significant predictor of patient compliance ( $P > 0.05$ , logistic regression analysis).

**Table 7: Results of socio-demographic factors of patients from multivariate analyses**

Variable	Significant	Non-significant
Age	Allan and Hodgson, 1968 Bartsch <i>et al.</i> 1993	Mandall <i>et al.</i> 2008 Southard <i>et al.</i> 1991 Nanda and Kierl, 1992
Gender	Cucalon and Smith, 1990 Daniels <i>et al.</i> 2009 Southard <i>et al.</i> 1991	Mandall <i>et al.</i> 2008 Nanda and Kierl, 1992
Socioeconomic status	Cucalon and Smith, 1990	Mandall <i>et al.</i> 2008 Nanda and Kierl, 1992
Parents marital status		Nanda and Kierl, 1992
Patient perceived parental interest	Bartsch <i>et al.</i> 1993	
Patient perceived parental supervision	Bartsch <i>et al.</i> 1993	
Family rapport		Southard <i>et al.</i> 1991

**Table 8: Results of individual characteristics of the patient from multivariate analyses**

Personality Variable	Significant	Non-significant
Dominance	Allan and Hodgson, 1968	Sergl <i>et al.</i> 1992 (6 ms after ttt) Nanda and Kierl, 1992
Autonomy	Allan and Hodgson, 1968	
Achievement	Allan and Hodgson, 1968	
Anxiety	Sergl <i>et al.</i> 1992 (3 ms after treatment)	Sergl <i>et al.</i> 1992 (6 ms after treatment)
Impulsiveness	Sergl <i>et al.</i> 1992 (6 ms after treatment)	Sergl <i>et al.</i> 1992 (3 ms after treatment) Southard <i>et al.</i> 1991
Societal conformity	Southard <i>et al.</i> 1991	

Personality Variable	Significant	Non-significant
Sensitive	Southard <i>et al.</i> 1991	
Sociable	Southard <i>et al.</i> 1991	
Forceful	Southard <i>et al.</i> 1991	
Confident	Southard <i>et al.</i> 1991	
Introversive		Southard <i>et al.</i> 1991
Inhibited		Southard <i>et al.</i> 1991
Cooperative		Southard <i>et al.</i> 1991
Respectful		Southard <i>et al.</i> 1991
Self-concept		Southard <i>et al.</i> 1991
Personal esteem		Southard <i>et al.</i> 1991
Body comfort		Southard <i>et al.</i> 1991
Sexual acceptance		Southard <i>et al.</i> 1991
Social tolerance		Southard <i>et al.</i> 1991
Cognitive competence	Gross <i>et al.</i> 1988	
Scholastic achievement	Southard <i>et al.</i> 1991	
Academic confidence		Southard <i>et al.</i> 1991
School attendance consistency		Southard <i>et al.</i> 1991
Peer influences	Southard <i>et al.</i> 1991	Nanda and Kierl, 1992
Perceptions and feelings		Cucalon and Smith, 1990
Alienation		Cucalon and Smith, 1990
Sensory perception of colour		Bartsch <i>et al.</i> 1997
Perceived self-image		Albino <i>et al.</i> 1991
Locus of control	Albino <i>et al.</i> 1991 Bartsch <i>et al.</i> 1993	

**Table 9: Results of treatment factors from multivariate analyses**

Variable	Significant	Non-significant
Type of appliance		Mandall <i>et al.</i> 2008
Doctor-patient relationship	Nanda and Kierl 1992 Bartsch <i>et al.</i> 1993 Sinha <i>et al.</i> 1996	
Orthodontic attitude	Sergl <i>et al.</i> 1992 (first 3 months of treatment)	Sergl <i>et al.</i> 1992 (6 months after treatment) Nanda and Kierl, 1992
Parental positive attitude	Albino <i>et al.</i> 1991	
Motivation to orthodontic treatment	El-Mangoury 1981	Albino <i>et al.</i> 1991
Importance of child's occlusion	Albino <i>et al.</i> 1991	Albino <i>et al.</i> 1991
Duration of treatment	Bartsch <i>et al.</i> 1993	
Feeling of tension	Doll <i>et al.</i> 2000	
Appl. Acceptance	Doll <i>et al.</i> 2000	
Regularity of wear	Bartsch <i>et al.</i> 1993	
Aversion to wearing appliance in public	Doll <i>et al.</i> 2000	
IOTN		Mandall <i>et al.</i> 2008
OASIS		Mandall <i>et al.</i> 2008

## **2.4 Discussion**

The aim of this systematic review was to identify factors that have been studied in the current literature and their associations with concordance and compliance with orthodontic treatment of children, as well as to inform the design and the content of the PDA. However, no studies investigating the factors associated with concordance were identified.

This systematic review suggests that current research in orthodontics has failed to embrace the shift from compliance to concordance. Cushing and Metcalfe state that “Concordance relies on open discussions about the condition and treatment options. Making decisions based upon shared information and respect for patient belief results in “compliance” and “adherence” becoming almost an irrelevance since the primary decision is made by the patient. The result is likely to be patients committed to actions they have chosen and thus optimized medicines management” (Cushing and Metcalfe, 2007). There was no evidence that this concept has been used in orthodontics and no single paper used the term ‘concordance’, though some relevant factors have been identified in relation to compliance.

Although, some factors identified through this review process had a consistent and significant association with patients’ levels of compliance, there were many other factors investigated where the associations were inconsistent or not significant.

The factors investigated with respect to compliance with orthodontic treatment were grouped into three categories; sociodemographic factors of patients, individual characteristics of patients and treatment factors.

The orthodontist-patient relationship and establishment of a good rapport, parents’ involvement in decision-making, attitude and motivation of patients and their parents toward orthodontic treatment, duration of the treatment and the patients discomfort from wearing orthodontic appliances were all found to be significant factors influencing patients’ compliance with orthodontic treatment. These factors are relevant for the need to develop a PDA for patients contemplating orthodontic treatment and are useful to feed into its development. The following section of the chapter will discuss the results of the systematic review with a focus on the results that are relevant to the aim of the thesis.

### **2.4.1 Sociodemographic factors**

This review found the effect of sociodemographic factors on compliance and its related terms to be complicated with no clear influence on compliance with orthodontic treatment. Age, gender, socioeconomic status, payment for treatment, family rapport, and religion had all been explored to assess their effect on the level of compliance with no consistent pattern found.

#### **2.4.1.1 Age**

From the included studies age was apparently unrelated to compliance and that levels of compliance are influenced by factors associated with age, rather than age itself. Two studies found that younger patients cooperated better than older patients (Allan and Hodgson, 1968; Bartsch *et al.*, 1993). Allan and Hodgson (1968) attributed their finding to the limited age range of the participants (12 to 18 years) and limited categories in cooperation ratings. Bartsch and colleagues (1993) elucidated that insufficient wearing of the appliance will start around the time of puberty because a patient's psychological satisfaction is more important than their initial level of motivation. In contrast, other researchers found no correlation between patients' age and their level of compliance (Southard *et al.*, 1991; Nanda and Kierl, 1992; Amado *et al.*, 2008; Mandall *et al.*, 2008). Findings from the medical literature suggested that for many treatments age is probably not significantly related to compliance, although this literature was largely from adults, rather than adolescent patients. However, it may be that patients' motivation to choose treatment and willingness to participate in decision-making may vary with age, so the need for PDA for patients of different ages may be necessary.

#### **2.4.1.2 Socio-economic status**

From the included studies, only Cucalon and Smith (1990) reported a significant relationship in which better compliance was observed in patients with higher socio-economic backgrounds. Conversely, other researchers (Starnbach and Kaplan, 1975; Nanda and Kierl, 1992; Mandall *et al.*, 2008) were unable to identify a significant association between compliance and socio-economic status. Starnbach and Kaplan (1975) attributed their finding to the reason that most of their participants were from families with similar incomes (\$10,000 – \$ 25,000 a year income). Similarly, no difference was identified in the compliance level of orthodontic patients whose treatment was paid through a Medicaid scheme when compared to non-Medicaid patients (Dickens *et al.*, 2008). Difficulties with investigating the relationship between

socio-economic status and compliance come from the choice of measures used. In the included orthodontic studies, socio-economic status was assessed using single-item indicators rather than looking at composite measures of deprivation; however, results from the medical literature regarding the relationship between socio-economic status and therapeutic non-compliance were contradictory, and this discrepancy was explained by the different healthcare systems in different countries (Jin *et al.*, 2008). This was in agreement with Marston (1970) who stated that “it is difficult to assess the significance of conflicting reports of the association between socio-economic status and compliance, since many of the studies referred to do not include very wide ranges in socio-economic status in their samples”.

The socioeconomic status may have an influence on the doctors’ communicative style with their patients. Willems and colleagues reported that patients from higher social classes communicate more actively and elicit more information from their doctor. Whereas doctors’ misperceptions of the desire and need for information and the ability of patients from lower social classes to take part in the care process may often occur. A more effective communication could be established by both doctors and patients through doctors’ awareness of the contextual communicative differences and empowering patients to express concerns and preferences (Willems *et al.*, 2005). This may be performed through the implications of methods to increase patient empowerment such as PDAs. There are several papers that show that PDAs can help address health literacy problems (Yin *et al.*, 2012; McCaffery *et al.*, 2013).

#### **2.4.1.3 Parental support**

Bartsch and colleagues (1993) revealed a consistent level of parental support on the patient’s level of compliance. They showed that patient’s acceptance of wearing removable orthodontic appliance was significantly influenced by parental interest in treatment. These findings necessitate involvement of parents in decision-making and ensuring the PDA incorporates their views and values. Similar findings from a medical literature were reported by Jin *et al.* (2008) who reviewed the factors influencing therapeutic compliance and cited that better compliance was exhibited by patients who had support from family members and friends, because this support can assist in reducing any negative attitudes towards therapy. On the other hand, other researchers found no conclusive evidence regarding the influence of patient-parent relationship on patient’s compliance during treatment (Southard *et al.*, 1991; Sergl and Zentner, 2000).

In summary, it seems that the socio-demographic factors that have been studied including age, gender, socio-economic status, and religion have an unclear relationship with compliance during orthodontic treatment. These complex relationships may be explained by variations in the choice of measures used and design of the studies.

#### **2.4.2 Individual characteristics**

Many studies in the review investigated the association between different individual characteristics of the patients and compliance; around 20 different characteristics were examined, but none were found to be significant. Many authors studied the relationship between LOC and compliance with orthodontic treatment. Albino *et al.* (1991) found that two subscales from the orthodontic LOC measure (external-chance and external powerful others) were negatively correlated with longer term cooperation, suggesting that if an orthodontic patient believed that the responsibility of treatment outcomes are outside his/her own control, then that patient will be less cooperative than others and therefore less likely to participate in shared decision making. These findings are in agreement with El-Mangoury (1981) who reported that patients will cooperate better if they scored higher on internal locus of control than those with external locus of control. In contrast, Bartsch *et al.* (1993) found that adherence in wearing of removable orthodontic appliances was closely related to external locus of control; however, in a more recent study, Lee and colleagues (2008) found that LOC was not a reliable predictor of compliance during orthodontic treatment. It may be that some patients feel that they are not involved in decisions about their treatment and feel it is out of their control due to the nature of the orthodontist-patient relationship rather than LOC. This has implications for the need for a PDA to enhance young peoples involvement in decision-making about treatment.

#### **2.4.3 Treatment factors**

##### ***2.4.3.1 Orthodontist-patient relationship***

Although, many researchers found that orthodontist-patient relationships are important (Allan and Hodgson, 1968; El-Mangoury, 1981; Southard *et al.*, 1991; Nanda and Kierl, 1992), few studies have investigated the effect of orthodontist-patient relationship on compliance with orthodontic treatment.

Bartsch and colleagues (1993) described provider-patient relationships to be the best predictors of patient compliance with orthodontic therapy. In their study, Sinha and

colleagues (1996) found that verbal communication and establishing a good rapport with patients had a positive influence on their levels of adherence with treatment, they also reported that politeness of the orthodontist and the way they criticized the patient's teeth and how they maintained their appliances had an influence on level of compliance. Similar findings were reported by Nanda and Kierl (1992) who asserted that, doctor-patient rapport can positively improve patients' compliance by encouraging them to cooperate and adhere to doctor's recommendations regarding maintaining good oral hygiene and wearing of their appliances.

In the medical literature, the patient-prescriber relationship is considered as a strong factor affecting patients' compliance, with better compliance found if doctors are supportive and are perceived to treat patients with respect (Moore *et al.*, 2004; Lawson *et al.*, 2005) with poor compliance resulting from poor communication between patients and healthcare providers (Apter *et al.*, 1998). These findings suggest that the nature of the orthodontist-patient interaction is important in predicting compliance and interventions, such as PDAs, which provide information and support for patients in their decision-making should be developed. PDAs have a potential for building the relationship between the doctor and patient (Charles *et al.*, 1999). Positive relationships between patient and healthcare provider will encourage patients to actively participate in decisions concerning their care, then they will be more committed to those decisions and ultimately achieve higher compliance levels (Lim and Ngah, 1991; Barry, 1993; Randolph and Fraser, 1999).

Charles and colleagues (1999) also suggested that the process of exchanging information will enable both the doctor and patient to get to know each other and to determine how well they can work together. This is particularly important for the patients as they will have the opportunity to assess the extent to which the physician's practice style, attitudes and behaviour will match their own expectations of and preferences for how they want the physician to interact with them (Charles *et al.*, 1999). PDAs are designed to facilitate communication between health professionals and patients (Whelan and Loprinzi, 2005; Coulter and Collins, 2011)

#### **2.4.3.2 Duration of treatment**

From the included studies in this review, only one study (Bartsch *et al.*, 1993) reported a clear association between compliance and duration of treatment, they found that, as the duration of treatment increased, the level of compliance decreased. These findings were

supported by previous results from orthodontic literature (Brezniak and Ben-Ya'ir, 1989) and medical literature (Menzies *et al.*, 1993; Dhanireddy *et al.*, 2005) who reported that, patient's level of compliance may be compromised as the period of treatment increased. In contrast, other studies found better compliance shown by patients with chronic diseases with longer duration of treatment (Garay-Sevilla *et al.*, 1995).

The results from the medical literature regarding duration of treatment and patient compliance seem to be inconsistent. Combs and colleagues (1987) compared compliance levels of patients with tuberculosis treated by two different regimens, and found that the compliance rate in the 6-months treatment group was 60%, and only 50% in the 9-months treatment group. This indicates that the longer treatment duration may reduce the rate of compliance. This finding was also supported by Gascon and colleagues (2004), who stated that, better patient compliance is usually associated with acute illnesses rather than chronic illnesses. This may be the case in orthodontic treatment, as it takes over two years before completion of treatment and removal of the appliance. It is important that patients are aware of the duration of treatment before it begins, this can be done through a PDA and discussion before making the decision about treatment. Patients who are willing to undergo treatment will most likely accept wearing their appliances for longer durations than those who are forced by others or have less desire for treatment.

#### ***2.4.3.3 Type of appliance***

The included studies in this review had patients wearing fixed, removable, or functional appliances. In many studies the type of the appliance worn by participants was not specified. In fact, studies investigating the effect of the type of orthodontic appliance on patient's compliance yielded conflicting results. Although, Murray (1989) found that non-compliance was associated with the use of removable appliances it was less frequently found if treatment was undertaken with fixed appliances. Murray suggested that non-compliance with removable appliances was much easier for patients than fixed appliances. On the other hand, Mandall *et al.* (2008) found no influence of the type of appliance used on cooperation with treatment, this could be attributed to the short period of time the removable appliances were used in their study, and evaluation of the effect of removable appliance on compliance could not be measured.

#### **2.4.3.4 Orthodontic attitude**

Elucidation of the relationship between compliance with orthodontic treatment and the patient's attitude toward treatment produced conflicting findings. Miller and Larson (1979) hypothesized that; patients who are willing to undergo orthodontic treatment usually show more compliance than those who are not willing to undergo treatment. It has also been suggested that attitude toward orthodontic treatment and health-related behaviour in general may strongly affect patient's compliance (Sergl and Zentner, 2000). Supporting results from a previous study by Sergl *et al.* (1992) found that orthodontic attitude was important in predicting cooperation in the first three months of the treatment. Similar results has been reported in medical literature (Kyngäs, 1999) who found that a negative attitude towards therapy can be regarded as a strong predictor of poor compliance in children and adolescent patients because they feel that they are not as 'normal' as their friends or classmates. These findings do not corroborate the findings of Nanda and Kierl (1992) who concluded that neither orthodontic attitude, nor the patient's orientation toward peers can be used as reliable predictors of patient cooperation.

Another equally important variable which has been investigated is the positive parental attitude toward orthodontic therapy. Albino and colleagues (1991) found that parental positive attitude toward appliances was an important predictor of patient's cooperation at the beginning of treatment, suggesting that initial cooperation can be predicted through parental views rather than the patient's own attitude, although, parental influence may diminish in predicting longer-term cooperation as the adolescent patient becomes older. A similar finding was previously reported by Burns *et al.* (1986) and Folger (1988) who concluded that parental attitude is of particular importance in predicting compliance. This finding suggests that parents should be involved in the development of PDAs for orthodontic treatment.

#### **2.4.3.5 Motivation for orthodontic treatment**

Motivation for orthodontic treatment has been regarded as an important factor in predicting a patient's level of compliance, and it has been hypothesized that evaluating patients' and their parents' motivation can provide wider representation of potential factors influencing cooperation with orthodontic treatment (Albino, 2000). Although, it has been demonstrated by Daniels *et al.* (2009) that patient's motivation is positively correlated with compliance during orthodontic treatment, with the more motivated

patients being more willing to cooperate with their treatment, they also found that parental motivation is not correlated with actual cooperation responses of their children, even though this finding cannot be generalized because their study used an indirect measure of compliance (self-report). In her study El-Mangoury (1981) found that high-need achievers cooperate better with orthodontic treatment than low-need achievers, and high-need affiliators cooperate better than low-need affiliators. This finding contradicts Albino *et al.* (1991) who showed that the need for achievement is not important in predicting patient cooperation during orthodontic treatment. Results from other medical fields showed that patient motivation was strongly related to compliance with treatment (Lim and Ngah, 1991), and lack of motivation is an important reason for stopping treatment in hypertension patients (Kyngäs, 2001). Therefore, increasing levels of patients' motivation towards treatment by helping them express and identify their needs, incorporating their perspectives and values in the decision-making process about their health condition, and enhancing doctor – patient communication may be helpful (Kyngäs, 2001).

Although, orthodontic patient attitude and motivation have been investigated separately in the included studies, it is likely these two factors are similar, and should be explored during decision-making.

#### **2.4.3.6 Discomfort**

In the orthodontic literature it is clearly stated that patient's acceptance of their orthodontic appliance and their overall compliance with treatment are negatively influenced by discomfort resulting from orthodontic appliances (Oliver and Knapman, 1985; Egolf *et al.*, 1990). This discomfort can be in the form of functional restrictions including impaired speech, chewing, swallowing, and oral constraints, or social discomfort (dissatisfaction with the appearance and aversion to wearing of the appliance in public).

Previous researchers (Bartsch *et al.*, 1993; Serogl *et al.*, 1998) found that patient's compliance is associated with the number of complaints and discomfort from the appliance. Similar findings were reported by Doll *et al.* (2000) who revealed that pain, dysfunctions, and external appearance are correlated with premature termination of orthodontic treatment.

In contrast, Serogl *et al.* (2000) claimed that the patient's level of compliance is correlated only with the lack of confidence in public, and not associated with impaired speech, impaired swallowing, or oral constraints, indicating that patient's compliance is not affected by oral function deterioration. Serogl *et al.* (1998) found a distinct correlation between attitude toward treatment and the intensity of discomfort after appliance insertion. They found that participants with higher attitude characteristics and higher concern about the condition of their malocclusion reported less intensity of discomfort. This could be explained by the fact that the impact of malocclusion and the desire for treatment can obviate the impact of discomfort from orthodontic appliances.

#### **2.4.4 Quality of included studies**

In terms of the quality of the included studies the criticisms can be summarised as follows; there are few attempts to define compliance and many different approaches were used to its measurement. While, the term 'compliance' has attracted widespread criticism and alternative concepts have been proposed, such as adherence, cooperation, mutuality, and therapeutic alliance, still these terms are poorly defined and usually used as synonyms containing elements of 'simply following medical instructions' (Kynge *et al.*, 2000), instead of emphasizing an individual's active role in the process of care.

The systematic review revealed that no studies have been conducted about concordance with orthodontic treatment despite calls for a shift in thinking from compliance to concordance in healthcare over fifteen years ago (Marinker and Sharp, 1997). Also, among the studies included, there is a lack of definition of factors provided and the rationale for choice of these factors, and there is a little evidence of use of theory to inform the choice of factors. Moreover, some studies had small sample sizes (less than  $n= 50$ ) and most studies were cross-sectional and lacked a sample size calculation. There were few longitudinal studies which are the ideal design to investigate concordance or compliance. Previous studies have focused on prediction of non-compliance and the results have largely been inconsistent due to the demographic nature of variables assessed. Although many studies have clarified some reasons for non-compliance, these studies were unable to provide solutions to improve compliance because practitioners cannot alter these demographic factors for their patients. Therefore the focus of research should rely on how to improve patient's cooperation during orthodontic treatment rather than focusing on prediction of the issue of non-compliance.

It was also noted that in the field of orthodontics, several studies relied on the orthodontists' assessment of compliance levels rather than capturing patients' perspectives, and many studies relied on bivariate analyses and have failed to control for confounding factors. Some recent studies have used a multivariate analysis, but these studies have often involved only a limited numbers of factors, and no single study has investigated the wide range of factors identified in the literature as possibly predicting compliance with orthodontic treatment in children. This would require a large longitudinal cohort study.

#### **2.4.5 Limitations**

Due to the substantial heterogeneity of methodological designs among studies, no meta-analysis could be performed, therefore we looked at the studies separately. The studies were separated according to type of analysis. This method of categorization was chosen because studies that undertook a multivariate analysis were generally considered to be of higher quality than studies undertaking a bivariate analysis, as they attempted to account for confounding factors.

One potential weakness of the study is in the selection of keywords used in the search strategy, which may have led to some articles not being identified. The selection was based on words used in the literature and the advice given by an experienced librarian. Attempts were made to ensure that all known studies were identified following the search. In addition the reference lists of identified articles were searched for additional studies.

#### **2.5 Conclusions**

Research in orthodontics has failed to embrace the shift from compliance to concordance. Successful orthodontic practice is highly dependent on the interaction between the orthodontist and patient, it is crucial to improve orthodontist-patient relationship, and this can be done through improved communication and shared decision-making. Therefore, the development of a PDA for orthodontic treatment is needed. Decision aids which present scientific information to patients about treatment benefits and risks are developed to encourage 'evidence-based decision-making' and build up the doctor-patient relationship. This approach assumes that transferring scientific information to patient in an accurate and unbiased way by physician could enhance the patient's level of involvement in decision-making process.

Orthodontist-patient relationship was found to be associated with compliance during treatment, with higher levels of cooperation found in patients who reported good relationship with their providers.

The next chapter of this thesis will describe the process of the development of the PDA for orthodontic treatment.

## **3 CHAPTER THREE: PDA DEVELOPMENT**

### **3.1 Introduction**

Establishing effective communication between the orthodontist and patient enables an understanding of the expectations regarding orthodontic treatment, resulting in greater motivation and cooperation, leading to a successful outcome (Souza *et al.*, 2013). The conclusion of the systematic review (Chapter Two) was that the interaction between the orthodontist and patient is crucial for successful completion of orthodontic treatment.

Other studies have reported that building a good relationship between patient and healthcare provider in the clinical encounter can be enhanced through the adoption of the concept of shared decision-making (Elwyn *et al.*, 2012). This can be facilitated by interventions, such as the use of a Patient Decision Aid (Menard *et al.*, 2010); therefore, it would appear that the development of a PDA for young people contemplating orthodontic treatment might be useful to enhance concordance.

The next two chapters will describe how the second and third objectives of the thesis were achieved:

2. To use a child-centred approach to develop a Patient Decision Aid for children considering fixed orthodontic appliance treatment to facilitate shared decision-making and improves patient-clinician interaction.
3. To undertake an initial evaluation of the PDA in reducing decisional conflict, increasing knowledge and meeting expectations in children and parents considering fixed orthodontic appliance treatment.

This chapter will describe the process of the PDA development.

### **3.2 Ethical approval and permission**

Ethical approval for the study was obtained from (NRES Committee Yorkshire and The Humber – Sheffield) (Appendix D). The NHS permission to undertake the study was obtained from Sheffield Teaching Hospitals (STH17202) (Appendix E).

### **3.3 Method**

#### **3.3.1 Overview**

The study was carried out in two stages using a combination of qualitative and quantitative methods. In stage one, the contents of the PDA were drafted, assessed, and revised through patients and their families, researchers, a psychologist, and clinical

practitioners. Stage two employed a pilot study to begin to evaluate the effect of the developed PDA on patients' decision. Stage two will be described in more details in the next chapter (Chapter Four).

Stage one, the PDA development stage involved two steps;

*Step 1: Qualitative interviews*

*Step 2: Formation of expert groups*

### **3.3.2 Theoretical model selected to guide the PDA development**

An important initial task in any PDA development is to establish a focused and measurable objective. This is important as the selected objective of the PDA influences its process of development and method of evaluation (Charles *et al.*, 2010; Trevena *et al.*, 2012). Depending on the objective, a number of frameworks are available to guide the development of the PDA (O'Connor and Jacobsen, 2003). The objective of this study was to develop a PDA for young people considering fixed orthodontic appliance treatment to facilitate shared decision-making and improve patient-clinician interaction. Also, to initially evaluate the developed PDA in reducing patients' decisional conflict, improving their knowledge about orthodontic treatment, and creating realistic expectations of treatment outcomes.

It is essential to select a conceptual framework to inform the development of the PDA (O'Connor and Jacobsen, 2003). The shared decision-making model (SDM) (Charles *et al.*, 1999) was the theoretical framework selected to guide the development of the decision aid. One of the main reasons to choose this model was that the shared decision-making model is characterised by the interactional nature between the doctor and patient in all decision-making stages including information exchange, deliberation and implementation of the final decision (see chapter one, section 1.9). In addition, as stated by Charles *et al.* (1999), the shared decision-making model emphasizes the direction of communication between patients and their healthcare providers as a two-way information exchange (i.e. from doctor to patient and vice versa) which is different from paternalistic and informed decision-making models, in which the direction of information is one-way (from healthcare provider to patient).

It has been stated that shared decision-making encourages active engagement of patients during the process of decision-making and the decision aids facilitate their participation (Carroll *et al.*, 2013). In this model, for shared decision-making to occur, patients need to be informed about all treatment options available and the related benefits and risks

before deciding, with the healthcare provider, which treatment to implement (Charles *et al.*, 1999). This approach corroborates with the overall purpose of the current decision aid.

### **3.3.3 Developing a decision aid for orthodontic treatment**

The PDA was developed based on the Ottawa Decision Support Framework (ODSF), which originates from the Ottawa Health Research Institute Patient Decision Aids Group, through the workbook produced by O'Connor and Jacobsen entitled "Workbook on Developing and Evaluating Patient Decision Aids". This involves two separate steps; qualitative interviews and formation of expert groups.

The development of the PDA also involved reviewing the literature to identify relevant studies to include as evidence in the PDA according to the aspects of malocclusion and its treatment that were raised by the interviews and expert groups. The hierarchy of evidence was used to identify evidence from systematic reviews or randomised controlled trials where systematic reviews had not been conducted.

#### **3.3.3.1 Step 1: Initial development of the PDA through qualitative interviews**

Qualitative research has been defined as "an umbrella term for an array of attitudes towards and strategies for conducting inquiry that are aimed at discovering how human beings understand, experience, interpret, and produce the social world" (Mason, 1996).

Qualitative research methods offer a basis for the interpretation and analysis of data, particularly for relatively new subjects or for topics that lack the necessary research information (Neuman, 2006). In a health or social care setting, qualitative research is useful where the exploration or identification of concepts and people's experiences and views are sought (Hancock *et al.*, 2007). It is commonly used to provide an in-depth description of procedures, beliefs and knowledge related to health issues, or to explore reasons for certain behaviours, including the opinions of respondents about particular issues (Ebrahim, 1978).

Interviews can be defined as the interaction between two people or groups in order to gather specific information and find out opinions. The qualitative interviews can be commonly divided into two types; personal (face-to-face) interviews and telephone interviews. Personal interviews are preferred by interviewees with higher response rates than for telephone interviews (Blumberg *et al.*, 2005), personal interviews were

conducted in this project, even though it was more costly in time and money (Blumberg *et al.*, 2005).

#### 3.3.3.1.1 Interviews

According to Neuman (2006), research interviews can be classified into three different forms, according to the degree of flexibility, namely; unstructured, semi-structured and structured. The form of interview selected for this research project was a face-to-face, semi-structured interview. The rationale for selecting a semi-structured interview was that the researcher needed to gain a deeper knowledge and understanding of the influential factors considered by patients and their parents in making decisions about whether to have fixed orthodontic appliance treatment. This approach was selected because it offers the participant the time to talk about their opinions on a particular subject or issue to enable understanding of the participant's point of view. It uses open-ended questions, some suggested by the researcher ("Tell me about...") and some that arise during the interview ("You said a moment ago...can you tell me more?").

The semi-structured interview is more formal than the unstructured interview; it involves a number of specific topics around which the interview is built. This form of interview uses open and closed-ended questions; however, the questions are not asked in a specific order. It usually starts by asking indirect questions and then raises specific issues that the interviewer has in mind.

The semi-structured method has several advantages over the other types of interviews. Firstly, it is a simple, efficient and practical way of obtaining data about an area that cannot be easily observed, such as feelings and emotions. Secondly, it has high validity, as participants can talk in depth and in detail about the area and the structure allows comparisons of different responses of participants, but is still flexible, reliable and easy to analyse. Like any technique, the semi-structured interview does place some demands on the researcher. Preparation for semi-structured interviews includes development of a topic guide with a list of topics the interviewer needs to discuss with the participants; however it should not restrict the interview. The guide requires careful planning, to avoid leading questions. In order to overcome some of these limitations, the topic guide was developed carefully from the literature and informal discussion with patients. The topic guide evolved as the interviews progressed and new areas emerged (Topic guide – see Appendix M).

However, semi-structured interviews are time consuming to undertake, require a high level of interviewing skills, as well as time and careful thought to analyse the data. To conduct a good interview the interviewer should be able to put an interviewee at ease by selecting a comfortable location for the interview and should be able to manage the interview situation, so as to collect data, which truly reflect the views and feelings of the participants (Hancock *et al.*, 2007).

In order to develop skills in conducting qualitative interviews, the main author (AE) attended a two day in-depth interviewing course at the National Centre for Social Research. This course allowed the researcher to gain valuable experience in practising qualitative interviewing techniques such as active listening and open questioning. It was also useful in helping the researcher to appreciate the importance of the appropriate use and development of topic guides in qualitative research. In addition, more training was received by the main investigator through watching the principal supervisor (ZM) conducting the first interview following the same topic guide.

#### 3.3.3.1.2 Recruitment

The researcher (AE) identified potential participants to the study among patients attending the Orthodontic Department of Charles Clifford Dental Hospital.

The following inclusion criteria were used:

- aged 12 to 16 years old and their parents
- children undergoing or have completed orthodontic treatment with fixed appliances and their parents
- young people referred to orthodontic clinics at Charles Clifford Dental Hospital for a consultation and their parents

Children were excluded if they:

- were outside the age range of 12-16 years
- required or were already undergoing orthodontic treatment with removable or functional appliances
- had craniofacial anomalies
- required or were already undergoing orthognathic surgery
- had severe learning disabilities who are unable to participate even with additional support from the research team
- were non-English speaker

- young people or parents who refuse to give consent

Eligible participants and their parents were approached by the researcher (AE) on the clinic and invited to take part in the study. A brief verbal explanation was given, as well as written information sheets (Appendices F1 and F2) for both parents and young people. Potential participants were asked to respond with their decision whether or not to take part in the study within one week using a standard reply slip and postage paid envelope (Appendix G). Those who agreed to take part were contacted by telephone to arrange an appointment, either at their home or in a suitable room in the dental school depending on participants' preferences. Written consent was obtained from children and their parents prior to the commencement of interviews (Appendices K and L).

#### 3.3.3.1.3 Interview procedure

The interviews were carried out by the researcher (AE) who followed a topic guide, and audio-recorded the interviews on a recording device. Each interview took approximately 30 to 45 minutes to complete and covered the factors involved in making the decision whether or not to undergo orthodontic treatment with fixed appliances. Areas covered included the value patients put on the benefits and risks of treatment, the information and support needs of young people and their parents in making the decision and included the content, format, and timing of decision-making resources (Topic guide – see Appendix M). The researcher interviewed children and their accompanying parents at the same time. Purposive sampling was employed to ensure that participants of different ages (12 to 16 years old), genders (males and females), backgrounds (different ethnicities including; White British, Pakistani, and Arab), and different stages of treatment (ranging between 3 months into treatment to just finished treatment) were included.

The ethics committee approved giving all the young people who participated in the qualitative interviews a £5 gift voucher, as a thank you for taking part.

#### 3.3.3.1.4 Sample size

A sample size of 10 young people with a parent or carer was estimated based on previous experience of conducting interviews with young people about their teeth and dental treatment (Marshman *et al.*, 2010). It was anticipated that data saturation would occur once this sample size had been achieved.

### 3.3.3.1.5 Analysis

Analysis of the qualitative data involved taking the participants' accounts at face value, without imposing any constructs on their views, as expressed by the children and their parents. Recordings were verbally transcribed and a framework analysis (see Appendix H) was employed to classify the data by organising it according to themes and categories (Ritchie and Spencer, 1994). The framework analysis involves the following stages: familiarisation, identifying a thematic framework, indexing, charting, and then mapping and interpretation.

Familiarisation; is the process in which the researchers becomes familiar with the transcripts to enable them to begin to develop ideas about the key themes. AE and ZM both read and became familiar with the transcripts.

Identifying a thematic framework; occurs after familiarisation when the researchers develop the emerging themes from the data. The concepts and themes expressed by participants form the basis of a thematic framework which can be further refined at subsequent stages of analysis. AE and ZM independently identified themes and discussed these before AE began the development of the thematic framework.

Indexing; refers to identification of sections of data that correspond to a particular theme. A numerical system was used for the indexing of data and annotated in the margin beside the text. Indexing was carried out by AE under the supervision of ZM.

Charting; is the process in which specific pieces of indexed data are arranged into charts of the themes. In other words, moving the data from its original textual context and placed in charts that consist of the headings and subheadings that were drawn during the thematic framework. AE carried out the charting and ZM reviewed the developed charts and these were discussed before they were finalised.

Finally, mapping and interpretation involves the analysis of the key themes to be incorporated into the PDA.

