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Background

Effective patient involvement is a fundamental aspect of shared decision-making. The NHS describes shared decision-making as a process where clinicians and patients jointly decide the optimal treatment option given the patient's personal circumstances (NHS, 2020). Using this approach when planning treatment can increase confidence, improve patient experience and health outcomes (The Health Foundation, 2013).

In orthodontics, there is often more than one suitable treatment option and treatment decisions need to be made by taking into account known risks and benefits, patient preferences and the best available evidence (Stacey et al., 2017). Patient involvement is perhaps even more important for patients undergoing orthognathic surgery, given the significant risks involved (McLeod and Gruber, 2012). The same is true with cleft lip and palate surgery, where patients and caregivers need to be aware of the extent of treatment and burden of care so they can evaluate the risk-benefit ratio (Vig and Mercado, 2015).

A variety of healthcare interventions to improve shared decision-making have been reported, targeting patients, healthcare professionals or both combined (Légaré at al., 2018). Interventions targeting patients include small-group training and empowerment sessions as well as informational tools, such as booklets and interactive digital aids (Durand et al., 2014). Patient Decision Aids (PDAs) help to facilitate shared decision-making by encouraging patients to understand their own preferences in relation to the current evidence base (Stacey et al., 2017). Interventions targeting healthcare professionals include educational materials and audits of shared decision-making skills (Légaré at al., 2018).

There are challenges in accurately evaluating patient involvement, with most outcome measures being patient-reported scales or questionnaires (Scholl et al., 2011). In general, the reporting of the methodological development and validity of instruments has been poor (Gärtner et al., 2018). Measuring improvement in patient knowledge is more straightforward, but greater knowledge does not necessarily equate to better involvement in the decision-making process (Sepucha et al., 2013). A more widely used measure is decisional conflict (Légaré at al., 2010) and changes in expectations of risks and benefits of treatment (Sepucha et al., 2013).

This review will examine the effectiveness of interventions that have been used in orthodontic, orthognathic and cleft treatment to encourage greater patient or parent involvement in treatment decisions. Describing the types of intervention and outcome measures used to date, and synthesising the key findings will enable areas for further development of this important topic.

Aim

To examine the effectiveness of interventions that aim to increase patient involvement in treatment decisions in orthodontic, orthognathic and cleft treatment, based on patient-reported outcomes and patient knowledge.

Design

Systematic review of empirical studies.

Methods

The systematic review was conducted following best practice guidance (Higgins et al., 2020) and is reported following PRISMA guidelines. A protocol for this review was registered and published with PROSPERO (The effectiveness of interventions to increase patient involvement in decision-making in orthodontics: a systematic review, CRD42020168543, published 06.07.2020).

The eligibility criteria for studies are given in Table 1. Studies with participants of any age considering or undergoing orthodontic, orthognathic and cleft lip/palate treatment were eligible. The review focussed on interventions to increase patient involvement in decision-making, such as changes to service organisation and delivery, or tools such as patient decision aids, communication aids and consultation prompts. Study design was limited to experimental studies. Given the increasing emphasis on patient involvement in care choices in the last two decades, only studies from 2000 onwards were included.

The search strategy is given in Table 2. Terms were developed using a scoping search to determine their sensitivity and specificity. OVID databases (including MEDLINE, EMBASE and EBM reviews) were searched as well as the Cochrane Central Register of Controlled Trials (CENTRAL) and WHO's International Clinical Trials Registry Platform.

Searches were performed by one reviewer (JS) and results were collected and imported into Microsoft Excel v14.7.4. References were screened by title then abstract against the eligibility criteria by two reviewers (JS and VAP) independently and in duplicate. Full text articles were obtained for studies meeting the inclusion criteria or where it was not possible to make a decision based on the abstract. Potential articles found through grey literature searches were included at this stage. Three reviewers (JS, VAP and SB) reviewed all full text articles to determine their suitability for inclusion. Excluded studies were indexed with reason for exclusion.

A data extraction form, modified from the Cochrane Public Health Group template, was used to extract data systematically from each study. Coding was piloted for suitability prior to commencing the review and developed through an iterative process until the form was judged fit for purpose. The following data items were extracted: Author, Date, Design, Setting & Country, Participants, Interventions, Comparator, Outcome, Outcome Measure, Follow-up, Key Findings. The full data extraction form is provided in the supplementary material. Data extraction was completed by one reviewer (JS) and checked for accuracy and consistency by a second and third reviewer (VAP and SB). Corrections were recorded to check for areas of ambiguity that would indicate internal inconsistency.

