National Institute for Health and Care Excellence

Draft for consultation

Babies, children and young people's experience of healthcare

[E] Understanding the risks and benefits of healthcare decisions

NICE guideline <number>

Evidence reviews underpinning recommendations 1.1.2 to 1.1.5 and 1.3.5 to 1.3.10 and research recommendations in the NICE guideline

March 2021

Draft for consultation

These evidence reviews were developed by the National Guideline Alliance which is a part of the Royal College of Obstetricians and Gynaecologists

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Understanding the risks and benefits of healthcare decisions

Review question

What are the best ways to help children and young people and the parents and carers of babies and young children understand the risks and benefits of healthcare decisions?

Introduction

In order to be involved in decisions about their care, children and young people, and the parents and carers of babies and young children, need to be provided with information about the risks and benefits of different options so that they can weigh up the choices. Promoting an understanding of the potential effectiveness or side-effects of any intervention is an essential component of shared decision-making, and this in turn has the potential to make young people feel more involved and empowered, more in control and better prepared for treatment, improve motivation and engagement with treatment, and potentially reduce any conflict in decisions between parents, children or young people, and healthcare providers.

The quality of information provided has been shown to be a key facilitator in promoting shared decision-making in paediatric settings, although the ability to make decisions based on this information also depends on clarity with which this information is shared and an individual's capacity to utilise this information.

Information about risks and benefits can be presented in a variety of formats. The most appropriate format for an individual child or young person will vary according to a number of factors including their age and cognitive development, their medical condition and the complexity of any interventions under consideration. Information also needs to be contextualised and personalised in order to make it most relevant to the individual.

The aim of this review is to determine the best way to help children and young people and the parents and carers of babies and young children understand the risks and benefits of healthcare decisions.

Summary of the protocol

See Table 1 for a summary of the Population, Intervention, Comparison and Outcome (PICO) characteristics of this review.

Table 1: Summary of the protocol (PICO table)

Population	• People <18 years old who have experience of healthcare
	• Studies that use the views of parents or carers as proxies will be included only if they are responding on behalf of their child or charge, and
	  ○ The baby or child of the parent or carer is under 5 years-old, or
	  ○ There is a clear rationale provided as to why the study is using parents' or carers' views on and experiences of healthcare as proxies for their child.

Intervention	• Any tool (booklet, online webpage, tape, other materials, including those intended for shared decision making) used to convey information about risk or benefits of healthcare decision

	• Included tools may use any means of conveying information (e.g. graphical depictions of risk, numbers, words, video). ○ Numerical measures used in decision aid might include risks or benefits expressed in absolute terms (e.g. absolute risk difference, attributable risk) and/or in relative terms (e.g. various ratios such as risk ratio, odds ratio, hazard ratio). ○ Graphical displays of risk information might include bar charts, Cates plots, crowd figures, icon arrays, pictograms, risk ladders, risk scale or thermometer scales)
Comparison	• Different tools used to convey information about risk or benefits of healthcare decision • No information tool used (e.g. verbal information only)
Outcome	**Critical:** • Children or young people's satisfaction with information tool used, or decision made • Knowledge or understanding of risks or benefits of decision **Important:** • Adverse outcomes due to intervention • Congruence of the child or young person's decision with the decision of the person that is engaging in shared decision-making • Decisional conflict

For further details, see the review protocol in appendix A.

Methods and process

This evidence review was developed using the methods and process described in Developing NICE guidelines: the manual. Methods for this review question are described in the review protocol in appendix A and the methods supplement.

Clinical evidence

Included studies

This was a quantitative review with the aim of:

- Establishing how the risks and benefits of healthcare-relevant decisions (e.g. about treatment alternatives) should be communicated to children and young people and the parents/carers of babies and young children in order to support informed decision making.

A systematic review of the literature was conducted. Five studies were included for this review, 4 randomised controlled trials (RCTs) and 1 systematic review (Hulin 2017, Parker 2017, Robbins 2003 and Rowe 2018, Wyatt 2015).

