

A randomized controlled trial of a patient decision-making aid for orthodontics

Kate Parker^a, Susan J. Cunningham^b, Aviva Petrie^c, Fiona S. Ryan^d

a. Orthodontic Specialty Registrar

University College London (UCL) Eastman Dental Institute and Eastman Dental Hospital,
University College London Hospitals (UCLH) Foundation Trust, London, United Kingdom

b. Professor of Orthodontics

University College London (UCL) Eastman Dental Institute, United Kingdom

c. Honorary Reader in Biostatistics

University College London (UCL) Eastman Dental Institute, London, United Kingdom

d. Consultant Orthodontist and Honorary Senior Clinical Lecturer

Eastman Dental Hospital, University College London Hospitals (UCLH) Foundation Trust,
London, United Kingdom

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ABSTRACT

Introduction: Patient decision-making aids (PDA) are instruments that facilitate shared decision-making and enable patients to reach informed, individual decisions regarding healthcare. The objective of this study was to assess the efficacy of a PDA compared with traditional information provision for adolescent patients considering fixed appliance orthodontic treatment.

Method: Pre-treatment orthodontic patients were randomly allocated into two groups; the intervention group received the PDA and standard information regarding fixed appliances, and the control group received the standard information only. Decisional conflict was measured using the Decisional Conflict Scale (DCS) and the levels of decisional conflict were compared between the two groups.

Results: Seventy-two patients were recruited and randomized in a ratio of 1:1 to the intervention (PDA) and control groups. Seventy-one patients completed the trial (36 control group, 35 intervention group) which satisfied the sample size calculation. The median total DCS score in the PDA group was lower than in the control group (15.63 and 19.53 respectively) however this difference was not statistically significant (Difference between groups 3.90; 95% CI of the difference -4.30 to 12.11). Gender, ethnicity, age and the time point at which patients were recruited did not have a significant effect on DCS scores. No harm was observed or reported for any participant in the study.

Conclusions: The results of this study showed that the provision of a PDA to adolescent patients prior to consenting for fixed appliances did not significantly reduce decisional conflict. There may be a benefit in providing a PDA for some individuals, however, it is not yet possible to say how these patients could be identified.

Registration: This trial was registered with the Harrow National Research Ethics Committee (Reference 12/LO/0279).

Protocol: The protocol was not published before trial commencement.

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INTRODUCTION

Patient-centred care, whereby patients are involved in decisions about their own healthcare and treatment options, is a core principle of modern healthcare. It is both an ethical and a legal obligation which is underpinned by legislation¹. Providing patient-centred care commonly involves shared decision-making (SDM) where clinicians and patients work together to ensure that patients are involved in decisions about their healthcare.

Patient decision-making aids (PDAs) are evidence-based tools that facilitate SDM and are used to help patients make personal decisions about their healthcare^{2,3}. They are designed to engage patients in the decision-making process, assist them in considering the risks and benefits of different treatment options in line with their own values and help them to put information into a personal context³. By doing this, PDAs encourage patients to establish their preferences and to make decisions that are appropriate for them as individuals².

A large body of evidence exists on the benefits of PDAs and they have been shown to help patients make choices in keeping with their own values as well as improving the quality of decision-making⁴. PDAs have also been shown to improve patient knowledge, increase appreciation of risks, reduce decisional conflict, reduce passive decision-making, reduce the number of people who are undecided about their treatment options and improve adherence to treatment because patients have taken a more active role in the decision-making process^{3,4}. Additionally using PDAs commonly results in patients choosing less invasive treatment options and their use has often been shown to be more cost effective than when they are not used^{3,5-7}.

Although PDAs are increasingly used in medicine, they are not commonly used in dentistry⁸⁻¹¹. This is despite research showing the need to consider patient values and preferences when making decisions about dental treatment and there is evidence that dental patients prefer a collaborative style of decision-making^{12,13}.

Orthodontics often involves decisions where there are several viable treatment options, and therefore, lends itself well to SDM and the use of PDAs. Currently, there are no published PDAs for use in orthodontics. Thus, the use of PDAs in orthodontics is an area which requires further research, to assess if the benefits of PDAs which have been shown to exist in medicine, also exist in orthodontics.