The risk of bias was assessed for each study by two reviewers independently (JS and SB) using the Cochrane Collaboration Risk of Bias Tool for RCTs (RoB2.0) (Sterne et al., 2019). Due to heterogeneity in study design and outcome measures, risk of bias assessment across studies and meta-analysis was not possible. Instead, a narrative synthesis was undertaken to describe:

- Characteristics of the included studies.
- Types of interventions used to increase patient involvement.
- The outcomes and the choice and validity of outcome measures.
- The overall level of evidence based on study findings and the risk of bias of included studies.

Results

Study selection

The date of the last search was 26th March 2020. Initial electronic database searches identified 1043 articles, which reduced to 962 after the removal of duplicates. Following screening of titles and abstracts, 35 full-text articles were assessed for eligibility. One further article was identified through the grey literature search. After assessment of full-text articles for eligibility, 13 studies were included in the systematic review (Figure 1).

Study characteristics

The 13 studies were all randomised controlled trials (RCTs).

Participants

Of the included studies, all but two recruited participants undergoing orthodontic treatment alone, with the majority of participants being young people (aged 9 and 18 years). Participants in one study were parents of children undergoing primary cleft palate surgery (Al-Taha et al., 2019), and in another were adults undergoing combined orthodontic and orthognathic treatment (Phillips et al., 2001). Thomson et al. (2003), Kang et al. (2009) and Pawlak et al. (2015) also included adult participants through recruitment of patient-parent pairs. Most studies (n=8) were undertaken in orthodontic departments in Dental Hospitals or District General Hospitals within the United Kingdom (UK). Of the remaining studies, four were undertaken in hospital settings in the United States of America (Al-Taha et al., 2019; Kang et al., 2009; Pawlak et al., 2015; Phillips et al., 2001) and one in UK primary schools (Anderson and Freer, 2005).

Interventions

A range of interventions were used in the studies, most frequently visual information (n=6) or written information (n=3) compared to the delivery of verbal information only (Table 3). One PDA was included (Parker et al., 2017). A form of interactive computer-based package was described as the intervention in three studies, with one being a computerised simulation. Reporting of the processes and theoretical basis for the development and testing of the interventions was variable, with only the PDA development following recognised best practice guidance using the International Patient Decision Aid Standards (IPDAS) (IPDAS Collaboration, 2019).

Outcomes

The majority of studies (n=8) measured knowledge and understanding as the primary outcome (Table 4). Of these studies, three measured recall immediately after the intervention only (Anderson and Freer, 2005; Kang et al., 2009; Pawlak et al., 2015), while one study measured after 14 days (Al-Taha et al. 2018) and four studies included a longer-term measurement (6-8 weeks post-intervention) (Thomson et al., 2003; Patel et al., 2008; Al-Silwadi et al. 2015; Ahn et al., 2019). Treatment expectations were measured in two studies but for different treatments, using different tools and at different timepoints; Nasr et al. (2011) measured orthodontic expectations immediately after the intervention, whereas Phillips et al. (2001) measured treatment expectations 2-4 weeks after a pre-surgery consultation. Patient-reported outcomes relating to decision-making included acceptability of the information delivery method (Ben Gassem et al., 2018), decisional conflict immediately after the intervention (Parker et al., 2017) and anxiety, motivation and compliance (Wright et al., 2010).

Outcome Measures

The majority (n=8) of included studies used either traditional or digital questionnaires as their outcome measure (Table 4). These varied in their style, including both open- and closed-ended questions about understanding, recall, motivation and behaviour. Of the five studies not to use questionnaires as the outcome measure, three used either telephone or face-to-face interviews to measure information recall (Kang et al., 2009; Pawlak et al., 2015; Al-Taha et al., 2018). The remaining two studies used existing tools as their outcome measures: The Treatment Evaluation Inventory (Ben Gassem et al., 2018) and Decisional Conflict Scale (Parker et al. 2017).