The RCTs included the following comparisons:

- Comparison 1: a decision aid plus conventional clinical counselling versus conventional clinical counselling alone, in decisions regarding dental anaesthesia (Hulin 2017)
- Comparison 2: a decision aid plus standard information versus standard information alone, in adolescents contemplating orthodontic fixed appliances (Parker 2017)
- Comparison 3: an information booklet for new parents plus a home visit versus standard care, for minor illnesses in infants (Robbins 2003)

- Comparison 4: a novel self-help decisional tool (My Self-Help Tool) versus the Childline webpage, in adolescents who had recently self-harmed (Rowe 2018)
- Comparison 5: this systematic review included studies that investigated the effectiveness of any decision aid tool in paediatric healthcare compared to a variety of control conditions (Wyatt 2015).

The included studies are summarised in Table 2.

See the literature search strategy in appendix B and study selection flow chart in appendix C.

Excluded studies

Studies not included in this review are listed, and reasons for their exclusion are provided in appendix K.

Summary of studies included in the evidence review

Summaries of the studies that were included in this review are presented in Table 2.

Table 2: Summary of included studies

Study	Population	Intervention	Comparison	Outcomes

Hulin 2017
 	
Study design
RCT
 	
Aim of the study
To develop and pilot a decision aid to assist young people and their parents with the anaesthetic decisions (inhalation sedation, intravenous sedation or general anaesthetic) while undergoing dental treatment.
 	
UK
	N=32 children and young people
	
	Characteristics
	Characteristics only reported for total study population rather than per group.
	
	Age in years [mean (SD)]: 13 (1.71)
	Age range in years: 10-16.
	
	Gender (M/F): 16/16
		<u>Decision aid + conventional clinical counselling</u>
		Conventional clinical counselling as per control group plus an A4 paper booklet containing information on dental anaesthesia.
		
		Content was informed by qualitative interviews and focus groups with children, young people, parents/guardians and dental professionals. It contained information on the anaesthesia options available and the advantages and disadvantages of the options. An explicit values clarification exercise and a short multiple-choice quiz were also included.
			<u>Conventional clinical counselling</u>
			Given to children and young people and their parents/guardians after initial dental assessment as part of the paediatric pre-sedation service at the study hospital. Children and young people were able to use these counselling sessions to further discuss treatments and anaesthesia with healthcare professionals.
				• Critical
				  ○ Knowledge
				• Important
				  ○ Decisional conflict

Study	Population	Intervention	Comparison	Outcomes
Parker 2017 **Study design** RCT **Aim of the study** To investigate the effectiveness of a patient decision-making aid in patients considering fixed appliance orthodontic treatment when compared to traditional information provision. UK	N=72 children and young people **Characteristics** Age in years [mean (SD)]: • Decision aid: 13.1 (1.7) ○ 10-13 [n (%)]: 22 (61.1) ○ 14-16 [n (%)]: 21 (38.9) • Standard information: 13.0 (1.8) ○ 10-13 [n (%)]: 21 (60.0) ○ 14-16 [n (%)]: 14 (40.0) Gender (M/F): • Decision aid (n): 16/20 • Standard information (n): 11/24	<u>Decision aid + standard information</u> Standard information as per the control group, plus an A4 booklet patient decision aid containing information on what fixed appliances are, what they are used for and what the patient can expect from them and the overall risk and benefits. Content was informed from interviews with children and young people. A decision-making tree was also included and questions to aid the decision-making process.	<u>Standard information</u> Verbal information and patients leaflets as per their clinicians standard care, plus standardised verbal information from a study researcher on the risks and benefits of fixed appliance orthodontic treatment.	• Critical ○ None • Important ○ Decisional conflict
Robbins 2003 **Study design** RCT **Aim of the study** To investigate the effectiveness of a home visit and minor illnesses decision aid booklet for parents of infants compared to standard care. UK	N=103 parental proxies of babies **Characteristics** Age: not reported but intervention visit coincided with babies being 6 weeks old. Gender (M/F): • Decision aid (n): 25/29 • Standard care (n): 27/22	<u>Information booklet + home visit</u> A booklet on minor illness education and care options was sent to families at the beginning of the study. A home visit with a study researcher occurred when the baby was 6 weeks old, discussing childhood illnesses, information on usual illnesses, details of how to contact health centre services. Booklet information were also discussed.	<u>Standard care</u> Standard care as offered by health visitors.	• Critical ○ Knowledge • Important ○ None