A draft version of the PDA was developed at this stage, based on the quality criteria proposed by the International Patient Decision Aid Standards (IPDAS) collaboration (Elwyn *et al.*, 2006), and informed by the data that emerged from interviews with young people and their parents, as well as evidence incorporated from the published literature. An iterative process was followed, as interviews were conducted with participants, new

data emerged and amendments were made to the draft PDA before showing it to the next participant. Sections of the PDA were changed in response to comments and a number of PDA draft versions resulted. The qualitative interview stage commenced at the beginning of August 2013 and the last PDA version from the qualitative interviews was achieved on December 2013 (see Appendix I, version 1).

### ***3.3.3.2 Step 2: Formation of expert groups to review and further develop the PDA***

The second step in the PDA development process involved the formation of expert groups to review and further develop the PDA. The groups included;

- Five expert patients and five parents, who had already experienced orthodontic treatment to assist in reviewing the developed PDA,
- Ten experts in clinical care settings including, general dental practitioners, who refer patients for orthodontic treatment, and orthodontists in primary and secondary care, as well as a psychologist with extensive experience in the development and evaluation of PDAs to assist in the development of the current PDA.

#### ***3.3.3.2.1 Expert patient group***

Participants in this group helped to refine the content, design and format of the PDA prototype.

##### ***3.3.3.2.1.1 Recruitment***

Potential participants for the expert patient group were again identified from patients attending the Orthodontic Department at the Charles Clifford Dental Hospital. The same inclusion and exclusion criteria were used as for those who participated in the initial development of the PDA (see section 3.3.3.1.2). The investigator checked clinic appointment lists and applied the inclusion and exclusion criteria to find suitable candidates. The project was explained to potential participants and information sheets were provided for both the young people and their parents (Appendices J1 and J2). Potential participants were allowed one week to think whether they wished to take part and they were asked to reply with a provided reply slip (Appendix G). If they agreed an appointment for an interview was made. Written consent (Appendices K and L) was obtained prior to the interview.

#### *3.3.3.2.1.2 Interviews - procedure*

Participants took part in either a one-to-one or small group qualitative interviews. The interviews were conducted at the young person's home or in a room on the clinic (depending on participant preference). The interviews were carried out by the researcher and recorded on a recording device. Each interview took approximately 30 to 45 minutes to complete and was based on a draft version of the PDA (Topic guide – see Appendix M). Again, purposive sampling (also called judgment sampling) was employed to ensure that participants of different ages, genders and backgrounds were included.

Once more, as approved by the ethics committee, all young people participating in this group were given a £5 gift voucher, as a thank you for taking part. The developed PDA was then revised using the same iterative process (O'Connor *et al.*, 2005).

#### *3.3.3.2.1.3 Sample size*

A sample size of five young people with a parent or carer was based on the workbook relating to development and evaluation of patient decision aids published by O'Connor and Jacobsen (2003).

#### *3.3.3.2.1.4 Analysis*

A framework analysis was employed to organise the data according to themes and categories (Ritchie and Spencer, 1994). These data were used to amend the PDA and a new draft PDA from expert patients group produced.

#### 3.3.3.2.2 Clinical expert group

The design, content and format of the PDA evolved further following a meeting of the clinical expert group.

##### *3.3.3.2.2.1 Recruitment*

A letter of invitation, together with an information sheet (Appendix N) was sent to general dental practitioners and orthodontists inviting them to participate in the study. Participants in this group were considered to be experts in clinical care settings, including general dental practitioners, who refer patients for orthodontic treatment, and orthodontists in primary and secondary care. The researcher contacted them after one week to ask whether they wished to take part. Those who agreed to participate were invited for interview. Interviews with general dental practitioners occurred face-to-face in a room at the dental school, and then orthodontists were invited from those who

attended the Sheffield and District Orthodontic Study Circle, as well as orthodontists from the Orthodontic Journal Club Group at Charles Clifford Dental Hospital. Written consent was obtained prior to the interview (Appendix O).

#### *3.3.3.2.2 Interviews-procedure*

Two general dental practitioners took part in one-to-one qualitative interviews. The interviews were conducted at a room in the dental school. The interviews were carried out by the researcher and recorded. Interviews lasted 45 to 60 minutes and were based on the draft version of the PDA resulting from the expert patients group (Topic guide – see Appendix P).

The interview with the orthodontists occurred as an interactive group discussion and was also conducted in a room at the dental school. The discussion took approximately 1 hour to complete and was based on a draft version of the PDA (Topic guide – see Appendix P). The discussion has been facilitated by the researcher (AE) through presenting the draft PDA in a PowerPoint presentation as well as giving a copy to all clinicians. The topic guide used covered both; general background questions regarding key information, format and challenges in giving information to young people, together with specific questions to the draft PDA such as design, length, or any suggestions to improve it (Topic guide – see Appendix P).

Purposive sampling was employed to ensure that participants of different views and experiences were included. Once more, an iterative process of the draft PDA was employed.

#### *3.3.3.2.3 Sample size*

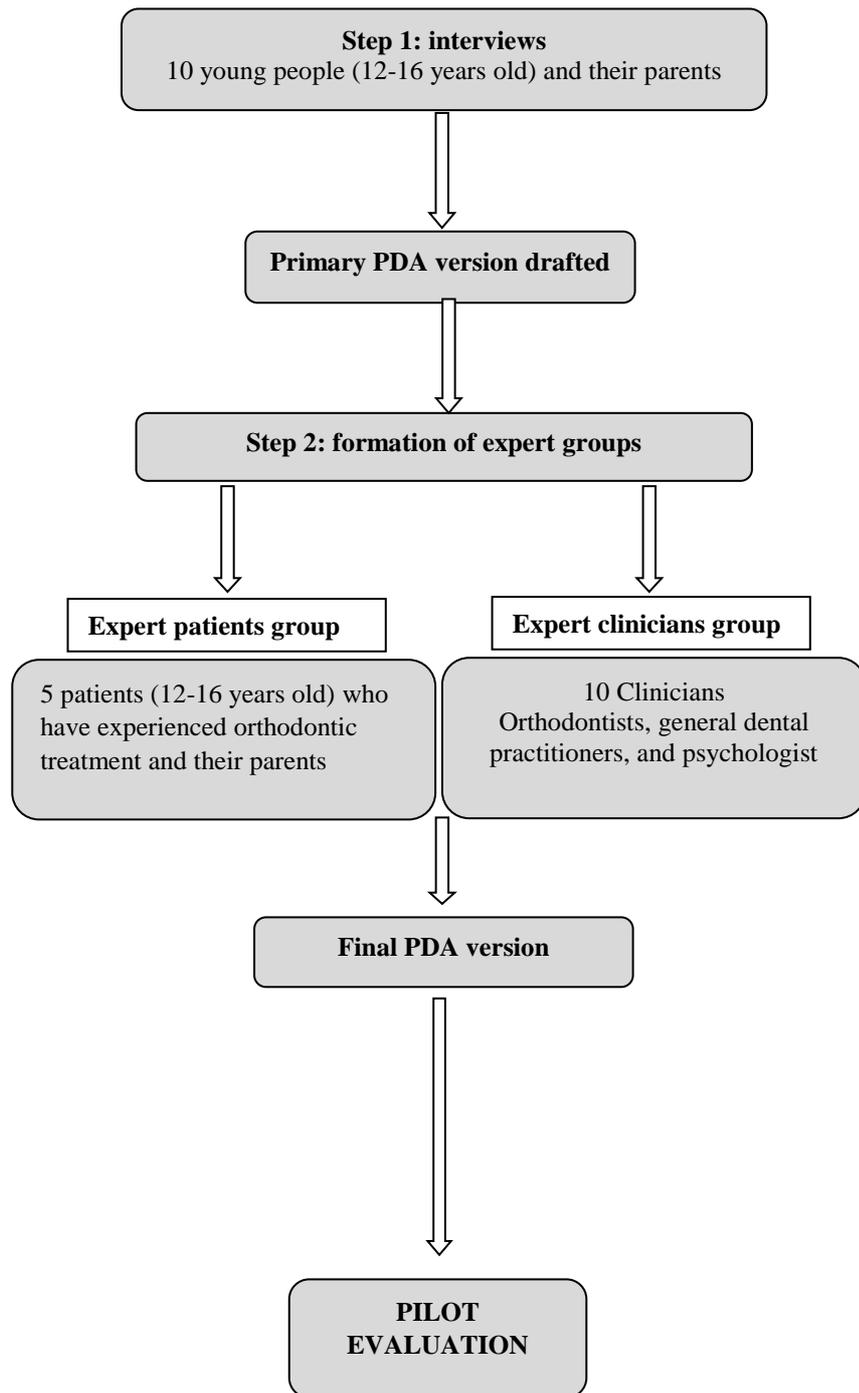
The recruitment of ten participants in the clinical expert group was based on the workbook relating to development and evaluation of patient decision aids published by O'Connor and Jacobsen (2003). This group comprised of two general dental practitioners and eight specialist orthodontists from primary and secondary care, as well as a psychologist with broad knowledge in shared decision-making and PDA development and evaluation.

#### *3.3.3.2.4 Analysis*

Framework analysis was employed to classify the data by organising it according to themes and categories (Ritchie and Spencer, 1994). The PDA was edited as new ideas

and suggestions were generated through discussion between clinical experts and a new draft of the PDA was attained.

The developed PDA was shown to an expert psychologist with extensive experience of PDAs to review and give feedback, and again a revised PDA was further refined. After the PDA was adapted according to the expert psychologist comments, a final PDA was produced and shown to two further young people, who had previously had treatment with fixed orthodontic appliances, to check if it remained appropriate in terms of design and contents included (see Appendix I, version 2).



**Figure 3: Flow diagram showing the development process of the PDA (Stage 1)**

### 3.4 Results of the PDA development process

This section will describe the main findings of the interviews conducted with participants and experts in the development process of the PDA.

#### 3.4.1 Step 1 qualitative interviews

This group comprised ten young people and their accompanying parents.

##### 3.4.1.1 Sample obtained

Table 10 shows the Demographic information of participants in the qualitative interviews. A range of young people of different ages (12 to 16 years old), males and females at different stages of treatment were interviewed.

**Table 10: Demographic details of participants in step 1 (Qualitative Interviews)**

Participant number	Age	Gender	Ethnicity	Stage of treatment	Postcode
1	12 years	Female	Pakistani	Over 1 year in treatment (14 months).	S3
2	13 years	Male	White British	Over 1 year in treatment (16 months).	S17
3	13 years	Female	White British	Just finished treatment (debond).	S5
4	14 years	Female	Pakistani	2 years in treatment.	S10
5	14 years	Male	White British	6 months in treatment.	S17
6	15 years	Female	White British	1 year in treatment.	S8
7	15 years	Female	Arab	Just finished treatment (debond).	S7
8	15 years	Female	White British	Beginning of treatment (3 months).	S20
9	16 years	Male	White British	1 year in treatment.	S10
10	16 years	Male	White British	Just finished treatment (debond).	S10

##### 3.4.1.2 Main results

The analysis revealed two main themes and seven sub themes Table 11;

*Treatment- related concerns:* this theme was further classified into four sub-themes including; benefits of treatment, risks of treatment, impact of the orthodontic appliance, and timing of orthodontic treatment.

*Information preferences:* classified into three sub-themes including; information patients need to know, sources of information, and format of information.

An example of the framework analysis from qualitative interviews with young people and their parents is included as Appendix H.

**Table 11: Themes and sub-themes of the analysis**

Main theme	Sub-themes
Treatment- related concerns	Benefits of treatment Risks of treatment Impact of orthodontic appliance Timing of orthodontic treatment
Information preferences	Information details Sources of information Format of information

**Table 12: Translation of data from interviews to PDA development**

Stage of the decision aid	Influential theme(s)	Revisions made to the PDA
<b>Introduction</b>	Availability	Original wording of ‘which treatment option to choose?’ changed to ‘The main options available to change the way teeth look are’.
	Language	A statement ‘No one way is best for everyone’ was added.
	Information	Inclusion of following information: <i>Regardless of which option you choose.....</i> <ol style="list-style-type: none"> <li>1. Keep sugary foods and drinks to meal times only</li> <li>2. Brush your teeth twice a day with fluoride toothpaste</li> <li>3. See a dentist for regular check-ups</li> </ol>
<b>Stage One</b>	Language	
	Alternative options	The options are changed from ‘fixed braces’ or ‘no treatment’ into ‘fixed braces with orthodontist’ or ‘other treatments to change the way your teeth look’
	Consequences	Some consequences were removed as participants thought irrelevant for decision-making e.g. <i>Will my gums bleed?</i> <i>What will my face look like?</i> <i>What are the emotional and social effects of treatment?</i>
	Added consequence	Additional row added to consequences table entitled ‘If I don’t have treatment now, will I be able to have the treatment later?’. This feedback was added to inform patients that adult orthodontics may take longer, more inconvenient, and they will pay for it.

<b>Stage Two: the value clarification exercise</b>	
<b>Reasons to consider treatment to straighten your teeth</b>	<b>Influential theme(s)</b>
How important is it to you to have your teeth straighter?	Benefits of treatment
How important is it to you to change the way your teeth bite together?	Benefits of treatment
How important is it to you to change the way your teeth look?	Benefits of treatment
<b>Reasons not to choose treatment to straighten your teeth</b>	<b>Influential theme(s)</b>
How bothered are you about what your teeth will look like with a brace on?	Impact of orthodontic appliance
How bothered are you and your parents about having to see the orthodontist every 4-6 weeks for checks on your brace?	Impact of orthodontic appliance
How bothered are you about having teeth taken out?	Risks of treatment
How bothered are you about having aching pain after braces are fitted?	Impact of orthodontic appliance
How bothered are you about having to wear a retainer for a long time after treatment is completed?	Impact of orthodontic appliance Timing of orthodontic treatment
How bothered are you about having white or brown spots on your teeth if you don't keep them clean while your brace is on?	Risks of treatment
How bothered are you about having white fillings on your front teeth replaced regularly?	No associated themes

#### 3.4.1.2.1 Benefits of treatment

Participants and their parents were asked about the benefits of having orthodontic treatment. Aesthetic reasons were the main benefits perceived by children and their parents. Participants expected that having orthodontic treatment would straighten their

teeth and improve the appearance of their smile. However, improved oral hygiene was also been cited as a reason for having orthodontic treatment.

*“I never liked my teeth, there were lots of gaps, quite a lot of gaps, also my over jet and overbite were quite strong, I knew that I want to get it sorted because I didn’t want to live with my teeth like that for the rest of my life, when you get the braces, you’re not looking at what your teeth look like, you will look forward, after you finish you will have a nice smile” (George, 16 years)*

*“My daughter had a missing tooth that won’t come through, and her teeth were very wonky especially the front teeth, braces can give her nice looking teeth.” (Parent)*

*“My bottom teeth were overlapping and I can’t brush them properly” (Jasmine, 15 years)*

#### 3.4.1.2.2 Risks of treatment

Perceived risks of having orthodontic treatment as revealed by young people and their parents included discolouration of teeth, gingival irritation, and shortening of the roots of teeth.

*“They told me about how sometimes when you get the brackets taken off, affecting your tooth enamel and leaves marks, but they also said as long as you keep your teeth clean and hygienic then you reduce the chance about that thing. It is down to the patients if they are going to have those effects of the braces.” (George, 16 years)*

*“The risks that we have been informed about is the importance of cleaning, that could leave a mark on teeth, also it might irritate the gums that’s why we’ve got wax to put on, and the importance of avoiding certain foods like sugary foods, and also what to do if it hurts your gums and they also discussed about that it might shorten the roots a little bit having the braces, for certain people it might cause a problem.” (Parent)*

#### 3.4.1.2.3 Impact of orthodontic appliance

Participants were asked to tell a story about their experience of orthodontic treatment and children were encouraged to talk about their feelings after having appliances fitted. Concerns were raised, especially from girls, about the discomfort and pain from appliances especially in the first few days after fitting.

*“When they put them on, it was really tight and causing achy pain maybe for the first three days it was quite bad, but then after that, well no for the first week it was really difficult to chew anything, I sort of can’t close my teeth together cause there was a lot of pain, there was pain inside my cheek and it was irritating the skin. But then after that week, like now its fine, I don’t feel any pain or anything.” (Chloe, 16 years)*

*“I don’t like braces because it hurt my teeth at the top, I normally get pain at the top more than the bottom teeth, for three days.... all my friends have braces, sometimes they do ask me if it hurts, I normally tell them about the pain it causes..... In the beginning when I first got my braces it was hard but then I got used to it.” (Shazia, 12 years)*

*“It was painful only the first night she had them fitted. But to be honest the dentist did say about paracetamol before she even comes to have it fitted. It can go on for 3-4 days. Just in case because some days it settles and then it can be painful again.” (Parent)*

Other impacts reported by young people and their parents of having orthodontic treatment on daily life included eating and brushing teeth. Children were more concerned about changing their diet to avoid damaging their appliances and stopping having fizzy drinks, whereas parents are more concerned about consequences, such as missing school and leaving work to take their children to their appointments.

*“Within the first week there was pain, it was not very hard. They told me that I need to brush for three times a day and I need to use small brushes going between the squares, and use of a mouthwash, and I need to avoid certain types of foods and drinks, and I can’t eat hard food as it breaks the squares. Generally, it was not difficult to have braces.” (Isabella, 13 years)*

*“Obviously it is the parent commitment as well because we have to leave work to get him to Charles Clifford Hospital and that may be quite difficult, so you’ve got to commit with parents as well as with the child.” (Parent)*

#### 3.4.1.2.4 Timing of orthodontic treatment

Timing of orthodontic treatment emerged as a theme. Children and their parents generally felt treatment earlier was preferential.

*“I think early is perfect, because all classmates had it so I felt confident, I don’t feel that it set me back. Braces become a trade mark, especially at the end of the primary school, if people grow old and got it for example in year 11 or during college it might bug them, but personally I don’t think I will change my mind just because of the appearance of the braces.” (Shahd, 15 years)*

*“I think younger is better, as parents it might be easier to encourage them when they are younger as they may listen to you a bit more than when they get older and have their mind, which might be good because they know what they want to do, but when they are younger I don’t know they listen to you a bit more.” (Parent)*

#### 3.4.1.2.5 Information details

Participants were asked about what information young people may need or want to make a decision, and what they think is really important for them to know. The main concerns that emerged were pain and discomfort from the appliances, the appearance of the orthodontic appliances particularly what other people may say about young people with them, how long the treatment takes, and the use of retainers after treatment. For some people having before and after photographs was raised as a helpful aid for decision-making.

*“They didn’t tell me what kind of brace, they said that I will need a brace, I never knew what sort of brace until the day of putting them on. No sort of discussion what brace I’ll be wearing, about different things, I was told that I need brace and that’s all. I would like to know what kind of brace and when I’m going to put them on and how long it will be on for, if they could tell me that it will be good”. (Chloe, 16 years)*

*“Definitely, before and after pictures always help, they encourage you. You hear about pain and other things, but pictures will actually help you thinking.” (Shahd, 15 years)*

*“I would like to see before and after pictures, especially if they are similar to your teeth. I think they really help.” (Parent)*

#### 3.4.1.2.6 Sources of information

Participants had different views regarding who should provide information about orthodontic treatment; the orthodontist, the general dentist, or the hygienist. Most felt it

was better to have information from the orthodontist, but some people also mentioned other dental or dentalcare professionals.

*“I think the orthodontist is the best person to give information because they know more and they are more trained in this profession. So, I prefer to have the information from the orthodontist.” (Isabella, 13 years)*

*“I assume the orthodontist because they are specialised, you know they have that knowledge and expertise that your general dentist wouldn’t have; they wouldn’t be able to give you the same sort of advice and confidence. So yeah, you expect to get the most accurate advice from the specialist.” (Parent)*

*“The hygienist obviously told me a lot of things about the commitment it takes and what I have to do and what I can eat and what to do when cleaning your teeth but I think the dentist as well told me that I should be having the treatment as well, because it will make my teeth look better and you can get good results and make it a lot easier to clean my teeth, also the orthodontist told me a lot, and I think it is just best to receive the information from all people involved in treatment.” (Thomas, 13 years)*

Regarding the level of involvement in making the decision about having orthodontic treatment, young people perceived that the decision to have orthodontic treatment was made by them after a discussion with their parents even if it was first mentioned by a general dentist or orthodontist.

*“I went to the dentist for check-up and he told me that it’s time to have braces because my teeth were quite missed up. My parents and the dentist just said that you are completely in charge of this decision and I said it is ok and now I’ve got the braces, I think I couldn’t really get more involvement.” (Thomas, 13 years)*

*“The dentist did mention about braces every time my son had an appointment, and obviously because it is a commitment, my son has to be the one to decide if he wants to go down that route.” (Parent)*

#### 3.4.1.2.7 Format of information

Participants were asked about what format of information about treatment they received, and what they prefer about other forms of giving information such as ‘apps’, leaflets, and links to the internet. Participants stated that at the beginning they were given lots of

verbal information from the orthodontist, and then they were given an information leaflet and links to the internet in case they needed any extra information.

*“Verbal from the dentist, but I’ve also searched on the internet, I also read a leaflet inside the waiting room. I think apps will not make a profit and it may be a wasting time making it because teenagers will not be interested in downloading an app about this kind of things.” (Shahd, 15 years)*

*“Spoken; quite a lot of talking in the meetings with the orthodontist. A leaflet I think and a sheet around what would happen in the procedure and a sort of what are the different parts of my braces and my retainer. I think talking to my orthodontist was the most important thing, because they know what are the important parts for the people involved, so they knew what the questions I wanted to ask and they were able to tell me a bit more than the sheets did. They would ask me if I had any question, and that will be the point where I do ask and they tell me about different parts of the treatment. But I think it would be important for an orthodontist to ask their patients if they have any problems or questions.” (Andrew, 16 years)*

*“When my son first came here, the orthodontist told him everything about what is going to happen, and then we went to see the general dentist who gave him a lot of encouragement as well.” (Parent)*

A draft (version1) of the decision aid resulted from these interviews (see Appendix I, version 1), which was shown to the review panel (expert patient group) to further develop it.

### **3.4.2 Step 2: Formation of expert groups to review and further develop the PDA**

The second step in the PDA development process involved the formation of expert groups to review and further develop the PDA. This step included an expert patient group and an expert clinicians group.

#### **3.4.2.1 Expert patient group**

This expert patient group consisted of five expert patients and five parents, who had already experienced orthodontic treatment to assist in reviewing the developed PDA. Five people of different age ranges (12 to 16 years old) and their accompanying parents were included in this group. Among this group there were three females and two males,

and the young people who took part were at different stages of treatment, ranging from four months in treatment to just having completed their orthodontic treatment. Participants in this group were taken through the developed PDA line by line and were asked to comment and suggest any changes the PDA needed. A topic guide was used (Appendix M).

#### 3.4.2.1.1 Main finding

The interviews with expert patients were based mainly on what had been raised by the interviews with the participants themselves. These included the design and format of the decision aid, whether to include before and after pictures for orthodontic treatment, and their comments on the questions on the last two pages of the decision aid. At the end of each interview participants were asked where they thought it was best to administer the PDA - at the general dental practice or at the orthodontic practice?

##### 3.4.2.1.1.1 *Design and format of the PDA*

At the beginning all participants were given a quick description of the draft PDA and asked to read the instructions on the first two pages and to be as critical as they could. Participants found the draft wording was straightforward and easy to understand. Comments were made that the PDA was easier to understand than the leaflets they had seen before, and recommendations were made to improve it further.

*“Definitely it is the easiest one I have seen, I can concentrate on it through the whole things, I think it is of good length, people can still be able to concentrate and take the information and understand it.” (Eva, 15 years)*

*“I think if you have it as short sentences or bullet points it may work a lot better, like have it in a tree with different points, it may make it easier for everybody to read and understand.” (Jacob, 14 years)*

##### 3.4.2.1.1.2 *Before and after pictures*

A range of views were expressed about before and after photos. Some participants felt they would be useful, others felt they already knew what the end results would look like.

*“Before and after photos will help people in deciding about having brace treatment. Because if I don’t like how my teeth look like, and I have been shown photos of how they will be after treatment, I will probably say that I want this treatment.” (Isabella, 13 years)*

*“I think everybody has got the idea of what the ideal set of teeth would look like.” (Parent)*

Expert patients and their parents commented on section 2 of the PDA, the section entitled ‘check your choice’ and proposed adding more options in case anyone needs more information, advice or discussion about their treatment. Participants thought that these options may help those who were still undecided.

*“I am not sure about the bit on support and advice to make a decision to have a brace or not, I’d say probably no I think, from reading this I don’t think there is things about support” (Jacob, 14 years)*

*“I think the only thing is about whether you are sure if you have enough support and advice, I don’t know anywhere to put something about where else you could find advice or information on.” (Parent)*

#### *3.4.2.1.1.3 Timing and setting for the use of the PDA*

Expert patients were asked whether to have the PDA given by the general dentist or to be given by the orthodontist. A range of views were expressed, some people thought using this PDA at the general dentist would save patients’ time if they decided not to have orthodontic treatment. However, some other participants thought that the orthodontist was the best person to provide them with information about orthodontic treatment.

*“I think once you read this their own dentist would be able to explain, I think it is better to be used at the general dentist.” (Parent)*

*“I think it is nice, and you’re still able to see the orthodontist in case you’ve got any extra questions.” (Grace, 13 years)*

*“Probably the orthodontist, because they are more specialised than the dentist, but the dentist can help in backing up the information. I don’t know I probably take it more from the orthodontist who is more informed about the information” (Adam, 14 years)*

A draft version of the decision aid resulted from interviews with the expert patients group, which was shown to the expert clinicians group for further review and development.

### **3.4.2.2 Expert clinician group**

#### **3.4.2.2.1 Sample obtained**

This group consisted of ten experts in clinical care including, one general dental practitioner, one community dentist, and orthodontists in primary and secondary care, as well as a psychologist with extensive experience in the development and evaluation of PDAs to assist with developing the current PDA.

#### **3.4.2.2.2 Main findings**

##### **3.4.2.2.2.1 *General dentists***

Face-to-face interviews with two dental practitioners were carried out and including taking them through the PDA and asking them to comment on the amount of information presented and the format of the decision aid. This revealed that they considered the PDA to be long, but it was clear and covered the essential information patients need in a balanced way.

*“I think it is fine; it covered what they need to know. It is quite clear and balanced, the questions patients ask are all here in one format; I think it will help them. It tries to cover all information which makes it a bit longer, you know six pages is quite long, but you try to give them quite a lot of information and get some information about them as well. I think for what you will use it, it has to be that long and I don’t think it can be shorter than this. You have not used any extra words that you don’t need and all information is precise to the point.”*  
(Dentist 1)

When asked about whether to have pictures in the PDA, dentists felt that pictures were always helpful for patients to know what to expect and how the appliances would look.

*“I think it is nice to keep the pictures. You covered all the risks and benefits of treatment so I don’t think the picture will push them toward having the braces, the draft presented in a balanced way and the picture is the only way of presenting that information.”* (Dentist 1)

*“It is attractive when you put some pictures, more attractive rather than just have it written only, also the way you put it in coloured blocks rather than have it in one colour. It looks visually attractive. I found the language is fine for teenagers 12 to 16 years old, they can understand and read.”* (Dentist 2)

A theme that emerged from the interviews was the impact of using the PDA on the time in the clinic. A range of views were expressed from the different experts. One community dentist thought that it would save time in the clinic, as it contained all the information asked by patients, whereas the general dental practitioner thought it was impractical in an NHS dental practice due to the length of time it would take to complete:

*“It will have an impact on time, but a lot of time is spent with the patient at the time of referral to orthodontics. The patients start asking questions and the parents asking questions as well and then you end up spending more time with them in anyway. So when you have a document like this beside you it may save time, all the information we need and patients ask about is already there. I think it is worth doing with the clinician at the time of referral. Also, after going on with it, you still can give it to them to take home if they want.” (Dentist 1)*

*“It is quite long. In General NHS practice they do not explain all of the information presented here. They will explain things like how to make your teeth clean, they will not explain what the brace will look like, they may explain about the appointments, and they probably wouldn’t explain about the discomfort. I think this is something that should be taken home by people, and it is not practical for general practice, because you have only 10 minutes to see a patient including everything such as assessment and take X rays and explain to patients about treatment. From a practical perspective, I think it is suitable for community services and not for the general NHS practice.” (Dentist 2)*

#### 3.4.2.2.2 Orthodontic experts

Nine orthodontists were included in a focus group to review the PDA. This group comprised of five orthodontic consultants and three specialist registrars from the Department of Orthodontics at the Charles Clifford Dental Hospital, and one orthodontist from the private sector.

Many suggestions regarding the wording of items were made. These suggestions were related to information about orthodontic treatment and the commitments required, the consequences of having braces, including the benefits, as well as the risks. For example, the orthodontists suggested changing the statement ‘some of the appointments’ will be at school time to ‘most of the appointments’ as this will usually be the case. They also proposed changing check-up appointments from ‘6 to 8 weeks’ into ‘4 to 6 weeks’.

Regarding pain associated with wearing an appliance, from their experiences, clinicians thought that pain happened in all cases and it worsened in the first few days. They recommended saying that ‘braces will cause an aching pain and rub your gums when first fitted and after the wires are changed. This can last for several days, but most people get used to it quickly, and you may need to take pain killers for a few days.’

About how teeth will look after treatment, clinicians proposed to search for a study to find data about the proportion of people who were satisfied with the look of their teeth after orthodontic treatment instead of just saying ‘people think their teeth look better after brace treatment’.

The group suggested expanding the explanation about retainers, as they thought it was very important for the patients to know. After a long discussion the group agreed on the following statement ‘To keep your teeth lined up once the brace is removed usually means wearing a retainer for at least a year. You should keep checking the retainers still fits as long as you want your teeth to remain straight. We can show you what a retainer looks like if you want’.

Regarding delaying treatment, orthodontists suggested the use of ‘you can still have fixed braces as an adult, but it may take longer and it will be more inconvenient and you may have to pay for it’.

The orthodontic experts discussed the evidence used in the PDA, especially about the risks, such as demineralisation and the prevalence of severe root resorption. The Quality Assessment Tool for Studies with Diverse Designs (QATSDD) was used to assess the quality criteria for each study cited in the decision aid (see Appendix Q). A conclusion summary of each of the cited studies is provided as an appendix (technical paper- see Appendix R).

Another PDA draft resulted after considering the amendments and suggestions of the expert clinicians group. This version was shown to a psychologist with extensive experience in the development and evaluation of decision aids.

#### *3.4.2.2.3 Psychologist comments*

Some suggestions were made to ensure a description of the health problem was included and to make the introduction section more neutral. For example, instead of being directive toward having teeth straightened; a statement like “*It is up to you and your*

*parent to decide whether you want to have your teeth straightened or to leave your teeth as they are. If you decide not to have treatment, your teeth will not be less healthy. If you decide to have them straightened there may be a few ways that it may be done. No one way is best for everyone”* was added to clarify that the decision belonged to the patients and their parents.

To make the information and consequences section of the PDA balanced, the psychologist recommended both columns should have equivalent amount of information without including pictures. From the psychologist point of view, it is difficult to include photos which do not influence the patient’s decision (Houts *et al.*, 2006).

Also she suggested changing the heading of the two columns from ‘fixed braces’ into ‘fixed braces with orthodontist’, and ‘other possible treatments’ into ‘other treatments to change the way your teeth look.’

A final PDA version resulted after considering these comments (see Appendix I, version 2). This version was achieved in March 2014 and used in the pilot evaluation of the PDA. First and last versions of the PDA can be found in Appendix I. The final version of the developed PDA consisted of three main categories, including information about treatment options, possible risks and changes to daily life, and finally there is a value-clarification exercise at the end. In order to assess the quality of the final draft of the PDA, it was checked against the International Patient Decision Aid Standards collaboration checklist (Appendix S).

## **3.5 Discussion**

### **3.5.1 Introduction**

As mentioned earlier, cooperation from orthodontic patients and their parents during treatment is essential in orthodontic care. Improved communication between the orthodontist and patient is an important way to inform patients about the course of treatment, as well as the possible benefits and risks in a format that they can understand and retain (Witt and Bartsch, 1996). Such communication would hopefully increase the possibilities of the patient making the appropriate decision about treatment for them (Bergström *et al.*, 1998), and as a consequence there might be greater patient satisfaction, reduced treatment time and improved treatment outcomes (Thomson *et al.*, 2001; Souza *et al.*, 2013).

In orthodontics, doctor-patient communication has been reported as the key to the establishment and maintenance of patient cooperation (Witt and Bartsch, 1996), therefore, in orthodontic clinical practice, an effective strategy to enhance doctor-patient communication would be useful.

It has been suggested that the use of patient decision aids encourage communication between doctor and patient (Nelson *et al.*, 2007; Reuland *et al.*, 2012), also, unlike the usual patient information leaflets, PDAs promote a more ‘informed’ decision-making process (Gillies *et al.*, 2014).

To our knowledge, no PDAs exist to assist young patients and parents in making a decision to undergo orthodontic treatment or not. In this part of the project, a PDA was developed, based on a recognised process (ODSF) and guided by a workbook for developing and evaluating PDAs published by O’Connor and Jacobsen (2003). Qualitative interviews were used to explore the impact of having orthodontic treatment with fixed appliances from the viewpoint of young people and their parents. Such interviews provided new insights into children’s and their accompanying parents’ experiences of having orthodontic treatment, as well as assisting in producing a child-centred decision aid.

### **3.5.2 Process of PDA development**

The ODSF, which has guided the development of many previous PDAs, was used to guide the development of this decision aid. The ODSF (O’Connor *et al.*, 1998a) is particularly relevant to ‘preference-sensitive’ decisions, in which a considerable amount of information on potential treatment risks and benefits is involved (Coulter *et al.*, 2013).

There are very few clinical situations where there is just one course of action that should be followed in all cases (Coulter and Collins, 2011). “In circumstances where there are a number of options leading to different outcomes, and the ‘right’ decision depends on a patient’s own particular set of needs and outcome goals, the condition is said to be a preference sensitive” (Wennberg *et al.*, 2010).

Orthodontic treatment is a preference sensitive decision, as it is an elective treatment carried out over a long period of time. In order to cover the first two steps as defined in the workbook of PDA development (assessment of need and feasibility) and described in section 1.10.1, a literature search was carried out for evidence about treatment

benefits and risks to incorporate into the PDA. Evidence was retrieved from clinical trials, systematic reviews and discussions with clinical experts.

The major steps involved in the development of this PDA consisted of gathering information through qualitative interviews with patients and parents, initial decision aid prototype construction, then refinement of the PDA by patients currently undergoing orthodontic treatment. Further amendments were undertaken following discussion of the PDA contents with experts, before starting the initial evaluation of the PDA. This is similar to the iterative development process outlined by O'Connor and colleagues (1998b), which involved the research team and panels of patients and experts. Figure 3 on page 91 outlines the flow diagram for the development process of the PDA.