Key findings from the studies

Key findings from the studies are given in Table 5, grouped according to type of intervention. Three of the six studies examining the effect of visual information reported a significant difference in outcomes between intervention and comparator groups, including higher information retention (Anderson and Freer, 2005; Kang et al., 2009; Al-Silwadi et al., 2015). The remaining three studies showed no significant difference in the intervention group (Thomson et al., 2003; Pawlak et al., 2015; Ahn et al., 2019).

Of the three studies using written information as the intervention, Wright et al. (2010) reported significantly increased motivation in the intervention group four weeks after the consent appointment, although no differences were found between the groups 12 weeks later. The other two studies found no significant differences between groups (Nasr et al., 2011; Al-Taha et al., 2018). The PDA intervention reported by Parker et al. (2017) did not lead to any significant differences in levels of decisional conflict between intervention and comparator groups.

Of the three studies evaluating computer packages, one reported significantly higher levels of satisfaction in the method of information delivery in the intervention group (Ben Gassem et al., 2018) and another found significantly higher levels of information retention (Patel et al., 2008). Phillips et al. (2001) reported no significant differences in treatment expectations following a computerised treatment simulation, however, psychological distress was found to be a significant moderating factor in short-term expectations.

Quality assessment

Quality assessment for the included studies is given in Figure 2. Overall, one study was assessed as being at low risk of bias (Ben Gassem et al., 2018). A high risk of bias was noted in four studies (Phillips et al., 2001; Thomson et al., 2003; Anderson and Freer, 2005; Al-Taha et al., 2018). Some concerns with the methodology were noted in the remaining eight studies.

In general, the randomisation process was well reported. There was notable variety in the choice of interventions and outcome measures and importantly, there was generally a lack of detail in the reporting of the development and validation process. The majority of studies (n=11) did not discuss whether a protocol had been published beforehand to assess whether changes were made to the trial design once data collection had started. Where this was not clear, email contact was attempted with the authors but only four responses were received, which resulted in concerns regarding methodology.

Discussion

Key Findings

This review provides an important and timely summary of current evidence for different interventions to increase patient involvement in decision-making in orthodontics. Generally, the findings suggest that certain interventions that aim to increase patient involvement in decision-making in orthodontics, orthognathic surgery and cleft surgery may improve patient reported outcomes and patient knowledge. However, variability in the population, interventions and outcome measures make it difficult to synthesise the findings to draw specific conclusions about which interventions are most effective. The study populations varied in age, level of education and health literacy as well as clinical setting, which may impact on the best way of engaging patients in each situation.

The majority of interventions that resulted in a significant difference in the chosen outcome often included a visual element to support verbal or written information. This suggests patient engagement methods may be more successful if they do not rely on written information alone. In healthcare in general, there is often a disparity between the complexity of written health information and the literacy level of the population (Rowlands et al., 2015). In orthodontics, it has been previously reported that patient information leaflets are not easy to read for most of the population (Harwood and Harrison, 2004).

It is important that interventions are grounded in theory about the mechanism by which better engagement is expected. This will support selection of the most appropriate outcome and outcome measure. Meaningful input from healthcare users in the design and validation process was rarely reported. Joseph-William et al. (2017) suggested that a dedicated working group of patient and public representatives may help to identify the needs of patients more accurately. While steps have been taken to try and formalise the process of producing and certifying decision aids in healthcare (Joseph-Williams et al., 2014), this is still lacking for the other types of interventions reported.

There was variation in the choice of outcome measures, with only a minority adequately tested for reliability and validity. Information recall was the most common outcome, however, there is much debate about whether simply improving knowledge and recall alone actually results in a better decision-making process (Sepucha et al., 2013). Improved knowledge alone does not automatically convey understanding or correlate with effective involvement in healthcare discussions. Although effective knowledge transfer is a fundamental aspect, it is only one of the outcomes of the shared decision-making process: patient understanding of risk and how treatment options align with their own values are equally important as well as recognising a decision is to be made (Sepucha et al., 2013; Stacey et al., 2017).

Measuring patient engagement from the patients' perspectives of their experiences is advocated (Parsons et al., 2010); however, there are challenges in finding valid measures of patient engagement (Gärtner et al., 2018). A number of different measurement tools for decision-making have undergone psychometric testing (Scholl et al., 2011), such as the 9-item Shared Decision-Making Questionnaire (Kriston et al. 2010), and greater use of these in future research is recommended.