Study	Population	Intervention	Comparison	Outcomes
Rowe 2018 **Study design** RCT **Aim of the study** To investigate the feasibility and acceptability of a RCT of self-harm decision aid in a school setting. UK	N=23 young people **Characteristics** Age in years [n (%)]: • Decision aid: ○ 12-15: 8 (80) ○ 16-18: 2 (20) • Childline webpage: ○ 12-15: 12 (92) ○ 16-18: 1 (8) Gender (M/F): • Decision aid (n): 4/6 • Childline webpage (n): 5/8	<u>My Self-Help Tool</u> A decision aid designed to inform young people with a history of self-harm of the difference help-seeking avenues. Users were also asked about what barriers to help-seeking were of particular concern to them (for example, confidentiality) and rated. After these questions, the aid presented users with a personalised set of help-seeking options, ranked according to acceptability to participants.	<u>Childline webpage</u> A non-interactive, static Childline webpage consisting of general information on feelings and emotions but no decision aid component.	• Critical ○ None • Important ○ Decisional conflict
Wyatt 2015 **Study design** Systematic review **Aim of the study** To investigate the various tools and techniques available to assist with implementing shared decision making in paediatric care and collate their reported effects on satisfaction, decisional conflict and knowledge using meta-analysis. Various countries	K=15 studies Range of sample size: N=22 to 509 **Characteristics** Participants: • Babies, children and young people, k=3 • Parents/guardians, k=13 • Clinicians, k=5 Format: • Electronic, k=37 • Paper, k=13 • Live sessions, k=7 • Other k=2	<u>Decision aids</u> Any tool or method designed to facilitate medical shared-decision making between babies, children and young people, their parents/carers and healthcare professionals.	<u>Control</u> Included studies were not limited by comparator groups.	• Critical ○ Satisfaction ○ Knowledge • Important ○ Decisional conflict

Study	Population	Intervention	Comparison	Outcomes

F: female; K: number of studies; M: male; N: number; RCT: randomised controlled trials; SD: standard deviation

See the full evidence tables in appendix D and the forest plots in appendix E.

Summary of the evidence

Evidence was found for 3 of the pre-defined outcomes listed in the protocol: satisfaction, knowledge and decisional conflict. No evidence was found for adverse effects or congruence of decision.

Three studies used interventions for children and young people themselves. One study compared the use of a written booklet plus conventional counselling with conventional counselling only when making a decision regarding dental anaesthesia (Hulin 2017). At follow-up, knowledge of young people was significantly higher (better) in the intervention group compared to the control group. No difference between the groups was found for decisional conflict. A second study compared the use of a booklet decision aid plus standard information with standard verbal and written information alone when making decisions about fixed appliance in orthodontic treatment (Parker 2017). No difference was found between groups for decisional conflict. The final study compared the use of an interactive My Self-Help Tool decisional aid with a static written information source (Rowe 2018). No difference in decisional conflict was found between groups. The quality of evidence for all the above results was judged to be very low.

One study used an intervention designed for parents of babies, using a home visit plus an information booklet with standard care to inform parents of childhood illnesses and the healthcare options available to them (Robbins 2003). No difference was found in measures of parental knowledge. Evidence for this study was judged to be very low to low quality.

The systematic review included studies that considered the use of a wide variety of decisional aids with a range of comparators. These decisional aids were designed for children and young people, parents and carers, or healthcare professionals (Wyatt 2015). Knowledge was significantly higher (better) and decisional conflict was significantly lower (better) when using decisional aids. No difference was found between groups in degree of satisfaction. Evidence was judged to be very low quality and should be interpreted with caution due to concerns over the suitability of meta-analysing such a heterogeneous population, differences in each studies concept of shared decision-making, and the variety of study designs included, how the format of decisional aids might affect these measures or if certain healthcare areas were more suited to decisional aids.

Quality assessment of studies included in the evidence review

See the evidence profiles in appendix F.

Evidence from reference groups and focus groups

The children and young people's reference groups and focus groups provided additional evidence for this review. A summary of the findings is presented in Table 3.

Table 3: Summary of the evidence from reference and focus groups

Age groups	• 7-11 years

	• 11-14 years
Areas covered	• Explaining risks and benefits in advance of medical procedures

Illustrative quotes	• 'If I know the risks it would make me feel better'
	• 'I want to know the risks but don't want to get scared, so could say what the risks are but then say all the things they were doing to stop the risks'
	• 'If they told you, you would be in pain you would be really worried and wouldn't want your teeth pulled out so might try to fix it yourself and not go in'
	• How should risks and benefits of having a vaccine be explained?
	  ○ 'A side effect is that you may feel sick after'
	  ○ 'When you're done you get stickers'
	  ○ 'There may be temporary side effects but I'm much more protected now'

See the full evidence summary in appendix M.