Although this PDA was developed in accordance with the IPDAS criteria, 11 out of the 54 criteria could not be met (see Appendix S). Five of the 11 unmet criteria were related to screening and test results, which are not used in orthodontics. The other six unmet criteria were related to comparing outcome probabilities using a scale and denominator, as well as using frames to show both survival and death rates, which are not relevant for orthodontic treatment.

The PDA was constructed along three categories, based on the workbook for developing and evaluating PDAs, these include:

- Information about treatment;
- Possible risks;
- Changes to daily life.

In addition to presenting information about treatment options, a specific value-clarification exercise was included at the end of the PDA. The concept of value refers to the qualities that patients consider important. The value-clarification exercise is important because it has been reported that decision aids incorporating value clarification exercises were more effective than simpler aids in improving patients' decisions and making them congruent with their values (Stacey *et al.*, 2014); however, not all authors agree that value clarification has a role in decision aids. Nelson and colleagues (2007) suggested that explicit value clarification and attention to detail may interfere with a patient's ability to focus on the relevant material. Despite these theoretical concerns, after discussion with the expert patients a short segment on value-clarification was included. To help clarify a patient's values, a group of questions was

listed and patients were asked to indicate on a Likert scale what matters most to them, see section 2 of the PDA in appendix I.

### ***3.5.2.1 Clinicians' perceptions of the impact of the use of PDA on their clinical practice***

Clinicians had different views regarding the length of the PDA and its impact on time in dental practice. For instance, salaried dentists thought that using a PDA would save time in the clinic, as it contained much of the information about orthodontic treatment that patients need to know. On the other hand, the general dental practitioner thought that there would not be enough time to use the PDA under current NHS arrangements. This was in agreement with findings from the wider medical literature, as time pressure was frequently cited as a reason for not engaging patients in SDM (Stevenson *et al.*, 2000; Legare *et al.*, 2008). Although, many clinicians are found to be enthusiastic and like the idea of PDAs, time pressures are a barrier frequently cited in regards to the failure to implement them in practice (Holmes-Rovner *et al.*, 2000); however, a more recent Cochrane review (Stacey *et al.*, 2014) revealed no consistent findings regarding the effect of decision aids on consultation length. It has been suggested that PDAs should be incorporated into the informed consent process, and use of PDAs be made a requirement in hospital quality assurance schemes (Holmes-Rovner *et al.*, 2000). Further studies are needed to investigate the impact of the use of PDAs in dental settings.

### ***3.5.2.2 Young people and parents perceptions of the content and format of the PDA***

Young people and parents thought that the PDA was of an appropriate length, but the interviews found that they generally wanted a lot of information about treatment. When they were asked about what they wanted to know, some participants were concerned about the effect of appliances on playing musical instruments, others were worried about whether wearing appliances may prevent them from contact sports. However, young people expressed the view that, while some of this information was felt to be of interest, not all of it was necessarily important for the decision-making process, therefore it was not included in the PDA to ensure that it was clinically practical to implement. Links to the internet were provided in the PDA to help those who want more information about orthodontic treatment.

### **3.5.2.3 Use of pictures**

The use of before and after pictures emerged as an issue of difference between young patients and their parents on one side, and clinical experts on the other. While some patients and parents stated that seeing these photos would help them in making the decision, others felt that they knew how teeth would look after treatment without the need for photos. Clinicians thought that using before and after pictures may be helpful, particularly as the PDA was aimed at children, but may bias children's decisions regarding orthodontic treatment. Also, the psychologist recommended avoiding the use of these pictures, based on the PDA literature (Trevena *et al.*, 2013), which states that PDA developers should take care to avoid the use of misleading images.

Even though the use of visual aids, such as before and after pictures, can be a powerful tool to convey health-related information, it is difficult to predict how people may respond to these pictures (Houts *et al.*, 2006); however, it seems that their use for orthodontic patients is not necessary and also finding images that would provide a balanced view was difficult. We decided, therefore not to include images in this decision aid, but instead indicate to young people where on the internet they might find them. Further research is needed to investigate the influence of including before and after treatment pictures on young peoples' decision-making.

Overall, there is general agreement regarding the paucity of research on PDAs for children and young people and most of the existing decision aids are designed mainly for adults (Wyatt *et al.*, 2013). Even when they are aimed at children, they usually focus on the parental role in the decision-making process. Future PDA developments should include aids for children and young people in making decisions related to their health problems.

The next section will discuss the main findings from interviews in relation to the themes that emerged.

## **3.5.3 Findings related to the themes from the qualitative interviews**

### **3.5.3.1 Benefits of having braces**

There are many reasons for a person to decide to undergo orthodontic treatment. Enhancing appearance and improving oral health status are frequently cited motivating factors behind the patient's decision to initiate orthodontic treatment. (Gochman, 1975;

Baldwin, 1980; Birkeland, 1999; Daniels *et al.*, 2009; Marques *et al.*, 2009; Wędrychowska-Szulc and Syryńska, 2010; Pabari *et al.*, 2011).

The data from qualitative enquiry revealed that improving the appearance of the teeth was the main reason for young people and their parents to have orthodontic treatment. The main benefit perceived was 'having straight teeth' with 'a nice smile'. This was in agreement with a recent systematic review of motivational factors for orthodontic treatment in children carried out by Samsonyanová and Broukal (2014); however, for some people improving oral hygiene was cited as a reason to have orthodontic treatment because they could not brush their teeth properly.

Souza and colleagues (2013) investigated patients' desires and doubts regarding orthodontic treatment in a cross sectional questionnaire survey in a sample of 60 adult orthodontic patients aged 18 to 25 years, occlusal deviation was expressed by 66.7% of participants as the main reason for seeking orthodontic treatment, whereas aesthetic reasons were reported by 48.3% of individuals. This inconsistency may be due to the variation in age groups between young people and adult patients in seeking orthodontic treatment, as in our sample we included young people aged 12 to 16 years old.

Findings in a recent report by the Picker institute (Goodall and Burger, 2013) who interviewed 11 young people aged 12 to 15 years and their parents to understand their priorities around wearing orthodontic appliances revealed that health reasons, such as overcrowding or thumbsucking, were cited as the main motivation for having fixed orthodontic appliances fitted, although there may be a cosmetic influences to this decision, and in some cases, improving appearance was the only reason for seeking orthodontic treatment. The authors attributed their finding to the fact that people mention health as the primary reason, because this is what is needed for NHS treatment, but aesthetic reasons may be the real driving force.

### ***Risks of treatment***

Different levels of awareness of the risks of orthodontic treatment were found among participants. It seems that young people have a number of concerns about having orthodontic treatment, these include discolouration of the teeth, avoiding certain types of food, irritation to cheek and gums, as well as shortening of the roots of teeth. Although, concerns about eating and irritation to oral tissues were mentioned by some

participants when talking about risks, they will be discussed in the next section about the 'Impacts of braces'.

In a study investigating perceptions of the benefits and risks of orthodontic treatment among potential orthodontic patients carried out by McComb *et al.* (1996), the results revealed that most parents were aware of the benefits of treatment in general. This awareness was greater, especially if the need for orthodontic treatment was based on aesthetic grounds. There was less awareness of the risks of treatment, probably because general dentists were less likely to communicate risks to patients and their accompanying parents. The study recommended that dentists could provide this information for patients before referring them for orthodontic treatment, as for some patients the risks of treatment may outweigh the benefits. For that reason, using interventions, such as the PDA, might be more helpful if delivered in the setting of the general dental practice, before being referred for an orthodontic opinion.

One of the most common risks of having fixed orthodontic treatment is the discolouration of teeth which results from enamel demineralisation. Warning patients about the prevalence of demineralised lesions, also known as white spot lesions (WSL), during treatment was found to be important by participants in this study. Previous studies have reported that the prevalence of white spot lesions (WSL) ranges between 0 to 97% (Sonis and Snell, 1989; Boersma *et al.*, 2004; Chapman *et al.*, 2010; Tufekci *et al.*, 2011). Recently, Julien and colleagues (2013) determined the prevalence of visible WSLs during orthodontic treatment in a sample of 885 patients who had completed treatment. Before and after treatment photographs for maxillary and mandibular six anterior teeth were evaluated for any visible lesions. The authors reported that 23% of patients had developed WSLs, and the prevalence was higher in maxillary teeth (73%) compared to mandibular teeth (27%). It has been stated that one out of four orthodontic patients could develop visible WSLs and this proportion increased to approximately 60% in patients who did not maintain a good level of oral hygiene throughout the period of treatment (Julien *et al.*, 2013). Although, the study by Julien and colleagues was based on a large sample size compared to previous studies, no sample size calculation was performed. However, it is crucial to fully inform patients about the risk of having discoloured teeth after fixed orthodontic appliance treatment and that this risk is increased if they do not properly brush their teeth.

Shortening of the roots of teeth is another common problem associated with orthodontic treatment. Evidence from a recent systematic review carried out by Weltman and colleagues (2010) suggested that orthodontic treatment increased the incidence and severity of root resorption especially with the use of heavy orthodontic forces. Root resorption occurs in more than 90% of orthodontically treated teeth, but this resorption is usually less than 2.5 mm and considered as clinically insignificant. However, the incidence of moderate to severe root resorption, resorption of more than one third of the original root length, has been reported to occur in around 5% to 12% of teeth (Weltman *et al.*, 2010). The authors stated that it is important to notify orthodontic patients of the risks of root resorption before starting treatment, because reduction in root length will lead to an unfavourable crown-root ratio of the affected teeth, making them inappropriate abutments and anchorage units for prosthetic restorations. Although this review included 11 RCTs, the risk of bias is still present because of the differences in methodologies and reporting. The authors recommended the need for studies with appropriate randomisation and masking of outcome assessment, based on sample size calculation, and be conducted over the full period of orthodontic treatment.

### ***3.5.3.2 Impacts of orthodontic appliance***

The most negative impact described by participants was the perceived pain and discomfort from orthodontic appliances. Girls were mainly concerned about the pain especially during the first few days after having braces fitted. This finding supports previous studies who found that pain is among the most cited negative effects of orthodontic treatment (Oliver and Knapman, 1985; Kluemper *et al.*, 2002; Asham, 2004; Keim, 2004), especially in females (Bergius *et al.*, 2000; Krishnan, 2007; Goodall and Burger, 2013).

From the literature it is well known that all orthodontic procedures, such as separator placement, archwire placement and activation, elastic wear, orthopaedic force application, and debonding, produce pain in patients. In a retrospective study of dental discomfort and pain conducted by Lew (1993), 91% of 203 adult orthodontic patients reported pain from orthodontic appliances. In 39% of these patients pain and discomfort were experienced during every step of treatment, such as changing an archwire or placement of elastics. Many studies reported that the majority of patients experienced pain after archwire placement for about four hours and this pain reached its peak after 24 hours, then it declined until it completely subsided (Jones, 1984; Ngan *et al.*, 1989;

Scheurer *et al.*, 1996; Erdinç and Dinçer, 2004; Polat and Karaman, 2005). Patients' perceptions of pain and discomfort were also found to have a strong negative effect on overall satisfaction with orthodontic treatment (Feldmann, 2014). Therefore patients need to be clearly warned about the pain and discomfort during the decision-making process, as not all patients expected orthodontic treatment would be painful.

Other impacts of having braces on daily life, as raised by children, included what they can eat or drink. Children were concerned about changing their diet and avoiding hard and sticky foods to prevent damaging their orthodontic appliances as well as stopping having fizzy drinks to avoid discolouration of teeth. In agreement with Goodall and Burger (2013) these restrictions were sometimes seen as a good thing for reasons of general health.

Although some were concerned about how others people may react to them wearing a fixed appliance, many children thought this was not an issue because many of their friends were having orthodontic treatment at the same time.

From the parental point of view, this study produced results which corroborate the findings of Goodall and Burger (2013) in which the main concern was the commitment that orthodontic treatment requires, such as the number of visits to the orthodontist, as this will usually interfere with school and parents need to have time off work to take their children. Parents indicated that this commitment was usually managed by selecting later appointments, such as at the end of the day, to avoid missing school and when it would be more convenient for them to leave their work.

### **3.5.3.3 *Timing of orthodontic treatment***

The optimal timing for initiating orthodontic treatment remains a matter of debate as it is largely influenced by the severity of the malocclusion and the maturation of the patient presented for treatment (Jang *et al.*, 2005; Jain and Dhakar, 2013). During this stage of the project the main focus was patients' and parents' perspectives about timing to initiate orthodontic treatment regardless of any other physiological or clinically related issues.

Young people and their parents generally felt treatment earlier was preferred because many of their friends and classmates were already undergoing orthodontic treatment. Previous research reported that the uptake of orthodontic treatment is greatly influenced by the individual's peer groups (Burden, 1995; Bergström *et al.*, 1998). The results of

this study were consistent with DiBiase (2002) who suggested that adolescents, who have concerns about the appearance of their teeth and have friends who are undergoing orthodontic treatment, will be more cooperative as the treatment will be accepted by their peers. This also corroborates with Proffit *et al.* (2000) who suggested that typical orthodontic treatment occurs about the time when most of permanent teeth are present in the mouth, around the age of 11 to 13 years old, and during this time children usually have a stronger orientation toward their peers. It has also been proposed that around the age of 11 years practitioners can explain treatment objectives and issues with the same language that could be used for adults (Bullwinkel, 2014); however, in this study, participants who expressed a preference about having treatment when they were older argued that they would be more responsible for taking care of their appliances and conform to the orthodontist recommendations.

#### **3.5.3.4 Information details**

Additional information that emerged from the interviews as being important to participants was the duration of treatment, and the wearing of retainers after active treatment was completed. Although, Goodall and Burger (2013) found that some parents thought their children were too young to understand about retainers and it may put them off, orthodontic experts recommended warning patients about the need for retainers. Discussing with patients and parents their malocclusion and treatment process, including different treatment options, is important in motivating orthodontic patients to make an informed choice and help them decide what would work best for them (Sinha, 2010). This approach has been successful in improving patients' cooperation in different areas of orthodontic therapy (Gross *et al.*, 1991; Rubin, 1995).

#### **3.5.3.5 Sources of information**

Although, it seems that most patients and their parents regard the orthodontist as the best person to provide them with information about orthodontic treatment, participants perceived that at the time of referral the general dentist should provide patients with an idea about the treatment and what to expect from having orthodontic treatment, then the orthodontist can supply the details. Some young people preferred to have information from their general dentist because they thought it was more comfortable to talk to someone they knew. Other young people noted that friends and others who have had braces had provided them with the information they needed.

In the UK, the role of general dental practitioners in orthodontic therapy is fundamental, as the referral for orthodontic treatment is usually initiated by them, therefore they need to discuss the benefits and risks of orthodontic treatment to patients before the referral is made (Ellis and Benson, 2002). Patients who are poorly informed about the risks of orthodontic treatment may fail to attend appointments and demonstrate poor cooperation (Brattström *et al.*, 1991; Thickett and Newton, 2006), therefore a PDA for orthodontic patients may be better introduced in general dental practice, before referral to the specialist.

In this study, young people perceived that the decision to have orthodontic treatment was made by them after a discussion with their parents, even if it was first mentioned by a general dentist or orthodontist. Some of the participants had already made a decision to have orthodontic treatment before seeing the orthodontist. This was in agreement with Goodall and Burger (2013) who asked children whether they felt involved in the decision making process and reported that nearly all the children felt the orthodontist and their parents were allowing them to make their own decision about having braces. Conversely, the results of this study contradict findings from the previous literature (Nel and Dawjee, 2012) who reported that 72% of children did not make their own final decision to undergo orthodontic treatment; however, this could be attributed to the large component of subjective evaluation in their study.

Further research is needed to explore the feasibility and acceptability of introducing the PDA in general dental practice for those considering orthodontic treatment.

#### **3.5.3.6 Format of information**

Verbal discussions with general dentists and orthodontists, and written information leaflets were the preferred ways of giving information about orthodontic treatment. During the interviews, participants showed interest in ‘apps’ or having links to the internet for delivering further information, in addition to that provided by dentalcare professionals and information leaflets. These findings were in agreement with previous researchers who found that combining verbal with written information about treatment increases patient understanding, cooperation and expectations of treatment, as well as enhancing motivation for orthodontic treatment (Culbertson *et al.*, 1988; Mayeaux *et al.*, 1996; Wright, 2010). Furthermore, Goodall and Burger (2013) found that leaflets and discussion with the healthcare professionals provide adequate information for children to make a decision and to take care of their appliances. However, the results of

a recent RCT revealed that supplementing verbal information with information leaflets does not have an impact on patients' expectation about orthodontic treatment (Nasr *et al.*, 2011). These authors recommended more research to explore other methods to maximise the retention of information before and during orthodontic treatment.

The results of this study indicate that some young people and their parents were not expecting pain or at least not for the length of time they experience it, were not very clear about what to eat and what to avoid. Some were also not expecting to wear a retainer at the end of any fixed orthodontic appliance treatment. Although this information is usually covered during the discussion with the orthodontist, it is possible that patients could not absorb all information given at the consultation appointment. Similar findings were also reported by Mortensen *et al.* (2003) who concluded that patients do not adequately comprehend the information given during the informed consent process and suggested that innovative methods of patient preparation would improve their cooperation and future research should focus on methods to improve the informed consent practice for orthodontic patients. Nel and colleagues (2012) stated that "lack of communication between the orthodontist and the patient and insufficient information about orthodontics can lead to premature termination of the treatment. Orthodontists should therefore look at the way they educate patients, ensuring that full comprehension has been achieved." Therefore, different formats for delivering information and facilitating discussions with healthcare professional such as PDAs may be useful to ensure that all patients are appropriately involved in the decision-making process.

The words that young people used to describe the reasons why they wanted orthodontic treatment and what they thought about the possible benefits and risks from having fixed appliances were included in the PDA.

#### **3.5.4 Limitations of PDA development**

The influences of parents on children's expressed views are complex. Therefore the impact of parental presence must also be addressed. In this instance, research has suggested that the presence of the parents/guardians during the interview process may actually inhibit child responses, with younger participants more likely to provide richer data when they can voice their personal views away from their parents/guardians (Gardner and Randall, 2012). Although, there may be some bias introduced by interviewing the child and the parent together, the decision was taken after giving

children the opportunity to choose if they want to be interviewed together. Children who stated that they wanted their parents to be included in the interview completed the PDA together.

Another possible limitation is that the findings may be affected by characteristics of the participants as their views might be different between those who are in treatment and others who just started treatment or considering the treatment.

While the evidence included in the PDA was based on a thorough review of the literature guided by the hierarchy of evidence, the quality of the included studies was assessed to be moderate. In general, there is a lack of evidence in the field of orthodontics due to the existence of few well-designed randomised controlled trials (Williams *et al.*, 2004).

In this chapter we carried out qualitative interviews involving young people and their parents as well as clinicians, and as a result a PDA has been developed. The next chapter will describe the process of the pilot evaluation of the developed PDA.

## **4 CHAPTER FOUR: PILOT EVALUATION OF THE PDA**

### **4.1. Introduction**

The final stage of the project was a pilot study to begin the evaluation of the PDA by children and their parents. As mentioned earlier, the Ottawa Decision Support Framework (ODSF) was the theoretical framework that was used to guide the development and evaluation of the decision aid (Appendix B). The framework emphasizes that the quality of decision-making can be adversely affected by decisional conflict, insufficient knowledge, and unrealistic expectations (O'Connor *et al.*, 1998b); therefore these outcomes were chosen in the evaluation of the developed PDA.

This chapter will describe the methods used for a pilot study to investigate whether the use of a PDA will improve patient outcomes, such as decisional conflict, patient expectations and knowledge. Ideally a randomised controlled trial would be used to evaluate the PDA; however there were little data available to inform the sample size of an RCT, therefore a pre-post-test design was chosen. This design has been used previously to evaluate PDAs (O'Connor *et al.*, 1998; Cranney *et al.*, 2002; Stacey *et al.*, 2003; Menard *et al.*, 2010), and in addition was expected to provide valuable information to inform the design of a future study.

### **4.2. Ethical approval and permission**

Ethical approval for the study was obtained from (NRES Committee Yorkshire and The Humber – Sheffield) before commencement of the study (reference number 13/YH/0166, 26 June 2013) (see Appendix D). The NHS approval was obtained from Sheffield Teaching Hospitals (STH17202) (see Appendix E).

### **4.3. Method**

#### **4.3.1. Overview**

Validated measures were used to begin the evaluation of the developed PDA, in terms of reducing decisional conflict, increasing knowledge, and developing more realistic and accurate expectations among patients making the choice whether or not to go ahead with fixed orthodontic appliance treatment. The details of the pilot study will be provided in this chapter.

### **4.3.2. Setting**

This study was carried out at the Orthodontic Department of the Charles Clifford Dental Hospital, Sheffield, UK. In this department there are five orthodontic consultants, each with one new patient clinic per week with approximately six patients - that is 30 new patients per week. It was estimated that around 30 – 50% of those patients might be eligible for this part of the project.

### **4.3.3. Participants**

To begin to evaluate the PDA, young people and their parents were invited to participate in the study.

Recruitment was based on the following inclusion and exclusion criteria:

- Young people aged 12 to 16 years old.
- Young people who have been referred to the Orthodontic Department of the Charles Clifford Dental Hospital for a consultation and who might be suitable for fixed orthodontic appliance treatment.

Exclusion criteria:

- Patients outside the age range 12 - 16 years.
- Patients who had orthodontic treatment in the past.
- Patients requiring or already undergoing orthodontic treatment with removable or functional appliances.
- Patients with craniofacial anomalies.
- Patients requiring or already undergoing orthognathic surgery.
- Patients who were to be reviewed after more than 6 months.
- Patients with severe learning disabilities, who were unable to participate even with additional support from the research team.
- Non-English speaking children.
- Young people or parents who refused to give consent.

### **4.3.4. Outcomes**

For the purpose of evaluating the PDA, the outcomes were derived from the following validated questionnaires: the Decisional Conflict Scale (DCS), and the Orthodontic Patient Expectation Questionnaire (OPEQ). More details about these measures, their properties and scoring systems will now be provided.

#### **4.3.4.1. Decisional Conflict Scale**

Decisional conflict has been defined as “a state of uncertainty about the course of action to be taken” (O'Connor, 1993 [updated 2010]). The Decisional Conflict Scale (DCS) is a questionnaire designed to measure the level of decisional conflict that patients encounter while making healthcare decisions (Koedoot *et al.*, 2001). The scale measures the constructs of overall decisional conflict and subscales relating to the factors contributing to uncertainty (e.g. feeling uncertain, uninformed, unclear about values, and unsupported in decision making), the final sub-scale measures perceived effective decision making. The scale has been adjusted to a grade eight reading level, which is equivalent to the UK school year 9 (age 13-14 years) and it was expected that the DCS usually takes about 5 to 10 minutes to complete (O'Connor, 1997).

The DCS consists of five subscales;

1. Informed Subscale (I know which options are available)
2. Value Clarity Subscale (I am clear about which benefits matter most to me)
3. Support Subscale (I am choosing without pressure from others)
4. Uncertainty Subscale (I feel sure about what to choose)
5. Effective Decision Subscale (I feel I have made an informed choice).

The original scale (see Appendix T) was adapted by the researcher to be used with parents by changing the question wording from ‘me’ to ‘my child’ for example, “I know which options are available to my child” instead of “I know which options are available to me”. These amendments to the original questionnaire were necessary for the purpose of this study because the treatment is for the child, not the parent. The parental version of the DCS is included as Appendix U.

##### **4.3.4.1.1. Scoring**

The DCS has 16 items using a five-point Likert format. The response categories are classified as follows; ‘Completely agree’ = 0, ‘Agree’ = 1, ‘Neither agree nor disagree’ = 2, ‘Disagree’ = 3, and ‘Completely disagree’ = 4. The total score is calculated by adding together the individual responses of the 16-items, then dividing this value by 16 and multiplying the resulting value by 25. This results in standardised scores ranging between 0 – 100. Low scores indicate low decisional conflict, i.e. score of 0 indicates no decisional conflict, whereas high scores represent high decisional conflict. A similar formula is used to obtain individual scores for each subscale, as follows;

*Informed Subscale*; scores from items 1, 2 and 3 are summed, divided by 3 and multiplied by 25. Scores range from 0 - 100. A score of 0 indicates the participant feels extremely informed, a score of 100 indicates the participant feels extremely uninformed.

*Values Clarity Subscale*; a score of 0 indicates the participant feels extremely clear about personal values for benefits and risks/side effects, a score of 100 indicates the participant feels extremely unclear about personal values.

*Support Subscale*; a score of 0 indicates the participant feels extremely supported in decision making, a score of 100 indicates the participant feels extremely unsupported in decision making.

*Uncertainty Subscale*; a score of 0 indicates the participant feels extremely certain about the best choice, a score of 100 indicates the participant feels extremely uncertain about the best choice.

*Effective Decision Subscale*; a score of 0 indicates a 'good decision', whereas a score of 100 indicates a 'bad decision'.

#### 4.3.4.1.2. Properties of the DCS

The DCS has been evaluated in several patient populations (Siminoff and Fetting, 1991). The scale has been used in more than 30 studies for numerous decisions (O'Connor, 1993 [updated 2010]). It is the most widely used scale in PDA evaluations, and it has been extensively evaluated and widely used both in the UK and internationally and across a broad range of treatment areas (Stacey *et al.*, 2011) updated (2014). Furthermore, in a recent report it was stated that the DCS is general in nature and does not need to be adjusted for each condition. It can be used alongside a decision aid and in conjunction with alternative decision support materials, making it an adaptable measure (Department of Health, 2012). It has also been reported that the DCS is effective in measuring decisional conflicts in children (Knapp *et al.*, 2009). The measure has good internal consistency and repeatability, with a Cronbach's alpha coefficient ranging from 0.78 to 0.92 and test-retest coefficients exceeding 0.80 (O'Connor, 1995). Sample sizes for studies using the DCS are usually selected based on detecting an effect size between 0.30 to 0.40 (O'Connor, 1993 [updated 2010]).

#### **4.3.4.2. Orthodontic Patient Expectation Questionnaire**

This scale was adapted from a questionnaire to measure patients' expectations of orthodontic treatment (Sayers and Newton, 2006). The original Orthodontic Patient Expectation Questionnaire (OPEQ) consists of 10 questions relating to expectations of

the initial visit, the type of treatment expected, problems associated with orthodontic treatment, duration and frequency of attendance and the expected benefits of treatment (see Appendix T).

The parental version of the questionnaire was obtained from the authors of the OPEQ (Sayers and Newton, 2006). Only minor changes to the main scale have been carried out by the developers of the original questionnaire (Sayers and Newton, 2006) to enable the OPEQ to be completed by parents.

For the purpose of this study, the first question regarding the expectations of the initial visit was removed because participants needed to be examined by consultant orthodontists to be eligible for the current study.

In addition, three questions to elicit the patient and their parents' knowledge regarding orthodontic treatment with fixed appliances were added by the researcher to the original questionnaire. The first two questions (number 10 and 11 of appendices T and U) were open ended, in which respondents were asked to write what they think are the possible benefits and risks from having fixed orthodontic appliance treatment. Question 12 is checking whether the patients and parents feel that they were given enough information to make the best treatment choice. The last question (number 13) was added to check the participant's decision whether to have orthodontic treatment or not. It was expected that the typical time taken for completion of the consent and the questionnaire would be approximately 5 to 10 minutes as stated by the original authors (Sayers and Newton, 2006).

#### 4.3.4.2.1. Scoring

The response format of the OPEQ is a 100 mm visual analogue scale (VAS) marked at 10-mm intervals, except for questions 7 and 8. The scale ranges from 0 = 'Extremely unlikely' to 100 'Extremely likely'. Respondents are asked to place a mark on the line nearest the point which best represents their expectations. The scores on the individual VAS were calculated by measuring the distance from the left hand site of the VAS to the participant mark in mm. The use of a VAS allows the participant to record more precisely the intensity of the domain being measured, instead of simply a yes/no response (Sayers and Newton, 2006). Furthermore, a VAS gives the maximum opportunity for the respondent to express their view in an individual personal response

style and can be used by children as young as 5 years old in a reliable and valid manner (Bergius *et al.*, 2000).

Responses to questions 7 and 8 (see appendices T and U) were categorical and were not answered on a visual analogue scale; these questions had variable time intervals for patients and their parents to choose. For question number 7 ‘How long do you expect orthodontic treatment to take?’, the respondent has 6 options ranging from ‘Don’t know’ up to ‘3 - 4 years’. For question number 8 ‘How often do you think you will need to attend for check-up?’ there were 6 response options ranging from ‘Don’t know’ up to every ‘6 - 8 months’.

#### 4.3.4.2.2. Properties of the OPEQ

The original measure was found to be a reliable and validated measure of orthodontic expectations of 12 - 14 year old patients and their parents in the UK. This measure has been found to be helpful in assessing unrealistic expectations and it is anticipated that OPEQ may be helpful in reducing failed appointments, and avoiding premature termination of treatment (Sayers and Newton, 2007). It has been used to investigate patient and parental expectation of orthodontic treatment in many countries, including the Netherlands (Hiemstra *et al.*, 2009), Pakistan (Mahmood *et al.*, 2011) and India (Duggal and Bansal, 2010; Singla *et al.*, 2013). The scale has also been used as an outcome measure in a randomised controlled trial to determine the impact of supplementation of verbal information with an information leaflet (Nasr *et al.*, 2011).

The internal consistency of the OPEQ has been shown to be good, with a Cronbach’s alpha of 0.76 and the face validity was judged by subjective assessment and relevance of the questionnaire to the participants (Sayers and Newton, 2006).

The measures used in the pilot evaluation of the decision aid were used for both patients and their accompanying parents.

#### **4.3.5. Recruitment procedure**

Figure 4 outlines the recruitment process in the form of a flow diagram. The researcher (AE) examined all the referral letters received by the Orthodontic Department of the Charles Clifford Dental Hospital. Potential participants were identified using the inclusion and exclusion criteria on page 119 and information sheets (Appendices V and W) were sent in the post, with the new patient appointment letter, at least one week

before their appointment. Two young people reviewed the information sheets, consent forms and the questionnaires to ensure that they were easily understandable.

The researcher then attended all orthodontic new patient clinics. Patients were seen and examined by the supervising consultant, who used the study inclusion and exclusion criteria and decided if they are suitable to take part in the study. Patients who did not fulfil the inclusion criteria followed the normal Orthodontic Department consultation process. Those who were judged as potentially eligible to enter the study were approached by the researcher (AE), who asked the patient and their parent if they had received and read the written information sheet. The researcher provided a verbal explanation describing the purpose of the study and asked if they were willing to take part. Young people and their parents were informed that all information was confidential, that they could withdraw at any time without giving a reason, and were given the opportunity to ask questions. A written, signed consent was obtained from those who agreed to participate (Appendices K and L). Participants and their parents were given standardized verbal and written information about orthodontic treatment by the researcher. Then they were asked to each complete a separate baseline questionnaire (Appendices T and U). The questionnaire included the decisional conflict scale (DCS) and patients' expectation and knowledge about orthodontic treatment (OPEQ).

On their next appointment, when the participants attended the Orthodontic Department for oral hygiene instruction and collection of orthodontic records, they were taken through the developed PDA by the researcher and they were asked to complete the list of questions in the PDA document before completing the same questionnaires again (post-decision aid questionnaire). While using the PDA, participants were encouraged to share their thoughts, ask questions about treatment options, and discuss any concerns that they may have. The completion of follow up questionnaires was performed prior to a visit with their orthodontist to discuss their decision or details of the treatment plan.

Participants completed the questionnaires in a quiet orthodontic surgery room in the Orthodontic Department. The researcher was available at the time of completion of the questionnaires for any assistance or explanation needed by the patients or their accompanying parents, and to ensure that parents did not assist their children in completing the questionnaires.

#### 4.3.6. Sample size

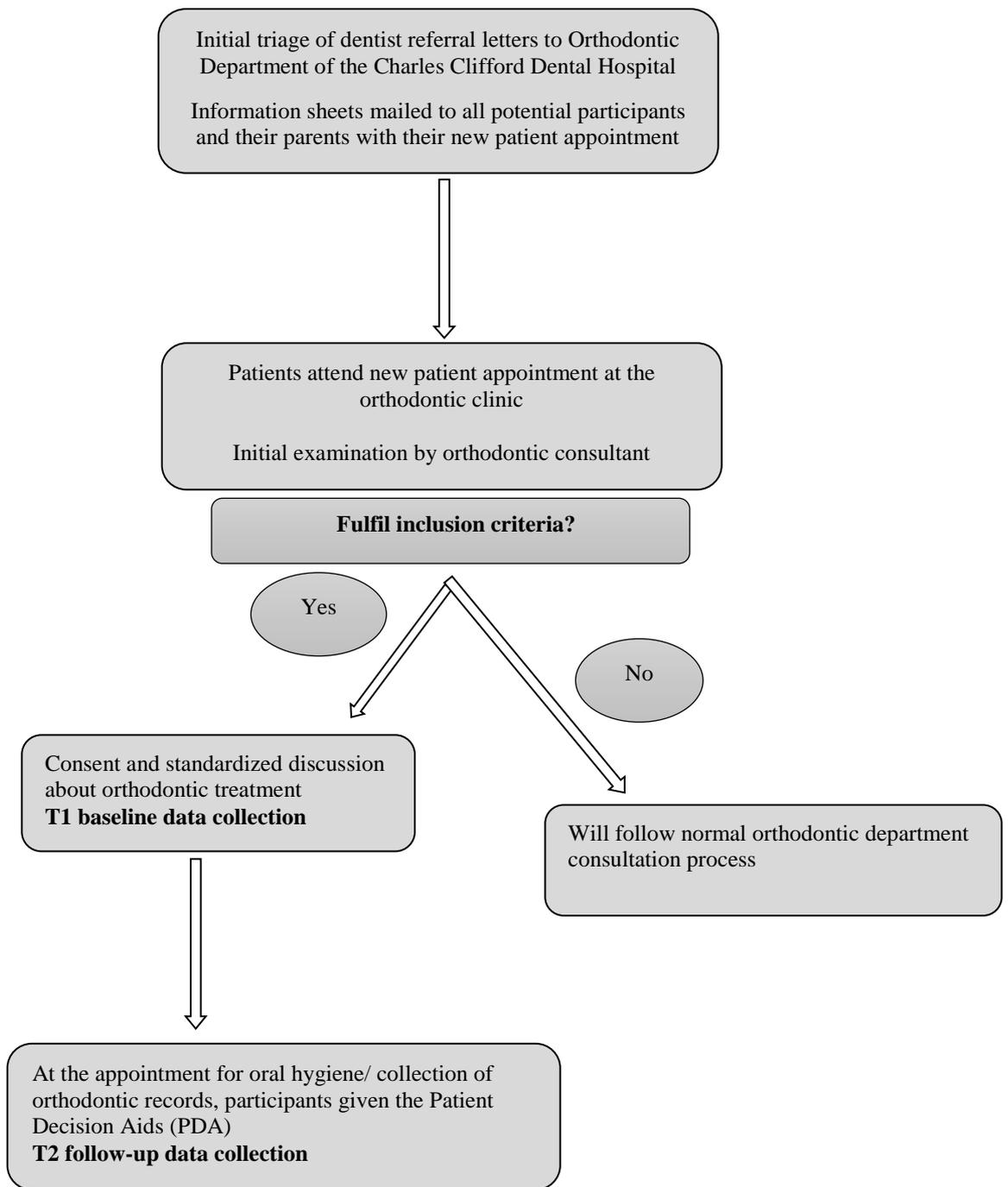
The sample size was estimated based on previous studies of the evaluation of PDAs. In a recent study of the development and preliminary evaluation of the effectiveness of a patient decision aid about treatment options for people with refractory angina carried out by McGillion and colleagues (2014) 20 patients were included in the pilot pre-test post-test evaluation phase, with decisional conflict as the primary outcome and knowledge of treatment options, and choice predisposition as secondary outcomes. The authors stated that this pilot evaluation would allow determination of the effect size of the PDA, which will then inform the required sample size for a randomized controlled trial (Kolbenstvedt *et al.*, 2002) of the effectiveness of the PDA as an intervention (McGillion *et al.*, 2014). The choice of their sample size was based on Hertzog's recommendation, who indicated that a minimum of 20 participants was needed for single sample pre-post pilot studies used to develop both estimates of effect size and variance for a RCT (Hertzog, 2008). In addition, they also based their sample on previous research data. Stacey and colleagues (2003) anticipated that for a level of significance of  $\alpha = 0.05$ , power ( $1 - \beta$ ) = 0.80, a standard deviation of 0.6, and a correlation between pre-test and post-tests scores of 0.80, the sample size needed was 17 to be able to detect a difference of 0.3 in the Decisional Conflict Scores (range: 1–5). This represents a moderate effect size, which is typical for PDAs and also clinically meaningful (Stacey *et al.*, 2011).