SPECIFIC OBJECTIVES AND HYPOTHESIS

The aim of this study was to test the efficacy of a PDA in adolescent patients considering fixed appliances. This was through the measurement of decisional conflict, using the Decisional Conflict Scale (DCS)¹⁴. The null hypothesis was that there was no difference in the average level of decisional conflict in patients who received the PDA (intervention group) compared with those who did not (control group).

MATERIALS AND METHODS

Trial design and any changes after trial commencement

This study was a single-centre, prospective, randomized controlled trial with a 1:1 allocation ratio. Ethical approval was granted from Harrow National Research Ethics Committee (Reference 12/LO/0279). There were no changes to the trial after its commencement.

Participants, eligibility criteria and settings

The study was carried out in one National Health Service (NHS) teaching hospital orthodontic department. Patients were eligible for inclusion if they were 10 to 16 years old, had not undergone any previous orthodontic treatment and did not have any craniofacial abnormalities. Patients were recruited from new patient clinic appointments and from appointments to take initial records for treatment planning, both time points were prior to a full discussion of treatment options and prior to patients/parents consenting for treatment. Information leaflets were given to potential subjects and their parents and consent and assent were obtained prior to recruitment to the study. Patients were recruited between July 2015 and February 2016.

Interventions

Participants in both the intervention and control groups received verbal information and patient information leaflets, according to their clinician's normal practice. To reduce the risk of bias due to different information being provided, all patients also received standardised verbal information from one of the researchers (KP) regarding the benefits and risks of fixed appliances. Participants in the intervention group additionally received the PDA which the researcher discussed in detail with the patient.

The PDA was developed using the International Patient Decision Aids Standards (IPDAS) Collaboration criteria¹⁵. The material incorporated into the PDA included information from

evidence based literature and from in-depth interviews with patients undergoing, or having recently completed, fixed appliance treatment. During the interviews patients were asked about their understanding of the risks and benefits of fixed appliances and also which risks and benefits mattered most to them. This information was then incorporated into the PDA alongside that obtained from the literature, which ensured that the PDA included topics which were considered important by both patients and clinicians. The decision aid comprised of four A4 pages; the first page gave general information on fixed appliances including what they are, what they are used for and what level of commitment is required from the patient. The second page detailed the overall benefits and risks of fixed appliance treatment, the third page contained a decision tree to guide patient decision-making and the final page contained questions to help patients in the final decision-making process.

All participants then completed the DCS unaided. This is standard methodology used in the majority of PDA research where participants receive all of the information provision and the intervention group receive the PDA, and then participants complete a DCS questionnaire only after all information has been given^{8,9,16,17}. The DCS is a validated, multi-dimensional questionnaire, which indirectly measures SDM by measuring the degree of uncertainty in a patient's decision-making¹⁸. It is the most popular tool used to measure SDM and the efficacy of PDAs³ and consists of 16 statements, each with 5 possible responses from 'strongly agree' to 'strongly disagree'. The DCS is completed by the patient and scored by the clinician/researcher to give a total score from 0 (no decisional conflict) to 100 (extremely high decisional conflict)¹⁴. The questionnaire has good psychometric properties and high reliability, with a test-retest correlation of 0.81 and a Cronbach alpha from 0.78 to 0.92¹⁸. Sub-sections of the DCS can also be scored separately to illustrate different elements of decisional conflict (uncertainty, informed, values clarity, support, effective decision)¹⁴.

Outcomes (primary and secondary) and any changes after trial commencement

The primary outcome measure was the level of decisional conflict, as given by the total DCS score, regarding whether or not to proceed with fixed appliances. Demographic information and the time point at which patients were recruited (new patient appointment or subsequent records appointment) was also recorded so that this information could be used in the statistical analysis to assess if any of these factors affected decisional conflict. There were no outcome changes after trial commencement.