Evidence from national surveys

No evidence from the grey literature review of national surveys of children and young people's experience was identified for this review so there is no evidence summary in appendix N.

Economic evidence

Included studies

A systematic review of the economic literature was conducted but no studies were identified which were applicable to this review question. A single economic search was undertaken for all topics included in the scope of this guideline. See supplementary material 6 for details.

Excluded studies

Economic studies not included in this review are listed, and reasons for their exclusion are provided in appendix K.

Summary of studies included in the economic evidence review

No studies were identified which were applicable to this review question.

Economic model

This review question was identified as an economic priority, however, no economic modelling was undertaken because there was insufficient effectiveness data.

The committee's discussion of the evidence

Interpreting the evidence

The outcomes that matter most

When discussing the outcomes that matter most, the committee were aware that an effective decision aid has to be both acceptable and educational for children and young people, or the parents or carers of babies and young children, to ensure it is used and assists in their decision-making, and therefore satisfaction and knowledge of risks and benefits were prioritised as critical outcomes by the committee.

The committee recognised that using a decision aid incorrectly or misunderstanding the information it provided could lead to adverse outcomes and so they selected this as an important outcome. The committee also recognised that decision aids may lead to children and young people making decisions that were different to those made by others involved in the decision-making process, and therefore chose congruence as an important outcome. Finally, the committee recognised that children and young people might find it difficult to make decisions and so selected decisional conflict as an important outcome.

The quality of the evidence

The quality of each study was appraised using the Cochrane Risk of Bias tool for randomised studies Version 2. The quality of the systematic review was appraised using the Cochrane ROBIS tool for Systematic Reviews.

The overall quality of evidence was assessed using GRADE methodology and was judged as being very low to low quality. The main reason for downgrading the evidence was due to concerns about the risk of bias of included studies and imprecision in the effect estimates.

The included systematic review (Wyatt 2015) reported a meta-analysis of evidence on decision aids. The evidence was judged to be low quality due to concerns over risk of bias in the study design and indirectness in the population. As noted in the risk of bias assessment, the degree of heterogeneity of included studies was very high, and was due to a number of factors: the studies were conducted in a range of countries and various clinical settings, and most importantly the included decision aids varied widely from simple leaflets to intensive series of educational sessions. Additionally, the systematic review pooled a variety of study designs in the meta analysis (RCTs, non-randomised controlled trials and pre/post designs). Caution must therefore be taken when interpreting the results from the Wyatt 2015 systematic review, as the effects seen cannot be assigned to one particular type of decision aid.

No evidence was found for 'adverse outcomes' or 'congruence'.

Benefits and harms

The committee discussed the fact that the included studies provided evidence for a limited number of specific methods of sharing risks and benefits information with children and young people and their parents or carers, but there was not enough evidence to recommend one specific method or decision aid over another. Because of this, the committee made a research recommendation about the relative effectiveness and acceptability of different decision aids.

However, taking the evidence as a whole, there was some evidence that use of decision aids increased knowledge of risks and benefits and may reduce decisional conflict. The

committee noted that a general recommendation about using decision aids to help in shared decision-making had already been included in the guideline (based on qualitative evidence on shared decision-making). The evidence from this review therefore reinforced the validity of that recommendation.

Based on this evidence, and also on their knowledge and expertise, the committee made a recommendation that children and young people, and the parents or carers of babies and young children, should be offered information about the risks and benefits of healthcare options to allow them to make informed decisions, and agreed that this should be standard practice. The committee agreed that this information could be provided in a variety of formats. As they did not have evidence to recommend one format over another, they made recommendations relating to the principles that should be followed – for example that the information should be appropriate for the child or young person, in a format they could understand, and relevant to them. The committee also agreed that as well as providing the information, it was important that this information should be discussed, and questions answered, and what would be done to mitigate risk explained, and they made recommendations to this effect.