Limitations

This is an important review with robust methodology that compares favourably to the scoring criteria used in a recent review of the quality of search strategies in orthodontic systematic reviews (AlMubarak et al., 2020). However, only studies published in English were included and it is important to acknowledge that this may present a publication bias.

The wide variety of interventions and outcomes included in the review provides a useful picture of the current evidence base, but it allows for limited synthesis of results and the work is essentially a mapping review. The decision not to undertake a meta-analysis was made after extensive discussion during data synthesis and analysis. Although studies have been grouped, this is according to intervention, then separately according to outcomes and outcome measures: studies that have similar interventions do not have similar outcome measures, and studies with similar outcome measures do not have similar interventions. Equally, despite grouping interventions, there is still considerable heterogeneity within these groups. For example, in the largest intervention group of ‘visual information’, interventions vary from completing a mind map to watching regular YouTube videos.

In line with recommendations for evaluating interventions, the review was limited to experimental studies and all those included were randomised controlled trials; however, more than half of the studies were assessed as being at high risk of bias or ‘some concerns’ according to the criteria defined in this review.

Implications for research

It is difficult to make any recommendations for clinical practice based on this review, as there is insufficient high-quality evidence that any one intervention is effective in improving patient engagement in decision-making. It is important that future research uses interventions that are developed following best practice guidance, with patient involvement and a basis in decision-making theory.

NICE has recently published a standards framework for tools developed to support shared decision-making, describing the necessary process as well as essential and enhanced standards (NICE, 2021). This was developed to be used as a self-assessment tool for those commissioning, developing, and reviewing PDAs, drawing on guidance including IPDAS, and the PDA certification criteria published by Washington State Health Care Authority (2019). Similarly, measures of the effectiveness of shared decision-making should ideally be recognised and subject to psychometric testing, such as the Decisional Conflict Scale identified in one of the included papers (Scholl et al., 2011). This should help to standardise outcome measures and improve comparisons between studies.

Difficulty synthesising data from multiple studies with similar interventions, caused by heterogeneity in study outcomes, has been identified in wider medical research (Glasziou et al., 2014) as well as in orthodontics specifically (Tsichlaki et al. 2021). Research has also shown presence of outcome reporting bias in orthodontics, such that studies with registered protocols tend to show less beneficial effects (Papageorgiou et al. 2018). A lack of methodological transparency may further hinder the ability to perform meta-analyses if similar outcomes are unpublished.

Core outcome sets (COSs) have been proposed as a standardised set of outcomes in a specific area of healthcare (Tsichlaki et al., 2020), although take up in orthodontic research is currently low on the Core Outcome Measures in Effectiveness Trials (COMET) Initiative's database (www.comet-initiative.org). Ideally some consensus on the most appropriate outcomes and a COS for orthodontic decision-making trials would facilitate greater synthesis of results to improve the evidence base.

Conclusions:

- A variety of interventions have been reported to increase patient involvement in decision-making in orthodontics, with some showing improved patient-reported outcomes and patient knowledge.
- In general, the development and validation of both interventions and outcome measures are poorly reported.
- Future research requires robust development of interventions and use of appropriate, valid outcome measures to allow more reliable evaluation of engagement tools.

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Table 1: Eligibility criteria for study inclusion in the review

	Inclusion Criteria	Exclusion Criteria
Population	People considering or undergoing orthodontic, orthognathic and cleft treatment All ages	Dental professionals
Intervention	Any intervention that aims to increase patient involvement in treatment (including but not limited to patient decision aids, communications aids, consultation prompts, tools to increase patient engagement, changes in service delivery)	Any other intervention
Control	Any other intervention Existing practice	Studies with no comparator
Outcomes	Patient-reported outcomes Patient/parent knowledge Any measure of patient involvement	Clinical outcomes
Study design	Experimental: RCT, CCT	Reviews and meta-analysis Retrospective and non-controlled studies Opinion
Publication	English language Full-text available	Not available
	Published between January 2000 and the date of the last search	Published prior to 2000

