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Title:

Development and evaluation of a Patient Decision Aid for young people and parents considering Fixed Orthodontic Appliances

Authors:

Abdussalam Eddaiki

Academic Unit of Oral Health and Development, School of Clinical Dentistry, University of Sheffield, Claremont Crescent, Sheffield, S10 2TA. Tel: 0114 271 7885/7895. Email: abdulsalamdaiki@yahoo.com

Philip E Benson

Academic Unit of Oral Health and Development, School of Clinical Dentistry, University of Sheffield, Claremont Crescent, Sheffield, S10 2TA. Tel: 0114 271 7885/7895. Email: p.benson@sheffield.ac.uk

Hilary L Bekker

Leeds Institute of Health Sciences, Charles Thackrah Building, University of Leeds. Tel: 0113 343 2726. Email: H.L.Bekker@leeds.ac.uk

Zoe Marshman

Academic Unit of Dental Public Health, School of Clinical Dentistry, University of Sheffield, Claremont Crescent, Sheffield, S10 2TA. Tel: 0114 2717896. Email: Z.Marshman@sheffield.ac.uk @zmarshman orcid.org/0000-0003-0943-9637

Address for correspondence:

Zoe Marshman, Z.Marshman@sheffield.ac.uk. Academic Unit of Dental Public Health, School of Clinical Dentistry, University of Sheffield, Claremont Crescent, Sheffield, S10 2TA.

Word Count = 3329

Abstract

Objectives: To develop and evaluate a child-centred patient decision aid for young-people, and their parents, supporting shared decision making about fixed orthodontic appliance treatment with dental health professionals, namely the Fixed Appliance Decision Aid (FADA).

Methods: The studies were undertaken in a UK teaching dental hospital orthodontic department in 2013-14. The development phase involved an interview study with: a) 10 patients (12-16 years old), and their parents, receiving orthodontic care to investigate treatment decision making and inform the content of the FADA and b) 23 stakeholders critiquing the draft decision aid's content, structure and utility. The evaluation phase employed a pre-/post-test study design, with 30 patients (12-16 years old) and 30 parents. Outcomes included the Decisional Conflict Scale; measures of orthodontic treatment expectations and knowledge.

Results: Qualitative analysis identified two informational needs: effectiveness of treatment on orthodontic outcomes and treatment consequences for patients' lives. Quantitative analysis found decisional conflict reduced in both patients (mean difference -12.3, sd 15.3, 95% CI 6.6 to 17.9; $p < 0.001$) and parents (mean difference - 8.6, sd 16.6, 95% CI 2.5 to 14.8; $p = 0.002$); knowledge about duration and frequency of orthodontic treatment increased; expectations about care were unchanged.

Conclusions: Using the FADA may enable dental professionals to support patients and their parents, decisions about fixed appliance treatments more effectively, ensuring young people's preferences are integrated into care planning.

(word count = 217)

Keywords: patient decision aid, shared decision making, orthodontics, child, fixed-appliance

Disclosure of interest: The authors report no conflicts of interest

Introduction

The prevalence of discontinued orthodontic treatment in the UK is approximately 12% (Turbill *et al.*, 2003, McMullan, 2005). It has been linked to patient factors, such as age and socio-economic status, as well as treatment factors, such as appliance type and clinician qualifications (Turbill *et al.*, 2003). Brattstrom and colleagues carried out telephone interviews with 63 patients who had not completed their treatment (Brattstrom *et al.*, 1991). The main reason for discontinuation was lack of motivation, discontent with orthodontics and having other priorities, such as sports or hobbies. Some participants had problems with their appliances and the authors suggest that these individuals should have better informed about the possible discomforts of treatment.

Patient decision aids help people make informed decisions between treatment options, and participate in care more effectively, than usual practice (Stacey *et al.*, 2014). Patient decision aids are designed using decision science to guide patients through the decision making process by providing accurate information about the condition and treatment options, structured to encourage patients to proactively evaluate information in accordance with their own values, and decrease the chance they use others' opinions to make their choices (Bekker *et al.*, 2013). Patient decision aids enable professionals to integrate patient preferences about treatment when planning care together (Stacey *et al.*, 2014).

While previous projects have been conducted on decision-making aids in orthodontics we were only able to find one published paper of the development and evaluation of a decision aid for dental patients (Johnson *et al.*, 2006). This decision aid is called Endodontic Decision Board (EndoDB) and is designed to help patients decide between undergoing root canal treatment or extraction of the tooth. Use of EndoDB was found to increase knowledge, compared to a control group who did not receive the aid, but had no effect on satisfaction or anxiety.

The aim of this study was to develop, and evaluate, a child-centred patient decision aid for young-people, and their parents considering fixed orthodontic appliances, namely the Fixed Appliance Decision Aid (FADA) supporting shared decision making about treatment with dental health professionals.

Methods

The FADA was developed using qualitative methods, and evaluated using a quasi-experimental (pre-/post-test) design. The study was carried out with patients aged 12-16, and their parents, receiving treatment from the Orthodontic Department, Charles Clifford Dental Hospital, Sheffield, UK (August 2013 - December 2014). Ethical approval was obtained (NRES Committee Yorkshire and The Humber; 13/YH/0166).

Fixed Orthodontic Appliance Patient Decision Aid - Development Study.