The data from the reference and focus groups provided more evidence that the committee used in addition to the evidence from the systematic literature review. The reference groups had considered a number of healthcare scenarios and there was a mix of views – some children and young people wanted to be informed of the risks, some were unsure and were worried that the risks would scare them, and others would not want to know the risks. Based on this evidence and their knowledge and experience, the committee made recommendations to ensure that personal preferences were taken into account, and that discussing risks and benefits might need to be phased and paced carefully so young people were not overwhelmed. The reference groups also mentioned in need for healthcare professionals to not only tell them about the risks, but also what is being done to mitigate those risks. However, the committee felt that this was already adequately covered in the recommendations they had made.

The committee agreed that, as with other discussions, children and young people might want to discuss risks and benefits without their parents or carers present and that this should be an option, and so they made a recommendation stating this.

The committee noted that the evidence from the reference groups was that it could help if measures to reduce risk could also be included in discussions about risk. The committee agreed that this reflected their experience too, and so made a recommendation relating to mitigation of risks.

There was no evidence for the outcomes of adverse events from use of decision aids, and the committee did not identify any specific harms from the evidence or from their recommendations. However, they realised it could be perceived as harmful to discuss the treatment risks with children and young people (and parents of babies and young children) as it might deter them from consenting to important treatment. However, they felt this was mitigated by their recommendations to recognise that some people may prefer not to know the risks, and that there should be opportunities to discuss concerns about risks, and what can be done to reduce risk.

Cost effectiveness and resource use

There was no existing economic evidence for this review. The committee discussed that ensuring that children and young people and the parents or carers of babies and young children are given information about the risks and benefits of healthcare options may take

more time to have the necessary discussions or additional conversations, but that in many settings it was already standard practice. The committee noted that there may be differences in costs associated with various decision aids. For example, it may be more expensive to develop and provide interactive tools then compared with written information only. However, once a decision aid is developed it could potentially be used by thousands of children, young people and the parents or carers of babies and young children and any costs of such decision aids per user will be negligible. Moreover, the use of a particular decision aid is likely to be dictated by needs of a user and additional costs, if any, will be offset by benefits associated with shared decision making and people making informed choices about their healthcare, for example, improvements in their knowledge and a reduction in decisional conflict. All other recommendations reflect current practice and are not expected to result in additional resource use.

Recommendations supported by this evidence review

This evidence review supports recommendations 1.1.2 to 1.1.5 and 1.3.5 to 1.3.10 and the research recommendation on decision aids.

References

Hulin 2017

Hulin, J., Baker, S. R., Marshman, Z., Albadri, S., Rodd, H. D., Development of a decision aid for children faced with the decision to undergo dental treatment with sedation or general anaesthesia, International Journal of Paediatric Dentistry, 27, 344-355, 2017

Parker 2017

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Robbins 2003

Robbins, H., Hundley, V., Osman, L. M., Minor illness education for parents of young children, Journal of Advanced Nursing, 44, 238-47, 2003

Rowe 2018

Rowe, Sarah L., Patel, Krisna, French, Rebecca S., Henderson, Claire, Ougrin, Dennis, Slade, Mike, Moran, Paul, Web-Based Decision Aid to Assist Help-Seeking Choices for Young People Who Self-Harm: Outcomes From a Randomized Controlled Feasibility Trial, JMIR Mental Health, 5, e10, 2018

Wyatt 2015

Wyatt, K. D., List, B., Brinkman, W. B., Prutsky Lopez, G., Asi, N., Erwin, P., Wang, Z., Domecq Garces, J. P., Montori, V. M., LeBlanc, A., Shared Decision Making in Pediatrics: A Systematic Review and Meta-analysis, Academic Pediatrics, 15, 573-583, 2015

Appendices

Appendix A – Review protocol

Review protocol for review question: What are the best ways to help children and young people and the parents and carers of babies and young children understand the risks and benefits of healthcare decisions?

Table 4: Review protocol

Field	Content
PROSPERO registration number	CRD42019159594
Review title	Explaining risks and benefits of healthcare decisions
Review question	What are the best ways to help children and young people and the parents and carers of babies and young children understand the risks and benefits of healthcare decisions?
Objective	The aim of this review is to establish how the risks and benefits of healthcare-relevant decisions (e.g. about treatment alternatives) should be communicated to children and young people and the parents/carers of babies and young children in order to support informed decision making.
Searches	The following databases will be searched: • CENTRAL • CDSR • Embase • MEDLINE • MEDLINE IN-Process • PsycINFO Searches will be restricted by: • Date: No restriction • Language of publication: English language only • Publication status: Conference abstracts will be excluded because these do not typically provide sufficient information to fully assess risk of bias • Standard exclusions filter (animal studies/low level publication types) will be applied