Sample size calculation

Using the data from the first 18 participants who completed the study as an internal pilot (where the common standard deviation was 11.5), it was calculated that a total of 54 participants (27 in each group) were required to demonstrate a clinically relevant difference between the two groups of nine points on the DCS, with 80% power and a significance level of 0.01. This was increased by 15% due to using the Mann Whitney U test and increased a further 15% to allow for any drop-outs or incomplete data. This gave a total sample size of 72 participants (36 in each group).

Interim analyses and stopping guidelines

Not applicable.

Randomisation (random number generation, allocation concealment, implementation)

A random number sequence was generated using a random number table. Patients were randomized in blocks of six to ensure that there were equal numbers of participants in the intervention and control groups throughout the study. Allocation concealment was achieved using sequentially numbered, sealed, opaque envelopes containing the group to which participants were to be allocated. These envelopes were prepared before the study commenced and were only opened once patients were recruited and consented for the study.

Blinding

Patients were recruited only after they had received the verbal information and patient information leaflets from their clinician, thus clinicians did not know if patients had been recruited to the study and to which arm of the study they had been allocated. The verbal information given to both the intervention and control groups by the researcher had been standardised and practised prior to commencing recruitment to ensure that all patients were given the same information. It was not possible to blind the researcher and the participants to the group allocation because the researcher worked through the PDA with those allocated to this group and patients knew whether or not they had received the PDA.

Statistical analysis

The total and subscale DCS scores for the control and intervention groups were compared to assess the efficacy of the PDA. Since the scores were not normally distributed, the non-parametric test Mann-Whitney U test was used to compare the two groups. Univariable

linear regression analyses were undertaken to assess if any of the demographic factors or the time point at which patients were recruited affected the total DCS scores. The assumptions of the regression analysis were verified by a study of the residuals. All statistical analyses were completed using SPSS (IBM Corp. Released 2013. IBM SPSS Statistics for Windows, Version 22.0. Armonk, NY: IBM Corp). A significance level of 0.01 was used for the Mann Whitney U tests instead of the conventional 0.05 to avoid spuriously significant results arising from multiple testing. A significance level of 0.10 was used for the univariable regression analyses in order to decide which, if any, of the variables to include in a multivariable regression analysis as potential confounders when comparing the scores in the two groups.

RESULTS

Participant flow

Seventy-two patients were randomized in total. One patient failed to fully complete the DCS, therefore data for 71 patients were analysed. A CONSORT diagram showing the flow of participants through the study is shown in Figure 1.