Similarly, in a study carried out by Menard and colleagues (2010) to evaluate a decision aid for menopausal women facing decisions about natural health products, the authors reported that for a significant level of  $\alpha = 0.05$ , power ( $1 - \beta$ ) = 0.80, a standard deviation of 0.60, and a correlation between pre-post scores of 0.25, the sample size required was estimated at 23 to detect a difference of 0.4 in the Decisional Conflict Scale total score. This corroborates with many other previous studies of development and pilot testing (single sample before-after design studies) of decision aids; therefore it is estimated that our sample size would be appropriate for the pilot evaluation phase of the current project.

A sample size of 30 patients referred for an orthodontic consultation and their parents was selected, and to allow for 30 to 40% drop out at follow-up data collection point, a total sample size of 40 young people and their parents were recruited at baseline.

#### **4.3.7. Data analysis**

Data were numerically coded, entered into Excel (Microsoft, version 2010, WA, USA), and transferred to the Statistical Package for the Social Sciences SPSS (Version 21-IBM, NY, USA). The Wilcoxon signed ranks test was used to analyse the responses from the DCS, this non-parametric test was selected because a test for normality showed the data to be skewed. A paired t-test was used to analyse the data from OPEQ, and descriptive statistics were used for the categorical responses. These tests were chosen because one of the most common applications of the paired t-test and its non-parametric equivalent (Wilcoxon signed ranks) is comparing the means of data from two observations before and after an intervention on the same participant.



**Figure 4: Flow diagram showing recruitment and data collection process for the pilot evaluation of the developed PDA**

## **4.4. Results**

The recruitment period for baseline data collection (T1) lasted 4 months, starting in March 2014 and was completed in July 2014. Follow up (T2) data collection (PDA and questionnaires) was completed in November 2014.

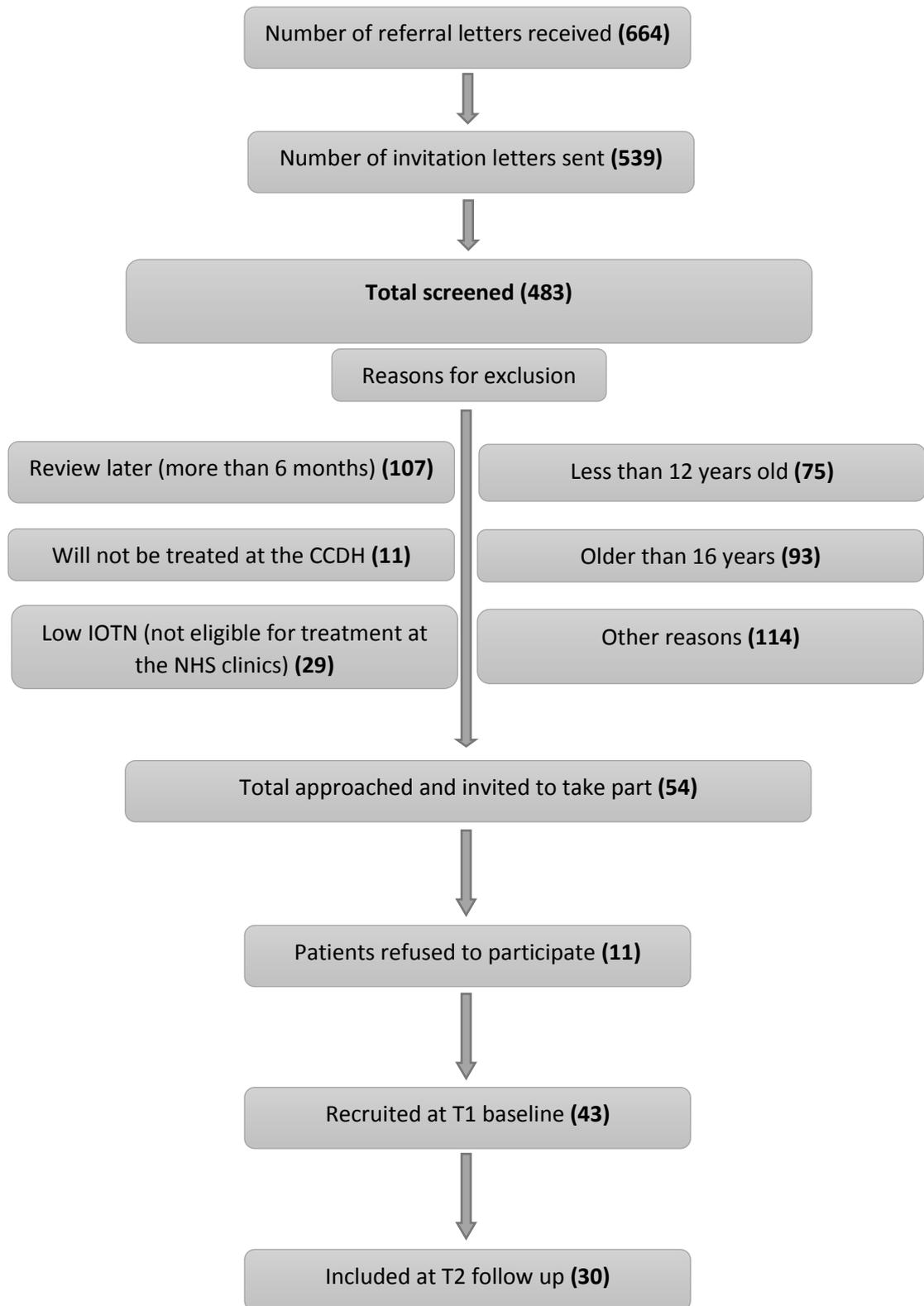
### **4.4.1. Participants**

#### ***4.4.1.1. Participants recruited at T1***

A total of 54 new patients and 54 parents were approached and invited to take part in the study. Of those 54 children approached, 11 refused to participate, and data from 43 patients and their parents were collected at T1. However, data from one participant was excluded because of incomplete responses from the parent (mother). A summary of recruitment data and the reasons for exclusions are presented in a flow diagram (Figure 5).

#### ***4.4.1.2. Participants at follow-up T2***

Data from 30 young participants and parents out of the total number of 42 who completed the questionnaires at T1 were included in the analysis. Data analysis was started once the number of 30 completed T2 questionnaires was achieved. It was estimated that 30 participants would be enough for the pilot evaluation stage based on previous similar studies (see section 4.3.6).



**Figure 5: Flow diagram showing summary of the recruitment data for the Evaluation stage of the developed PDA.**

#### **4.4.1.3. Characteristics of the sample**

The sample consisted of slightly more females (n= 17 - 56.6%) than males (n= 13 - 43.3%), which is consistent with the gender proportions of referrals received. The mean age of participants was 13.7 years, with an age range of 12 to 16 years (Table 13). Participants lived in areas with differing levels of deprivation as shown by the Index of Multiple Deprivation scores (IMD). These scores derived from the postcode of the patient's home address. Half of participants lived in areas which are the most deprived and one third came from areas which are the least deprived (Table 14).

**Table 13: Age distribution among the study sample**

Age	Number of participants	Percentage (%)
12 years	8	26.7
13 years	8	26.7
14 years	5	16.7
15 years	4	13.2
16 years	5	16.7
Total	30	100

**Table 14: The distribution of Index of Multiple Deprivation (IMD) scores among the study sample**

Level of deprivation	Number of participants	Percentage (%)
Most deprived	15	50
Average	5	16.7
Least deprived	10	33.3
Total	30	100

#### ***4.4.1.4. Decisional Conflict***

A Wilcoxon Signed Ranks test was used to compare the Decisional Conflict Scale scores for young people and their parents before and after the use of the PDA.

##### ***4.4.1.4.1. Decisional conflict of young people***

Table 15 below provides the mean, standard deviation (SD), 95% Confidence Intervals (CI) and the effect size of the Decisional Conflict Scale scores with its five subscales in young people before and after the use of the PDA. The mean differences, standard deviation of the differences, 95% confidence interval of the differences, as well as P-value between T1 and T2 are presented in Table 16.

As hypothesized, there was a general decrease in the DCS scores of young people from a mean total pre- PDA score of 27.0 (SD= 18.1; 95% CI 20.3, 33.8) to a mean total post- PDA score of 14.7 (SD= 13.5; 95% CI 9.7, 19.8). This change of 12.3 was statistically significant, ( $P < 0.001$ , Wilcoxon signed ranks test). Four subscale scores (Uninformed, Unclear values, Uncertainty, and Ineffective decision) showed significant reductions post-decision aid, with the greatest reduction of 16.1 for the Uninformed subscale scores (pre- PDA mean: 31.9 (SD= 19.5; 95% CI 24.7, 39.2); post- PDA mean: 15.8 (SD= 14.4; 95% CI 10.5, 21.2),  $P < 0.001$ , Wilcoxon signed ranks test).

The only subscale with a statistically non-significant decrease in scores before and after the use of the PDA was the Unsupported subscale. This subscale showed a reduction of 6.4 from mean pre- PDA score of 16.7 (SD= 21.3; 95% CI 8.7, 24.6) to 10.3 (SD= 13.9; 95% CI 5.1, 15.5) post- PDA, ( $P = 0.066$ , Wilcoxon signed ranks test).

The reduction in the total DCS score represents an effect size of 0.36, which is considered moderate (Cohen, 2013). The Cronbach's alpha for the total sub-scales for the DCS ranged between 0.71 - 0.94 indicating good internal consistency. This was in agreement with the results of O'Connor in the original validation (1995).

##### ***4.4.1.4.2. Decisional conflict of parents***

Table 17 shows the mean, standard deviation, 95% Confidence Intervals (CI), and the effect size for the parental total and subscale DCS before and after the use of the PDA. Table 18 provides the mean differences, standard deviation of the difference, 95% confidence interval (CI) of the differences, and the P-value between T1 and T2.

Overall, there was a general decrease in the parental DCS scores with the total DCS scores declining from a mean total of 20.9 (SD= 15.9; 95% CI 14.9, 26.8) pre- PDA to 12.2 (SD= 11.6; 95% CI 7.9, 16.6) post- PDA. The reduction of 8.7 was statistically significant ( $p = 0.002$ , Wilcoxon signed ranks test). The four subscale scores were significantly reduced post-decision aid. The highest reduction was in the Unclear values subscale scores, from a mean of 24.4 (SD= 21.4; 95% CI 16.4, 32.4) pre- PDA to 13.3 (SD= 14.4; 95% CI 7.9, 18.7) post- PDA, ( $P = 0.004$ , Wilcoxon signed ranks test).

Unlike the young peoples' DCS scores, the Uncertainty subscale was the only subscale with a reduction in scores pre- and post- PDA that was not statistically significant. This subscale showed a reduction from a mean score of 20.6 (SD= 16.9; 95% CI 14.2, 26.9) pre- PDA to 15.8 (SD= 15.8; 95% CI 9.9, 21.7) post- PDA, ( $P = 0.133$ , Wilcoxon signed ranks test).

The change in the total DCS scores represents an effect size of 0.3, which again might be considered moderate (Cohen, 2013). The Cronbach's alpha ranged between 0.77 - 0.95, indicating good internal consistency.

Based on the above findings, a sample size estimation for a future randomised trial could be calculated. An online sample size calculator (AI-Therapy Statistics, 2015) revealed that for a level of significance of  $\alpha = 0.05$  (the probability of falsely rejecting the null hypothesis), power ( $1 - \beta$ ) = 0.80 (the probability of correctly rejecting the null hypothesis), a total of 200 participants would be required (100 in the control group and 100 in the intervention group) to detect an effect size of 0.4. According to Cohen this is a 'medium effect size' (Cohen, 2013) and is clinically important when using the DCS as an outcome, because it is commonly observed between those who make or delay decisions (O'Connor *et al.*, 1998c).

**Table 15: Mean, standard deviation, and 95% Confidence Intervals (CI) of items on Decisional Conflict Scale for the young people before and after use of PDA (Wilcoxon Signed Ranks test)**

Sub-scale	Items	Pre-test			Post-test			Effect size
		Mean	SD	95% CI	Mean	SD	95% CI	
<b>Uninformed</b>	I know which options are available to me. I know the benefits of each option. I know the risks and side effects of each option.	31.9	19.5	24.7 to 39.2	15.8	14.4	10.5 to 21.2	0.4
<b>Unclear values</b>	I am clear about which benefits matter most to me. I am clear about which risks and side effects matter most. I am clear about which is more important to me (the benefits or the risk and side effects).	32.8	22.3	24.4 to 41.1	17.5	16.4	11.4 to 23.6	0.4
<b>Unsupported</b>	I have enough support from others to make a choice. I am choosing without pressure from others. I have enough advice to make a choice.	16.7	21.3	8.7 to 24.6	10.3	13.9	5.1 to 15.5	0.2
<b>Uncertainty</b>	I am clear about the best choice for me. I feel sure about what to choose. This decision is easy for me to make.	30.3	25.2	20.9 to 39.7	17.8	20.5	10.1 to 25.4	0.3
<b>Ineffective decision</b>	I feel I have made an informed choice (a choice based on enough information). My decision shows what is important to me. I expect to stick with my decision. I am satisfied with my decision.	24.4	16.4	18.2 to 30.5	12.9	13.3	7.9 to 17.9	0.4
<b>Total Decisional Conflict Scale score</b>		27.0	18.1	20.3 to 33.8	14.7	13.5	9.7 to 19.8	0.4

**Table 16: Mean differences, standard deviation of the differences, 95% confidence interval (CI) of the differences, and P-value of items on Decisional Conflict Scale for the young people (paired sample t test) P value from Wilcoxon signed ranks test**

Sub-scale	Mean difference	SD of the difference	95% CI of the difference	P-value
<b>Uninformed</b>	16.1	16.2	10.1 to 22.2	P< 0.001
<b>Unclear values</b>	15.3	20.5	7.6 to 22.9	P= 0.001
<b>Unsupported</b>	6.4	19.9	-1.0 to 13.8	P= 0.066
<b>Uncertainty</b>	12.5	24.1	3.5 to 21.5	P= 0.008
<b>Ineffective decision</b>	11.5	14.8	5.9 to 16.9	P< 0.001
<b>Total Decisional Conflict Scale score</b>	12.3	15.3	6.6 to 17.9	P< 0.001

**Table 17: Mean, Standard deviation, and 95% Confidence Intervals (CI) of items on Decisional Conflict Scale for the parents before and after use of PDA (Wilcoxon Signed Ranks test)**

Sub-scale	Items	Pre-test			Post-test			Effect size
		Mean	SD	95% CI	Mean	SD	95% CI	
<b>Uninformed</b>	I know which options are available to my child. I know the benefits of each option. I know the risks and side effects of each option.	22.8	19.1	15.7 to 29.9	11.9	11.9	7.5 to 16.4	0.3
<b>Unclear values</b>	I am clear about which benefits matter most to my child. I am clear about which risks and side effects matter most. I am clear about which is more important to my child (the benefits or the risk and side effects).	24.4	21.4	16.4 to 32.4	13.3	14.4	7.9 to 18.7	0.3
<b>Unsupported</b>	I have enough support from others to make a choice. I am choosing without pressure from others. I have enough advice to make a choice.	18.6	17.3	12.1 to 25.1	10.8	10.3	6.9 to 14.7	0.3
<b>Uncertainty</b>	I am clear about the best choice for my child. I feel sure about what to choose. This decision is easy for me to make.	20.6	16.9	14.2 to 26.9	15.8	15.8	9.9 to 21.7	0.2
<b>Ineffective decision</b>	I feel I have made an informed choice (a choice based on enough information). My decision shows what is important to my child. I expect to stick with my decision. I am satisfied with my decision.	18.8	14.7	13.3 to 24.2	10.0	12.2	5.4 to 14.6	0.3
<b>Total Decisional Conflict Scale score</b>		20.9	15.9	14.9 to 26.8	12.2	11.6	7.9 to 16.6	0.3

**Table 18: Mean differences, standard deviation of the differences, 95% confidence interval of the differences, and P-value of items on Decisional Conflict Scale for parents (paired sample t test) P value from Wilcoxon signed ranks test**

Sub-scale	Mean difference	SD of the difference	95% CI of the difference	P-value
<b>Uninformed</b>	10.8	18.1	4.1 to 17.6	0.004
<b>Unclear values</b>	11.1	19.4	3.9 to 18.3	0.004
<b>Unsupported</b>	7.8	16.9	1.5 to 14.1	0.020
<b>Uncertainty</b>	4.7	20.5	-2.9 to 12.4	0.133
<b>Ineffective decision</b>	8.8	18.9	1.7 to 15.8	0.008
<b>Total Decisional Conflict Scale score</b>	8.7	16.6	2.5 to 14.8	0.002

#### **4.4.1.5. Orthodontic Patient Expectation Questionnaire (OPEQ)**

##### **4.4.1.5.1. Questions 1-9 of the OPEQ**

A paired sample t-test was conducted to evaluate the impact of the PDA on participants' OPEQ scores. Table 19 and Table 20 shows the mean, standard deviation, and 95% Confidence Intervals for the responses to each item of the OPEQ for young people and their parents before and after the use of the decision aid. The mean differences, standard deviation of the differences, 95% confidence intervals of the differences, and P-values for young people and parents are shown in Tables 21 and 22.

##### **4.4.1.5.1.1. Young people's responses**

Significant changes were found in only three items with the young peoples' responses: question 1c: *'What type of orthodontic treatment do you expect? (Teeth extracted/taken out)?'* (p = 0.007, paired sample t-test), questions 9b and 9c: *Do you expect brace treatment to: Produce a better smile? - Make it easier to eat?* (p = 0.004, and p = 0.046 respectively, paired sample t-test). All other items of the OPEQ showed changes in the scores before and after participants' exposure to the PDA that were not significant. The test of the reliability of the OPEQ found a Cronbach's alpha of 0.71 indicating good internal consistency.

##### **4.4.1.5.1.2. Parent's responses**

In the parental responses, significant changes were seen in only two items: question 1c: *'What type of orthodontic treatment do you expect? (Teeth extracted)?'* (p = 0.031, paired sample t-test), and question 9d: *'Do you expect brace treatment to: Make it easier to speak?'* (p = 0.049, paired sample t-test). None of the other items showed significant changes in parental scores before and after completing the PDA. The Cronbach's alpha of 0.59 indicates acceptable internal consistency.

**Table 19: Mean, standard deviation, and 95% Confidence Intervals (CI) of items of the OPEQ for young people before and after use of the PDA (Paired sample t-test)**

Question	Pre-test			Post-test		
	Mean	SD	95%CI	Mean	SD	95%CI
1. What type of orthodontic treatment do you expect? a. Braces, don't know what type?	61.9	26.4	52.0 to 71.8	52.9	26.2	43.2 to 62.7
b. Train track braces?	69.4	20.5	61.7 to 77.1	71.9	22.4	63.6 to 80.3
c. Teeth extracted (taken out)?	50.6	26.9	40.6 to 60.7	68.3	28.2	57.8 to 78.8
d. Head brace?	12.1	20.6	4.4 to 19.8	14.5	24.8	5.2 to 23.8
e. Jaw surgery?	17.7	24.9	8.4 to 27.0	23.8	32.1	11.8 to 35.8
2. Do you think brace treatment will give you any problems?	32.4	23.9	23.5 to 41.4	39.0	26.3	29.2 to 48.8
3. Do you think wearing a brace will be painful?	60.1	23.6	51.3 to 68.9	59.7	24.6	50.6 to 68.9
4. Do you think brace treatment will produce problems with eating?	52.0	22.0	43.8 to 60.2	57.1	22.4	48.7 to 65.4
5. Do you expect brace treatment to restrict (limit) what you can eat or drink?	63.5	21.4	55.5 to 71.5	71.9	23.5	63.2 to 80.8
6. How you think people will react to you wearing a brace?	57.3	24.8	48.1 to 66.6	62.9	19.8	55.5 to 70.3

Question	Pre-test			Post-test		
	Mean	SD	95%CI	Mean	SD	95%CI
9. Do you expect brace treatment to:						
a. Straighten your teeth?	83.6	19.3	76.4 to 90.8	87.8	14.1	82.6 to 93.1
b. Produce a better smile?	78.4	22.4	70.1 to 86.8	88.9	10.7	84.9 to 92.9
c. Make it easier to eat?	55.4	27.5	45.2 to 65.7	64.7	23.9	55.8 to 73.7
d. Make it easier to speak?	54.7	28.9	43.9 to 65.5	61.6	24.5	52.4 to 70.8
e. Make it easier to keep my teeth clean?	64.6	25.1	55.2 to 73.9	71.8	26.9	61.7 to 81.8
f. Improve my chances of a good career?	50.3	28.0	39.9 to 60.8	56.9	26.3	47.1 to 66.7
g. Give you confidence socially?	73.6	23.0	65.0 to 82.2	74.7	25.5	65.2 to 84.2

**Table 20: Mean, standard deviation, and 95% Confidence Intervals (CI) of items of the OPEQ for the parents before and after the use of the PDA (Paired sample t-test)**

Question	Pre-test			Post-test		
	Mean	SD	95%CI	Mean	SD	95%CI
1. What type of orthodontic treatment do you expect for your child?						
a. Braces, don't know what type?	55.3	30.3	43.5 to 66.0	59.2	29.8	48.8 to 69.4
b. Train track braces?	71.9	28.0	61.1 to 81.2	81.3	17.8	74.4 to 87.2
c. Teeth extracted (taken out)?	58.8	28.9	48.8 to 68.3	70.3	26.4	60.9 to 78.9
d. Head brace?	14.0	18.8	8.0 to 20.7	14.4	17.9	8.9 to 21.2
e. Jaw surgery?	19.4	26.2	10.8 to 28.2	18.6	24.0	10.5 to 27.5
2. Do you think brace treatment will give any problems to your child?	35.9	21.6	28.3 to 43.7	32.9	22.8	25.2 to 41.1
3. Do you think wearing a brace will be painful for your child?	51.1	21.9	43.4 to 59.1	50.7	19.0	43.9 to 57.5
4. Do you think brace treatment will produce problems with eating?	54.7	23.6	46.6 to 63.1	46.7	23.4	38.5 to 55.7
5. Do you expect brace treatment to restrict (limit) what your child can eat or drink?	59.0	23.7	50.4 to 66.9	53.2	24.6	44.3 to 61.5
6. How you think people will react to your child wearing a brace?	64.0	16.4	58.6 to 70.1	57.5	17.2	52.0 to 63.9

Question	Pre-test			Post-test		
	Mean	SD	95%CI	Mean	SD	95%CI
9. Do you expect brace treatment to:						
a. Straighten your child's teeth?	84.2	12.7	79.4 to 88.3	85.9	15.6	79.6 to 90.8
b. Produce a better smile?	79.3	18.5	71.7 to 85.7	84.8	17.5	77.8 to 90.2
c. Make it easier to eat?	55.7	22.4	47.3 to 64.0	66.8	22.7	58.9 to 75.0
d. Make it easier to speak?	52.2	24.2	43.3 to 60.9	62.9	21.4	55.4 to 70.9
e. Make it easier to keep your child's teeth clean?	62.7	29.1	52.3 to 73.3	68.9	26.2	59.3 to 77.9
f. Improve chances of a good career for your child in the future?	58.9	23.7	50.1 to 67.6	63.2	24.4	54.0 to 72.0
g. Give your child confidence socially?	79.1	20.0	71.4 to 85.5	83.6	19.4	75.8 to 89.7

**Table 21: Mean differences, standard deviation of the differences, 95% confidence interval of the differences (CI), and P-value of items of the OPEQ for young people (paired sample t test)**

Question	Mean difference	SD of the difference	95% CI of the difference	P-value
1. What type of orthodontic treatment do you expect? a. Braces, don't know what type?	8.9	36.1	-4.5 to 22.4	0.184
b. Train track braces?	-2.6	25.9	-12.2 to 7.1	0.591
c. Teeth extracted (taken out)?	-17.7	33.1	-30.0 to -5.3	0.007
d. Head brace?	-2.4	29.9	-13.6 to 8.7	0.660
e. Jaw surgery?	-6.1	33.9	-18.7 to 6.5	0.332
2. Do you think brace treatment will give you any problems?	-6.6	24.8	-15.8 to 2.6	0.155
3. Do you think wearing a brace will be painful?	0.4	24.9	-8.9 to 9.7	0.936
4. Do you think brace treatment will produce problems with eating?	-5.1	21.4	-13.0 to 2.9	0.204
5. Do you expect brace treatment to restrict (limit) what you can eat or drink?	-8.4	23.1	-17.1 to 0.2	0.055
6. How you think people will react to you wearing a brace?	-5.6	32.1	-17.5 to 6.4	0.350

Question	Mean difference	SD of the difference	95% CI of the difference	P-value
9. Do you expect brace treatment to:				
a. Straighten your teeth?	-4.2	13.5	-9.3 to 0.86	0.100
b. Produce a better smile?	-10.5	18.2	-17.3 to -3.7	0.004
c. Make it easier to eat?	-9.3	24.3	-18.3 to -0.2	0.046
d. Make it easier to speak?	-6.9	25.9	-16.6 to 2.8	0.154
e. Make it easier to keep my teeth clean?	-7.2	22.9	-15.7 to 1.3	0.095
f. Improve my chances of a good career?	-6.6	28.9	-17.4 to 4.2	0.223
g. Give you confidence socially?	-1.1	22.9	-9.6 to 7.4	0.794

**Table 22: Mean differences, standard deviation of the differences, 95% confidence interval of the differences (CI), and P-value of items of the OPEQ for parents (paired sample t test)**

Question	Mean difference	SD of the difference	95% CI of the difference	P-value
1. What type of orthodontic treatment do you expect? a. Braces, don't know what type?	-3.8	39.1	-18.4 to 10.8	0.596
b. Train track braces?	-9.4	34.1	-22.1 to 3.3	0.142
c. Teeth extracted (taken out)?	-11.5	27.7	-21.9 to -1.1	0.031
d. Head brace?	-0.4	25.7	-9.9 to 9.2	0.938
e. Jaw surgery?	0.8	24.4	-8.4 to 9.9	0.865
2. Do you think brace treatment will give any problems to your child?	3.1	18.5	-3.9 to 9.9	0.373
3. Do you think wearing a brace will be painful for your child?	0.3	22.4	-8.0 to 8.7	0.936
4. Do you think brace treatment will produce problems with eating?	8.1	27.2	-2.1 to 18.2	0.115
5. Do you expect brace treatment to restrict (limit) what your child can eat or drink?	5.8	28.2	-4.7 to 16.3	0.269
6. How you think people will react to your child wearing a brace?	6.5	17.5	-0.0 to 13.0	0.051

Question	Mean difference	SD of the difference	95% CI of the difference	P-value
9. Do you expect brace treatment to:				
a. Straighten your child's teeth?	-1.7	19.3	-9.0 to 5.7	0.642
b. Produce a better smile?	-5.5	22.7	-14.1 to 3.1	0.203
c. Make it easier to eat?	-11.1	30.6	-22.8 to 0.5	0.060
d. Make it easier to speak?	-10.7	28.0	-21.4 to -0.1	0.049
e. Make it easier to keep your child's teeth clean?	-6.3	30.8	-17.9 to 5.4	0.282
f. Improve chances of a good career for your child in the future?	-4.3	28.8	-15.2 to 6.7	0.430
g. Give your child confidence socially?	-4.4	25.9	-14.3 to 5.4	0.364

#### 4.4.1.5.2. Questions 7 and 8 of the OPEQ

##### 4.4.1.5.2.1. *Expectations about the duration of orthodontic treatment*

Tables 23 and 24 show the descriptive statistics of the responses of young people and their parents to question 7: ‘How long do you expect brace treatment to take?’

Five patients (16.7%) had no idea about the duration of treatment before seeing the PDA, compared to only one patient (3.3%) after the use of the PDA. The number of young people who expected that orthodontic treatment would be finished within 2-3 years was doubled after use of the PDA [from n= 12 (40%) to n= 25 (83.3%)]. See Table 23 below.

From Table 24, it can be seen that six parents (20%) did not know the duration of treatment before seeing the PDA, whereas none of them stated ‘Don’t know’ after seeing the PDA. The number of parents who expected that fixed orthodontic appliance treatment would take 2-3 years to be completed was largely increased after seeing the PDA [from n= 12 (40% pre- PDA) to n= 21 (70% post- PDA)]. In contrast, ten parents (33.3% pre-PDA) expected that orthodontic treatment would take 1-2 years to finish, this number reduced to only three parents (10%) after receiving the PDA.

**Table 23: Young peoples’ expectations about the duration of orthodontic treatment (question 7)**

Duration of treatment	Child participant pre-PDA (n=30)	Percentage (%)	Child participant post-PDA (n=30)	Percentage (%)
3-4 years	4	13.3	2	6.7
2-3 years	12	40.0	25	83.3
1-2 years	5	16.7	2	6.7
6 months-1 year	2	6.7	0	0
1 month-6 months	2	6.7	0	0
Don’t know	5	16.7	1	3.3
Total	30	100	30	100

**Table 24: Parents' expectations about the duration of orthodontic treatment (question 7)**

Duration of treatment	Parent participant pre-PDA (n=30)	Percentage (%)	Parent participant post-PDA (n=30)	Percentage (%)
3-4 years	2	6.7	5	16.7
2-3 years	12	40.0	21	70.0
1-2 years	10	33.3	3	10.0
6 months-1 year	0	0	1	3.3
1 month-6 months	0	0	0	0
Don't know	6	20	0	0
Total	30	100	30	100

#### 4.4.1.5.2.2. Expectations about the frequency of orthodontic treatment appointments

Tables 25 and 26 show the descriptive statistics of the responses of young people and their parents to question 8: 'How often do you think you will need to attend for check-up?'

Table 25 shows that only two patients (6.7%) did not know the frequency of appointments, after seeing the PDA twice as many patients expected they would need to attend for a check-up every 4-6 weeks (36.7% pre- PDA to 70% post- PDA).

It can be seen from Table 26 that parents who expected that their child would need to attend for regular check-ups every 6-8 weeks were reduced by half approximately after the use of PDA (from 66.7% n= 20 pre- PDA to 30% n= 9 post- PDA). In addition, the number of parents who expected review appointments every 4-6 weeks was largely increased after seeing the PDA (from 10% n= 3 pre- PDA to 70% n= 21 post- PDA).

It can also be shown that children and parents' responses regarding the frequency of orthodontic appointments were identical after the use of the decision aid.