Design and Sample: Semi-structured interviews were undertaken with ten patients and ten parents, undergoing or just completing orthodontic treatment between August - December 2013. Patients with craniofacial anomalies, required orthognathic surgery, had severe learning disabilities or could not speak English or Arabic were excluded from participation. Purposive sampling was used to ensure that there was a range of participants recruited regarding age (12 to 16 years), gender (six female, four male), ethnicity (seven white British, three from black/minority ethnic groups) and at different stages of treatment (3 months - completed). Recruitment continued until data saturation was achieved

Procedure and Analysis: interviews were carried out by AE and ZM using a topic guide exploring factors involved in making the decision whether or not to undergo orthodontic treatment, the value patients put on the benefits and risks of treatment, the information and support needs of young people and their parents, and recommendations for the content, format, and timing of a patient decision aid. Patients and parents were interviewed together, and interviews were audio-recorded, transcribed and analysed using framework analysis (Ritchie and Spencer, 1994).

Findings: two themes emerged from the data:

- **Treatment concerns:** This theme consisted of four subthemes about treatment benefits, treatment risks, the impact of the orthodontic appliance, and timing of orthodontic treatment. Benefits included an expectation that teeth would be straighter and their smile improved. Risks included discolouration of teeth, gingival irritation, and shortening of the roots. Young people were concerned about changing diet to avoid damage from braces and stopping fizzy drinks; parents were concerned with missing school and work to take children to appointments. Young people and parents thought that having treatment younger was better.

- Information preferences: This theme consisted of four subthemes including the perceived involvement in decision-making, impact on patients' life, sources of information and the format of information. Young people perceived the decision was made by them, after discussion with their parents, even if it was first mentioned by a general dentist or orthodontist. Although, most people stated they were given verbal information and written information by the orthodontist, young people and parents felt there was a need for post-fitting information, particularly pain and discomfort from orthodontic appliances, length of treatment and use of retainers.

Intervention development: An initial version of the decision aid was drafted in accordance with the International Patient Decision Aid Standards criteria (Anon, Elwyn *et al.*, 2006, Coulter *et al.*, 2013). The content of the FADA was informed by clinical evidence (Brin *et al.*, 2003, Julien *et al.*, 2013), patient experience of orthodontic treatment (Feldmann, 2014) and the findings from the interviews described above (January 2014 - March 2014) (Figure 1).

To test the acceptability of the draft decision aid for orthodontic patients, parents and dental professionals, an expert group of stakeholders critiqued the draft decision aid, identifying limitations and strengths of its content, structure, and accessibility. The expert patient/parent group included five young people of different ages (12 to 16 years old), genders (three females, two males), and at different stages of treatment, ranging from four months in treatment to just having completed their orthodontic treatment. with their parents. The expert professional group included ten dental professionals (general dental practitioners who refer to orthodontic services, orthodontists in primary and secondary care), and a decision scientist (Hilary Bekker) with expertise in patient decision aid development. The findings from all participants were:

1. Design and format: Patients and their parents found the content easy to understand. They suggested having a space to write down notes or questions, and a section 'sign-posting' other resources. Some dental professionals felt the decision aid was too long, others wanted more detail about the risks and benefits of treatment. The decision scientist noted the decision problem, and its consequences, needed to be made more explicit, with details about the options being presented in a more balanced way.

2. Photographs: Different views were expressed about the usefulness of before and after treatment photographs in the decision aid. On balance, the use of photographs was not seen as necessary at this point in making the treatment decision.
3. Distribution: Most felt patients would benefit from getting the decision aid as part of their usual dental care; some from the general dentists, before referral, to make informed decisions between having and not having orthodontic care; others from the orthodontist to provide specialist follow-up information if needed.

The revised FADA (July 2014) was reviewed by two further patients (one female, one male aged 12 and 15 years) to clarify specific minor issues raised by the decision scientist. This version was six pages long, with a Flesch-reading ease test score of 90.1 (very easy to read by an average 11-year-old student) and Flesch-Kincaid grade level 2.8. The FADA included the following sections: clarification of the decision problem and orthodontic treatment options; good teeth-hygiene tips; a table comparing risks and benefits of fixed orthodontic appliance and white filling treatments; value scales to rate importance of outcomes for the patient; a screening measure of decisional conflict (Legare *et al.*, 2010); treatment preference; points to discuss with dental professional.

Fixed Orthodontic Appliance Patient Decision Aid - Evaluation Study.

Design and Sample: A pre-/post-test study design using questionnaires to evaluate the decision aid's impact on patients', and their parents', fixed orthodontic appliance decision making. All written referrals to the hospital orthodontic department (UK) who met the inclusion criteria above were sent a study information sheet with their appointment letter. The required sample size was estimated to be a minimum of 30 participants, based on an effect size of 0.3 which is typical for PDAs and also clinically meaningful (significance level $\alpha=0.05$; power $1-\beta=0.80$) using change in the Decisional Conflict Scale as the primary outcome (O'Connor *et al.*, 1999) (Stacey *et al.*, 2003). We aimed to recruit 30 young people, and 30 parents, during a 4 month recruitment phase (March – July 2014).