Table 2: Search strategy

Data sources	Ovid (MEDLINE, EMBASE and EBM reviews) Cochrane Oral Health’s Trials Register Cochrane Central Register of Controlled Trials (CENTRAL) US National Institutes of Health Ongoing Trials Register (clinicaltrials.gov) World health Organization International Clinical Trials Registry platform (http://apps.who.int/trialsearch/)
Search terms	1. (orthodontic or orthognathic or (cleft adj1 (lip or palate)) or ((fixed or functional) adj1 appliance*) or (facemask or face-mask or (face adj1 mask))).tw. 2. (person-cent$red or patient-cent$red or (patient adj1 (expectation* or education or knowledge or decision aid* or communication)) or (informed adj1 consent) or (deliver* adj1 information) or (shared adj1 decision adj1 making)).tw. 3. 1 AND 2 4. Restricted to humans 5. Restricted to 2000 onwards 6. Restricted to English language
Grey literature	Hand searching of reference lists of relevant publications & reviews Citation searching for relevant papers identified in searches

Table 3: Summary of the interventions used to increase patient involvement in treatment decisions

Study	Intervention(s)	Control	Process for developing intervention	Reporting of validity / testing of intervention
Visual information (n=6)				
Ahn et al., 2019	Control plus 1. Pre-prepared mind map 2. Custom-made mind map	45 minute audio-visual presentation on orthodontic treatment.	Modelled from BOS leaflet. Approved by orthodontists and patients.	Mind map approved by two Consultant Orthodontists. Also shown to a group of patients who provided positive feedback about it being easy to read and understand.
Al-Silwadi et al., 2015	Control plus YouTube videos with information about five themes around oral care and fixed appliances.	Routine verbal and written patient information related to fixed appliances.	Modelled from BOS leaflet.	Not reported.
Anderson and Freer, 2005	Video information package describing orthodontic treatment process and requirements of orthodontic treatment.	Unrelated task.	Video content developed for the study based on a literature review and patient/orthodontist interviews.	Not reported.
Kang et al., 2009	1. Orthodontic case presentation and modified informed consent document 2. As above plus narrated slideshow	Orthodontic case presentation and AAO informed consent form.	Development process reported in a pilot study published as a conference abstract, but this was not accessible to review. Modelled from AAO consent document containing images and statements with audio and visual clues.	Validation process reported in a pilot study, but this was not available to review. Improved processability (presentation of information) and readability tested.
Pawlak et al., 2015	Control plus video presentation summarising 18 elements of informed consent	Customised computer slide show.	Standardised summary of a modified version of the narrated slideshow originally developed by Kang et al. (2009). General and patient-specific risks of treatment included, determined by the treating orthodontist.	Not reported.
Thomson et al., 2003	1. Written leaflet about orthodontic treatment 2. PowerPoint slideshow providing information in pictorial format	Verbal information about orthodontic treatment.	No information about development of leaflet. PowerPoint developed by scanning images adding captions.	Readability of leaflet tested using Gunning Fog. No other testing reported.

Written information (n=3)				
Al-Taha et al., 2018	Control plus pamphlet covering same information.	Verbal information about risks and complications of surgery given as standardised script.	Content based on literature review and information mirrored verbal script used.	Readability assessed using Flesch-Kincaid.
Nasr et al., 2011	Written information about orthodontic treatment – British Orthodontic Society leaflet plus colourful mind map.	Written information about fluoride – Health Foundation leaflet.	Existing leaflet used. No information given about process for developing mind map.	Not reported.
Wright et al., 2010	Verbal information plus leaflet about fixed appliances.	Verbal information about orthodontic treatment.	Content of verbal information standardised according to BOS guidelines. Information leaflet designed and illustrated to be appealing and comprehensible to children.	Piloting of information leaflet but no information given. Readability of leaflet assessed using Gunning Fog.
Patient Decision Aid (n=1)				
Parker et al., 2017	Control plus fixed appliance patient decision aid (PDA).	Standard verbal and written information about fixed appliances.	Developed using best practice guidance from IPDAS. Content based on literature review and in-depth interviews with patients.	Reported following best practice guidance from IPDAS.
Computer package (n=3)				
Ben Gassem et al., 2018	Control plus hypodontia-specific interactive educational package.	British Orthodontic Society leaflet about hypodontia.	Content based on literature review and patient interviews. Interactive package developed using educational tool.	No testing reporting.
Patel et al., 2008	Verbal information plus PowerPoint presentation with same information as leaflet but given in pictorial format.	Verbal information plus British Orthodontic Society leaflet about orthodontic treatment	'Play specialists' advised on appropriate images to be used for children.	Pilot study with 10 people aged 10-28 years to ensure speed of presentation and information consistent.
Phillips et al., 2001	Control plus individualised treatment simulation of orthognathic surgery planned by orthodontist and/or surgeon.	Video information about orthognathic surgery.	No information provided about method for producing individualised simulation.	Not reported.