**Table 25: Young peoples' expectations about the frequency of orthodontic treatment check-up appointments (question 8)**

Frequency of appointments	Child participant pre-PDA (n=30)	Percentage (%)	Child participant post-PDA (n=30)	Percentage (%)
Every 6-8 months	0	0	0	0
Every 3-5 months	2	6.7	0	0
Every 6-8 weeks	14	46.7	9	30
Every 4-6 weeks	11	36.7	21	70
Every 1-2 weeks	1	3.3	0	0
Don't know	2	6.7	0	0
Total	30	100	30	100

**Table 26: Parents' expectations about the frequency of orthodontic treatment check-up appointments (question 8)**

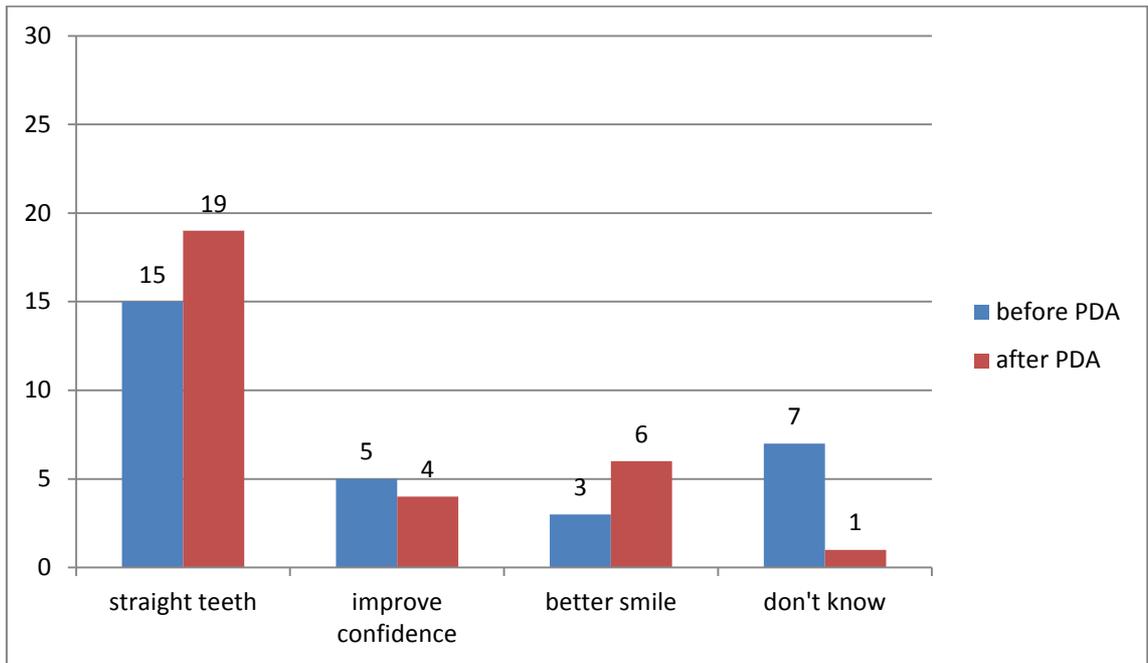
Frequency of appointments	Parent participant pre-PDA (n=30)	Percentage (%)	Parent participant post-PDA (n=30)	Percentage (%)
Every 6-8 months	2	6.7	0	0
Every 3-5 months	1	3.3	0	0
Every 6-8 weeks	20	66.7	9	30
Every 4-6 weeks	3	10	21	70
Every 1-2 weeks	0	0	0	0
Don't know	4	13.3	0	0
Total	30	100	30	100

#### 4.4.1.5.3. Questions 10-12 of the OPEQ

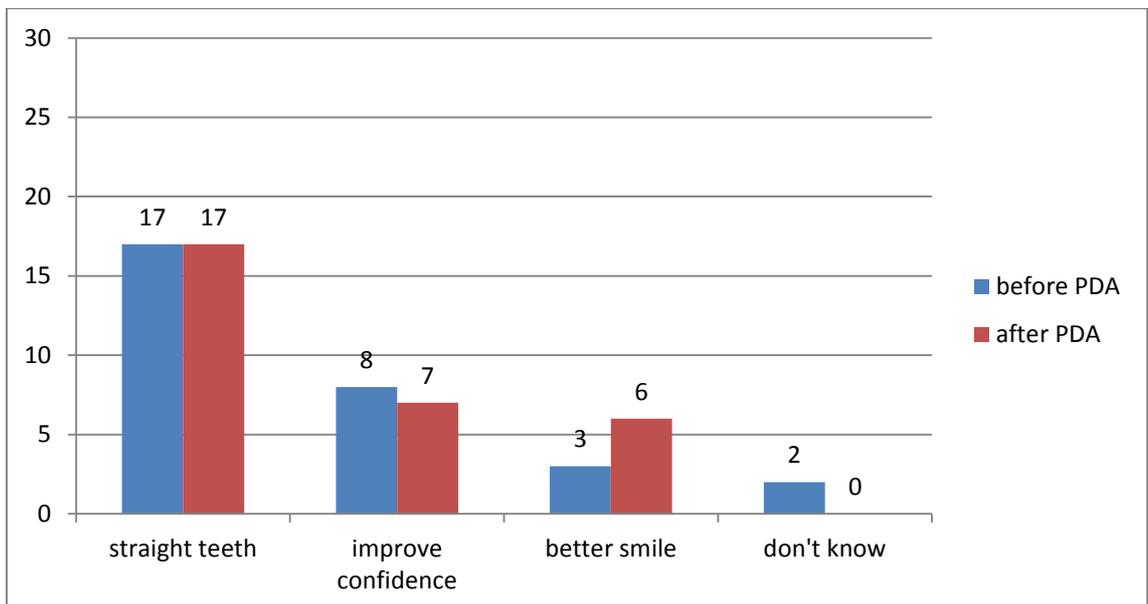
##### 4.4.1.5.3.1. *Possible benefits of orthodontic treatment*

Figure 6 shows young peoples' perceptions of the possible benefits of having orthodontic treatment with fixed appliances before and after the use of the PDA. Half of respondents perceived that braces will straighten their teeth and this number increased from 15 (50%) to 19 (63.3%) after seeing the PDA. Also, the number of young people who did not know of any benefits of having fixed orthodontic treatment reduced from 7 people (23.3%) before the PDA to only one person after PDA.

The proportion of parents who perceived that orthodontic treatment would straighten the teeth of their child was not changed after seeing the PDA (56.7%), whereas the number of parents who thought that braces will produce a better smile was increased from 3 (10%) to 6 participants (20%) after the PDA, and the number of parents who did not know any benefits of having orthodontic treatment was reduced from 2 (6.7%) to 0 after seeing the PDA (see Figure 7).



**Figure 6: Young people's perceptions of the benefits of having orthodontic treatment before and after the PDA.**



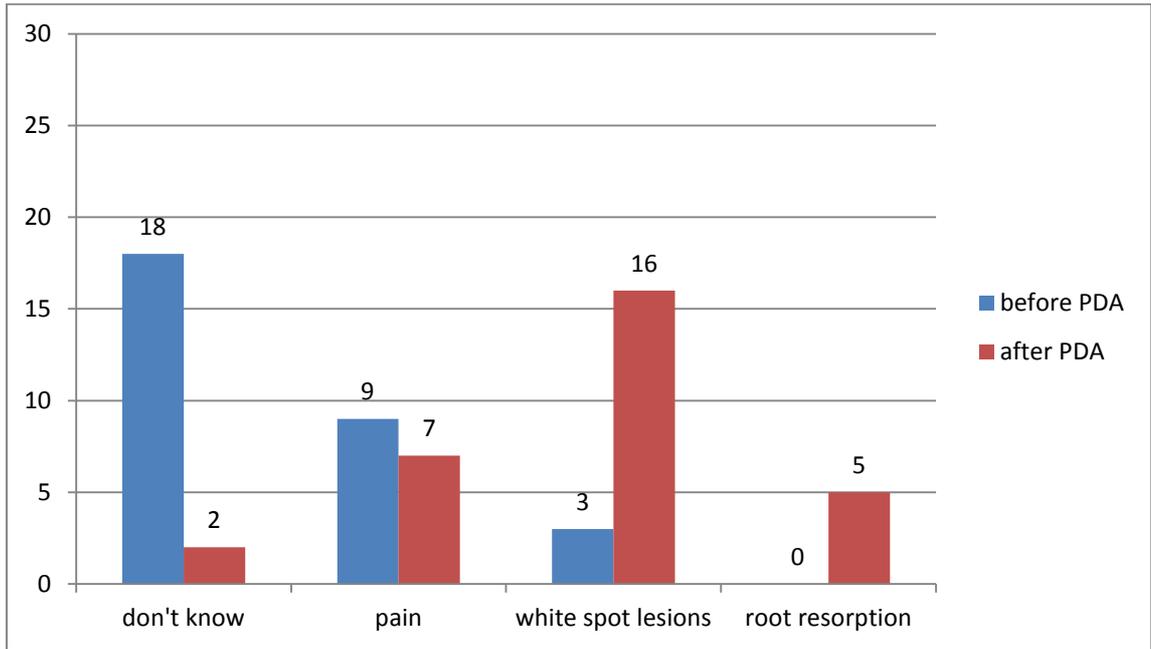
**Figure 7: Parents' perceptions of the benefits of having orthodontic treatment before and after the PDA.**

#### *4.4.1.5.3.2. Potential risks of orthodontic treatment*

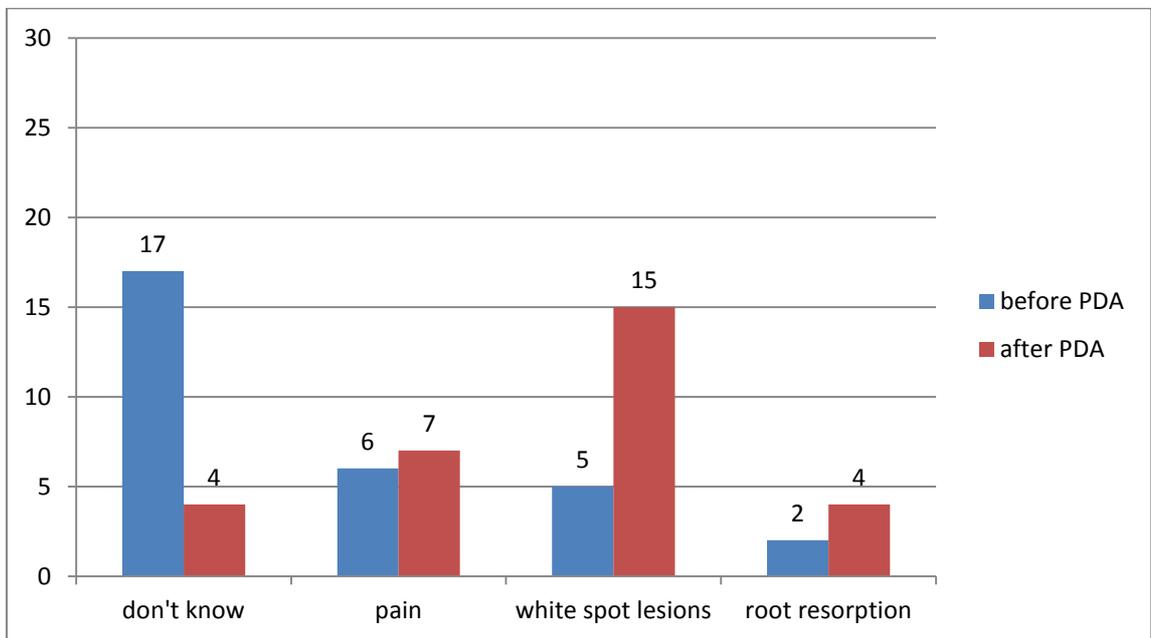
Figure 8 and Figure 9 show the young people and parents' perceptions of the risks of having fixed orthodontic appliance treatment.

The number of young people who were not aware of any risks of having fixed orthodontic appliance treatment was reduced from 18 participants (60%) before the PDA to only 2 people (6.7%) after receiving the PDA. Also, the number of participants who perceived that WSLs were one of the risks of having orthodontic treatment was increased from 3 young people (10%) before the PDA to 16 (53.3%) after seeing the PDA. None of the young people were aware that orthodontic treatment would lead to the resorption of roots of their teeth before receiving the PDA, this number increased to 5 participants (16.7%) after seeing the PDA (see Figure 8).

Similar findings were reported from the parental responses. The number of parents who did not know the risks from having orthodontic treatment was reduced from 17 (56.7%) before the PDA to only 4 people (13.3%) after seeing the PDA. In addition, the number of parents who thought that braces would produce WSLs on their children's teeth was increased from 5 (16.7%) to 15 parents (50%) after exposure to the PDA (see Figure 9).



**Figure 8: Young people's perceptions of the risks of having orthodontic treatment before and after the PDA.**



**Figure 9: Parents' perceptions of the risks of having orthodontic treatment before and after the PDA.**

#### 4.4.1.5.3.3. Information needs

Table 27 represents young peoples' and parents' responses to whether they have received enough information to make a decision regarding having fixed orthodontic brace treatment or not.

The number of young people who perceived that they had enough information to make a decision was increased from 25 (83.3%) before receiving the PDA to 29 (96.7%) after completing the PDA. Similarly, the number of parents who stated that they were informed enough to make a choice regarding treatment was increased from 27 (90%) before the PDA to 30 (100%) after the PDA. However, this changes in the young peoples' and parents' perceptions regarding the information given were not statistically significant ( $P = 0.125$ , and  $P = 0.250$  respectively; McNemar test).

**Table 27: Patients' and parents' perceptions of the information about orthodontic treatment (question 12)**

Do you feel that you were given enough information to make the best treatment choice for you?	Before PDA		After PDA		P-value McNemar test
	Yes	No	Yes	No	
Young people	25	5	29	1	P= 0.125
	83.3%	16.7%	96.7%	3.3%	
Parent	27	3	30	0	P= 0.250
	90%	10%	100%	0%	

#### ***4.4.1.6. Value clarification exercise***

Table 28 - 31 represent the young people and parental responses to the value clarification exercise. To simplify description of the data and due to the similarity of categories, the responses have been collapsed from five to three categories, as follows; 'Not at all important' and 'Not so important' were summed together and presented as 'Not important', and 'Important' and 'Very much important' were summed together and presented as 'Important'. Similarly, 'Not at all bothered' and 'Not bothered' were presented as 'Not bothered', and 'Quite bothered' and 'Very much bothered' as 'Bothered'.

##### **4.4.1.6.1. Reasons to consider treatment to straighten teeth**

Table 28 shows that 90% of young people (n= 27) considered that it is important to have fixed orthodontic appliance treatment to straighten their teeth, and 93.3% (n= 28) thought that it is important to change the way their teeth look; however, only 60% of young people (n= 18) believed that it is important to have braces in order to change the way their teeth bite together.

The parental answers were nearly identical to their children. Twenty eight parents (93.3%) reported that orthodontic treatment is important to straighten their children's teeth, and 86.7% (n= 26) thought it is important to have braces to change the way the teeth look. In addition, 80% of parents (n= 24) stated that brace treatment is needed to change the way the teeth bite together (Table 29).

**Table 28: The frequency of young people responses to the value clarification exercise ‘Reasons to consider treatment to straighten your teeth’**

Question	Not important	Don’t know	Important
	N (%)	N (%)	N (%)
How important is it to you to have your teeth straighter?	0 (0)	3 (10)	27 (90)
How important is it to you to change the way your teeth bite together?	7 (23.3)	5 (16.7)	18 (60)
How important is it to you to change the way your teeth look?	0 (0)	2 (6.7)	28 (93.3)

**Table 29: The frequency of parental responses to the value clarification exercise ‘Reasons to consider treatment to straighten your child’s teeth’**

Question	Not important	Don’t know	Important
	N (%)	N (%)	N (%)
How important is it to you to have your child’s teeth straighter?	0 (0)	2 (6.7)	28 (93.3)
How important is it to you to change the way your child’s teeth bite together?	2 (6.7)	4 (13.3)	24 (80)
How important is it to you to change the way your child’s teeth look?	0 (0)	4 (13.3)	26 (86.7)

#### 4.4.1.6.2. Reasons not to choose treatment to straighten teeth

From the 30 young people, 63.3% (n= 19) were not bothered about what their teeth will look like with a brace on, and 70% (n= 21) were not worried about having to see their orthodontist every 4-6 weeks for follow-up appointments. Nearly a third of young people were bothered about having teeth extracted for orthodontic treatment, and having aching pain after braces were fitted (36.7% n= 11; and 33.3% n= 10 respectively). Around 60% of young people (n= 18) were not bothered about wearing a retainer for a long time after treatment was completed; however, 13.3% (n= 4) were bothered about the retainer wear, and 22 participants (73.4%) were concerned about having WSLs on their teeth from orthodontic appliances (see Table 30).

More than half of parents 56.7% (n= 17) were not bothered about the appearance of their children’s teeth while their braces were on, and 63.4% (n= 19) were not worried about visiting the orthodontist every 4-6 weeks, although 7 parents 23.3% were worried about the frequency of check-up visits. A third of parents were bothered about their children having teeth taken out, and the pain resulted from having braces (36.7% n= 11, and 30% n= 9 respectively). Ten parents (33.3%) expressed concern about retainer wear after treatment is completed, 40% (n= 12) considered retainer wear after treatment was not a problem. Most parents 80% (n= 24) were worried regarding their children having white or brown spots following brace treatment, and nearly half of them 43.3% (n= 13) considered fixed orthodontic appliance treatment is better than the other options, such as having a white filling to close gaps between the teeth (Table 31).

**Table 30: The frequency of young people responses to the value clarification exercise ‘Reasons not to choose treatment to straighten your teeth’**

Question	Not bothered N (%)	Don’t know N (%)	Bothered N (%)
How bothered are you about what your teeth will look like with a brace on?	19 (63.3)	0 (0)	11 (36.7)
How bothered are you and your parents about having to see the orthodontist every 4-6 weeks for checks on your brace?	21 (70)	8 (26.7)	1 (3.3)
How bothered are you about having teeth taken out?	10 (33.3)	9 (30)	11 (36.7)
How bothered are you about having aching pain after braces are fitted?	13 (43.4)	7 (23.3)	10 (33.3)
How bothered are you about having to wear a retainer for a long time after treatment is completed?	18 (60)	8 (26.7)	4 (13.3)
How bothered are you about having white or brown spots on your teeth if you don’t keep them clean while your brace is on?	4 (13.3)	4 (13.3)	22 (73.4)
How bothered are you about having white fillings on your front teeth replaced regularly?	10 (33.3)	11 (36.7)	9 (30)

**Table 31: The frequency of parental responses to the value clarification exercise ‘Reasons not to choose treatment to straighten your child’s teeth’**

Question	Not bothered	Don’t know	Bothered
	N (%)	N (%)	N (%)
How bothered are you about what your child’s teeth will look like with a brace on?	17 (56.7)	6 (20)	7 (23.3)
How bothered are you about having to see the orthodontist every 4-6 weeks for checks on your child’s brace?	19 (63.4)	4 (13.3)	7 (23.3)
How bothered are you about having teeth taken out?	8 (26.6)	11 (36.7)	11 (36.7)
How bothered are you about having aching pain after braces are fitted?	10 (33.3)	11 (36.7)	9 (30)
How bothered are you about having to wear a retainer for a long time after treatment is completed?	12 (40)	8 (26.7)	10 (33.3)
How bothered are you about having white or brown spots on your child’s teeth if don’t keep them clean while brace is on?	1 (3.3)	5 (16.7)	24 (80)
How bothered are you about having white fillings on your child’s front teeth replaced regularly?	5 (16.7)	12 (40)	13 (43.3)

#### 4.4.1.6.3. Decision-making needs

Table 32 shows young people and parents’ responses to the decision-making need questions at the end of the PDA document (Appendix I). This exercise involves questions to elicit whether participants had enough knowledge, were clear about their values, had enough support to make a decision and were certain about what to choose, as well as their decision about having braces or not.

It can be seen that 96.7% of participants thought that they had enough knowledge about what to choose, 93.3% of young people (n= 28), and 96.7% of parents (n= 29) were clear about which benefits and risks matters most to them. All participants stated that they had enough support and advice to make a decision about which treatment to choose. Although, all parents were certain about their decision, 2 young people (6.7%) were uncertain regarding their choice.

From the Table 32, it can also be seen that the number of participants who chose to have fixed braces was 25 patients and 26 parents. Only one child decided not to have a brace, and one child chose not to have any treatment to straighten teeth. Furthermore, three young people and one parent stated that they needed to find out more about their options, and three parents thought that they would discuss options with others.

**Table 32: The young people and parental responses to the decision-making need questions**

Questions	Young people N (%)		Parents N (%)	
	Yes	No	Yes	No
<b>Knowledge:</b> Do you know enough about the reasons to choose either to have a fixed brace or other ways to straighten your teeth?	29 (96.7)	1 (3.3)	29 (96.7)	1 (3.3)
<b>Values:</b> Are you clear about which benefits and risks matter most to you?	28 (93.3)	2 (6.7)	29 (96.7)	1 (3.3)
<b>Support:</b> Do you have enough support and advice to make a choice about which treatment is best for you?	30 (100)	0 (0)	30 (100)	0 (0)
<b>Uncertainty:</b> Do you feel sure about the best choice for you?	28 (93.3)	2 (6.7)	30 (100)	0 (0)
<b>What are the next steps?</b>	Young people N (%)		Parents N (%)	
I would like to have a fixed brace	25 (83.3)		26 (86.7)	
I have decided not to have a fixed brace and will talk to my dentist about other options	1 (3.3)		0 (0)	
I don't want any treatment to straighten my teeth	1 (3.3)		0 (0)	
I need to find out more about my options	3 (10)		1 (3.3)	
I need to discuss options with other	0 (0)		3 (10)	

## **4.5. Discussion**

### **4.5.1. Overview**

The aim of this study was to evaluate the impact of using the PDA on the decision of young people and their parents considering fixed orthodontic appliance treatment. This is the first study to assess the effectiveness of using a decision aid in this area. The findings of this pilot study suggest that we have developed a promising PDA that may improve the quality of patients and parents decisions about whether or not to undergo orthodontic treatment.

As this project focused on the development and pilot evaluation of the PDA, examination of the effect of participant characteristics such as age, sex, and level of education on the outcomes of decisional conflict, expectations and knowledge of treatment were not included in the analysis. Examination of the influence of such characteristics may be undertaken in a larger study.

This discussion section will now consider the impact of using the PDA on decisional conflict, participants' expectations and knowledge regarding fixed orthodontic appliance treatment, and a brief discussion of the PDA value clarification exercise. Also, the strengths, limitations, and difficulties encountered during the study will be highlighted. The recommendations made for the future research will be described in Chapter Six of this thesis.

### **4.5.2. Impact of the PDA on decisional conflict**

The decision aid improved decision quality by reducing the decisional conflict of both young people and their parents by nearly 50% after exposure to the PDA. This reduction in decisional conflict should help those who were uncertain about making this decision. The level of reduction in total mean decisional conflict scores of 12.3 points in young people (mean total pre- PDA 27.0 to post- PDA score of 14.7) and 8.7 points in parents (mean total pre- PDA 20.9 to post- PDA score of 12.2) was significant. According to O'Connor user's manual (2010) a score of 25 or lower, indicates that participants are more likely to make a decision, whereas scores exceeding 38 are associated with delay in decision making (O'Connor *et al.*, 1998c).

Our results tend to show that after using the PDA, young people perceived themselves to be more informed, clearer in their values, and more certain about their choice. The greatest reduction was found in the Uninformed subscale which revealed that the PDA

left patients well informed about the available treatment options, as well as the benefits and risks of each option.

The changes in the Support subscale scores were reduced after seeing the PDA, but the difference was not significant and the effect size was small. This finding might be because the baseline scores were low, suggesting that young people were already feeling well supported before using the PDA. Similar findings were reported by Schonberg *et al.* (2014) who found no significant reduction in Support subscale scores after using the PDA in women considering mammography screening.

Some differences were reported from parents, the only reduction which was not significant was in the Uncertainty subscale (pre- PDA mean = 20.6, post- PDA mean = 15.8). The lack of difference in the DCS Uncertainty subscale suggests that the parents were more certain that orthodontic treatment is the right choice for their child. The lack of shift in the Uncertainty subscale scores was found in a previous study involving a decision aid for family members considering long term care options for a relative with dementia (Comeau, 2001).

The findings from this study support the results of other studies which have evaluated the effectiveness of using PDAs in clinical consultations (Mathers *et al.*, 2012; McGillion *et al.*, 2014). The results from this study are also in agreement with the findings from a recent Cochrane review (Stacey *et al.*, 2014), which reported that decisional conflict decreased in all of the included studies when comparing the decision aid versus the usual care for a variety of decisions. The authors also reported that PDAs reduce patients' decisional conflict related to feeling uninformed and unclear about their personal values.

In addition, this study further supports the previous findings from Brohan and colleagues (2014) who reported that the mean DCS scores reduced from 51.98 to 35.52 after completing the PDA, and Menard *et al.* (2010) who detected that the total decisional conflict was significantly reduced after the use of the PDA from 63% to 24% ( $P < 0.001$ ). However, while the reduction in decisional conflict is considered an important goal of using the PDAs, some researchers argue that the decisional conflict can encourage appropriate deliberation and enhance doctor-patient relationship (O'Connor, 1995; Nelson *et al.*, 2007).

The reduction in decisional conflict after completion of the PDA was expected and supports the hypothesis that people who use a decision aid are more likely to make an informed and value-based decision, and as a result, they are more likely to persist with their decision (de Achaval *et al.*, 2012). In other words, “concordance with the agreed treatment is more likely to lead to better health outcomes” (Mathers *et al.*, 2012).

As the current PDA has reduced young peoples’ decisional conflict in this pilot study it suggests further PDAs may be effective for other health conditions where young people are faced with difficult decisions.

#### **4.5.3. Impact of the PDA on expectations of orthodontic treatment**

This study found that the use of the PDA has a limited effect on patients’ and parents’ expectations about orthodontic treatment. In general there was an overall increase in the mean scores after the use of the PDA. However, the changes in expectations of young people were found to be significant in only a few items related to teeth extraction, aesthetics, and eating, whereas parents were more concerned about whether orthodontic treatment will affect their child’s ability to speak. The limited effect of the PDA on expectations could be explained by the fact that orthodontic treatment is prevalent and patients may have friends or classmates wearing braces and parents may have had orthodontic treatment in the past, which might have resulted in realistic expectations regarding orthodontic treatment.

Previous studies have measured patients’ expectations of orthodontic treatment after their initial consultation or during treatment (Shaw *et al.*, 1979; Tung and Kiyak, 1998). Bennett and colleagues measured only parents’ expectations about orthodontic treatment and not the expectations of the children (Bennett *et al.*, 1997). Recent studies have assessed both patients’ and parents’ expectation of orthodontic treatment prior to their first consultation (Bos *et al.*, 2003; Sayers and Newton, 2006, 2007; Hiemstra *et al.*, 2009; Duggal and Bansal, 2010); however, only one study found in the literature has assessed orthodontic patients’ expectations before and after the use of an intervention (Nasr *et al.*, 2011), and this trial did not included parents. The current study is the first to evaluate the change in young people and their parents’ expectations of orthodontic treatment before and after exposure to an intervention. Therefore, a comparison between previous studies and the current study is difficult due to the variations in study design but some comparisons have been attempted:

#### **4.5.3.1. Expectations regarding extraction of teeth for orthodontic treatment**

Both patients and parents expectations regarding the possibility of having teeth extracted for orthodontic reasons increased significantly after using the PDA. This suggests that not all patients and parents are aware that they might have their teeth extracted for orthodontic reasons. This was in agreement with Nasr *et al.* (2011) who reported an increase, although not significant, in the number of participants who expected teeth extraction after receiving information leaflets, together with verbal information, compared to those who received only verbal information about orthodontic treatment. In their study, the mean score increased from 41.8 pre-intervention to 46.5 post-intervention, compared with the increase in mean scores in this study which was 50.6 pre- PDA to 68.3 post- PDA. This suggests that the use of the PDA has a greater impact in creating realistic expectations.

#### **4.5.3.2. Expectations that orthodontic treatment will produce a better smile**

Patients' expectations that orthodontic treatment will produce a better smile increased significantly after receiving the PDA from mean 78.4 pre- PDA to 88.9 post- PDA. This is in agreement with Nasr and colleagues (2011) who found high expectations from participants of a better smile following orthodontic treatment (mean 72.0 pre-intervention to 82.5 post-intervention). Also, Fleming *et al.* (2008) found that most patients (87%) were concerned with the appearance of their teeth. This finding is not surprising, because many previous researchers have found aesthetics as the most common reason for seeking orthodontic treatment (Shaw, 1981; Lew, 1993; Albino, 2000; Rasool *et al.*, 2012; Samsonyanová and Broukal, 2014).

#### **4.5.3.3. Expectations that orthodontic treatment will make it easier to eat**

Young people's expectations that orthodontic treatment will improve mastication was increased after seeing the PDA (pre- PDA mean= 55.4, post- PDA mean= 64.7). This finding is in agreement with Shaw *et al.* (1979) who stated that patients and parents expected orthodontic treatment to improve mastication, and Henrikson *et al.* (2001) who reported a significant increase in self-perceived masticatory ability after orthodontic treatment. However, our results contradict the findings of other researchers who found that orthodontic patients did not expect improvement in mastication after brace treatment (Sayers and Newton, 2007; Hiemstra *et al.*, 2009; Nasr *et al.*, 2011). Nasr and colleagues (2011) did not find a significant difference in expectations that orthodontic treatment would improve mastication (pre-intervention

mean= 52.8, post-intervention mean= 52.0). Although, it does appear that having a normal occlusion improves mastication and function, most of the studies evaluating the influences of the orthodontic treatment on masticatory performance did not find a difference (Magalhães *et al.*, 2010).

#### **4.5.3.4. Expectations that orthodontic treatment will make it easier to speak**

The findings of this study revealed that expectations about speech are more important to parents than their children, although there was an increase in patients' expectations that orthodontic treatment could improve their speech. The significant increase in parents' expectations after using the PDA (pre- PDA mean= 52.2, post- PDA mean= 62.9) could be attributed to the perception that correction of malocclusion may improve speech. This is in agreement with the previous findings of Uslu and Akcam (2007) who asked orthodontic patients if they felt a decrease in their speech quality after treatment, and found that 27.5% of patients thought that orthodontic treatment had improved their speech quality.

Although, following the use of the PDA, there is higher expectations of patients and their parents of improved mastication and speech, these findings were inconclusive in the current orthodontic literature. This limitation will benefit from further investigation in a longitudinal study.

#### **4.5.4. Impact of the use of the PDA on knowledge**

In this study we used two questions from the OPEQ by Sayers and Newton, 2006 to elicit knowledge, in the absence of an appropriate specific knowledge scale.

The use of the PDA improved knowledge regarding the duration of orthodontic treatment and the frequency of orthodontic appointments. Most participants, after seeing the PDA, expected that orthodontic treatment takes 2-3 years to be completed, and they will need to visit the orthodontist every 4-6 weeks as stated in the PDA. This finding reflects the effect of the PDA in creating more realistic expectations regarding treatment. Despite the paucity of studies of PDAs in the dental field, this finding confirms the results of previous research using PDAs in dentistry (Johnson *et al.*, 2006; Kupke *et al.*, 2013) who reported that the use of PDAs was effective in increasing patients' knowledge about treatment compared to knowledge gained through consultation alone. This finding is in line with the views of Bekker *et al.* (2010) who stated that it is vital for patients to have sufficient information about what

treatment entails, and whether or not it will meet their expectations before they take the decision to undergo orthodontic treatment.

In the present study most participants perceived that orthodontic treatment will straighten their teeth, and their knowledge regarding the benefits of having treatment increased after seeing the PDA when compared to those who have no idea about the benefits of having braces before the PDA. This suggests that some people seek orthodontic treatment only because they have been referred by their general dentist. Only one child did not change his response after seeing the PDA. The possible explanation is that this child had a palatally displaced canine, with well aligned teeth; therefore he could not see any benefits from having orthodontic treatment.

The use of the PDA has increased participants' knowledge regarding the risks of having orthodontic treatment. Surprisingly, in this study 60% of participants were not aware of any risks from orthodontic treatment before seeing the PDA, and this was reduced to only 2 young people and 4 parents after its use. This finding highlights the need for the use of interventions, such as a PDA in orthodontics, and supports the previous finding by Mortensen *et al.* (2003) that the traditional informed consent did not produce an understanding or recall of the risks of orthodontic treatment.

Nearly all participants perceived that they had enough information to make a decision after seeing the PDA. This finding is important and corroborates the suggestion made by Bergstrom and colleagues (1998) who stated that correct information to patients and parents about the risks and benefits of orthodontic treatment is essential in orthodontic care to increase the possibility of the patient making the decision about treatment. It also supports previous research by Brattström *et al.* (1991) and Nel and Dawjee (2012) who noted that insufficient information and lack of communication between the orthodontist and the patient can lead to premature termination of the treatment.

#### **4.5.5. Value clarification exercise**

In agreement with previous research, achieving straight teeth and changing the way they look was the main reason for most participants to have orthodontic treatment (section 4.5.4). However, this finding contradicts that of Souza *et al.* (2013) who reported that 'occlusal deviation' was the most important factor in motivating people to seek orthodontic treatment. This variation in findings could be attributed to the

difference in the expectations between young people and adults, as in their study they included adult patients aged 18 – 25 years old, also their study sample composed of individuals with high levels of education. This may suggest the need for different PDAs for different ages. Young people and parents were bothered about having teeth extraction and the pain associated with fixed appliances, as well as having WSLs on their teeth. In addition, one third of parents were mainly concerned about the frequency of visits to the orthodontist. This may be due to the inconvenience this would cause as they need to have time off work to bring their children to the clinic and the children miss school.

At the end of the PDA, responses to decision-making need questions revealed that the majority of participants thought that the PDA increased their knowledge; they were clear about the benefits and risks of having treatment, and all of them stated that they had enough support about which treatment to choose. However, although all parents were certain about their decision, two young people were still undecided regarding what to choose. This may suggest further discussion is needed about treatment with the orthodontist or the general dentist.

The use of the PDA in orthodontic treatment was designed to encourage further discussion between the patient, parents and the orthodontist to improve the doctor-patient relationship. This finding is in agreement with Stacey *et al.* (2014) who reported that decision aids appeared to have a positive effect on patient-practitioner communication and can lead patients to desire a more active role in the decision-making process. This increased participation being a key in the implementation of shared decision-making throughout healthcare.

#### **4.5.6. Recruitment of participants**

The difficulties of recruiting children and young people to medical research are well recognised, particularly those from ethnic minority groups (Rice and Broome, 2004; Spears *et al.*, 2011). Recruitment of the 30 young people and 30 parents to this study was difficult. Details regarding the reasons for exclusion are presented in the flow diagram (Figure 5) in the Results section. In general, this could be attributed to the extensive exclusion criteria applied in the study, such as the age limit of 12 – 16 years old which resulted in the exclusion of 168 children. Also, the need to schedule a further review appointment (more than 6 months later), was responsible for excluding 107 children. Perhaps we initially over-estimated the proportion of new referrals who

might be eligible. It is surprising that there were a higher proportion of children younger than 12 years referred. However, the reason for selecting this age group was based on the fact that the majority of orthodontic patients fall in the age group of 12-16 years. Also this age group was considered old enough to possess the perceptual awareness to make an autonomous decision about having a need for orthodontic treatment (Singla *et al.*, 2013).

Despite these difficulties, a high response rate (43 children out of the total 54 young people approached - 80%) were included in the study, although only 30 children completed T1 and T2. Furthermore, there was a high representation from ethnic minority children, which may ensure good generalisability of the findings. The first aspect that may have encouraged participation in this study was the simple information sheets that children and their parents received, with sufficient time period allowed for them to decide whether they wished to participate in this research or not. Participants were also given a personal and clear explanation about the study and why it was being conducted by the researcher. This approach is in line with the recommendations of Marshman *et al.* (2012) who carried out a qualitative study to explore recruitment of young people to a randomised clinical trial. It was found that a clear explanation about the research from a dentist was a major factor in encouraging parents to consent to their child's participation.

The higher engagement of young people and parents from ethnic minorities (nearly half of the participants in this study) may relate to the ethnicity of the investigator (Arabic-speaking Libyan man). It can be assumed that some ethnic groups may have felt more comfortable in agreeing to participate in the study because they felt commonality with the researcher. A recent systematic review on the barriers and facilitators to minorities participating in clinical research reported that having research staff representative of the research participants' ethnic group was the key to successful recruitment (George *et al.*, 2014). It was found that patients from ethnic minority groups valued research staff that they could relate to culturally and communicate with in their first language. These issues may be considered in future studies to ensure that ethnic minority groups are adequately represented in clinical research.

#### **4.5.7. Limitations of the study**

In this study the PDA was administered to participants when they attended the department for oral hygiene instructions and collection of orthodontic records, which

may imply that patients had already decided to have the treatment. Ideally the PDA should be given before that time, i.e. at their first appointment when they attend the orthodontic department, but this could not be done due to ethical issues, as the ethics committee required participants to have sufficient time to consider being involved in the study.

The pre- post- test study design has been widely used to test interventions, such as PDAs (O'Connor *et al.*, 1998; Cranney *et al.*, 2002; Stacey *et al.*, 2003; Menard *et al.*, 2010). However, it is one of the simplest methods of testing and in the absence of a control group, one cannot attribute all of the observed effect to the PDA. For this PDA, the pre-post-test design was chosen in the absence of any pilot data to inform a power calculation. Therefore, further evaluation of the current PDA in a randomised controlled trial is required. Data gained from this study has been used to estimate the sample size required to conduct a larger trial.