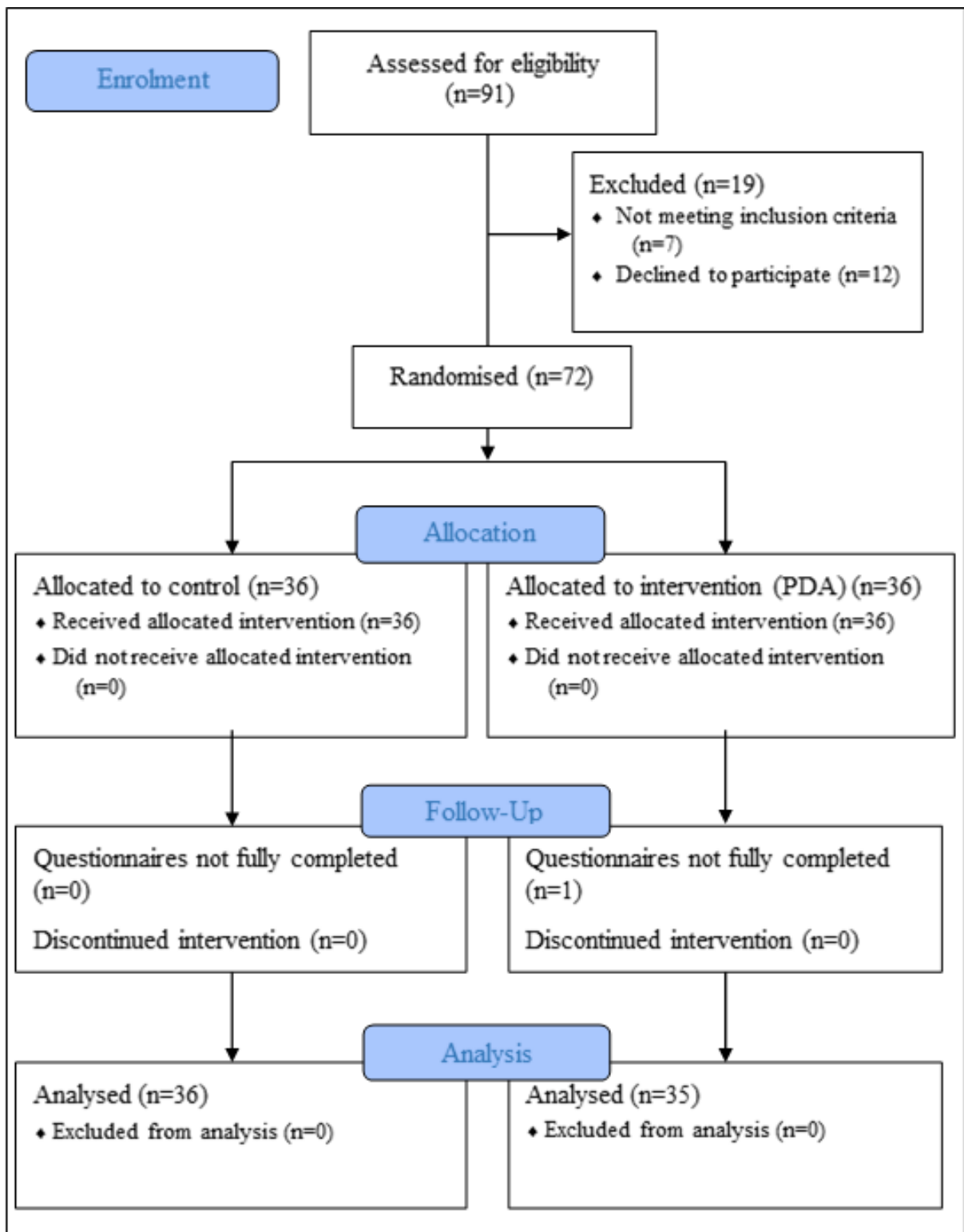


Figure 1. CONSORT diagram showing the flow of participants through the study.

Baseline data

The baseline characteristics for age, gender, ethnicity and the time point at which patients were recruited were similar in both groups (Table I).

		Control Group (n=36)	Intervention Group (n=35)
Mean Age [Years (SD)]		13.1 (1.7)	13.0 (1.8)
Age Category	10-13 years [n (%)]	22 (61.1%)	21 (60.0%)
	14-16 years [n (%)]	14 (38.9%)	14 (40.0%)
Gender	Male [n (%)]	16 (44.4%)	11 (31.4%)
	Female [n (%)]	20 (55.6%)	24 (68.6%)
Ethnicity	White British/Irish [n (%)]	15 (41.7%)	21 (60.0%)
	Other [n (%)]	21 (58.3%)	14 (40.0%)
Time Point of Patient Recruitment	New Patient [n (%)]	9 (25%)	12 (34.3%)
	Records [n (%)]	27 (75%)	23 (65.7%)

Table I. Baseline characteristics for patients in each group.

Numbers analysed for each outcome, estimation and precision, subgroup analysis

The median total DCS scores and the median DCS subscale scores were calculated¹⁴. For all of the DCS subscale scores, the median scores were lower for the intervention group than the control group, however, none of these reached statistical significance (Table II).

DCS Subscale Scores	Control Group Median score (Range)	Intervention Group Median score (Range)	Difference between groups (95% CIs of differences)	Significance (p-value)
Uncertainty	25.00 (0.00 to 50.00)	16.67 (0.00 to 58.30)	8.33 (-8.08 to 24.74)	0.36
Informed	20.83 (0.00 to 50.00)	16.67 (0.00 to 50.00)	4.16 (-4.65 to 12.99)	0.38
Values Clarity	20.83 (0.00 to 50.00)	16.67 (0.00 to 41.70)	4.16 (-6.77 to 15.11)	0.47
Support	8.33 (0.00 to 41.70)	8.33 (0.00 to 50.00)	0.00 (-10.94 to 10.94)	0.27
Effective Decision	15.63 (0.00 to 50.00)	12.50 (0.00 to 43.80)	3.13 (-9.18 to 15.43)	0.39

Table II. DCS subscale scores: summary measures and levels of significance.