Measures: The questionnaires for patients and parents included measures of:

- Demographics of the patient (T1 only): age; gender and home postcode from which the Index of Multiple Deprivation was calculated;
- Perception of satisfaction with information provided (T1; T2):
- Decisional Conflict Scale (DCS) (O'Connor, 1995a, Koedoot *et al.*, 2001) (T1; T2): assesses patient reported outcomes of informed decision making about healthcare decisions. This 16 item scale measures decisional conflict, with subscales for feeling uncertain, uninformed, unclear about values, unsupported in decision making, and perceived efficacy in decision making, using a five-point Likert format ('Completely agree'=0 to 'Completely disagree'=4). The total score is calculated by adding the individual responses of the 16-items, dividing by 16 and multiplying by 25. The resulting standardised score ranges between 0–100; scores above 37.5 are associated with difficulty in implementing a choice.
- Orthodontic Patient Expectation Questionnaire (OPEQ) (Sayers and Newton, 2006, Sayers and Newton, 2007) (T1; T2): assesses patients' expectations of orthodontic treatment. This 10 item scale measures expectations of the initial visit, type of treatment, problems with orthodontic treatment, duration and frequency of attendance, and expected benefits of treatment, using a 100 mm visual analogue scale marked at 10-mm intervals (0 'Extremely unlikely' to 100 'Extremely likely'). Scores are calculated by measuring the distance from the left hand site of the visual analogue scale to the participant's mark in mm. For the purpose of this study, the first question was excluded, and three open ended questions which has been used previously eliciting knowledge about orthodontic treatment with fixed appliances were added.

The questionnaire is available on request from the authors.

Procedure: on attendance, patients were assessed by their orthodontic consultant and those eligible for fixed orthodontic appliances were asked for written consent. Those who agreed were given standardised information about fixed appliances by AE and the young person and parent completed separate questionnaires (T1). At their follow-up appointment, approximately four weeks later, both young person and parent were taken through the

FADA, by AE, and completed the questionnaire for the second time (T2). The recruitment period was between March – July 2014 (T1) and completed by November 2014 (T2).

Analysis: Data were managed using SPSS (Version 21, IBM Corp, NY, USA). The DCS data were found to have a non-normal distribution; Wilcoxon signed ranks test were applied to assess differences in pre- and post-scores. The OPEQ and knowledge data were normally distributed; paired t-tests were used to assess pre- and post-scores. Effect sizes (Cohen's d) were calculated using the following formula

$$d = \frac{\text{Pre-PDA score minus Post-PDA score}}{\sigma}$$

Where σ is the standard deviation of the pre-FADA scores to represent the best estimate of the population standard deviation before the intervention of the FADA. The effect sizes were interpreted using Cohen's criteria of small numbers.

Results

A total of 43 young people and 43 parents were recruited to the study and 30 young people and their parents (70%) completed both the before (T1) and after (T2) questionnaires (Figure 2); 57% of the young people were female (17/30); the mean age was 13.7 years (range 12-16 years). Based on the Index of Multiple Deprivation scores for England, derived from the participant home postcodes, 50% lived in the most deprivation areas, 33% in the least deprived areas, and 17% in average areas of deprivation. The main reasons for loss to follow-up were patients failing to attend or cancelling appointments.

Participants' decisional conflict showed significant decrease between T1 (standard information) and T2 (afterFADA). The mean patient total DCS scores decreased from 27.0 (sd 18.1; 95% CI 20.3 - 33.8) to 14.7 (sd 13.5; 95% CI 9.7 - 19.8) ($p < 0.001$) (Table 1). The Uninformed, Unclear values, Uncertainty, and Ineffective decision sub-scores showed significant reductions post-FADA ($p < 0.001$). The mean parental total DCS scores

decreased from 20.9 (sd 15.9; 95% CI 14.9 - 26.8) to 12.2 (sd 11.6; 95% CI 7.9 - 16.6) ($p=0.002$), with the same pattern of change in subscale scores (Table 2).

Participants showed some differences in their expectations for orthodontic treatment between the standard information and after patient decision aid measures. Patients had more realistic expectations for having teeth extracted ($p=0.007$), treatment producing a better smile ($p=0.004$) and making it easier to eat ($p=0.046$) (Table 3). Parents had more realistic expectations about having teeth extracted ($p=0.031$) and treatment making speaking easier ($p=0.049$) (Table 4).

In regard to knowledge about treatment the number of young people who expected that orthodontic treatment would be finished within 2-3 years doubled after use of the FADA, from $n=12$ (40%) pre-FADA to $n=25$ (83.3%) post-FADA. This figure also increased for parents from $n=12$ (40%) pre-FADA to $n=21$ (70%) post-FADA. The number of 'Don't knows' regarding treatment duration reduced from five (16.7%) young people pre-FADA to one (3.3%) post-FADA and for parents it reduced from six parents (20%) to zero. The expectations that the frequency of orthodontic treatment appointments would be about every 4 to 6 weeks also increased from 11 (36.7%) pre-FADA to 21 (70%) post-FADA in young people and 3 (10%) pre-FADA to 21 (70%) post-FADA in parents.

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 FADA to only 2 people (6.7%) after receiving the FADA. Also, the number of participants who perceived that WSLs were a risk of having orthodontic treatment increased from 3 young people (10%) before the FADA to 16 (53.3%) after seeing the FADA. None of the young people were aware that orthodontic treatment would lead to the resorption of roots of their teeth before receiving the FADA, this number increased to 5 participants (16.7%) after seeing the FADA.

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 FADA to only 4 people (13.3%) after seeing the FADA. 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 FADA.

More patients (17%), than parents (10%), felt the standard information did not support their decision making about orthodontic treatment. After receipt of the patient decision aid, only one patient still felt that the information was not sufficient (Table 5).