No follow up was conducted to assess whether any pre- post- change in the scores persisted over time. This was planned in the study to follow patients in two time points, T1 after 4-6 weeks from the baseline data collection stage, and T2 after another 4-6 weeks from T1. Though, this could not be achieved due to practicality issues, such as the repeated cancellation of appointments, which made the recruitment period longer than expected, and the time period for PhD project. This was disappointing and necessitated a change in the study protocol.

Further limitations related to the project in general are described in next chapter (see section 5.7).

#### **4.5.8. Strengths of the study**

This decision aid was developed in an area where no decision aids are currently available and a need was identified. We used a prospective pre-test/post-test study design in which participants are followed forward over time. This PDA was evaluated from the perspective of young people and parents. We feel confident that the responses of children reflect their true feelings and not what their parents expected, because the study was designed for the participants to fill the questionnaire in front of the researcher in order to prevent parents from helping their children in answering the questions. Also, all measures used were previously assessed as valid and reliable for use in the UK.

In this study the PDA was useful in improving knowledge and reducing decisional conflict because the present PDA is an interactive intervention in which patients and their parents need to answer a value clarification exercise at the end. Also this PDA was administered by a clinician, who took time to go through it with participants, to get the advantage of verbal communication and give the opportunity for participants to ask any questions, rather than just send it through the post to let patients have information about treatment.

## **5 CHAPTER FIVE: OVERALL DISCUSSION**

### **5.1. Introduction**

This thesis forms an original addition to existing knowledge. First, the existing literature was reviewed systematically to ascertain the degree to which a shift in thinking from compliance to concordance had been considered in orthodontics. The research was also novel in so far as it was the first study in orthodontics to develop and explore the effect of using a PDA for young people and parents considering orthodontic treatment with fixed appliances.

### **5.2. Achievement of study aims and objectives**

It is worth reviewing the study's original aims and objectives in order to consider whether they have been met. The overall aim of this study was to develop a PDA for patients with malocclusion considering whether to have fixed orthodontic appliance treatment or not.

The specific objectives of the study were:

- A systematic review of the orthodontic literature to identify the factors associated with concordance and compliance with orthodontic treatment and to establish the status of the research in this field and the degree to which the shift has been reflected in the literature.
- Using a child-centred approach to develop a PDA for young people undergoing fixed orthodontic appliance treatment to facilitate shared decision-making and improve patient-clinician interaction.
- A pilot evaluation of the developed PDA to assess its effect in reducing decisional conflict, increasing knowledge and meeting expectations.

### **5.3. Main findings**

Interviews can be used to inform the development of age-appropriate materials for research projects. The findings from this study indicate that using a PDA with patients thinking of undertaking orthodontic treatment with fixed appliances might facilitate shared decision-making, and help participants decide whether to have the treatment or not. In fact the concept of concordance is based on shared decision-making and consensual agreement between patient and healthcare provider as equal parties (Marinker and Sharp, 1997).

The PDA we developed is based on the ODSF framework and assessed against IPDAS criteria, which showed that it is a good quality PDA. Also it is a novel PDA because it has been developed and evaluated with children, it is the first PDA in the field of orthodontics, and one of the first PDAs in dentistry. Though, it still needs to be evaluated in a larger trial and in centres other than the Orthodontic Department of the Charles Clifford Dental Hospital in Sheffield.

The findings from the systematic review did not find a shift in thinking toward concordance in orthodontic treatment, but it did reveal that the orthodontist-patient relationship is an important factor in determining a successful outcome of orthodontic treatment. Previous studies reported that building a good relationship between the patient and healthcare provider in the clinical encounter can be enhanced through the adoption of the concept of shared decision-making (Elwyn *et al.*, 2012), and this might be facilitated by interventions, such as the PDAs (Menard *et al.*, 2010). Therefore, the development of a PDA for patients considering orthodontic treatment was needed.

Newton and Cunningham (2013) highlighted that the key aspect to managing patient expectations is communication. They stated that “the patient’s expectations of treatment are a key determinant of satisfaction with treatment”, therefore it is important to spend sufficient time outlining and documenting the patient’s concerns and expectations. The orthodontist/patient relationship enables an understanding of the expectations regarding orthodontic treatment, resulting in greater motivation and cooperation, and leads to a successful outcome (Souza *et al.*, 2013).

Interviews with young people showed that they want to be effectively involved in the decision-making process regarding their health conditions. The development of a PDA from the view point of young people and their parents provided new understanding into their experiences of orthodontic treatment. The results of the pilot evaluation showed that participants, after exposure to the PDA, had a significant reduction in decisional conflict, improved knowledge regarding the available treatment options, and the benefits and risks of each option, and felt clear about their values. Also, its completion was helpful in reducing the proportion of people who remained undecided about whether to undergo fixed orthodontic appliance treatment or not. Such findings provide sufficient evidence for its use in clinical practice. Similar findings were also reported in a recent Cochrane review carried out by Stacey and colleagues (2014).

## **5.4. Ethical considerations**

The application for ethical approval through the National Research Ethics Service, as well as obtaining local research governance, proved a lengthy and complex process. Although ultimately successful, the process took around six months and did delay the start of the project. However, following initial submission of the application for ethical approval, only minor amendments were required, such as giving parents a postage paid slip to return if they were interested in taking part in the study, instead of telephoning them 1 week after receiving information about the study. Also, as requested by the ethics committee, the information sheet for young people was revised to ensure that the language was appropriate for 12-16 year olds. Two young people had reviewed these information sheets and changes were made in line with their suggestions. No major amendment of the protocol was required. The lesson to be learnt from this experience is that ethical approval should be sought very early during a finite period of research, such as PhD, so that progress is not compromised.

The study subsequently progressed well and adhered to all good practices required for ethical research. Patients and parents had adequate time to reflect whether or not to participate in the study. No ethical concerns arose during the study and there were no patient complaints.

## **5.5. Children's involvement**

The present study involved children and their parents and sought their views regarding fixed orthodontic appliance treatment. Previous research in this field has focused mainly on parental views and has not concentrated on patients' perspectives. There is a growing emphasis in paediatric healthcare in general towards the involvement of children and young people in both research service evaluation and delivery.

The lack of children's involvement in oral health research was first highlighted in a systematic review undertaken by Marshman and colleagues (2007) who found that out of 3266 papers identified from dental literature from 2000 -2005, children were involved as active participants in only 7.3% of the published papers. They suggested that future researchers should attempt to work with children, involving them as fully as possible throughout the research process (Marshman *et al.*, 2007).

Since that time, there has been a steadily emerging literature which has involved children in dental research (Grant and Ramcharan, 2010). More recently, Marshman

and colleagues (2015) updated their systematic review on including children in dental research. The authors noted that there is evidence of movement towards involving children in the research process, and they found an increase in the active involvement of children in dental research from 7.3% in 2000-2005 to 17.4% in 2006 to 2014.

The PDA used in this project has been developed and evaluated with young people and their parents.

## **5.6. Challenges for implementing PDA in clinical practice**

One of the most common challenges to the implementation of the PDAs in clinical practice is the time required to adequately complete it with the patient. The view is that shared decision-making consultations take longer, compared to consultations where clinicians make the decision; however, as stated by Bekker and colleagues (2004), time spent engaging patients in the decisions may reduce the overall time spent dealing with someone who is unsure or unhappy about a decision in which they were not involved. Therefore, incorporating time for shared decision-making in clinical practice should be considered. However, further research is required to investigate whether GPs or orthodontists will use the PDA in their practices, depending on which setting is deemed most appropriate.

Healthcare professionals often think they are sharing the decisions more than their patients do (Stevenson *et al.*, 2000). This is because some clinicians do not differentiate between informed consent, which involves provision of basic information about a single treatment, and shared decision-making. This leads to a patchy implementation of PDA, and can be improved by training clinicians in shared decision-making programmes and incentivising the use of PDAs in practices (Coulter and Collins, 2011).

Segal (2007) stated that there is a lack of progress in this field mainly because clinicians have failed to embrace the concept of concordance. Some clinicians do not believe patients should be involved in the decision-making process, and even when they have tried to involve them, they failed to provide them with sufficient support and information, regarding their treatment options and outcomes. For many medical interventions this has been facilitated by the development and implementation of PDAs. Decision aids have been found to be effective at reducing the uncertainty in making decisions (decisional conflict), improving knowledge and creating more

realistic expectations about outcomes, as well as enhancing doctor-patient interaction and therefore increasing peoples' participation in decision-making (Stacey *et al.*, 2014).

## **5.7. Limitations**

Compared to the wider medical literature, shifts from compliance to concordance have not been reported in the orthodontic literature or in dentistry in general, despite previous calls over the past 15 years. In dentistry, the paternalistic model is still widely used. The main barriers to introducing a more shared style of decision-making include the lack of tools and training of dental care providers, as well as the desire of clinicians to provide patients only with information about what they see as the 'best' treatment (Röing and Holmström, 2014).

The findings of this study reflect the responses of patients attending the Charles Clifford Dental Hospital (CCDH) for orthodontic consultation; therefore, the results may not reflect the views of orthodontic patients in general. It would be interesting to conduct a larger study including other orthodontic centres.

The current PDA was appropriate for certain ages of referred people 12 to 16 years old, so the need for a PDA for patients of different ages may be necessary. In addition, its use is limited to people who are capable of reading English; however with the positive findings there is the potential for the decision aid to be translated into other languages.

Another suggested limitation was that the current PDA did not detail the cost of treatment which may be important for some people; however, this was because the current study was conducted in NHS clinics where treatment for children is free. Therefore these results may be applicable only in settings where patients or parents do not need to factor in the cost of treatment into their decision-making process.

The sample used to evaluate the current PDA was drawn from secondary care (CCDH) and it should ideally be used in primary dental care practices. Future research should plan to use the PDA in primary care before patients are referred to see a specialist or consultant to save time for those who might not want orthodontic treatment.

Implementation of a PDA in clinical practice will be a challenge in terms of its effect on increasing the length of time of the initial consultations. Other factors that need to

be taken into account include the patient/parental level of education and clinicians' awareness of the concept of shared decision-making. It will also be necessary to keep the PDA up-to-date.

Finally, the continuous commitment and costs associated with maintaining the current and up-to-date information in the PDA is another possible limitation in any PDA, but making this PDA available in a web-based format, hosted by, for example the British Orthodontic Society website could overcome these weaknesses and make it easier to update and less expensive to maintain.

### **5.8. Impact on clinical practice**

The results of this study demonstrate that the use of the PDA in clinical practice could increase patients' understanding of the available treatment options and improve the doctor-patient relationship resulting in successful treatment outcomes. This is likely to make its use in general dental practice acceptable to all parties, although, its use may need some initial 'investment' in consultation time. A further potential advantage is that the decision aid could be used by other clinical members of the primary care team such as orthodontic therapists or extended duties dental nurses; this may result in an increase in the consultation time available to clinicians for other patients.

## **6 CHAPTER SIX: CONCLUSIONS AND RECOMMENDATIONS**

This thesis forms a distinct contribution to current knowledge with novel findings of impact of using PDA for people considering orthodontic treatment. This chapter summarises the conclusions of the study, implications for future research and for clinical care and policy.

### **6.1. Conclusions**

In conclusion, this study has shown:

- The systematic review in this project did not find a shift from compliance to concordance in orthodontics and significant work is needed in this area.
- Factors related to concordance, such as the relationship between the patient and the orthodontist, have been identified as important factors in achieving successful orthodontic treatment.
- The current PDA has been developed and evaluated based on a recognised framework (Ottawa Decision Support Framework), and it was the first study to develop and initially evaluate the impact of using a PDA, in an orthodontic setting, using a child-centred approach.
- The use of the PDA was found to have a significant effect in reducing decisional conflict by about 50% in young patients and their parents.
- The PDA increased knowledge regarding duration of treatment and frequency of orthodontic appointments, although it has a limited effect on patients and parents expectations about orthodontic therapy.

### **6.2. Recommendations for further research**

- There are still several gaps in the literature. Only a few studies have examined the effects of PDAs on patients' persistence with choices or health outcomes. We also know little about orthodontists' views about decision aids, and its influence on the orthodontist-patient interaction. Therefore, a longitudinal study to assess the long term effect of the PDA is needed, and more studies are required to deepen our understanding of the interaction between the use of the PDA and the patterns of orthodontist-patient communication.
- Despite the exponential growth in the field of PDAs, gaps in knowledge remain for their effective implementation in clinical practice which could be prioritised in future studies.

- While this thesis has advanced knowledge about the impact of a PDA in an orthodontic setting, it would need further testing through a randomised controlled trial to determine if using the PDA affects patients' and parents' decisions regarding having fixed orthodontic appliance treatment or not. Also, research on the effect of PDAs on attendance, and treatment completion rates needs to be considered.
- Further research is needed to investigate the impact of using the developed PDA in primary care settings to see if it reduces the number of inappropriate referrals. The contribution of other factors, such as socioeconomic status, ethnicities, and cultures to completion rates could also be investigated.
- The current study was carried out with UK patients, who were eligible to receive free orthodontic treatment through the NHS. Further research is required concerning the effect of PDAs on patients who pay for their orthodontic treatment.
- More PDAs need to be developed for other dental treatments, and consideration should be given to developing an online version of the PDA.

### **6.3. Implication for policy**

- The benefits of incorporating shared decision-making into clinical practice will result in more informed patients, which will hopefully make clinical consultations more focused, potentially improve patient outcomes and result in greater patient satisfaction with the treatment.
- By using PDAs, clinicians can be confident that the patients are fully informed regarding their treatment options and less likely to experience decisional conflict.
- The evidence from Cochrane reviews suggests that using a PDA reduces the number of contacts a patient has with their healthcare providers along the patient pathway, as it promotes a greater understanding of their condition and in turn greater concordance is achieved. Therefore orthodontists need to consider the importance of shared decision-making and the use of PDAs in their practice.
- Use of PDAs could be included as an outcome measure in contracts for orthodontic services provided in primary care. This could be enhanced through incentives for clinicians to make time to implement PDAs in their practices and creating effective systems for delivering shared decision-making.

In summary, the concept of shared decision making is an important emerging trend in clinical medicine, but has received little or no attention in the dental literature. Orthodontists, as well as other dental care providers, need to gain a deeper understanding of the preferences of patients and their parents. They should gain insight into the range of considerations which influence their decision and this could be achieved through the use of PDAs. However, more research in this field is needed to investigate the impact of PDAs further.

## 7 CHAPTER SEVEN: REFERENCES

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## **8 CHAPTER EIGHT: APPENDICES**

## Appendix A1: Endodontic Decision Board (EndoDB)

Adopted from Johnson et al., (2006)

Your dentist has advised you that your tooth has an inflamed or infected pulp (nerve) and needs treatment. You have five options. Each option has different benefits, risks, costs, and probable outcomes.

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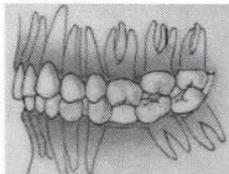
### No treatment



- No time is required other than the consultation.
- No cost other than the consultation fee.
- There is about a 50% chance that this tooth will cause you significant discomfort and/or a serious infection over the next five years.
- 50% chance of keeping this tooth for five or more years.

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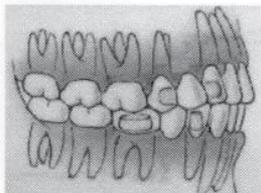
### Extraction and no tooth replacement



- One to three appointments will be required.
- The cost is about \$50 to \$260.
- The infection will be cured but there is a moderate risk that your other teeth will move and you will lose some chewing ability.
- 0% chance of keeping this tooth for five or more years.

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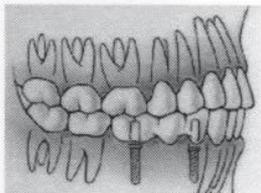
### Extraction and placement of a bridge



- Five to seven appointments over three to four months will be required to replace the missing tooth
- The cost is about \$1500 to \$2000.
- The infection will be cured. The teeth on either side will be shaped to attach the bridge. The bridge will look and function almost as well as your natural tooth.
- 95% chance of keeping this tooth replacement for five or more years.

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### Extraction and placement of an implant



- Seven to eight appointments over nine to 10 months will be required to replace the missing tooth.
- The cost is about \$1850 to \$2000.
- The infection will be cured. There is a slight chance of discomfort, infection, and/or failure of the implant to attach to the bone. The implant will look and function like your natural tooth.
- 95% chance of keeping this tooth replacement for five or more years.

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### Root canal treatment



- Four to six appointments over three to four months will be required for treatment.
- The cost is about \$900 to \$1100.
- The infection will be cured although there is a slight risk of short-term discomfort and a slight future possibility that the infection will return and the tooth may need additional treatment.
- 90% chance of keeping this tooth for five or more years.

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## Appendix A2: Decision Board for Class-II therapy options

Adopted from Kupke et al., (2013)

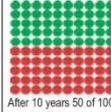
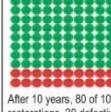
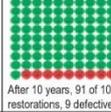
Kupke et al.

Decision board for class-II therapy options

**A**

**UNIKLINIK KÖLN** | Zentrum für Zahn-, Mund- und Kieferheilkunde | Poliklinik für Zahnerhaltung und Parodontologie

Your dentist has advised you that you have a defect restoration or decay in a posterior tooth, which in case of therapy may lead to a **multi-surface restoration**.

Type of care	Treatment time	Costs / self-payment €	Characteristics	Survival rate
 <b>No therapy</b>	 None, except consulting	 Costs: ca. 20 € Self-payment: 0 €	<ul style="list-style-type: none"> <li>★ Uncontrolled loss of healthy tooth substance</li> <li>★ High probability of progression of caries and pain</li> <li>★ Impaired mastication</li> </ul>	 After 10 years 50 of 100 teeth cause pain
 <b>Amalgam</b>	 1 session à 1 h 20 min and 1 session of 20 min	 Costs: ca. 60 € Self-payment: 0 €	<ul style="list-style-type: none"> <li>★ Excessive loss of healthy tooth substance</li> <li>★ Well-tolerated and moderate occurrences of side effects</li> <li>★ Low abrasion</li> </ul>	 After 10 years, 80 of 100 intact restorations, 20 defective
 <b>Gold cast</b>	 2 sessions à 3 h	 Costs: ca. 460 € Self-payment: ca. 330€	<ul style="list-style-type: none"> <li>★ High loss of healthy tooth substance</li> <li>★ Well-tolerated and very rare occurrences of side effects</li> <li>★ Low abrasion</li> </ul>	 After 10 years, 91 of 100 intact restorations, 9 defective

**B**

**UNIKLINIK KÖLN** | Zentrum für Zahn-, Mund- und Kieferheilkunde | Poliklinik für Zahnerhaltung und Parodontologie

Your dentist has advised you that you have a defect restoration or decay in a posterior tooth, which in case of therapy may lead to a **multi-surface restoration**.

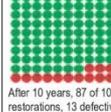
Type of care	Treatment time	Costs / self-payment €	Characteristics	Survival rate
 <b>Composite (simple)</b> Quix® , SDR® , Xeno V®	 1 session à 1 h 30 min	 Costs: ca. 60 € Self-payment: 10 €	<ul style="list-style-type: none"> <li>★ Minimal loss of healthy tooth substance</li> <li>★ Well-tolerated and very rare occurrences of side effects</li> <li>★ Moderate abrasion</li> </ul>	 After 10 years, 73 of 100 intact restorations, 27 defective
 <b>Composite (multilayer technology)</b> CeramX Mono® , OptiBond FL®	 1 session à 2 h	 Costs: ca. 130 € Self-payment: ca. 70 €	<ul style="list-style-type: none"> <li>★ Minimal loss of healthy tooth substance</li> <li>★ Well-tolerated and very rare occurrences of side effects</li> <li>★ Moderate abrasion</li> </ul>	 After 10 years, 83 of 100 intact restorations, 17 defective
 <b>Ceramic</b>	 2 sessions à 3 h	 Costs: ca. 350 € Self-payment: ca. 220 €	<ul style="list-style-type: none"> <li>★ High loss of healthy tooth substance</li> <li>★ Well-tolerated and very rare occurrences of side effects</li> <li>★ Low abrasion</li> </ul>	 After 10 years, 87 of 100 intact restorations, 13 defective

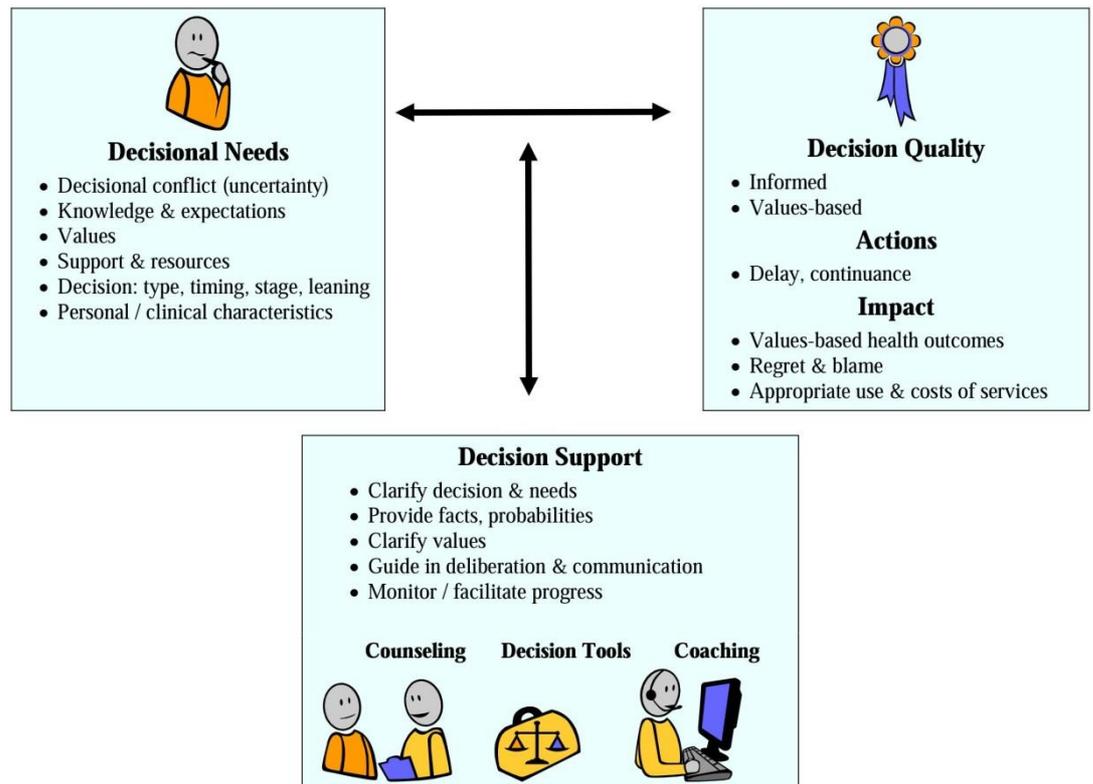
Fig. 2. Decision Board used in the clinical trial. Smileys, used to visualize the information of the 'success-rate', had already been implemented in patient communication and the bullet points used to visualize the information of the 'characteristics of the therapeutic options' were designed according to a traffic light. With regard to quality assurance, the DB was developed according to a list of criteria which had been established as guidelines for the development of novel decision aids (2). To ensure the understandability of the summary and the simplified presentation of the information on the DB, the facts as described above were additionally visualised. The DB fulfils the key requirements expressed as a checklist of the (IPDAS). \*Treatment times are calculated as worst case scenarios.

# Appendix B1: Ottawa Decision Support Framework

## Ottawa Decision Support Framework to Address Decisional Conflict

The Ottawa Decision Support Framework (Fig 1) uses concepts and theories from general psychology (Tversky & Kahneman, 1981), social psychology (Ajzen & Fishbein, 1980), decision analysis (Keeney, 1982), decisional conflict (Janis & Mann, 1977), values (Fischhoff, Slovic & Lichtenstein), social support (Norbeck, 1988; Orem, 1995), and self efficacy (Bandura, 1982).

**Figure 1. Ottawa Decision Support Framework**



The framework applies to all participants involved in decision making, including the individual, couple, or family, and their health practitioner. The framework asserts that participants' decisional needs will affect decision quality (informed, values-based choices), which in turn affects actions or behaviour (e.g. delay), health outcomes, emotions (regret, blame), and appropriate use of health services. (See **Glossary of Terms for Ottawa Decision Support Framework**)

Decision support in the form of clinical counselling, decision aids and coaching can improve decision quality, by addressing unresolved decisional needs.

# Appendix B2: Ottawa Personal Decision Guide

## Ottawa Personal Decision Guide

For People Facing Tough Health or Social Decisions  
You will be guided through four steps: 1 2 3 4



### 1 Clarify your decision.

What decision do you face?

What is your reason for making this decision?

When do you need to make a choice?

How far along are you with making a choice?  Not yet thought about the options  Close to making a choice  
 Thinking about the options  Already made a choice

### 2 Explore your decision.



#### Knowledge

List the options and main benefits and risks you already know.



#### Values

Use stars (★) to show how much each benefit and risk matters to you. 5 stars means that it matters "a lot". No stars means "not at all".



#### Certainty

Consider the option with the benefits that matter most to you and are most likely to happen. Avoid the options with the risks that matter most to you.

	Reasons to Choose this Option (Benefits / Advantages / Pros)	How much it matters Use 0 to 5 ★s	Reasons to Avoid this Option (Risks / Disadvantages / Cons)	How much it matters Use 0 to 5 ★s
Option #1				
Option #2				
Option #3				

Which option do you prefer?  #1  #2  #3  Unsure



#### Support

Who else is involved?

Which option do they prefer?

Is this person pressuring you?  Yes  No  Yes  No  Yes  No

How can they support you?

What role do you prefer in making the choice?  
 Share the decision with...  
 Decide myself after hearing views of...  
 Someone else decides...

Who?

**3 Identify your decision making needs.**

	<b>Knowledge</b>	Do you know the benefits and risks of each option?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
	<b>Values</b>	Are you clear about which benefits and risks matter most to you?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
	<b>Support</b>	Do you have enough support and advice to make a choice?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
	<b>Certainty</b>	Do you feel sure about the best choice for you?	<input type="checkbox"/> Yes	<input type="checkbox"/> No

The SURE Test © 2008 O'Connor & Légaré.

People who answer "No" to one or more of these questions are more likely to delay their decision, change their mind, feel regret about their choice or blame others for bad outcomes. Therefore, it is important to work through steps two  and four  that focus on your needs.

**4 Plan the next steps based on your needs.**

**Decision making needs**      ✓ **Things you would like to try**

 **Knowledge**

If you feel you do NOT have enough facts

- Find out more about the options and the chances of the benefits and risks.
- List your questions.
- List where to find the answers (e.g. library, health professionals, counsellors):

 **Values**

If you are NOT sure which benefits and risks matter most to you

- Review the stars in the balance scale to see what matters most to you.
- Find people who know what it is like to experience the benefits and risks.
- Talk to others who have made the decision.
- Read stories of what mattered most to others.
- Discuss with others what mattered most to you.

 **Support**

If you feel you do NOT have enough support

- Discuss your options with a trusted person (e.g. health professional, counsellor, family, friends).
- Find help to support your choice (e.g. funds, transport, child care).

If you feel PRESSURE from others to make a specific choice

- Focus on the opinions of others who matter most.
- Share your guide with others.
- Ask others to complete this guide. Find areas of agreement. When you disagree on facts, agree to get information. When you disagree on what matters most, consider the other person's opinion. Take turns to listen to what the other person says matters most to them.
- Find a neutral person to help you and others involved.

Other factors making the decision DIFFICULT

List anything else you need:

## Appendix C1: Data extraction sheet for the systematic review

No	Author and year	Meet sample criteria	Study design	Country	Type of appliance	Main term used for 'compliance'	Compliance measure	Theory used to inform choice of factors	Statistical test(s) used for compliance	n
1										
2										
3										
4										
5										
6										
7										
8										
9										
10										
11										
12										
13										
14										
15										
16										
17										
18										
19										
20										
21										
22										

**Meet sample criteria:** yes or no; **Study design:** (a) Cross-sectional questionnaire survey, (b) Case note review, (c) Longitudinal survey, (d) RCT, e) Experimental; **Type of appliance:** (1)not specified, (2) removable, (3) fixed, (4) functional, (5) removable, fixed & functional; **Main term used for 'compliance':** (1) compliance, (2) cooperation, (3) other, specify; **Compliance measure:** (1) patient questionnaire, (2) clinical records, (3) orthodontist rating, (4) parent questionnaire; **Theory used to inform choice of factors:** (y) if whole study guided by a theory, if (y) specify; **Statistical test(s) used for compliance:** Test used for compliance analysis 1= bivariate, 2= multivariate, 3= don't know, **n=** number of participants for which compliance data analysed

## Appendix C2: Measures used to assess patient's level of compliance

Study	Measures of compliance used
<b>Albino 1991</b>	Orthodontic Patient Cooperation Scale (OPCS)
<b>Allan 1968</b>	Orthodontist rating
<b>Amado 2008</b>	OPCS
<b>Bartsch 1997</b>	Orthodontist rating
<b>Bartsch 1993</b>	Patient and parents questionnaires Electronic timing devices
<b>Cucalon 1990</b>	Orthodontist rating (oral hygiene, appliance maintenance & care, elastic/headgear wear, and missing or being late for their orthodontic appointments)
<b>Daniels 2009</b>	Patient and parent questionnaires
<b>Dickens 2008</b>	Orthodontist rating (Broken appointments, broken appliances, and poor oral hygiene)
<b>Doll 2000</b>	OPCS
<b>El-Mangoury 1981</b>	Headgear/elastic wear, appliance maintenance, nonbroken appointments, oral hygiene, and plaque index.
<b>Gross 1988</b>	Orthodontist rating (oral hygiene, frequency of broken appliances, headgear/elastic wear, and tooth mobility)
<b>Lee 2008</b>	Orthodontist and hygienists rating (oral hygiene, keeping appointments, and headgear/elastic wear)
<b>Mandall 2008</b>	Clinical records (missed appointments, oral hygiene, and appliance breakage)
<b>Miller 1979</b>	Orthodontist rating (missed appointments, appliance breakage, oral hygiene, headgear and elastic wear, and general behaviour in the clinic)
<b>Sergl 1992</b>	OPCS
<b>Sergl 1998</b>	OPCS
<b>Sergl 2000</b>	OPCS
<b>Sinha 1996</b>	OPCS
<b>Southard 1991</b>	Orthodontist rating (headgear/elastic wear, oral hygiene, keeping appointments, willingness to follow instructions, broken appliances, cooperation during appliance placement and adjustment, and patient and parent attitude)
<b>Starnbach 1975</b>	Orthodontist and assistant/receptionist (Oral hygiene, appliance maintenance and care, and appointment keeping)
<b>Woolass 1988</b>	Orthodontist and researcher rating (failed appointments, late arrival, appliance loss or breakage, and lack of oral hygiene)
<b>Nanda 1992</b>	Orthodontist rating (broken appointments, appliance maintenance, broken arch wires/loose bands, oral hygiene, use of functional appliances, headgear/elastics wear) Orthodontist, patient, and parent follow-up questionnaires

**OPCS** = orthodontic patient cooperation scale by Slakter and colleagues (1980). It includes: keeping appointments, maintenance of appliance, oral hygiene, and positive attitudes of both patient and parent toward orthodontic treatment.

## Appendix D: Ethical approval



### NRES Committee Yorkshire & The Humber - Sheffield

HRA NRES Centre Manchester  
Barlow House  
3rd Floor  
4 Minshull Street  
Manchester  
M1 3DZ

Telephone: 0161 625 7832  
Facsimile: 0161 625 7299

26 June 2013

**Mr Abdussalam M Eddaiki**  
Postgraduate student  
Academic Unit of Oral Health and Development  
School of Clinical Dentistry  
Claremont Crescent  
S10 2TA

Dear Mr Eddaiki

**Study title:** From Compliance to Concordance in Orthodontic Treatment- Development of a Patient Decision Aid  
**REC reference:** 13/YH/0166  
**IRAS project ID:** 122632

Thank you for your letter of 19 June 2013, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

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 Miss Helen Penistone, nrescommittee.yorkandhumber-sheffield@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 sites

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).