The median total DCS score was lower in the intervention group than in the control group (15.63 and 19.53 respectively) although this was not statistically significant (Difference between groups 3.90; 95% CI of the difference -4.30 to 12.11) (Table III). It was also noted that there was marked individual variation.

Total DCS Score	Median Score (Range)	Difference between groups (95% CI of the difference)	Significance (p-value)
Control	19.53 (0.00 to 40.60)	3.90 (-4.30 to 12.11)	0.32
Intervention	15.63 (0.00 to 37.50)		

Table III. Summary measures and level of significance for the total DCS scores.

Univariable linear regression analyses were undertaken to explore if any of the demographic factors or the time point at which patients were recruited affected levels of decisional conflict (Table IV). None of these variables had a statistically significant effect on the total DCS scores.

Independent Variable		Regression Coefficient	95% Confidence Interval		r^2	Significance (p-value)
			Lower	Upper		
Group	Control	Reference	-8.24	3.26	0.011	0.39
	PDA	-2.49				
Age	Years (per year increase in age)	-0.67	-2.37	1.03	0.009	0.43
Age Category	10-13 years	Reference	-7.13	4.69	0.002	0.68
	14-16 years	-1.22				
Gender	Female	Reference	-1.30	10.45	0.034	0.12
	Male	4.60				
Ethnicity	White British/Irish	Reference	-6.51	5.05	0.001	0.80
	Other	-0.73				
Time Point of Recruitment	New Patient Clinic	Reference	-8.41	4.22	0.006	0.51
	Records Clinic	-2.10				

Table IV. Univariable linear regression analyses for the total DCS score and the independent variables.

Harms

No harm was observed or reported from the participants in the study.

DISCUSSION

Main findings in the context of existing evidence, interpretation

This study assessed the efficacy of a PDA for adolescents considering fixed appliances compared with traditional information provision through the comparison of decisional conflict scores between the intervention and control groups. The patients in the PDA group had a lower median DCS score than those in the control group, however, this did not reach statistical significance for the total score ($p=0.32$) or any of the subscale scores. The

univariable linear regression analysis showed that patients in the PDA group had, on average, a lower total DCS score than those in the control group and confirmed that this did not reach statistical significance.

The PDA was clearly beneficial for some patients but not for everybody, therefore it is not yet possible to identify which patients will benefit from the PDA. The majority of research into the efficacy of PDAs has been within medicine, where PDAs are commonly found to reduce decisional conflict³, however, there is little research on the use of PDAs in dentistry, and there is limited research with which to compare the results from this study.

A recent study on the efficacy of a PDA for children facing decisions regarding dental treatment under sedation or general anaesthesia also found that the decision-making aid reduced decisional conflict, but statistical significance was not reached¹⁷. The lack of statistical significance was attributed to low levels of decisional conflict (control group median 20.0, intervention group median 5.0) therefore it was not possible to gain much further reduction in scores as a “floor level” had already been reached. The relatively low levels of total decisional conflict in the current study (control median 19.53, intervention median 15.63 out of 100) may also have precluded large reductions in decisional conflict.

During this study it was observed that a number of patients appeared to have already made a definite decision regarding treatment at the point at which they were recruited to the study, prior to being given the standardised information. The decision aid may therefore not have had a statistically significant effect because it may not have been given sufficiently early in the decision-making process. It may be that patients were in the decision-making phase prior to their hospital appointment and that it would be more appropriate for the PDA to be used by the referring practitioner prior to referral. However, the clinician who goes through the PDA with the patient must be adequately qualified to do so, which raises the question as to whether referring general dental practitioners have adequate knowledge of orthodontics to undertake this and to answer any questions that patients may have.