Discussion

This study used mixed methods to develop a child-centred patient decision aid for people making fixed orthodontic appliance choices. The decision aid development research identified a) information needs from patients aged 12-16, and their parents, not usually addressed in orthodontic information, and b) a decision aid acceptable to patients and their parents when making this treatment choice. The decision aid evaluation suggests the FADA has face validity, i.e. provides young people with information to support their orthodontic treatment choices with their parents and dental professional. After receiving the decision aid, patients, and their parents, reported being more informed, having clearer values, and being more certain about their choice after their assessment consultation and standard information. The study indicates dental health professionals may be able to use this decision aid with their patients to ensure patient preferences are integrated more effectively into orthodontic care plans than current practice. Improving patient and parent involvement in decision-making through the use of decision aids such as FADA may have important implications for rates of discontinuation of orthodontic treatment.

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 FADA. According to the Decisional Conflict Scale users-manual a total score of 25 or lower is associated with implementing a decision (O'Connor, 2010). This indicates that participants were more likely to make a decision following use of the FADA; however, the mean total score of the participants at baseline was lower than the minimum threshold of 38 which is associated with delay in decision making (O'Connor *et al.*, 1998).

Our results show that after using the FADA, 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 FADA 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 was not-significant. This finding might be because the baseline scores were low, suggesting that young people were already feeling well supported before using the FADA. Similar findings were reported by Schonberg and colleagues, who found non-significant reduction in Support subscale after using a PDA in women considering mammography screening (Schonberg *et al.*, 2014).

Similar reductions in decisional conflict were found in the parental scores pre- and post-decision aid; however, the mean baseline parental DCS was lower than the threshold of 25, which is associated with implementing a decision. In addition, the reduction in the Uncertainty subscale was not statistically significant, which suggests that parents were more certain that orthodontic treatment is the right choice for their child.

The results from this study are in agreement with the findings from a recent Cochrane review, 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 (Stacey *et al.*, 2014). The reduction in decisional conflict after completion of the FADA 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) and may have better outcomes (Mathers *et al.*, 2012). However, others have argued that the decisional conflict can encourage appropriate deliberation and enhance doctor-patient relationship (O'Connor, 1995b, O'Connor, 1995a, Nelson *et al.*, 2007a, Nelson *et al.*, 2007b).

This study found that the use of the FADA has a little effect on patients' and parents' expectations about orthodontic treatment. This is probably because the level of the participant's knowledge about orthodontic treatment was already high at baseline due to existing information from dentists, orthodontists, friends and family members. 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.

The FADA improved knowledge of the duration of orthodontic treatment and the frequency of appointments. Bekker and colleagues 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 (Bekker *et al.*, 2010). Most participants perceived that orthodontic treatment would straighten their teeth, and their knowledge regarding the benefits of having treatment increased. This suggests that some people are referred for treatment without being made aware of the benefits. The FADA increased participants' knowledge of the risks of orthodontic treatment with surprisingly few being aware of these risks before seeing the FADA. Mortensen and colleagues reported that traditional informed consent did not produce an understanding or recall of the risks of orthodontic treatment (Mortensen *et al.*, 2003).

Limitations of the study

The purpose of this study was to develop an evidence-based, patient centred decision aid that was acceptable to patients and professionals. However, the pre-/post-test design with a relatively small sample size was not sufficient to evaluate the effectiveness of the decision aid with a feasibility trial required to assess its impact on patient and orthodontic outcomes and explore the cost-effectiveness and implementation of the decision aid in clinical practice,.

This study used a range of patient-reported measures which, although carefully selected, had their own inherent limitations. In addition, the FADA was implemented as part of a research study and its impact may be augmented by the additional time spent discussing the treatment options in-depth with a dental health professional.

Conclusions

- The FADA provides patient-relevant information to support young people, and their parents', decisions about orthodontic care.
- Dental professionals using this patient decision aid with their patients are more likely to be able to integrate more consistently their patients' preferences into care planning than current practice.
- A feasibility study is needed to investigate the implementation of this patient decision aid in practice and assess its impact on patient and orthodontic outcomes.