A Research Ethics Committee established by the Health Research Authority

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:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Covering Letter from Abdussalam Eddaiki		03 May 2013
REC application: 122632/446089/1/179		09 May 2013
Protocol	1	06 February 2013
Investigator CV: Abdussalam Eddaiki		
Investigator CV: Zoe Marshman		
Investigator CV: Philip Benson		23 March 2013
Parent Information Sheet Stage 1 Interviews	1	06 February 2013
Parent Consent Form Stage 1/Step 1 Interviews	1	06 February 2013
Parent/Guardian Consent Form Stage 1/Step 1 Interviews	1	06 February 2013
Young Person Assent Form - Stage 1/Step 1 Interviews	1	06 February 2013
Parents Information Sheet Stage 1 Expert Group	1	06 February 2013
Parent Consent Form - Stage 1/Step 2 Expert Group	1	06 February 2013
Clinicians Information Sheet Stage 1 Expert Group	1	06 February 2013
Clinician Consent Form Stage 1/Step 2 Expert Group	1	06 February 2013
Parent/Guardian Consent Form Stage 1/Step 2 Expert Group	1	06 February 2013
Young Person Assent Form Stage 1/Step 2 Expert Group	1	06 February 2013
Parents Information Sheet Stage 2 Evaluation	1	06 February 2013
Parent Consent Form - Stage 2 Evaluation	1	06 February 2013
Parent/Guardian Consent Form - Stage 2 Evaluation	1	06 February 2013
Young Person Assent Form - Stage 2 Evaluation	1	06 February 2013

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Interview Schedules/Topic Guides: Stage 1/Step 1 - Young Person Interview	v1	06 February 2013
Interview Schedules/Topic Guides: Stage 1/Step 1 - Parent Interview	v1	06 February 2013
Interview Schedules/Topic Guides: Stage 1/Step 2 - Expert Group (Clinicians)	v1	06 February 2013
Interview Schedules/Topic Guides: Stage 1/Step 2 - Expert Group (Patients and Parents)	v1	06 February 2013
Questionnaire: Young Person Questionnaire	1	06 February 2013
Questionnaire: Parent Questionnaire	1	06 February 2013
Referees or other scientific critique report by Zoe Marshman		24 April 2013
Referees or other scientific critique report by Philip Benson		30 April 2013
Letter from funder Libyan Cultural Attache		18 July 2012
Response to Request for Further Information from Mr Eddaiki		19 June 2013
Letter of Authority		14 February 2012
Participant Information Sheet: Young People - Stage 1 Interviews	2.0 clean	14 June 2013
Participant Information Sheet: Young People - Stage 1 Expert Group	2.0 clean	14 June 2013
Participant Information Sheet: Young People - Stage 2 Evaluation	2.0 clean	14 June 2013
Other: Reply Slip	1	14 June 2013

### 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.

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

**13/YH/0166**

**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



**On behalf of  
Professor Basil Sharrack  
Chair**

**Email:** nrescommittee.yorkandhumber-sheffield@nhs.net

**Enclosures:** "After ethical review – guidance for researchers"

**Copy to:** Dr Nana Theodorou  
Clinical Research Office  
1<sup>st</sup> Floor, 11 Broomfield Road  
S10 2SE

## Appendix E: NHS permission (Project authorization)

Sheffield Teaching Hospitals   
NHS Foundation Trust

27 June 2013

Dr Philip Benson  
School of Clinical Dentistry  
31 Claremont Crescent  
Sheffield, S10 2TA

Dear Dr Benson

**Project Authorisation  
NHS Permission for Research to Commence**

**STH ref:** STH17202  
**REC ref:** 13/YH/0166  
**Study title:** Development of a Patient Decision Aid for Fixed orthodontic Appliance Treatment

**Chief Investigator:** Mr Abdussalam Eddaiki, University of Sheffield  
**Principal Investigator:** Dr Philip Benson, University of Sheffield  
**Sponsor:** Sheffield Teaching Hospitals NHS Foundation Trust

**Funder:** Libyan Government Studentship

The Research Department has received the required documentation as listed below:

- |   |  |
|---|--|
| 1. Sponsorship Agreement                            | Not applicable   |
| Clinical Trial Agreement                            | Not applicable   |
| Material Transfer Agreement                         | Not applicable   |
| Funding Award Letter                                | Libyan Government Studentship  |
| 2. Monitoring Arrangements                          | Sheffield Teaching Hospitals NHS FT                                  |
| 3. STH registration document                        | R & D Form<br>A Eddaiki, 27 Jun 2013<br>A Pinder, 27 Jun 2013        |
| 4. Evidence of favourable scientific review         | Supervisor's ISR<br>Z Marshman, 24 Apr 2013<br>P Benson, 30 Apr 2013 |
| 5. Protocol – final version                         | Version 1, 6 Feb 2013  |
| 6. Participant Information sheet                    |  |
| Parent Information Sheet Stage 1 interviews         | Version 1, 6 Feb 2013  |
| Parent Information Sheet Stage 1 expert group       | Version 1, 6 Feb 2013  |
| Clinicians Information Sheet Stage 1 expert group   | Version 1, 6 Feb 2013  |
| Parent Information Sheet Stage 2 evaluation         | Version 1, 6 Feb 2013  |
| Participant Information sheet: Young people-Stage 1 | Version 2, 14 Jun 2013   |
| Participant Information sheet: Young people-Stage 1 | Version 2, 14 Jun 2013   |

Ref: STH17202/NT

1

expert Participant Information sheet: Young people-Stage 2 evaluation	Version 2, 14 Jun 2013
<b>7. Consent form</b>	
Parent consent form Stage 1/Step 1 interviews	Version 1, 6 Feb 2013
Parent/guardian consent form Stage 1/Step 1 interviews	Version 1, 6 Feb 2013
Young person assent form Stage 1/Step 1 interviews	Version 1, 6 Feb 2013
Parent consent form Stage 1/Step 2 expert group	Version 1, 6 Feb 2013
Clinician consent form Stage 1/Step 2 expert group	Version 1, 6 Feb 2013
Parent/guardian consent form Stage 1/Step 2 expert group	Version 1, 6 Feb 2013
Young person assent form Stage 1/Step 2 expert group	Version 1, 6 Feb 2013
Parent consent form Stage 2 evaluation	Version 1, 6 Feb 2013
Parent/guardian consent form Stage 2 evaluation	Version 1, 6 Feb 2013
Young person assent form Stage 2 evaluation	Version 1, 6 Feb 2013
<b>8. Insurance Certificate (non-clinical trial)</b>	University of Sheffield 3 May 2013
<b>9. ARSAC certificate / IRMER assessment</b>	Not applicable
<b>10. Ethical review- Letter of approval from NHS REC</b>	NRES Committee Yorkshire & The Humber - Sheffield, 13/YH/0166, 26 Jun 2013
<b>11. Site Specific Assessment</b>	SSI Form P Benson, 27 Jun 2013
<b>12. Clinical Trial Authorisation from MHRA</b>	Not applicable
<b>13. Evidence of hosting approvals</b>	STH Finance Form
- STH Principal Investigator	P Benson, 9 May 2013
- Clinical Director	I Brook, 8 May 2013
- Research Finance	L Fraser, 16 May 2013
- Data Protection Officer	P Wilson, 23 May 2013
<b>Host Directorate Approval Form</b>	
- Research Lead	M Thornhill, 1 May 2013
- Group Accountant	A Lowe, 1 May 2013
<b>14. Honorary Contract/Letter of Access</b>	Not applicable
<b>15. Associated documents</b>	
Interview schedules/topic guides: Stage 1/Step 1- young person interview	Version 1, 6 Feb 2013
Interview schedules/topic guides: Stage 1/Step 1- parent interview	Version 1, 6 Feb 2013
Interview schedules/topic guides: Stage 1/Step 2- expert group (clinicians)	Version 1, 6 Feb 2013
Interview schedules/topic guides: Stage 1/Step 2- expert group (patients and parents)	Version 1, 6 Feb 2013
Questionnaire: young person	Version 1, 6 Feb 2013
Questionnaire: parent	Version 1, 6 Feb 2013
Reply slip	Version 2, 14 Jun 2013

**This project has been reviewed by the Research Department. NHS permission for the above research to commence has been granted on the basis described in the application form, protocol and supporting documentation** on the understanding that the study is conducted in accordance with the Research Governance Framework, GCP and Sheffield Teaching Hospitals policies and procedures (see attached appendix).

Yours sincerely

  
R Professor S Heller  
Director of R&D, Sheffield Teaching Hospitals NHS Foundation Trust  
Telephone +44 (0) 114 2265934  
Fax +44 (0) 114 2265937

cc- CI

## Appendix F1: Young people information sheet (Stage 1-interviews)



### Young Persons' Information Sheet Project: 'Making choices about having braces easier'

Hello, my name is Abdussalam Eddaiki and I am a research student at the University of Sheffield. You are being invited to take part in a research project. Before you decide whether you want to take part in the study, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information sheet and ask us if there is anything that is not clear or if you would like more information.

Thank you for reading this.

#### What is the project's purpose?

The project will help us understand what young people know about brace treatment and how they decided whether to have braces or not. By answering some questions, you will help us make sure young people have better information in the future. The overall aim of the study is to develop a booklet to help young people and their parents or carers in their choices about having brace treatment.

#### Why have I been invited?

I have invited you to take part in this study because you have already been referred to the orthodontic department. You will not be the only person taking part. I want to speak to about 10 young people in total and their parents or carers. If you do choose to take part we will give you a £5 gift voucher as a thank you for taking part.

#### What will I have to do?

If you choose to take part you will first need to sign a consent form to say you agree. We will give you a copy of this consent form along with a copy of this information sheet. We will ask you some questions about yourself and your brace treatment during an interview. The interview can last as long as you wish but they usually last 45 minutes and we will record it, so we can look at it again afterwards and ensure that we will not miss anything you said.

You will be free to stop taking part at any time and you will not need to give a reason for this choice. If you do decide to stop, this will not affect the care you receive.

#### **What are the possible benefits of taking part?**

The study will not change the treatment or care you receive at the Dental Hospital. Although this study will not help you, we hope that it will help other young people in the future.

#### **Will anyone else know I've taken part in the study?**

No one apart from the research team will know you took part. We will not use your name on anything. All the information and recordings will be kept private, nothing identifying you will be kept on a computer.

#### **What if there is a problem or something goes wrong?**

If you or your parents are unhappy about anything, please tell me so we can talk about it. You can stop taking part at anytime. You or your parent/carer can also contact Mrs Tracey Plant, Clinical Hospital Manager, Charles Clifford Dental Hospital, Sheffield S10 2SZ or the Patient Services Team on 0114 271 2400 or email PST@sth.nhs.uk

#### **Is there any a disadvantage or risks of taking part?**

There are no known risks to you or your parents from taking part in the study. You don't have to talk about anything you don't want to. You can choose a different name so that no one will be able to tell what you said.

#### **What will happen to the results?**

The results will be published in a science magazine, but your answers will be private; and we will not use your name. All the tapes and other information from the study will be kept safely at the University of Sheffield and destroyed five years after the study has been completed. We will write a report to let all young people in this study know about what we found.

#### **Who has reviewed the study?**

Before any research goes ahead it is checked by an Ethics Committee, their job is to make sure that the research is OK and safe to do.

#### **Do I have to take part?**

No, not if you don't want to - we will not ask you why.

#### **Contact details**

If you don't understand something, or want to know more, please contact me by telephone: 0114 2717877 or email: aeddaiki1@sheffield.ac.uk

***Thanks for thinking about taking part.***

## Appendix F2: Parents information sheet (Stage 1-interviews)



### Parents Information Sheet Project: 'Making choices about having braces easier'

Hello, my name is Abdussalam Eddaiki and I am a PhD student at the University of Sheffield. You and your child are being invited to take part in a research project. Before deciding whether you are happy for your child to take part in the study, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information sheet and ask us if there is anything that is not clear or if you would like more information.

Thank you for reading this.

#### What is the project's purpose?

It will help us understand what young people know about brace treatment and how they decided whether or not to have the braces. By answering some questions, you will help us make sure young people have better information in the future. The overall aim of the study is to develop a booklet to help young people and their parents or carers in their choices about having orthodontic brace treatment.

#### Why have I been invited?

I have invited you and your child to participate in this study because your child has already been referred to orthodontic department. I want to speak to about 10 young people in total and their parents or carers. If you and your child do choose to take part your child will receive a £5 gift voucher.

#### What will I have to do?

If you choose to take part you will first need to sign a consent form to say you agree. We will give you a copy of this consent form along with a copy of this information sheet. We will ask you some questions about yourself and your child and their brace treatment during an interview. The interview can last as long as you wish but on average it lasts 45 minutes and we will record it, so we can look at it again afterwards and ensure that we will not miss anything you said.

You and your child will be free to stop taking part at any time and you will not need to give a reason for this choice. If you do decide to stop, this will not affect the care your child receives.

#### **What are the possible benefits of taking part?**

The study will not change the treatment or care your child receives at the Dental Hospital. Although this study will not benefit either you or your child directly, we hope that it will help other young people in the future.

#### **Will anyone else know I've taken part in the study?**

No one apart from the research team will know you took part. We will not use your or your child's name on anything. All the information and recordings will be kept private, nothing identifying you or your child will be kept on a computer.

#### **What if there is a problem or something goes wrong?**

If you become unhappy about anything, please tell me so we can talk about it. You and your child can stop taking part at anytime. You can also contact Mrs Tracey Plant, Clinical Hospital Manager, Charles Clifford Dental Hospital, Sheffield S10 2SZ or the Patient Services Team on 0114 271 2400 or email PST@sth.nhs.uk

#### **Is there any a disadvantage or risks of taking part?**

There are no known risks to you or your child from taking part in the study. You and your child don't have to talk about anything you don't want to.

#### **What will happen to the results?**

The results will be published in a scientific journal, but your answers will be private; and we will not use your or your child's name. All the tapes and other information from the study will be kept securely at the University of Sheffield and destroyed five years after the study has been completed. We will write a report to let all participants in this study to know about what we found.

#### **Who has reviewed the study?**

Before any research goes ahead it is checked by an Ethics Committee. They make sure that the research is OK and safe to do.

#### **Do I have to take part?**

No, not if you don't want to - we will not ask you why.

#### **Contact details**

If you don't understand something, or want to know more, please contact me by telephone: 0114 2717877 or email: aeddaiki1@sheffield.ac.uk

***Thanks for thinking about taking part.***

## Appendix G: Reply slip

Decision aid for orthodontic treatment. Protocol version 2. Reply slip. June 14<sup>th</sup> 2013



### Reply slip

**Name of Parent/Carer:**

\_\_\_\_\_

**Address:**

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

**Postcode:** \_\_\_\_\_

**Telephone number:** \_\_\_\_\_

Please tick as appropriate:

Yes, I would be willing for my child and myself to participate in this research project

No, I am not willing for us to participate

Signature: \_\_\_\_\_ Date: \_\_/\_\_/\_\_

Please return in the stamped-addressed envelope provided

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## Appendix H: Framework analysis for qualitative interviews with young people and their parents

Name of participant	Age	Gender	Benefits of treatment	Risks	Impact of appliance treatment	Timing of treatment	Source of information	Information they would like to know	Who deliver information
Chloe	16y	F	<p>I have really wonky teeth since I had my adult teeth, and I always wanted braces because I wanted straight teeth, they was not sort of in line, they were sort of inwards and outwards</p> <p>I think I thought I need the braces just because how wonky they were I've always wanted one. Even before the dentist said anything about a brace, I knew that I would need one.</p> <p>Before I have a gap between my teeth and now the gap is gone so it's doing what it should do</p>	Brown teeth	<p>When they put them on, it was really tight and causing achy pain may be for the first three days it was quit bad, but then after that, well no for the first week, it was really difficult to chew anything, I sort of can't close my teeth together cause there was a lot of pain, there was pain inside my cheek and it was irritating the skin. But then after that week, like now its fine, I don't feel any pain or anything.</p> <p>Keeping them clean was easy, really. I think it may be more difficult than it was before without them, I will probably brush for longer that the only difference, just to make sure they are clean.</p> <p>Certain things you can't have now than was before, like chewing gum</p>	<p>I'd like to have it earlier, like, the earlier the better.</p> <p>I would like to have them when I was much younger, not now, I think it is easier to have them when you are younger</p>	My friends and people I know who've had braces	<p>They didn't tell me what kind of brace, they said that I will need a brace, I never knew what sort of brace until the day of putting them on. No sort of discussion what brace I'll be wearing, I was told that I need brace and that's all.</p> <p>I would like to know what kind of brace and when I'm going to put them on and how long it will be on for. The main thing I want to know is what sort of brace and how long it will be on for, if they could tell me that it will be good, yes, what sort of brace is the main thing.</p> <p>I think if you see a photo of what sort of brace, you will know what it will look like and the main thing I was worried about is how the braces going to look like. I knew there will be a little bit of pain but I was worried more about if they going to like suit or not</p>	I think the orthodontist, because they can explain to me very well and give lots of information for you

Name of participant	Age	Gender	Benefits of treatment	Risks	Impact of appliance treatment	Timing of treatment	Source of information	Information they would like to know	Who deliver information
Chloe's Mum			Also you have a tooth that hasn't come down, so you have got a missing tooth won't come through, teeth were very wonky specially the front teeth	<p>The risks that we have informed about is the important of cleaning, that could leave a mark on teeth, also it might irritate the gums that's why we've got a wax to put on, so the importance of cleaning and the importance of avoiding certain foods like sugary foods, and also what to do if it hurt your gums</p> <p>They also discussed about that it might shorten the roots little bit having the braces.</p>	Too many kids have braces now, so I think nobody seems to get teased by having braces	Better if she could've had them earlier The earlier you get them on the earlier you get all finish	I am interested in any information leaflet that had pictures	<p>A lot of information, right from the beginning, roughly how long it expected you to have braces on and sort of how many visits, and that was probably the only thing we didn't really know, was exactly what they were going to consist of and what they were going to look like really.</p> <p>I was interested in photos about what the braces were going to look like. I had braces when I was young and they are changed so much, so the braces that I had when I was a girl are completely different to the braces that they put on now, so I would personally be interested in any information leaflet that had pictures for that reason really.</p>	I assume orthodontist because they are specialised, you know they have that knowledge and expertise that your general dentist wouldn't have; they wouldn't be able to give you the same sort of advice and confidence. So yeah, you expect to get the most accurate advice from the specialist.

## Appendix I: PDA Version 1 (Initial interviews)

### Making choices about having braces easier

A decision aid for fixed brace treatment

for young people and their parents



### Which treatment option to choose?

#### Introduction

Making a decision about having braces or not is difficult for young people and parents. It is important to choose the option that fits in with your values and lifestyles. The two treatment options available to you are:

- Fixed braces fitted to your teeth by a specialist orthodontist that will straighten your teeth, adjust your bite and the way your teeth look. Some people call these 'train tracks'.
- No braces, the appearance and position of your teeth will not be changed. You will continue your usual dental treatment with your dentist.

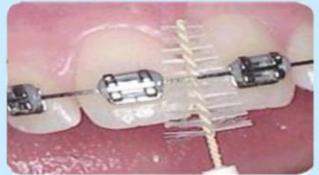
This document consists of;

**Section 1:** will provide you with information about each treatment option and what will happen in the short and long-term.

**Section 2:** contains questions to help check which decision is right for you.

**Section 1: Information about the two options:**

The two options are fixed braces or no treatment. This table helps you compare these two options.

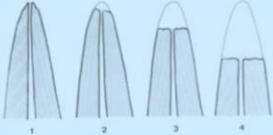
TREATMENT DETAILS	No treatment	Fixed braces
How long will treatment take?	No treatment will be carried out. You will only need regular check-ups at the general dentist	Fixed braces will take around 2 years to work. You may have to wear removable braces first.
What will my teeth look like during treatment?	Your teeth will look the same	Most of your teeth will have squares on them and a wire that joins the squares. 
Will I need teeth taken out?	No	Some people do need teeth taken out as part of fixed brace treatment. This will involve an injection in your gum.
Will I need to spend more time looking after my teeth at home?	No, usual brushing only	Yes, you need to take extra care to keep your teeth clean including using special brushes for your braces all the time the braces are on. 
How often will I need to visit the dentist and orthodontist?	You will only need to attend your check-ups at the general dentist	You will need to attend review and brace tightening appointments every 4 to 6 weeks at the orthodontist and 6 month check-ups with a general dentist. Some of the appointments may mean you will miss school and your parents will miss work.

What are the short-term consequences of these treatment options?

SHORT-TERM CONSEQUENCES	No treatment	Fixed braces
Will I experience discomfort or pain?	No	<p>Braces can be uncomfortable at the start of treatment and after the wires are changed, but most children get used to it quickly.</p> <p>A packet of wax will be given to stop the brace rubbing the inside of your cheeks.</p> 
Will my eating or drinking habits change?	No	<p>People with braces should avoid hard and sticky foods and sugary drinks during the treatment, for example nuts, sweets and fizzy drink.</p> <p>Certain foods need to be chopped up, it may take longer to eat.</p>
What else may be affected?	Nothing	<p>Braces may interfere with playing musical instruments. For some contact sports and activities you will need to wear a mouth guard.</p> 
Will my gums bleed?	Yes, if your teeth are not clean.	Your gums will only bleed if you have teeth removed or if they are not clean.

What are the long-term consequences of these treatment options?

LONG-TERM CONSEQUENCES	No treatment	Fixed braces
What will my teeth look like?	No change	Most people think their teeth look better after brace treatment.
Will the bite of my teeth change?	No change	<p>Your teeth will be straighter (lined up).</p> <div style="display: flex; align-items: center;"> <div style="margin-right: 10px;"><u>Before</u></div>  </div> <div style="display: flex; align-items: center; margin-top: 10px;"> <div style="margin-right: 10px;"><u>After</u></div>  </div>
What will my face look like?	Your facial appearance will not change	Some people notice some facial changes as well as having straighter teeth.
What will I have to do at the end of orthodontic treatment?	Nothing	<p>People who have fixed braces need to wear retainers on their teeth for at least a year after their treatment is completed. You may be asked to wear the retainer for the rest of your life.</p> 

LONG-TERM CONSEQUENCES	No treatment	Fixed braces
<p>Are there any problems that might happen to my teeth?</p>	<p>For some people, crooked teeth may be difficult to keep clean</p>	<p>White or brown spots may result from braces if you didn't keep your teeth clean.</p> 
<p>Will there be any problems with the roots of my teeth due to fixed braces?</p>	<p>No problems</p>	<p>3 out of 100 people can experience severe shortening of the roots of their teeth as a result of fixed brace treatment.</p> 
<p>If I don't have treatment now, will I be able to have the treatment later?</p>	<p>No treatment</p>	<p>It may be more complicated once you have stopped growing and you may have to pay for it.</p>

## Section 2: Check your decision

1. The decision you face is to have fixed brace treatment or not?  YES  NO

2. How far along are you with making a choice?

- Not yet thought about the options       Close to making a choice  
 Thinking about the options                       Already made a choice



### Which of the reasons for each option matter most to you?

Mark with an X how much each reason matters to you on a scale from '1' to '5'. '1' means it is not important to you. '5' means it is very important to you.

Reasons to accept fixed brace treatment	Not important      Very important				
	1	2	3	4	5
How important is it to you to have your teeth straight?					
How important is it to you to change the way your teeth bite together?					
How important is it to you to change the way your teeth look?					

Reasons not to have fixed brace treatment	Not at all      Very much				
	1	2	3	4	5
How bothered are you about keeping your teeth as they are now?					
How bothered are you about what your teeth will look like with a brace on?					
How bothered are you about having to avoid sugary drinks and eating hard or sticky foods if you wear a brace?					

Reasons not to have fixed brace treatment	Not at all					Very much				
	1	2	3	4	5	1	2	3	4	5
How bothered are you and your parents about having to see the orthodontist every 4-6 weeks for checks on your brace?										
How important is it to you to avoid having teeth taken out?										
How important is it to you to have treatment to improve your bite?										



### Support

Who else is involved in this decision?

Who is the person? (please name)	Name:	Name:	Name:
Which option does this person prefer?			
How can this person support you in the decision-making?			
I prefer to	<input type="checkbox"/> share the decision with:	<input type="checkbox"/> Decide myself after hearing the views of:	<input type="checkbox"/> Have someone else decide for me. Who?

## Identify your decision-making needs



### Knowledge

Do you know enough about the reasons to choose either to have a fixed brace or not?

YES  NO



### Values

Are you clear about which benefits and risks matter most to you?

YES  NO



### Support

Do you have enough support and advice to make a decision about whether or not to have a brace?

YES  NO



### Certainty

Do you feel sure about the best choice for you?

YES  NO

Will you be willing for us to contact you again?

YES  NO

What are the next steps?

- I have decided to have a fixed brace.
- I have decided not to have a fixed brace.
- I need to read more about my options.
- I need to discuss the options with -----
- Other, please specify-----

## Appendix I: PDA Version 2 (Final PDA version)

### Helping you make choices about treatments to straighten teeth

#### A decision aid for young people and their parents



This booklet is here to help young people make a decision that is best for them between having a treatment to straighten their teeth or leaving their teeth as they are.

#### Wanting straight teeth

Some young people want to change the way their teeth are lined up. They want their teeth to be straightened. People who have their teeth straightened usually say they are happier smiling and showing their teeth to others.

#### Having teeth straightened

It is up to you and your parent to decide whether you want to have your teeth straightened or to leave your teeth as they are. If you decide not to have treatment, your teeth will not be less healthy. If you decide to have them straightened there may be a few ways that it may be done. No one way is best for everyone.

The main options available to change the way teeth look are:

- A. Fixed braces fitted to teeth by an orthodontist, some young people call these 'train tracks'. During the treatment most teeth will have "brackets" or "squares" around them and a wire that joins the squares. Braces will take between 2 to 3 years to work.
- B. There may be other treatments that can change the way teeth look but do not involve braces, for example, having tooth-coloured filling material added to change the shape of front teeth or having teeth taken out to make more space. You can talk to the orthodontist about what other treatments might work for you and your teeth.
- C. If you don't want to have your teeth straightened you can choose not to have any treatment.

Regardless of which option you choose there are some important things that you and all young people need to do to keep your teeth healthy, these include;

1. Keep sugary foods and drinks to meal times only.
2. Brush your teeth twice a day with fluoride toothpaste.
3. See a dentist for regular check-ups.

To help you and your parents choose what treatment is best to have your teeth straightened this booklet has 2 sections;

**Section 1:** will provide you with information about each option and what will happen as a consequence.

**Section 2:** contains questions to help check which choice is right for you.

## Section 1: Information about the two options

The two main options are either having a brace fitted or asking the orthodontist about other treatments that might change the way your teeth look. This table helps you compare these options.

TREATMENT DETAILS	Fixed braces with orthodontist	Other treatments to change the way your teeth look
Will I need teeth taken out?	At your meeting with the orthodontist, the orthodontist will talk about whether or not you need to have teeth out to fit the fixed brace.	You can talk to the orthodontist about whether or not you need to have teeth out to change the way your teeth look.
Will I need to make extra visits to an orthodontist or dentist?	You will need to visit the orthodontist every 4 to 6 weeks about your braces. Dentist and orthodontist appointments mean that you and your parents may miss school or work.	You may need to see a dentist for 1 or 2 extra visits depending on what other treatment you decide to have to change the way your teeth look. You and your parents may miss school or work to attend these.
CONSEQUENCES	Fixed braces with orthodontist	Other treatments to change the way your teeth look
How will my teeth look after treatment?	Your teeth will look straighter. About 99 out of 100 people are happy with the way their teeth looked after having brace treatment.	Other treatments such as white fillings or having teeth out can improve the way some people's teeth look. Talk to the orthodontist about ways to make your teeth look better.
Will I experience discomfort or pain?	After the braces are put on and when the wires are changed your mouth will ache and the inside of your cheeks will feel sore. This can last for several days, but most people get used to it quickly. You will be given some comfort wax which can stop the brace rubbing and you may need to take painkillers for a few days.	No, you will not have discomfort or pain if you have white fillings to change the look of your teeth. If you just have teeth out it will be sore for a couple of days.

CONSEQUENCES	Fixed braces with orthodontist	Other treatments to change the way your teeth look
What will I have to do at the end of treatment?	To keep your teeth lined up once the brace is removed usually means wearing a retainer for at least a year. You should keep checking the retainers still fits as long as you want your teeth to remain straight. We can show you what a retainer looks like if you want.	If you had white fillings put on your teeth to close small gaps or change the shape of your teeth they will need to be checked regularly by your dentist.
Are there any risks to my teeth?	About 1 out of 4 people can get white or brown spots from braces although most of these spots are not noticeable to other people. The chances of getting brace spots are more likely when people do not keep their teeth and braces clean.	You need to check with the orthodontist about any risks from the other treatments available to you.
Will there be any problems with the roots of my teeth?	About 1 out of 8 people have severe changes to the roots of their teeth as a result of fixed brace treatment. For most people this will not cause problems but your orthodontist can explain the risks to your teeth.	Other treatments to change the way teeth look do not affect the roots of your teeth.
If I don't have treatment now, will I be able to have the treatment later?	You can still have fixed braces as an adult, but it may take longer, and it will be more inconvenient and you will have to pay for it.	Other treatments to change the way your teeth look can be done at any time. If you have treatment done when you are an adult you will have to pay for it.

## Section 2: Check your choice

**Which of the reasons for each option matter most to you?**

Circle how much each reason matters to you on a scale from 1 to 5.

1 means it is not important to you, 5 means it is very important to you.



Reasons to consider treatment to straighten your teeth	Not important					Very important				
How important is it to you to have your teeth straighter?	1	2	3	4	5	1	2	3	4	5
How important is it to you to change the way your teeth bite together?	1	2	3	4	5	1	2	3	4	5
How important is it to you to change the way your teeth look?	1	2	3	4	5	1	2	3	4	5
Reasons not to choose treatment to straighten your teeth	Not at all					Very much				
How bothered are you about what your teeth will look like with a brace on?	1	2	3	4	5	1	2	3	4	5
How bothered are you and your parents about having to see the orthodontist every 4-6 weeks for checks on your brace?	1	2	3	4	5	1	2	3	4	5
How bothered are you about having teeth taken out?	1	2	3	4	5	1	2	3	4	5
How bothered are you about having aching pain after braces are fitted?	1	2	3	4	5	1	2	3	4	5
How bothered are you about having to wear a retainer for a long time after treatment is completed?	1	2	3	4	5	1	2	3	4	5
How bothered are you about having white or brown spots on your teeth if you don't keep them clean while your brace is on?	1	2	3	4	5	1	2	3	4	5
How bothered are you about having white fillings on your front teeth replaced regularly?	1	2	3	4	5	1	2	3	4	5

Filling this in will help you think about what is important to you in making your choice. Your dentist will also be able to see what matters most to you.

### Knowledge



Do you know enough about the reasons to choose either to have a fixed brace or other ways to straighten your teeth?

YES  NO

### Values



Are you clear about which benefits and risks matter most to you?

YES  NO

### Support



Do you have enough support and advice to make a choice about which treatment is best for you?

YES  NO

### Uncertainty



Do you feel sure about the best choice for you?

YES  NO

### What are the next steps?

- would like to have a fixed brace.
- have decided not to have a fixed brace and will talk to my dentist about other options.
- don't want any treatment to straighten my teeth now.
- need to find out more about my options.
- need to discuss the options with -----
- O Other, please specify -----  
-----

### I would like to discuss these things with the orthodontist or my dentist:

- 1.-----  
-----
- 2.-----  
-----
- 3.-----  
-----

If you want to see more pictures of people having braces or you want to know more about braces you can visit the following website; <http://www.bos.org.uk>

Would you be willing for us to contact you again for future research?

YES  NO

## Appendix J1: Young people information sheet (Stage 1-expert group)



### Young Persons' Information Sheet

#### Project: 'Making choices about having braces easier'

Hello, my name is Abdussalam Eddaiki and I am a research student at the University of Sheffield. You are being invited to take part in a research project. Before you decide whether you want to take part in the study, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information sheet and ask us if there is anything that is not clear or if you would like more information.

Thank you for reading this.

#### What is the project's purpose?

The project will help us understand what young people know about brace treatment and how they decided to have braces on their teeth. By answering some questions, you will help us make sure young people have better information in the future. The overall aim of the study is to develop a booklet to help young people and their parents or carers in their choices about having brace treatment.

#### Why have I been invited?

I have invited you to take part in this study because you already have completed or are currently having brace treatment. You will not be the only person taking part. I want to speak to about 5 young people in total and their parents or carers. If you do choose to take part we will give you a £5 gift voucher as a thank you for taking part.

#### What will I have to do?

If you choose to take part you will first need to sign a consent form to say you agree. We will give you a copy of this consent form along with a copy of this information sheet. You will have either a one-to-one or small group interview about your brace treatment and a new booklet for young people about choosing brace treatment. The interviews will be conducted at a room on the clinic or at your home (depending on what you prefer). The interview can last as long as you wish but they usually last 45 minutes and we will record it, so we can look at it again afterwards and ensure that we will not miss anything you said.

You will be free to stop taking part at any time and you will not need to give a reason for this choice. If you do decide to stop, this will not affect the care you receive.

#### **What are the possible benefits of taking part?**

The study will not change the treatment or care you receive at the Dental Hospital. Although this study will not help you, we hope that it will help other young people in the future.

#### **Will anyone else know I've taken part in the study?**

No one apart from the research team will know you took part. We will not use your name on anything. All the information and recordings will be kept private, nothing identifying you will be kept on a computer.

#### **What if there is a problem or something goes wrong?**

If you or your parents are unhappy about anything, please tell me so we can talk about it. You can stop taking part at any time. You or your parent/carer can also contact Mrs Tracey Plant, Clinical Hospital Manager, Charles Clifford Dental Hospital, Sheffield S10 2SZ or the Patient Services Team on 0114 271 2400 or email PST@sth.nhs.uk

#### **Is there any a disadvantage or risks of taking part?**

There are no known risks to you or your parents from taking part in the study. You don't have to talk about anything you don't want to. You can choose a different name so that no one will be able to tell what you said.

#### **What will happen to the results?**

The results will be published in a science magazine, but your answers will be private; and we will not use your name. All the tapes and other information from the study will be kept safely at the University of Sheffield and destroyed five years after the study has been completed. We will write a report to let all young people in this study know about what we found.

#### **Who has reviewed the study?**

Before any research goes ahead it is checked by an Ethics Committee, their job is to make sure that the research is OK and safe to do.

#### **Do I have to take part?**

No, not if you don't want to - we will not ask you why.

#### **Contact details**

If you don't understand something, or want to know more, please contact me by telephone: 0114 2717877 or email: aeddaiki1@sheffield.ac.uk

***Thanks for thinking about taking part.***

## Appendix J2: Parents information sheet (Stage 1-expert group)



### Parents Information Sheet

#### Project: 'Making choices about having braces easier'

Hello, my name is Abdussalam Eddaiki and I am a PhD student at the University of Sheffield. You and your child are being invited to take part in a research project. Before deciding whether you are happy for your child to take part in the study, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information sheet and ask us if there is anything that is not clear or if you would like more information.

Thank you for reading this.

#### What is the project's purpose?

It will help us understand what young people know about brace treatment and how they decided to have the braces. By answering some questions, you will help us make sure young people have better information in the future. The overall aim of the study is to develop a booklet to help young people and their parents or carers in their choices about having orthodontic brace treatment.

#### Why have I been invited?

I have invited you and your child to participate in this study because your child has already completed or currently undertaking orthodontic treatment. I want to speak to about 5 young people in total and their parents or carers. If you and your child do choose to take part your child will receive a £5 gift voucher

#### What will I have to do?

If you choose to take part you will first need to sign a consent form to say you agree. We will give you a copy of this consent form along with a copy of this information sheet. You will participate in either a one-to-one or small group qualitative interviews about your child's brace treatment and a newly developed decision tool for young people. The interviews will be conducted at a room on the clinic or at your home (depending on what you prefer). The interview can last as long as you wish but on average it lasts 45 minutes and we will record it, so we can look at it again afterwards and ensure that we will not miss anything you said.

You and your child will be free to stop taking part at any time and you will not need to give a reason for this choice. If you do decide to stop, this will not affect the care your child receives.

#### **What are the possible benefits of taking part?**

The study will not change the treatment or care your child receives at the Dental Hospital. Although this study will not benefit either you or your child directly, we hope that it will help other young people in the future.

#### **Will anyone else know I've taken part in the study?**

No one apart from the research team will know you took part. We will not use yours or your child's name on anything. All the information and recordings will be kept private, nothing identifying you or your child will be kept on a computer.

#### **What if there is a problem or something goes wrong?**

If you become unhappy about anything, please tell me so we can talk about it. You and your child can stop taking part at any time. You can also contact Mrs Tracey Plant, Clinical Hospital Manager, Charles Clifford Dental Hospital, Sheffield S10 2SZ or the Patient Services Team on 0114 271 2400 or email [PST@sth.nhs.uk](mailto:PST@sth.nhs.uk)

#### **Is there any a disadvantage or risks of taking part?**

There are no known risks to you or your child from taking part in the study. You and your child don't have to talk about anything you don't want to.

#### **What will happen to the results?**

The results will be published in a scientific journal, but your answers will be private; and we will not use your or your child's name. All the tapes and other information from the study will be kept securely at the University of Sheffield and destroyed five years after the study has been completed. We will write a report to let all participants in this study know about what we found.

#### **Who has reviewed the study?**

Before any research goes ahead it is checked by an Ethics Committee. They make sure that the research is OK and safe to do.

#### **Do I have to take part?**

No, not if you don't want to - we will not ask you why.