Table 4: Summary of the outcomes and outcomes measures used in the studies

Study	Relevant outcome(s)	Outcome measure	Process for developing and testing outcome measure
Knowledge and understanding of treatment (n=8)			
Ahn et al., 2019	Knowledge recall 30 minutes after intervention and 6 weeks later.	Questionnaire – 13 questions, closed-ended format for uniformity of responses.	Not reported.
Al-Silwadi et al., 2015	Knowledge recall 6-8 weeks post-intervention.	Questionnaire – 15 multiple-choice questions with a single best answer.	Reported as 'piloted and amended'. No information given about pilot participants and process.
Al-Taha et al., 2018	Understanding of cleft surgery risks 14 days after consultation.	Telephone interview– blinded researcher used standardised script to ask participant to recall the specific risks of cleft. Coding system used for recalled words.	Not reported.
Anderson and Freer, 2005	Understanding of orthodontic treatment immediately after intervention.	Questionnaire – 10 questions on orthodontic treatment knowledge, further four questions related to attitudes and opinion regarding orthodontics.	Not reported.
Kang et al., 2009	Recall of orthodontic risks 45 minutes after consultation.	Face-to-face interview by trained researchers using a standardised script and questionnaire. Open-ended questions to assess recall and comprehension, with knowledge-based questions focusing on recall and scenario-based questions measuring comprehension.	Development and validation process reported in a pilot study, but this was not available to review. Researchers trained in using the interview script. Validity and testing not reported.
Patel et al., 2008	Information recall immediately after intervention and 8 weeks later.	Questionnaire – 15 questions, one open-ended free text response, 14 closed questions.	Piloted with 10 people aged 10-27 years. Amended to improve readability and reduce ambiguity.
Pawlak et al., 2015	Recall of orthodontic risks immediately after intervention.	Face-to-face interviews and a validated measurement tool to evaluate recall and comprehension. Questionnaire to record self-assessment of informed consent and an anxiety inventory.	Interview questions based on the elements of informed consent on the AAO consent form. Extensive training of researcher who scored interviews. Codebook developed and published in a separate article. Interrater reliability test included in study.
Thomson et al., 2003	Knowledge recall immediately after intervention and 8 weeks later.	Questionnaire – 14 questions with a mixture of open- and closed-ended questions.	Designed with statistician and psychologist. No testing reported.
Expectations of treatment (n=2)			

Nasr et al., 2011	Orthodontic expectations measured immediately after intervention.	Questionnaire – 10 questions with eight using a visual analogue scale and two questions using categorical response codes.	Psychometrically validated questionnaire.
Phillips et al., 2001	Treatment expectations measured 2-4 weeks after pre-surgery consultation.	Short-term expectations (STE) 20-item form and Long-term expectations (LTE) 23-item form questionnaires, with each item measured using a 7-point scale about whether it is expected to be worse or better after treatment.	Questionnaires adapted from previous specified research, but no further details of testing or validity reported.
Patient-reported outcomes relating to decision-making (n=5)			
Ben Gassem et al., 2018	Acceptability of information delivery method immediately after intervention.	Treatment Evaluation Inventory (TEI) assessing the acceptability of the intervention, consisting of 15 questions with a 5-point Likert scale format.	TEI is a validated tool.
Kang et al., 2009	Self-assessment of informed consent and anxiety 45 minutes after consultation.	Questionnaire with self-assessment of informed consent using VAS. 6-item State-Trait Anxiety Inventory (STAI-6).	Development and testing of VAS not reported. STAI-6 is an existing validated tool.
Parker et al., 2017	Decisional conflict relating to fixed appliance treatment immediately after intervention.	Decisional Conflict Scale (DCS)	DCS is a validated tool.
Pawlak et al., 2015	Self-assessment of understanding and anxiety immediately after intervention.	Questionnaire with self-assessment of understanding of risks, benefits and limitation of orthodontic treatment using VAS. 6-item State-Trait Anxiety Inventory (STAI-6).	Development and testing of VAS not reported. STAI-6 is an existing validated tool.
Wright et al., 2010	Treatment-related anxiety, motivation and apprehension measured 4 weeks and 12 weeks after consultation.	Questionnaire – 6 questions measuring anxiety based on State-Trait Anxiety Inventory, 6 questions assessing motivation using a visual analogue scale and 4 questions measuring apprehension. Questions about motivation and apprehension developed from focus group interviews.	Anxiety questions based on validated questionnaire. Questionnaire piloted but no further information given. Reproducibility testing of questionnaire included.