References

- Anon, *International Patient Decision Aid Standards (IPDAS) Collaboration* [online]. <http://ipdas.ohri.ca/> [Accessed Access Date 2016].
- Bekker, H.L., Luther, F. & Buchanan, H., 2010. Developments in making patients' orthodontic choices better. *J Orthod*, 37, 217-24.
- Bekker, H.L., Winterbottom, A.E., Butow, P., Dillard, A.J., Feldman-Stewart, D., Fowler, F.J., Jibaja-Weiss, M.L., Shaffer, V.A. & Volk, R.J., 2013. Do personal stories make patient decision aids more effective? A critical review of theory and evidence. *BMC Med Inform Decis Mak*, 13 Suppl 2, S9.
- Brattstrom, V., Ingelsson, M. & Aberg, E., 1991. Treatment co-operation in orthodontic patients. *British Journal of Orthodontics*, 18, 37-42.
- Brin, I., Tulloch, J.F., Koroluk, L. & Philips, C., 2003. External apical root resorption in Class II malocclusion: a retrospective review of 1- versus 2-phase treatment. *Am J Orthod Dentofacial Orthop*, 124, 151-6.
- Coulter, A., Stilwell, D., Kryworuchko, J., Mullen, P.D., Ng, C.J. & Van Der Weijden, T., 2013. A systematic development process for patient decision aids. *BMC Med Inform Decis Mak*, 13 Suppl 2, S2.
- De Achaval, S., Fraenkel, L., Volk, R.J., Cox, V. & Suarez-Almazor, M.E., 2012. Impact of educational and patient decision aids on decisional conflict associated with total knee arthroplasty. *Arthritis Care Res (Hoboken)*, 64, 229-37.
- Elwyn, G., O'connor, A., Stacey, D., Volk, R., Edwards, A., Coulter, A., Thomson, R., Barratt, A., Barry, M., Bernstein, S., Butow, P., Clarke, A., Entwistle, V., Feldman-Stewart, D., Holmes-Rovner, M., Llewellyn-Thomas, H., Moumjid, N., Mulley, A., Ruland, C., Sepucha, K., Sykes, A., Whelan, T. & International Patient Decision Aids Standards, C., 2006. Developing a quality criteria framework for patient decision aids: online international Delphi consensus process. *BMJ*, 333, 417.
- Feldmann, I., 2014. Satisfaction with orthodontic treatment outcome. *Angle Orthod*, 84, 581-7.
- Johnson, B.R., Schwartz, A., Goldberg, J. & Koerber, A., 2006. A chairside aid for shared decision making in dentistry: a randomized controlled trial. *J Dent Educ*, 70, 133-41.
- Julien, K.C., Buschang, P.H. & Campbell, P.M., 2013. Prevalence of white spot lesion formation during orthodontic treatment. *Angle Orthod*, 83, 641-7.
- Koedoot, N., Molenaar, S., Oosterveld, P., Bakker, P., De Graeff, A., Nooy, M., Varekamp, I. & De Haes, H., 2001. The decisional conflict scale: further validation in two samples of Dutch oncology patients. *Patient Educ Couns*, 45, 187-93.
- Legare, F., Kearing, S., Clay, K., Gagnon, S., D'amours, D., Rousseau, M. & O'connor, A., 2010. Are you SURE?: Assessing patient decisional conflict with a 4-item screening test. *Can Fam Physician*, 56, e308-14.
- Mathers, N., Ng, C.J., Campbell, M.J., Colwell, B., Brown, I. & Bradley, A., 2012. Clinical effectiveness of a patient decision aid to improve decision quality and glycaemic control in people with diabetes making treatment choices: a cluster randomised controlled trial (PANDAs) in general practice. *BMJ Open*, 2.
- Mcmullan, R.E., 2005. An audit of 'early debond' cases in the national outcomes audit of patients treated with upper and lower fixed appliances by Consultant Orthodontists in the UK. *J Orthod*, 32, 257-61; discussion 247-8.
- Mortensen, M.G., Kiyak, H.A. & Omnell, L., 2003. Patient and parent understanding of informed consent in orthodontics. *Am J Orthod Dentofacial Orthop*, 124, 541-50.
- Nelson, W.L., Han, P.K., Fagerlin, A., Stefanek, M. & Ubel, P.A., 2007a. Rethinking the objectives of decision aids: a call for conceptual clarity. *Medical Decision Making*, 27, 609-618.
- Nelson, W.L., Han, P.K., Fagerlin, A., Stefanek, M. & Ubel, P.A., 2007b. Rethinking the objectives of decision aids: a call for conceptual clarity. *Med Decis Making*, 27, 609-18.
- O'connor, A.M., 1995a. Validation of a decisional conflict scale. *Med Decis Making*, 15, 25-30.
- O'connor, A.M., 1995b. Validation of a decisional conflict scale. *Medical Decision Making*, 15, 25-30.
- O'connor, A.M., 2010. *Decisional Conflict Scale - User Manual* [online]. https://decisionaid.ohri.ca/docs/develop/User_Manuals/UM_Decisional_Conflict.pdf [Accessed Access Date 2016].

- O'Connor, A.M., Rostom, A., Fiset, V., Tetroe, J., Entwistle, V., Llewellyn-Thomas, H., Holmes-Rovner, M., Barry, M. & Jones, J., 1999. Decision aids for patients facing health treatment or screening decisions: systematic review. *BMJ*, 319, 731-4.
- O'Connor, A.M., Tugwell, P., Wells, G.A., Elmslie, T., Jolly, E., Hollingworth, G., Mcpherson, R., Drake, E., Hopman, W. & Mackenzie, T., 1998. Randomized trial of a portable, self-administered decision aid for postmenopausal women considering long-term preventive hormone therapy. *Med Decis Making*, 18, 295-303.
- Ritchie, J. & Spencer, E., 1994. Qualitative data analysis for applied policy research. In A. Bryman & R.G. Burgess (eds.) *Analyzing qualitative data*. London: Routledge, 173-194.
- Sayers, M.S. & Newton, J.T., 2006. Patients' expectations of orthodontic treatment: part 1 - development of a questionnaire. *J Orthod*, 33, 258-69; discussion 256.
- Sayers, M.S. & Newton, J.T., 2007. Patients' expectations of orthodontic treatment: part 2--findings from a questionnaire survey. *J Orthod*, 34, 25-35.
- Schonberg, M.A., Hamel, M.B., Davis, R.B., Griggs, M.C., Wee, C.C., Fagerlin, A. & Marcantonio, E.R., 2014. Development and evaluation of a decision aid on mammography screening for women 75 years and older. *JAMA Intern Med*, 174, 417-24.
- Stacey, D., Legare, F., Col, N.F., Bennett, C.L., Barry, M.J., Eden, K.B., Holmes-Rovner, M., Llewellyn-Thomas, H., Lyddiatt, A., Thomson, R., Trevena, L. & Wu, J.H., 2014. Decision aids for people facing health treatment or screening decisions. *Cochrane Database Syst Rev*, 1, CD001431.
- Stacey, D., O'Connor, A.M., Degrasse, C. & Verma, S., 2003. Development and evaluation of a breast cancer prevention decision aid for higher-risk women. *Health Expect*, 6, 3-18.
- Turbill, E.A., Richmond, S. & Wright, J.L., 2003. Social inequality and discontinuation of orthodontic treatment: is there a link? *Eur J Orthod*, 25, 175-83.