#### **Contact details**

If you don't understand something, or want to know more, please contact me by telephone: 0114 2717877 or email: [aeddaiki1@sheffield.ac.uk](mailto:aeddaiki1@sheffield.ac.uk)

***Thanks for thinking about taking part.***

# Appendix K: Young person assent form

Decision aid for orthodontic treatment. Protocol version 2. Young person assent form (stage2-evaluation). June 14<sup>th</sup> 2013



## Project: 'Making choices about having braces easier'

### Young Person Assent Form

Participant study number.....Name of Researcher.....

**Please initial the boxes**

1. I have read and understand the information sheet and have asked any questions.
2. I have had enough time to think about taking part in this project.
3. I understand that taking part in this project is my choice and I can change my mind at any time without giving a reason.
4. I understand that any information will be used for research reasons only; including articles and reports. All information will be kept private.
5. I agree to take part in the above study

Name of young person: \_\_\_\_\_  
Signature: \_\_\_\_\_  
Date: \_\_\_\_\_

Name of researcher: \_\_\_\_\_  
Signature: \_\_\_\_\_  
Date: \_\_\_\_\_

One copy for participant, one for researcher, one for hospital notes

# Appendix L: Parent consent form

Decision aid for orthodontic treatment. Protocol version 2. Parent/Guardian consent form (stage2-evaluation). June 14<sup>th</sup> 2013



## Project: 'Making choices about having braces easier'

### Parent Consent Form

Participant study number.....Name of Researcher.....

**Please initial the boxes**

1. I have read and understand the information sheet and have asked any questions.
2. I have had enough time to think about taking part in this project.
3. I understand that taking part in this project is entirely voluntary and I can change my mind at any time without giving a reason.
4. I understand that any information will be used for research purposes only; including research publications and reports. Anonymity and confidentiality will be preserved at all times.
5. I agree to take part in the above study

Name of participant: \_\_\_\_\_  
Signature: \_\_\_\_\_  
Date: \_\_\_\_\_

Name of researcher: \_\_\_\_\_  
Signature: \_\_\_\_\_  
Date: \_\_\_\_\_

One copy for participant, one for researcher, one for hospital notes

## Appendix M: Topic guide – Interviews with expert patients and parents

### Topic Guide- Review Stage

#### Stage 1 (step2) - Expert Group (patients and parents)

- How easy did you find this decision aid to work through?
- What did you like about the decision aid? (*what they think about each part in turn*)
- How do you feel about the length of the decision aid?
- Could you understand the information presented? (*Ask about each item*)
- Are there any aspects of the decision aid you had difficulty working through?
- Is there any other information you feel the decision aid required?
- How do you feel about the design of the decision aid?
- In terms of format, how would you prefer the decision aid to be presented (e. g. electronic copy, hard copy...)?
- What suggestions do you have to improve the decision aid?
- How do you think decision aid would have influenced your decision to undergo orthodontic treatment?

*Q: If you knew that your treatment will involve teeth taking out. Means you will have injection or laughing gas; will that change your decision to have treatment?*

*Q: Braces will effect playing on musical instruments, is that changes your decision?*

*Q: If you knew about choice of elastic module colours, will that affect you decision?*

*Q: Can you describe what the brace looks like?*

## Appendix N: Clinicians information sheet



### Clinicians Information Sheet

#### Project: 'Making choices about having braces easier'

Dear Orthodontist/Dentist Colleague,

As part of my PhD project, I would be most grateful for your participation in the review of this Patient Decision Aid (PDA). I hope you could take the time to read this Information Sheet. Please do not hesitate to contact me if you require any further clarification.

Abdussalam Eddaiki

#### What is the project's purpose?

It will help us understand what young people know about orthodontic appliance treatment and how they decided to have the orthodontic treatment. By answering some questions, you will help us make sure young people have better information in the future. The overall aim of the study is to develop a patient decision aid to help young people and their parents or carers in their choices about having orthodontic appliance treatment.

#### Why have I been invited?

I have approached you to participate in this study because you are an expert in the orthodontic clinical care or involved in referral of patients to the orthodontic department at Charles Clifford Dental Hospital. I want to speak to about 10 clinicians in total.

#### What will I have to do?

If you do choose to take part you will first need to sign a consent form. We will give you a copy of this consent form along with a copy of this information sheet. The research will involve a one to one or group discussion which will help develop and review the decision aid. The discussion may be carried out at the Dental School or at your practice. The session should last approximately 45 minutes and will be digitally recorded so all information gathered is accurate.

You will be free to stop taking part at any time and you will not need to give a reason for this choice.

#### **What are the possible benefits of taking part?**

This study will not benefit you directly; we hope that it will help young people in the future.

#### **Will anyone else know I've taken part in the study?**

No one apart from the research team will know you took part. We will not use your name on anything. All the information and recordings will be kept private, nothing identifying you will be kept on a computer.

#### **What if there is a problem or something goes wrong?**

If you become unhappy about anything, please tell me so we can talk about it. You can stop taking part at anytime. You can also contact Mrs Tracey Plant, Clinical Hospital Manager, Charles Clifford Dental Hospital, Sheffield S10 2SZ or the Patient Services Team on 0114 271 2400 or email [PST@sth.nhs.uk](mailto:PST@sth.nhs.uk)

#### **Is there any a disadvantage or risks of taking part?**

There are no known risks to you from taking part in the study.

#### **What will happen to the results?**

The results will be published in a scientific journal, but your answers will be private; and we will not use your name. All the data from the study will be kept securely at the University of Sheffield and destroyed five years after the study has been completed. I will then write a report on my findings and send you a copy.

#### **Who has reviewed the study?**

Before any research goes ahead it is checked by an Ethics Committee. They make sure that the research is OK and safe to do.

#### **Do I have to take part?**

No, not if you don't want to - we will not ask you why.

#### **Contact details**

If you don't understand something, or want to know more, please contact me by telephone: 0114 2717877 or email: [aeddaiki1@sheffield.ac.uk](mailto:aeddaiki1@sheffield.ac.uk)

***Thanks for thinking about taking part.***

# Appendix O: Clinicians consent form



## Decision aid in orthodontic treatment Clinician Consent Form

Participant study number.....Name of Researcher.....

Please initial the boxes

- 1. I have read and understand the information sheet and I have had the opportunity to ask questions.
- 2. I understand that sound recordings will be made and that the reason they will be used has been explained in terms which I have understood.
- 3. I have had enough time to think about taking part in this project.
- 4. I understand that taking part in this project is my choice and I can change my mind at any time without giving a reason.
- 5. I understand that any information will be used for research purposes only; including research publications and reports. Anonymity and confidentiality will be preserved at all times.
- 6. I agree to take part in the above study

Name of participant: \_\_\_\_\_  
Signature: \_\_\_\_\_  
Date: \_\_\_\_\_

Name of researcher: \_\_\_\_\_  
Signature: \_\_\_\_\_  
Date: \_\_\_\_\_

One copy for participant, one for researcher

## **Appendix P: Topic guide- Interviews with clinicians**

### **Topic Guide**

#### **Stage 1 (step2) - Expert Group (Clinicians)**

##### ***General background questions:***

- What key information do you feel should be provided to young people (aged 12-16) and their carers who are undergoing the decision to receive orthodontic treatment?
- In what format do you think this information should be given?
- What challenges are there in giving this information?
- Are there any aspects of the orthodontic treatment that require specific information or instructions?
- Have you noted any particular aspects of undergoing orthodontic treatment with fixed appliance that patients and parents find difficult to understand?

##### ***Questions specific to the initial draft of the decision aid:***

- Are there any specific items in the decision aid you feel should be excluded/included?
- How do you feel about the length of the decision aid and the amount of information presented?
- How do you feel about the design of the decision aid?
- How do you feel about the format of the decision aid?
- Do you have any suggestions to improve the PDA?
- How do you think using a PDA would work in your practice on a day-to-day basis?
- How do you think PDA will influence the decisions made by patients and their parents?

# Appendix Q: Quality assessment tool and scoring guidance notes (Sirriyeh et al, 2012)

**Table 1** Quality assessment tool and scoring guidance notes

Criteria	0 = Not at all	1 = Very slightly	2 = Moderately	3 = Complete
Explicit theoretical framework	No mention at all.	Reference to broad theoretical basis.	Reference to a specific theoretical basis.	Explicit statement of theoretical framework and/or constructs applied to the research.
Statement of aims/objectives in main body of report	No mention at all.	General reference to aim/objective at some point in the report including abstract.	Reference to broad aims/objectives in main body of report.	Explicit statement of aims/objectives in main body of report.
Clear description of research setting	No mention at all.	General description of research area and background, e.g. 'in primary care'.	General description of research problem in the target population, e.g. 'among GPs in primary care'.	Specific description of the research problem and target population in the context of the study, e.g. nurses and doctors from GP practices in the east midlands.
Evidence of sample size considered in terms of analysis	No mention at all.	Basic explanation for choice of sample size. Evidence that size of the sample has been considered in study design.	Evidence of consideration of sample size in terms of saturation/information redundancy or to fit generic analytical requirements.	Explicit statement of data being gathered until information redundancy/saturation was reached or to fit exact calculations for analytical requirements.
Representative sample of target group of a reasonable size	No statement of target group.	Sample is limited but represents some of the target group or representative but very small.	Sample is somewhat diverse but not entirely representative, e.g. inclusive of all age groups, experience but only one workplace. Requires discussion of target population to determine what sample is required to be representative.	Sample includes individuals to represent a cross section of the target population, considering factors such as experience, age and workplace.
Description of procedure for data collection	No mention at all.	Very basic and brief outline of data collection procedure, e.g. 'using a questionnaire distributed to staff'.	States each stage of data collection procedure but with limited detail, or states some stages in details but omits others.	Detailed description of each stage of the data collection procedure, including when, where and how data were gathered.
Rationale for choice of data collection tool(s)	No mention at all.	Very limited explanation for choice of data collection tool(s).	Basic explanation of rationale for choice of data collection tool(s), e.g. based on use in a prior similar study.	Detailed explanation of rationale for choice of data collection tool(s), e.g. relevance to the study aims and assessments of tool quality either statistically, e.g. for reliability & validity, or relevant qualitative assessment. Complete data regarding no, approached, no, recruited, attrition data where relevant, method of recruitment.
Detailed recruitment data	No mention at all.	Minimal recruitment data, e.g. no. of questionnaire sent and no. returned.	Some recruitment information but not complete account of the recruitment process, e.g. recruitment figures but no information on strategy used.	Suitable and thorough statistical assessment of reliability and validity of measurement tool(s) with reference to the quality of evidence as a result of the measures used.
Statistical assessment of reliability and validity of measurement tool(s)	No mention at all.	Reliability and validity of measurement tool(s) discussed, but not statistically assessed.	Some attempt to assess reliability and validity of measurement tool(s) but insufficient, e.g. attempt to establish test-retest reliability is unsuccessful but no action is taken.	Method of data collection selected is the most suitable approach to attempt answer the research question
(Quantitative only) Fit between stated research question and method of data collection	No research question stated.	Method of data collection can only address some aspects of the research question.	Method of data collection can address the research question but there is a more suitable alternative that could have been used or used in addition.	Method of data collection selected is the most suitable approach to attempt answer the research question
(Quantitative) Fit between stated research question and formal and content of data collection tool e.g. interview schedule	No research question stated.	Structure and/or content only suitable to address the research question in some aspects or superficially.	Structure & content allows for data to be gathered broadly addressing the stated research question(s) but could benefit from greater detail.	Structure & content allows for detailed data to be gathered around all relevant issues required to address the stated research question(s).
(Qualitative) Fit between research question and method of analysis	No mention at all.	Method of analysis can only address the research question basically or broadly.	Method of analysis can address the research question but there is a more suitable alternative that could have been used or used in addition to offer greater detail.	Method of analysis selected is the most suitable approach to attempt answer the research question in detail, e.g. for qualitative IPA, preferable for experiences vs. content analysis to elicit frequency of occurrence of events, etc.
Good justification for analytical method selected	No mention at all.	Basic explanation for choice of analytical method	Fairly detailed explanation of choice of analytical method.	Detailed explanation for choice of analytical method based on nature of research question(s).
Assessment of reliability of analytical process (Qualitative only)	No mention at all.	More than one researcher involved in the analytical process but no further reliability assessment.	Limited attempt to assess reliability, e.g. reliance on one method.	Use of a range of methods to assess reliability, e.g. triangulation, multiple researchers, varying research backgrounds.
Evidence of user involvement in design	No mention at all.	Use of pilot study but no involvement in planning stages of study design.	Pilot study with feedback from users informing changes to the design.	Explicit consultation with steering group or statement of formal consultation with users in planning of study design.
Strengths and limitations critically discussed	No mention at all.	Very limited mention of strengths and limitations with omissions of many key issues.	Discussion of some of the key strengths and weaknesses of the study but not complete.	Discussion of strengths and limitations of all aspects of study including design, measures, procedure, sample & analysis.

## Appendix R: Technical paper

### A decision aid for young people and their parents

Quality Assessment Tool for Studies with Diverse Designs (QATSDD) was used to assess the quality criteria for studies used in the decision aid. The scoring guidance for QATSDD as follows; 0= not at all, 1= very slightly, 2= moderately, and 3= complete. QATSDD was developed at the University of Leeds and it contains 16 reporting criteria scored on a scale from 0 to 3. These criteria apply to quantitative and qualitative studies. (Low quality =1-14, Moderate quality =15-28, High quality =29-42).

**Study 1:** Feldmann, I. (2014). Satisfaction with orthodontic treatment outcome. *Angle Orthodontist*.

Criteria		QATSDD Score
1	Explicit theoretical framework.	0
2	Statement of aims/objectives in main body of report.	1
3	Clear description of research setting.	2
4	Evidence of sample size considered in terms of analysis.	0
5	Representative sample of target group of a reasonable size.	2
6	Description of procedure for data collection.	2
7	Rationale for choice of data collection tools.	2
8	Detailed recruitment data.	2
9	Statistical assessment of reliability and validity of measurements tools.	2
10	Fit between stated research question and method of data collection.	2
11	Fit between stated research question and format and content of data collection tool.	2
12	Good justification for analytical method selected.	2
13	Assessment of reliability of analytical process.	0
14	Strength and limitations critically discussed.	2
<b>Total score</b>		<b>21</b>
<p><b>Conclusion:</b>            According to QATSDD scores, this study is of moderate quality. Sufficient sample size included, 120 orthodontic patients (60 girls and 60 boys) were consecutively recruited to avoid selection bias. Also, to avoid treatment bias, a strict study protocol was followed for all patients. However, as stated in the study, the questionnaires used cover several domains but with only a few questions targeting each domain. Also patients' perceptions of pain and discomfort were assessed retrospectively and not with several questionnaires in real time. The study reported that the median satisfaction with the appearance of the teeth after treatment, using a VAS was 99 out of 100 (interquartile range 91-100).</p>		

**Study 2:** Julien, K. C., Buschang, P. H. and Campbell, P. M. (2013). Prevalence of white spot lesion formation during orthodontic treatment. *The Angle orthodontist*, 83, 641-647.

Criteria		QATSDD Score
1	Explicit theoretical framework.	0
2	Statement of aims/objectives in main body of report.	2
3	Clear description of research setting.	3
4	Evidence of sample size considered in terms of analysis.	0

5	Representative sample of target group of a reasonable size.	3
6	Description of procedure for data collection.	3
7	Rationale for choice of data collection tools.	0
8	Detailed recruitment data.	3
9	Statistical assessment of reliability and validity of measurements tools.	2
10	Fit between stated research question and method of data collection.	3
11	Fit between stated research question and format and content of data collection tool.	3
12	Good justification for analytical method selected.	2
13	Assessment of reliability of analytical process.	3
14	Strength and limitations critically discussed.	1
<b>Total score</b>		<b>28</b>
<b>Conclusion:</b> According to QATSDD scores, this is a moderate quality study. A large sample (885 pre and post-treatment photographs) randomly selected from finished orthodontic cases. Although, no sample size calculation was performed, this study was based on a large sample size compared to previous studies. The study reported that the prevalence of white spot lesion after orthodontic treatment is 23%, and it is 2.5 times more frequent in maxillary than the mandibular arch.		

**Study 3:** Brin, I., Tulloch, J., Koroluk, L. and Philips, C. (2003). External apical root resorption in Class II malocclusion: a retrospective review of 1-versus 2-phase treatment. American journal of orthodontics and dentofacial orthopedics, 124, 151-156.

<b>Criteria</b>		<b>QATSDD Score</b>
1	Explicit theoretical framework.	0
2	Statement of aims/objectives in main body of report.	1
3	Clear description of research setting.	2
4	Evidence of sample size considered in terms of analysis.	0
5	Representative sample of target group of a reasonable size.	2
6	Description of procedure for data collection.	3
7	Rationale for choice of data collection tools.	2
8	Detailed recruitment data.	3
9	Statistical assessment of reliability and validity of measurement tools.	3
10	Fit between stated research question and method of data collection.	3
11	Fit between stated research question and format and content of data collection tool.	2
12	Good justification for analytical method selected.	2
13	Assessment of reliability of analytical process.	2
14	Strength and limitations critically discussed.	0
<b>Total score</b>		<b>25</b>
<b>Conclusion:</b> A retrospective study of moderate quality based on data collected from clinical records of children participating in a RCT investigating effect of 1-phase versus 2-phase orthodontic treatment. A sample of 138 Class II children with increased over jet (>7mm). Panoramic radiographs taken before and after treatment and intra-oral periapical radiographs of maxillary incisors were assessed by two examiners to evaluate External Apical Root Resorption (EARR). This study reported that 12% of incisors had moderate to severe root resorption ( $\geq 2$ mm loss of root length) with more prevalence in lateral than in central maxillary incisors.		

## Appendix S: International Patient Decision Aid Standards (IPDAS) Criteria Checklist

I. <b>Content</b>		
<b>Provide information about options in sufficient detail for decision making?</b>		
Does the patient decision aid describe the health condition?	Y	
Does the patient decision aid list the options?	Y	
Does the patient decision aid list the options of doing nothing?	Y	
Does the patient decision aid describe the natural course without options?	Y	
Does the patient decision aid describe procedures?	Y	
Does the patient decision aid describe positive features [benefits]?	Y	
Does the patient decision aid describe negative features of options [harms / side effects / disadvantages]?	Y	
Does the patient decision aid include chances of positive / negative outcomes?	Y	
Does the patient decision aid describe what test is designed to measure?		NA
Does the patient decision aid include chances of true positive, true negative, false positive, false negative test results?		NA
Does the patient decision aid describe possible next steps based on test result?		NA
Does the patient decision aid include chances the disease is found with / without screening?		NA
Does the patient decision aid describe detection / treatment that would never have caused problems if one was not screened?		NA
<b>Present probabilities of outcomes in an unbiased and understandable way?</b>		
Does the patient decision aid use event rates specifying the population and time period?	Y	
Does the patient decision aid compare outcome probabilities using the same denominator?		NA
Does the patient decision aid compare outcome probabilities using the time period?	Y	
Does the patient decision aid compare outcome probabilities using the scale?		NA
Does the patient decision aid describe uncertainty around probabilities [words, numbers, diagrams]?		NA
Does the patient decision aid allow the patient to select a way of viewing probabilities based on their own situation [e.g. age]?		NA
Does the patient decision aid place probabilities in context of other events?		NA
Does the patient decision aid use both positive and negative frames [e.g. showing both survival and death rates]?		NA
<b>Include methods for clarifying and expressing patients' values?</b>		
Does the patient decision aid describe the procedures and outcomes to help patients imagine what it is like to experience their physical, emotional and social effects?	Y	
Does the patient decision aid ask patients to consider which positive and negative features matter most?	Y	
Does the patient decision aid suggest ways for patients to share what matters most with others?	Y	

**Include structured guidance in deliberation and communication?**

Does the patient decision aid provide steps to make a decision?	Y	
Does the patient decision aid suggest ways to talk about the decision with a health professional?	Y	
Does the patient decision aid include tools [worksheet, question list] to discuss options with others	Y	

**II. Development Process**

**Present information in a balanced manner?**

Is the patient decision aid able to compare positive / negative features of options?	Y	
Does the patient decision aid show negative / positive features with equal detail [fonts, order, display if statistics]?	Y	

**Have a development process?**

Does the patient decision aid include developers' credentials / qualifications?	Y	
Does the patient decision aid find out what users [patients, practitioners] need to discuss options?	Y	
Does the patient decision aid have a peer review by patient / professional experts not involved in development and field testing?	Y	
Has the patient decision aid been field tested with users patients facing the decision?	Y	
Has the patient decision aid been field tested with practitioners presenting options?	Y	
The field tests with users [patients, practitioners] show the patient decision aid is acceptable?	Y	
The field tests with users [patients, practitioners] show the patient decision aid is balanced for undecided patients?	Y	
The field tests with users [patients, practitioners] show the patient decision aid is understood by those with limited reading skills?	Y	

**Use up to date scientific evidence that is cited in a reference section or technical document?**

Does the patient decision aid provide references to evidence used?	Y	
Does the patient decision aid report steps to find, appraise, summarise evidence?	Y	
Does the patient decision aid report date of last update?	Y	
Does the patient decision aid report how often patient decision aid id updated?	Y	
Does the patient decision aid describe quality of scientific evidence [including lack of evidence]?	Y	
Does the patient decision aid use evidence from studies of patients similar to those of target audience?		NA

**Disclose conflicts of interest?**

Does the patient decision aid report source of funding to develop and distribute the patient decision aid?	Y	
Does the patient decision aid report whether authors or their affiliations stand to gain or lose by choices patients make after using the patient decision aid?	Y	

Use plain language?		
Is the patient decision aid written at a level that can be understood by the majority of patients in the target group?	Y	
Is the patient decision aid written at a grade 9 or equivalent level or less according to readability score [SMOG or FRY]?	Y	
Does the patient decision aid provide ways to help patients understand information other than reading [audio, video, in-person discussion]?	Y	

NA Meet additional criteria if the patient decision aid is <u>internet based</u> ?		
Does the patient decision aid provide a step-by step way to move through the web pages?		NA
Does the patient decision aid allow patients to search for key words?		NA
Does the patient decision aid provide feedback on personal health information that is entered into the patient decision aid?		NA
Does the patient decision aid provide security for personal health information entered into the decision aid?		NA
Does the patient decision aid make it easy for patients to return to the decision aid after linking to other web pages?		NA
Does the patient decision aid permit printing as a single document?		NA

NA Meet additional criteria if <u>stories</u> are used in the patient decision aid?		
Does the patient decision aid use stories that represent a range of positive and negative experiences?		NA
Does the patient decision aid report if there was a financial or other reason why patients decided to share their story?		NA
Does the patient decision aid state in an accessible document that the patient gave informed consent to use their stories?		NA

III. **Effectiveness:** Does the patient decision aid ensure decision making is informed and values based?

Decision process leading to <b>decision quality</b> ...		
The patient decision aid helps patients to recognise a decision needs to be made?	Y	
The patient decision aid helps patients to know options and their features?	Y	
The patient decision aid helps patients to understand that values affect decision?	Y	
The patient decision aid helps patients to be clear about option features that matter most?	Y	
The patient decision aid helps patients to discuss values with their practitioner?	Y	
The patient decision aid helps patients to become involved in preferred ways?	Y	

## Appendix T: Young people questionnaire

Identification Number: \_\_\_\_\_



### Questionnaire about 'Making choices about having braces easier'

#### Hello

Thanks for agreeing to help us with our study. This study is being done so we understand more about how young people make choices about having braces. By answering the questions, you will help us make sure young people have better information in the future.

In this booklet, you will find some sets of questions about you, your decision, and what you know and expect from brace treatment if you choose it. You may choose not to have brace treatment.

Please answer all the questions using the instructions. There is no right or wrong answer.

#### Section 1: About you

1. Are you: (please tick)      A boy       A girl

2. When were you born?      \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  
DAY   MONTH   YEAR

3. What is your home postcode     

Please ask your parent or carer if you need help with this



## Section 2: About your choice

For these questions I would like you to tell me whether you agree or disagree with the following statements (**Please tick appropriate box**). There are no right or wrong answers.

	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree
I know which options are available to me	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I know the benefits of each option	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I know the risks and side effects of each option	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I am clear about which benefits matter most to me	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I am clear about which risks and side effects matter most	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I am clear about which is more important to me (the benefits or the risk and side effects)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I have enough support from others to make a choice	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I am choosing without pressure from others	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I have enough advice to make a choice	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I am clear about the best choice for me	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I feel sure about what to choose	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
This decision is easy for me to make	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I feel I have made an informed choice (a choice based on enough information)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
My decision shows what is important to me	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I expect to stick with my decision	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I am satisfied with my decision	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>







10. What do you think are the possible benefits of any brace treatment you might choose?

.....

.....

.....

.....

11. What do you think are the risk(s) of any brace treatment you might choose?

.....

.....

.....

.....

12. Do you feel that you were given enough information to make the best treatment choice for you? **(Circle one)**

Yes

No

13. Thinking about whether or not you would like to have a brace, what decision have you made? **(Please tick)**

Yes, I'm going to have a brace

No, I don't want a brace

I have not decided yet



**Thank you very much for your help**



## Section 2: About your choice

For these questions I would like you to tell me whether you agree or disagree with the following statements **(Please tick appropriate box)**.

	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree
I know which options are available to my child	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I know the benefits of each option	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I know the risks and side effects of each option	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I am clear about which benefits matter most to my child	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I am clear about which risks and side effects matter most	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I am clear about which is more important to my child (the benefits or the risk and side effects)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I have enough support from others to make a choice	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I am choosing without pressure from others	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I have enough advice to make a choice	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I am clear about the best choice for my child	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I feel sure about what to choose	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
This decision is easy for me to make	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I feel I have made an informed choice (a choice based on enough information)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
My decision shows what is important to my child	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I expect to stick with my decision	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I am satisfied with my decision	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**Section 3: Your expectations about any brace treatment you might have.**

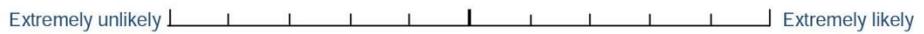
We would like to know what you expect may happen if your child chooses to have a brace. You and your child may choose not to have a brace. Please read each question, and answer by placing a mark on the line nearest your expectation.

For example:

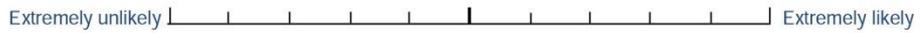


**1. What type of brace treatment do you expect for your child?**

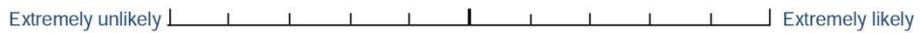
a. Braces, don't know what type?



b. Train track braces?



c. Teeth extracted (taken out)?



d. Head brace?



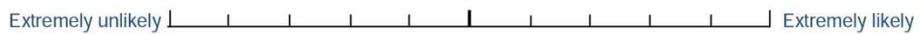
e. Jaw surgery?



**2. Do you think brace treatment will give any problems to your child?**



**3. Do you think wearing a brace will be painful for your child?**



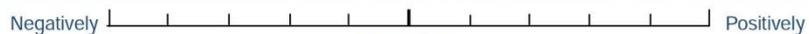
**4. Do you think brace treatment will produce problems with eating?**



**5. Do you expect brace treatment to restrict (limit) what your child can eat or drink?**



**6. How you think people will react to your child wearing a brace?**



No reaction

7. How long do you expect brace treatment to take if you and your child choose it?  
 (Please tick appropriate box)

3-4 years	
2-3 years	
1-2 years	
6 months-1 year	
1 month-6months	
Don't know	

8. How often do you think you will need to attend for check up if you and your child choose to have a brace? (Please tick appropriate box)

Every 6-8 months	
Every 3-5 months	
Every 6-8 weeks	
Every 4-6 weeks	
Every 1-2 weeks	
Don't know	

9. Do you expect brace treatment to:

a. Straighten your child's teeth?

Extremely unlikely |-----| Extremely likely

b. Produce a better smile?

Extremely unlikely |-----| Extremely likely

c. Make it easier to eat?

Extremely unlikely |-----| Extremely likely

d. Make it easier to speak?

Extremely unlikely |-----| Extremely likely

e. Make it easier to keep your child's teeth clean?

Extremely unlikely |-----| Extremely likely

f. Improve chances of a good career for your child in the future?

Extremely unlikely |-----| Extremely likely

g. Give your child confidence socially?

Extremely unlikely |-----| Extremely likely

**You and your child may choose not to have brace treatment.**

10. What do you think are the possible benefits of any brace treatment you and your child might choose?

.....  
.....  
.....  
.....

11. What do you think are the risk(s) of any brace treatment you and your child might choose?

.....  
.....  
.....  
.....

12. Do you feel that you were given enough information to make the best treatment choice for you and your child? **(Circle one)**

Yes

No

13. Thinking about whether or not you would like to have a brace for your child, what decision have you made? **(Please tick)**

- Yes, my child is going to have a brace
- No, I don't want my child to have a brace
- We have not decided yet

**Thank you very much for your help**

## Appendix V: Young persons' information sheet (Stage 2-evaluation)



### Young Persons' Information Sheet

#### Project: 'Making choices about having braces easier'

Hello, my name is Abdussalam Eddaiki and I am a research student at the University of Sheffield. You are being invited to take part in a research project. Before you decide whether you want to take part in the study, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information sheet and ask us if there is anything that is not clear or if you would like more information.

Thank you for reading this.

#### What is the project's purpose?

The project will help us understand what young people know about brace treatment and how they decided to have braces or not. By answering some questions, you will help us make sure young people have better information in the future. The overall aim of the study is to develop a booklet to help young people and their parents or carers in their choices about having brace treatment.

#### Why have I been invited?

I have invited you to take part in this study because you have already been referred to the orthodontic department at Charles Clifford Dental Hospital. You will not be the only person taking part. I want to speak to about 50 young people in total and their parents or carers. Please note that you may or may not be invited for the study, it depends if the dentist thinks you need a brace and what type is best for you.

#### What will I have to do?

If you do choose to take part you will first need to sign a consent form. We will give you a copy of this consent form along with a copy of this information sheet. We will ask you and your parent to answer some questions about yourself and your brace treatment by completing questionnaires. You will be asked to complete these questionnaires three different times. You will complete the first questionnaire at your first appointment when you come to the clinic, the second questionnaire will then be completed 4 weeks later and the final questionnaire after a further 4 weeks. The questionnaire usually takes 10 to 15 minutes to complete.

You will be free to stop taking part at any time and you will not need to give a reason for this choice. If you do decide to stop, this will not affect the care you receive.

#### **What are the possible benefits of taking part?**

The study will not change the treatment or care you receive at the Dental Hospital. Although this study will not help you, we hope that it will help other young people in the future.

#### **Will anyone else know I've taken part in the study?**

No one apart from the research team will know you took part. We will not use your name on anything. All the information will be kept private, nothing identifying you will be kept on a computer.

#### **What if there is a problem or something goes wrong?**

If you or your parents are unhappy about anything, please tell me so we can talk about it. You can stop taking part at anytime. You or your parent/carer can also contact Mrs Tracey Plant, Clinical Hospital Manager, Charles Clifford Dental Hospital, Sheffield S10 2SZ or the Patient Services Team on 0114 271 2400 or email PST@sth.nhs.uk

#### **Is there any a disadvantage or risks of taking part?**

There are no known risks to you or your parents from taking part in the study.

#### **What will happen to the results?**

The results will be published in a science magazine, but your answers will be private; and we will not use your name. All the questionnaires and other information from the study will be kept safely at the University of Sheffield and destroyed five years after the study has been completed. We will write a report to let all young people in this study know about what we found.

#### **Who has reviewed the study?**

Before any research goes ahead it is checked by an Ethics Committee, their job is to make sure that the research is OK and safe to do.

#### **Do I have to take part?**

No, not if you don't want to - we will not ask you why.

#### **Contact details**

If you don't understand something, or want to know more, please contact me by telephone: 0114 2717877 or email: aeddaiki1@sheffield.ac.uk

***Thanks for thinking about taking part.***

## Appendix W: Parents information sheet (Stage 2-evaluation)



### Parents Information Sheet

#### Project: 'Making choices about having braces easier'

Hello, my name is Abdussalam Eddaiki and I am a PhD student at the University of Sheffield. You and your child are being invited to take part in a research project. Before deciding whether you are happy for your child to take part in the study, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information sheet and ask us if there is anything that is not clear or if you would like more information.

Thank you for reading this.

#### What is the project's purpose?

It will help us understand what young people know about brace treatment and how they decided to have the braces. By answering some questions, you will help us make sure young people have better information in the future. The overall aim of the study is to develop a booklet to help young people and their parents or carers in their choices about having orthodontic brace treatment.

#### Why have I been invited?

I have invited you and your child to participate in this study because your child has already been referred to orthodontic department at Charles Clifford Dental Hospital. I want to speak to about 23 young people in total and their parents or carers. Please note that you and your child may or may not be invited for the study, it depends if the dentist thinks your child needs a brace and if so what type would be best.

#### What will I have to do?

If you and your child do choose to take part you will each first need to sign a consent form. We will give you both a copy of this consent form along with a copy of this information sheet. The actual research will require you and your child to complete a questionnaire measuring different aspects of the decision making process and some questions about brace treatment. You will be asked to complete these questionnaires on three different occasions. You will complete the first questionnaire at your first appointment when you come to the clinic, the second questionnaire will then be completed 4 weeks later and the final questionnaire after a further 4 weeks. The questionnaire may take an average of 10-15 minutes to complete.

You and your child will be free to stop taking part at any time and you will not need to give a reason for this choice. If you do decide to stop, this will not affect the care your child receives.

#### **What are the possible benefits of taking part?**

The study will not change the treatment or care your child receives at the Dental Hospital. Although this study will not benefit either you or your child directly, we hope that it will help other young people in the future.

#### **Will anyone else know I've taken part in the study?**

No one apart from the research team will know you took part. We will not use yours or your child's name on anything. All the questionnaires and information will be kept private, nothing identifying you or your child will be kept on a computer.

#### **What if there is a problem or something goes wrong?**

If you become unhappy about anything, please tell me so we can talk about it. You and your child can stop taking part at anytime. You can also contact Mrs Tracey Plant, Clinical Hospital Manager, Charles Clifford Dental Hospital, Sheffield S10 2SZ or the Patient Services Team on 0114 271 2400 or email PST@sth.nhs.uk

#### **Is there any a disadvantage or risks of taking part?**

There are no known risks to you or your child from taking part in the study. You and your child don't have to talk about anything you don't want to.

#### **What will happen to the results?**

The results will be published in a scientific journal, but your answers will be private; and we will not use your or your child's name. All the information from the study will be kept securely at the University of Sheffield and destroyed five years after the study has been completed. We will write a report to let all participants in this study to know about what we found.

#### **Who has reviewed the study?**

Before any research goes ahead it is checked by an Ethics Committee. They make sure that the research is OK and safe to do.

#### **Do I have to take part?**

No, not if you don't want to - we will not ask you why.

#### **Contact details**

If you don't understand something, or want to know more, please contact me by telephone: 0114 2717877 or email: aeddaiki1@sheffield.ac.uk

***Thanks for thinking about taking part.***