The univariable linear regression analyses found no significant effects on decisional conflict due to age, gender or ethnicity. However, it must be noted that the age range was relatively narrow and only included adolescents. The majority of published PDAs focus on adults and very few PDA studies have analysed if age has an effect on the results^{3,19-21}. Whilst carrying

out this study, the researchers observed that older patients appeared more certain about their decision regarding treatment and this supports the trend for reduced decisional conflict in older patients. It was also observed that younger patients did not appear to engage as well with the PDA and it may be that older patients benefit more from a PDA or patients of different ages may benefit from the PDA being in different formats.

Although statistical significance was not reached for gender, the largest difference in decisional conflict was seen between males and females. The majority of PDA research does not report on gender differences due to a large number of decision aids being gender specific, for example those used for decisions concerning breast cancer, prostate cancer, vasectomy, and pregnancy decisions, therefore there is little research available with which to compare this finding^{17,22}.

Although there was a trend for White British/Irish patients to have reduced decisional conflict in this study, the results were not statistically significant and the differences may well be due to individual variation and personal experiences rather than the ethnicity of the patients having a direct effect.

Based on the results of this study, the future use of the PDA must be carefully considered. Although some patients experienced reduced decisional conflict, others had increased decisional conflict, and it is not yet possible to identify which patients will benefit most. It is also important to recognise that increased decisional conflict may not be detrimental if the patients are then considering their treatment options more fully, thus making a more informed decision. Therefore, whether the PDA reduces or increases decisional conflict, it may still be beneficial in helping patients to think about their treatment options more carefully.

Generalisability

The patients recruited for this study were aged 10 to 16 years old, which represents the age range of the majority of orthodontic patients and therefore allows the results to be generalised across this age range. The information given to patients by their clinicians was carried out according to each treating clinician's normal practice. It is important to recognise that clinicians' standard practices may vary but by randomly allocating patients to the control or intervention group, this confounding factor was controlled for. It is also important to

acknowledge that, in reality, information provision to patients may vary from clinician to clinician and therefore this represents a real world situation.

Limitations

This study was conducted in one NHS teaching hospital, therefore, it is not possible to say if the same results would be found in different clinical settings and if carried out by different clinicians.

Patients were recruited from both new patient clinics and subsequent records appointments because no definite treatment decisions had been reached at either of these time points and patients were still in the decision-making phase. There are benefits and limitations to recruiting patients from these different clinical settings. One limitation is that this may introduce heterogeneity due to different levels of knowledge and understanding of fixed appliances. However, it was decided to recruit patients from the two different time points so that this could be included in the regression analysis to assess if this factor had an effect on decisional conflict. Whilst this is an interesting factor to consider when analysing the results, randomising patients to the control or the intervention group ensured that fairly equal numbers of patients from each time point were included into each arm of the study. The univariable regression analysis found that the time point from which patients were recruited did not have a statistically significant effect on decisional conflict. Previous studies have used a similar methodology, recruiting patients from different clinical settings or time points, and none of these studies found the differences in patient recruitment to affect decisional conflict which supports the methodology used in our study^{18,23,24}.

Whilst this study found a trend for reduced decisional conflict in patients who received the PDA compared with those who did not, because patients did not complete a DCS questionnaire prior to the information provision, it cannot be said how much their decisional conflict changed, it is purely the difference between the two groups which can be commented on. Future studies could investigate such changes further.

CONCLUSIONS

There was no evidence of a difference in the median decisional conflict scores in patients who received the PDA compared with those who did not. Age, gender, ethnicity and the time point at which patients were recruited did not have a statistically significant effect on total DCS scores. There was noticeable individual variation in the effect of the PDA and, at

present, it is not possible to identify those patients who would benefit from the PDA and those who would not. Therefore, the routine use of this PDA in adolescent patients considering fixed appliances is not recommended in the format used in this study. However, shared decision-making is a multi-factorial and dynamic area and there is merit in providing patients with tools which help to increase their understanding and knowledge of their treatment options and which encourage valid consent and patient-centred care.

INFORMATION REGARDING THE PDA

For further details about the PDA and requests to use it, please contact the authors.

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Please see title page due to containing identifiable information.

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