Figures

Figure 1: Stages of development for the fixed orthodontic treatment patient decision aid (Phase 1)

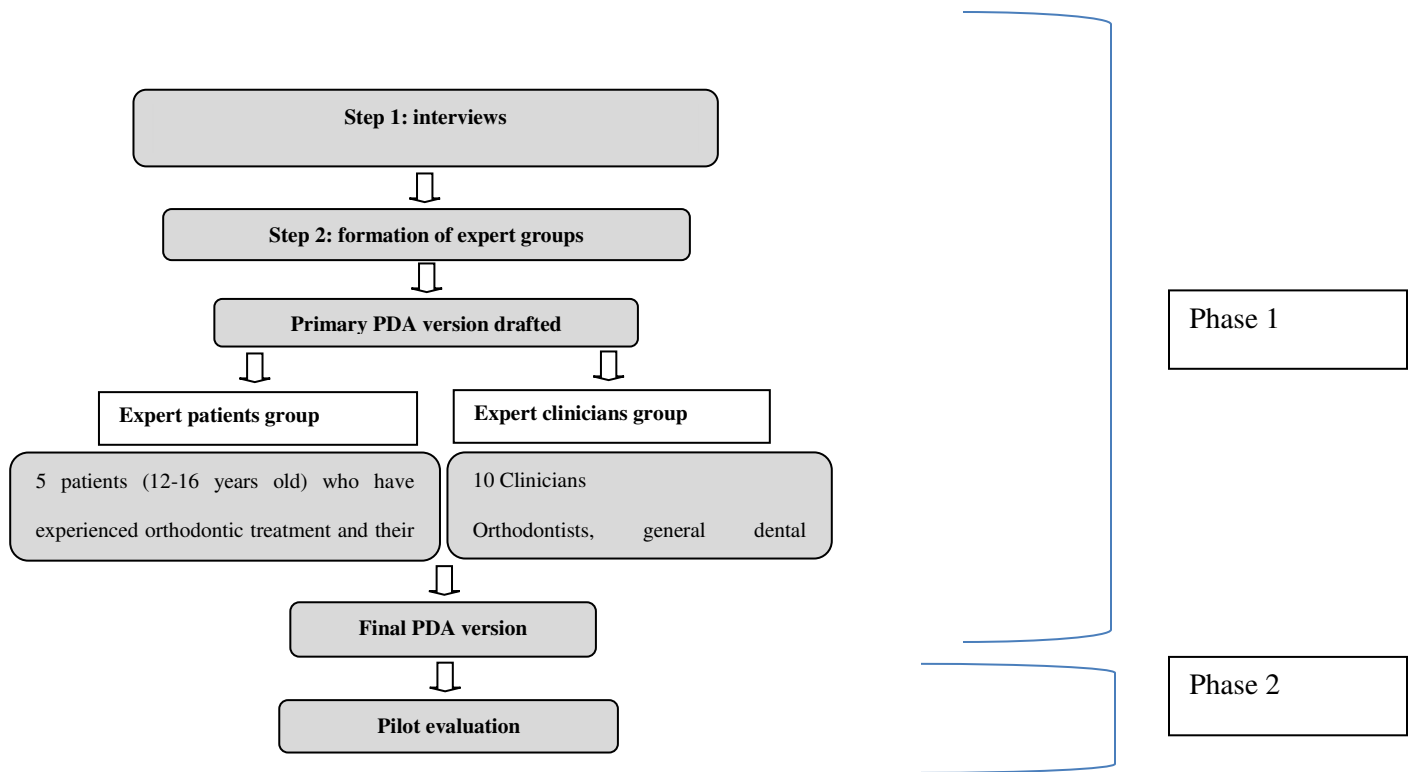
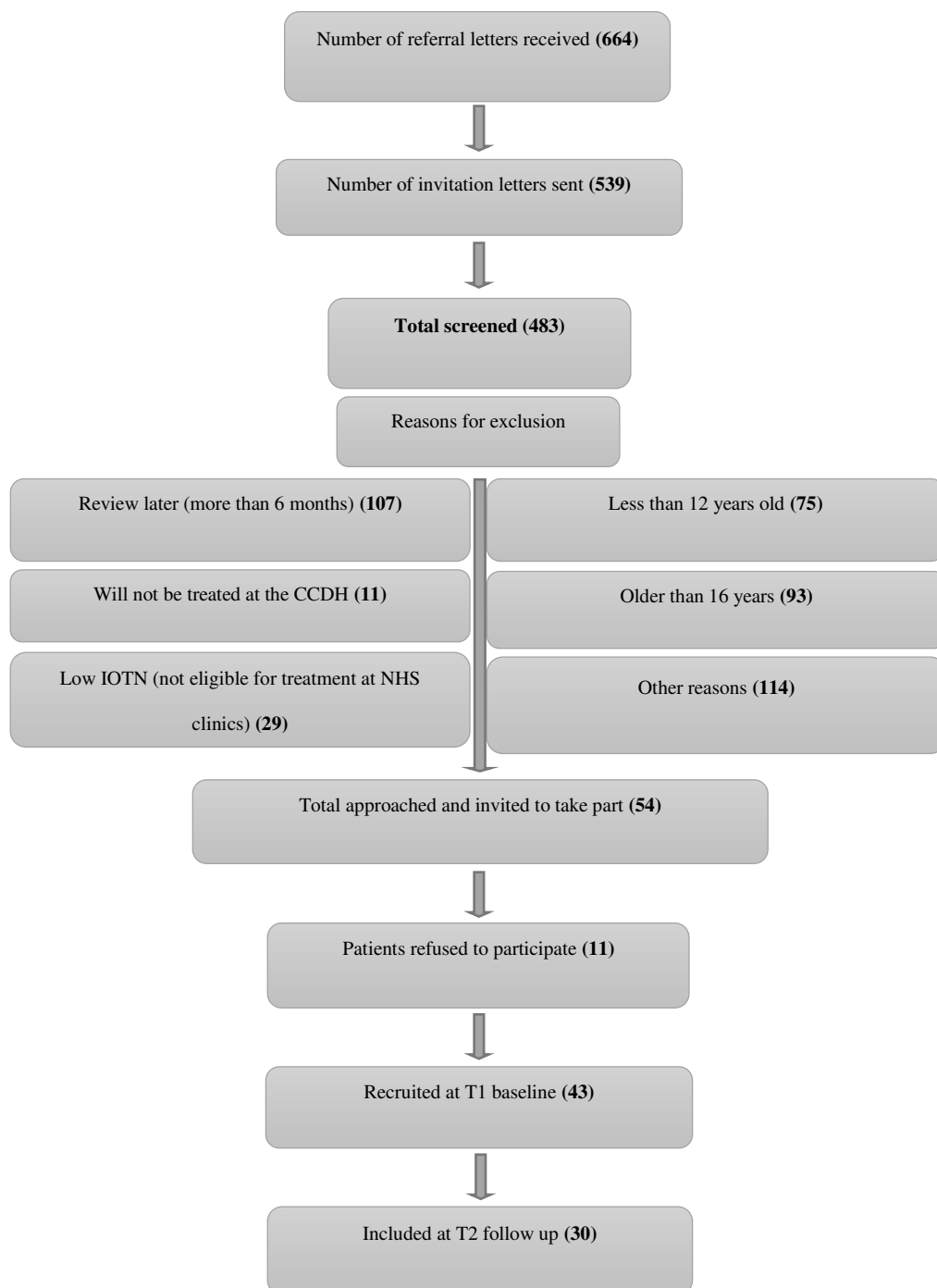