Table 5: Summary of the key findings related to the effectiveness of different interventions

Study	Intervention	Outcome and stated clinically important difference	Key finding
Visual information (n=6)			
Ahn et al., 2019	Addition of pre-prepared or customised mind maps to standard audio-visual information.	Change in orthodontic knowledge recall Effect size of 0.4 stated as important.	No significant difference.
Al-Silwadi et al., 2015	Addition of YouTube videos to standard verbal and written information.	Change in orthodontic knowledge recall. Difference of 1 point out of 15 (standardised difference of 0.91) considered important difference based on pilot data.	Significantly higher information retention in intervention group: Average score in the intervention group almost 1 point higher than those in the control group (95% CI 0.305-1.602).
Anderson and Freer, 2005	Video information package compared to unrelated task.	Change in knowledge and attitude of orthodontic treatment. Stated important difference was: A change of 1/10 questions for knowledge. A change of 1 point on a 10 unit analogue scale for attitude.	Knowledge: Significant mean change in questionnaire score pre/post-intervention: 1.5 in the intervention group vs -0.2 in control group. Attitude: Median change pre/post intervention was 1 point in the intervention groups vs 0 points in the control, with significant increases relating to appearance of appliances and potential compliance.
Kang et al., 2009	Case presentation plus either 1) standard AAO informed consent form (control); 2) modified consent form; 3) modified consent form plus narrated slideshow.	Change in recall of orthodontic risks. Based on previous research, an improvement in mean score of 1 point for each intervention was considered to represent improved processability.	Modified consent form plus narrated slideshow led to significantly increased patient recall, parental recall and parental comprehension. No significant differences in recall or comprehension in the modified consent form only group.
Pawlak et al., 2015	Addition of video presentation to customised computer slide show.	Change in recall of orthodontic risks. A 15% points difference was judged to be important.	No significant difference.
Thomson et al., 2003	Comparison of verbal information, written information in a leaflet and pictorial information in a slideshow.	Change in orthodontic knowledge recall. No important difference stated a priori.	Significant difference in proportion of people giving correct response for 3 of the 12 questions based on intervention; however, there was generally high recall of information in all groups regardless of intervention.
Written information (n=3)			
Al-Taha et al., 2018	Verbal information only compared to verbal and written information.	Change in understanding of cleft surgery risks. Gain of 2/9 correct answers judged to be important.	No significant difference in mean total number of risks recalled.
Nasr et al., 2011	Provision of written information about orthodontic treatment	Change in orthodontic expectations. Cohen medium effect size of 0.6 considered important.	Significant difference found only in one question. Overall, no difference between groups.

	compared to control (fluoride leaflet).		
Wright et al., 2010	Verbal information only compared to verbal and written information.	Change in treatment-related anxiety, motivation and apprehension. No important difference stated a priori.	No change in median anxiety scores. Significant increase in motivation in the intervention group immediately after consent appointment (median change difference of 6.8). No significant differences after 12 weeks.
Patient Decision Aid (n=1)			
Parker et al., 2017	Addition of patient decision aid to standard verbal and written information.	Change in decisional conflict. Difference of 9 points considered clinically relevant.	No significant difference.
Computer package (n=3)			
Ben Gassem et al., 2018	Interactive educational package compared to standard written information.	Acceptability of information delivery. Cohen medium effect size of 0.7 judged to be important.	Significantly more satisfied in intervention group (effect size 0.74).
Patel et al., 2008	PowerPoint presentation with pictorial information (visual group) compared to information leaflet only (written group)	Change in orthodontic information recall. A 10% difference between the groups considered clinically relevant.	Significantly higher information retention in visual group compared to written at both timepoints. Difference in questionnaire score was on average 1.85 when adjusted for confounders.
Phillips et al., 2001	Treatment simulation in addition to standard information provision.	Difference in treatment expectations. No important difference stated a priori.	No significant difference in expectations based on information provision method. Patient's psychological distress was a significant moderating factor in short-term expectations.