Figure 2: Flow diagram showing summary of the recruitment data for the evaluation stage of the Fixed Appliance Decision Aid (Phase 2).



Tables

Table 1: Summary data for the Decisional Conflict Scale total and subscale scores of the young people, pre- and post FADA, as well as the differences (pre-FADA score minus post-PDA score; P = Wilcoxon Signed Ranks test)

Sub-scale	Items	Pre-FADA			Post-FADA			Differences			P	Effect sizes
		Mean	SD	95% CI	Mean	SD	95% CI	Mean	SD	95% CI		
Uninformed	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	16.1	16.2	10.1 to 22.2	P<0.001	0.83
Unclear values	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	15.3	20.5	7.6 to 22.9	P=0.001	0.67
Unsupported	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	6.4	19.9	-1.0 to 13.8	P=0.066	0.30
Uncertainty	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	12.5	24.1	3.5 to 21.5	P=0.008	0.50
Ineffective decision	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	11.5	14.8	5.9 to 16.9	P<0.001	0.70
Total decisional conflict score		27.0	18.1	20.3 to 33.8	14.7	13.5	9.7 to 19.8	12.3	15.3	6.6 to 17.9	P<0.001	0.4 (0.68)

Table 2: Summary data for the Decisional Conflict Scale total and subscale scores of the parents, pre- and post FADA, as well as the differences (pre-FADA score minus post-FADA score; P = Wilcoxon Signed Ranks test)

Sub-scale	Items	Pre-FADA			Post-FADA			Differences			P	Effect sizes
		Mean	SD	95% CI	Mean	SD	95% CI	Mean	SD	95% CI		
Uninformed	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.	22.8	19.1	15.7 to 29.9	11.9	11.9	7.5 to 16.4	10.8	18.1	4.1 to 17.6	0.004	0.57
Unclear values	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).	24.4	21.4	16.4 to 32.4	13.3	14.4	7.9 to 18.7	11.1	19.4	3.9 to 18.3	0.004	0.52
Unsupported	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	7.8	16.9	1.5 to 14.1	0.020	0.45
Uncertainty	I am clear about the best choice for me. 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	4.7	20.5	-2.9 to 12.4	0.133	0.28
Ineffective decision	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.	18.8	14.7	13.3 to 24.2	10.0	12.2	5.4 to 14.6	8.8	18.9	1.7 to 15.8	0.008	0.60
Total decisional conflict score		20.9	15.9	14.9 to 26.8	12.2	11.6	7.9 to 16.6	8.6	16.6	2.5 to 14.8	0.002	0.3 (0.54)

Table 3: Summary data for the OPEQ items of the young people, pre- and post FADA, as well as the differences (pre-FADA score minus post-FADA score; P = paired samples *t* test)

Question	Pre-FADA			Post-FADA			Differences			P
	Mean	SD	95%CI	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	8.9	36.1	-4.5 to 22.4	0.184
b. Train track braces?	69.4	20.5	61.7 to 77.1	71.9	22.4	63.6 to 80.3	-2.6	25.9	-12.2 to 7.1	0.591
c. Teeth extracted (taken out)?	50.6	26.9	40.6 to 60.7	68.3	28.2	57.8 to 78.8	-17.7	33.1	-30.0 to -5.3	0.007
d. Head brace?	12.1	20.6	4.4 to 19.8	14.5	24.8	5.2 to 23.8	-2.4	29.9	-13.6 to 8.7	0.660
e. Jaw surgery?	17.7	24.9	8.4 to 27.0	23.8	32.1	11.8 to 35.8	-6.1	33.9	-18.7 to 6.5	0.332
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	-6.6	24.8	-15.8 to 2.6	0.155
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	0.4	24.9	-8.9 to 9.7	0.936
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	-5.1	21.4	-13.0 to 2.9	0.204
5. Do you expect brace treatment to restrict (limit) what you can eat or drink?	63.5	21.4	55.5 to 71.5	71.9	23.5	63.2 to 80.8	-8.4	23.1	-17.1 to 0.2	0.055
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	-5.6	32.1	-17.5 to 6.4	0.350
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	-4.2	13.5	-9.3 to 0.86	0.100
b. Produce a better smile?	78.4	22.4	70.1 to 86.8	88.9	10.7	84.9 to 92.9	-10.5	18.2	-17.3 to -3.7	0.004
c. Make it easier to eat?	55.4	27.5	45.2 to 65.7	64.7	23.9	55.8 to 73.7	-9.3	24.3	-18.3 to -0.2	0.046
d. Make it easier to speak?	54.7	28.9	43.9 to 65.5	61.6	24.5	52.4 to 70.8	-6.9	25.9	-16.6 to 2.8	0.154
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	-7.2	22.9	-15.7 to 1.3	0.095
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	-6.6	28.9	-17.4 to 4.2	0.223
g. Give you confidence socially?	73.6	23.0	65.0 to 82.2	74.7	25.5	65.2 to 84.2	-1.1	22.9	-9.6 to 7.4	0.794

Table 4: Summary data for the OPEQ items of the parents, pre- and post FADA, as well as the differences (pre-FADA score minus post-FADA score; P =paired samples *t* test)

Question	Pre-FADA			Post-FADA			Differences			P
	Mean	SD	95%CI	Mean	SD	95%CI	Mean	SD	95%CI	
1. What type of orthodontic treatment do you expect? 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	-3.8	39.1	-18.4 to 10.8	0.596
b. Train track braces?	71.9	28.0	61.1 to 81.2	81.3	17.8	74.4 to 87.2	-9.4	34.1	-22.1 to 3.3	0.142
c. Teeth extracted (taken out)?	58.8	28.9	48.8 to 68.3	70.3	26.4	60.9 to 78.9	-11.5	27.7	-21.9 to -1.1	0.031
d. Head brace?	14.0	18.8	8.0 to 20.7	14.4	17.9	8.9 to 21.2	-0.4	25.7	-9.9 to 9.2	0.938
e. Jaw surgery?	19.4	26.2	10.8 to 28.2	18.6	24.0	10.5 to 27.5	0.8	24.4	-8.4 to 9.9	0.865
2. Do you think brace treatment will give you any problems?	35.9	21.6	28.3 to 43.7	32.9	22.8	25.2 to 41.1	3.1	18.5	-3.9 to 9.9	0.373
3. Do you think wearing a brace will be painful?	51.1	21.9	43.4 to 59.1	50.7	19.0	43.9 to 57.5	0.3	22.4	-8.0 to 8.7	0.936
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	8.1	27.2	-2.1 to 18.2	0.115
5. Do you expect brace treatment to restrict (limit) what you can eat or drink?	59.0	23.7	50.4 to 66.9	53.2	24.6	44.3 to 61.5	5.8	28.2	-4.7 to 16.3	0.269
6. How you think people will react to you wearing a brace?	64.0	16.4	58.6 to 70.1	57.5	17.2	52.0 to 63.9	6.5	17.5	-0.0 to 13.0	0.051
9. Do you expect brace treatment to: a. Straighten your teeth?	84.2	12.7	79.4 to 88.3	85.9	15.6	79.6 to 90.8	-1.7	19.3	-9.0 to 5.7	0.642
b. Produce a better smile?	79.3	18.5	71.7 to 85.7	84.8	17.5	77.8 to 90.2	-5.5	22.7	-14.1 to 3.1	0.203
c. Make it easier to eat?	55.7	22.4	47.3 to 64.0	66.8	22.7	58.9 to 75.0	-11.1	30.6	-22.8 to 0.5	0.060
d. Make it easier to speak?	52.2	24.2	43.3 to 60.9	62.9	21.4	55.4 to 70.9	-10.7	28.0	-21.4 to -0.1	0.049
e. Make it easier to keep my teeth clean?	62.7	29.1	52.3 to 73.3	68.9	26.2	59.3 to 77.9	-6.3	30.8	-17.9 to 5.4	0.282
f. Improve my chances of a good career?	58.9	23.7	50.1 to 67.6	63.2	24.4	54.0 to 72.0	-4.3	28.8	-15.2 to 6.7	0.430
g. Give you confidence socially?	79.1	20.0	71.4 to 85.5	83.6	19.4	75.8 to 89.7	-4.4	25.9	-14.3 to 5.4	0.364

Table 5: Patients' and parents' perceptions of whether they had been given enough information.

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