Field	Content
	• For each search (including economic searches), the principal database search strategy is quality assured by a second information specialist using an adaption of the PRESS 2015 Guideline Evidence-Based Checklist • A UK filter will be applied to identify relevant UK studies, and a systematic review filter will be applied to the remainder of the results to identify relevant reviews that include evidence from non-UK high-income countries If no systematic reviews of this type are identified, then a more focused search may be conducted to identify studies conducted in the following high-income countries: Australia, Austria, Belgium, Canada Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Monaco, Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, and USA
Condition or domain being studied	• Explaining risks and benefits of healthcare decisions

Population	• People <18 years-old who have experience of healthcare
	• Studies that use the views of parents or carers as proxies will be included only if they are responding on behalf of their child or charge, and
	  ○ The baby or child of the parent or carer is under-5 years-old, or
	  ○ There is a clear rationale provided as to why the study is using parents' or carers' views on and experiences of healthcare as proxies for their child.
	Note: Studies where part of the population is <18 years-old and part of the population is ≥18 years-old will only be included if >66% of the population is in the former group.

Intervention/Exposure/Test	• Any tool (booklet, online webpage, tape, other materials, including those intended for shared decision making), used to convey information about risk or benefits of healthcare decision Included tools may use any means of conveying information (e.g. graphical depictions of risk, numbers, words, video). Numerical measures used in decision aid might include risks or benefits expressed in absolute terms (e.g. absolute risk difference, attributable risk) and/or in relative terms (e.g. various ratios such as risk, odds, hazard). Graphical displays of risk information might include: • Bar chart • Cates plot • Crowd figure • Icon array • Pictogram • Risk ladder • Risk scale • Thermometer scale

Field	Content
Comparator/Reference standard/Confounding factors	• Different tools used to convey information about risk or benefits of healthcare decision • No information provided used (e.g. verbal information only)
Types of study to be included	• Systematic reviews of randomised or quasi-randomised controlled trials on use of shared decision making tools for babies, children and young people to convey information about risks and benefits of healthcare decision • Randomised or quasi-randomised controlled trials (individual or cluster) If no studies of the above type are identified, the following study types will be considered in order of priority: • Non-randomised controlled trials • Comparative observational studies published in or after 2009 • Non-comparative observational studies published in or after 2009 that adjust for at least age, sex and severity of babies, children and young people's condition Note: Cross-over controlled trials will be included but only data from the first stage will be extracted due to risk of contamination bias. Quantitative data from mixed methods studies will be included but qualitative data will not. For further details, see the algorithm in appendix H, Developing NICE guidelines: the manual.
Other exclusion criteria	STUDY DESIGN • Epidemiological reviews or reviews on associations • Non-comparative studies • Studies using qualitative methods TOPIC OF STUDY Studies on the following topics will also be excluded: • Explaining risks and benefits of non-NHS commissioned health promotion interventions Studies that focus explicitly on the following topics rather than focussing on the views on and experiences of babies, children and young people in healthcare will be excluded as they are covered by the following NICE guidelines: • Child abuse and maltreatment: ○ Child abuse and neglect (NG76) ○ Child maltreatment: when to suspect maltreatment in under 18s (CG89) • Community engagement:

Field	Content
	○ Community engagement (NG44) • Drug misuse in children and young people: ○ Alcohol: school-based interventions (PH7) ○ Alcohol-use disorders: diagnosis, assessment and management of harmful drinking and alcohol dependence (CG115) ○ Alcohol-use disorders: prevention (PH24) ○ Drug misuse prevention: targeted interventions (NG64) • End of life care for infants, children and young people with life-limiting conditions: planning and management (NG61) • Immunisations: reducing differences in uptake in under 19s (PH21) • Oral health promotion: general dental practice (NG30) • Physical activity and weight management: ○ Maternal and child nutrition (PH11) ○ Obesity prevention (CG43) ○ Physical activity for children and young people (PH17) ○ Weight management: lifestyle services for overweight or obese children and young people (PH47) • Pregnancy, including routine antenatal, intrapartum or postnatal care: ○ Antenatal and postnatal mental health: clinical management and service guidance (CG192) ○ Antenatal care for uncomplicated pregnancies (CG62) ○ Intrapartum care for healthy women and babies (CG190) ○ Intrapartum care for women with existing medical conditions or obstetric complications and their babies (NG121) ○ Multiple pregnancy: antenatal care for twin and triplet pregnancies (CG129) ○ Postnatal care up to 8 weeks after birth (CG37) ○ Pregnancy and complex social factors: a model for service provision for pregnant women with complex social factors (CG110) • Self-harm: ○ Self-harm in over 8s: long-term management (CG133) ○ Self-harm in over 8s: short-term management and prevention of recurrence (CG16) • Sexual health and contraception:

Field	Content
	○ Contraceptive services for under 25s (PH51) ○ Sexually transmitted infections and under-18 conceptions: prevention (PH3) ○ Harmful sexual behaviour among children and young people (NG55) • Smoking prevention: ○ Smoking: preventing uptake in children and young people (PH14) ○ Smoking prevention in schools (PH23) ○ Stop smoking interventions and services (NG92) • Transition from children's to adults services for young people using health or social care services (NG43)
Context	UK studies from 2009 onwards will be prioritised for decision making by the committee as those conducted in other countries may not be representative of current expectations about either services or current attitudes and behaviours of healthcare professionals. The committee presumes that due to their development, particular circumstances and/or condition, there are some topics that babies, children and young people may not be in a position to pronounce on, and that in these circumstances, it may be necessary to treat the 'indirect' views of their parents or carers as proxies for their own views on and experiences of healthcare in order to make recommendations. The guideline committee will be consulted on whether a study should be included if it is unclear why parents' or carer's views are being reported instead of their child or charge, and reasons for exclusion if appropriate will be documented. The topic about which the children and young people are talking should be generalizable to the wider healthcare context (e.g. a study on the views on and experience of communication with healthcare professionals whilst receiving chemotherapy would be included, whilst a study on experience of chemotherapy would be too narrow and not generalizable to wider healthcare context and therefore excluded). Recommendations will apply to those receiving care in all settings where NHS- or local authority- commissioned healthcare is provided (including home, school, community, hospital, specialist and transport settings). Specific recommendations for groups listed in the Equality Considerations section of the scope may be also be made as appropriate.
Primary outcomes (critical outcomes)	• Babies, children or young people's satisfaction with information tool used, or decision made • Knowledge or understanding of risks or benefits of decision (e.g. percentage of correct answers about a course of treatment)
Secondary outcomes (important outcomes)	• Adverse outcomes due to intervention (e.g. missing information, unintended messages, increased decisional conflict and anxiety) • Congruence of children or young people's decision with the decision of the person that is engaging in shared decision making • Decisional conflict

Field	Content
Data extraction (selection and coding)	• All references identified by the searches and from other sources will be uploaded into STAR and de-duplicated. Titles and abstracts of the retrieved citations will be screened to identify studies that potentially meet the inclusion criteria outlined in the review protocol. • Duplicate screening will not be undertaken for this question. • Full versions of the selected studies will be obtained for assessment. Studies that fail to meet the inclusion criteria once the full version has been checked will be excluded at this stage. Each study excluded after checking the full version will be listed, along with the reason for its exclusion. A standardised form will be used to extract data from studies, including: study reference, study characteristics (e.g. design, type of statistical analysis), participant characteristics (e.g. age, ethnicity, sex, reason for using healthcare (e.g. condition, disease), decision aid characteristics (e.g. length, duration, frequency, mode), outcomes, and risk of bias. One reviewer will extract relevant data into a standardised form, and this will be quality assessed by a senior reviewer.
Risk of bias (quality) assessment	Risk of bias of systematic reviews of quantitative studies will be assessed using the ROBIS checklist. Risk of bias of individual quantitative studies will be assessed using the preferred checklist for the relevant study design as described in Developing NICE guidelines: the manual. (e.g. Cochrane RoB tool, v.2 for RCTs or quasi-RCTs; Cochrane ROBINS-I checklist for non-randomised controlled trials and cohort studies etc). The quality assessment will be performed by one reviewer and this will be quality assessed by a senior reviewer.
Strategy for data synthesis	• Depending on the availability of the evidence, the findings will be summarised narratively or quantitatively. Where possible, meta-analyses will be conducted using Cochrane's Review Manager software. A fixed effect meta-analysis will be conducted and data will be presented as risk ratios or odds ratios for dichotomous outcomes, and mean differences or standardised mean differences for continuous outcomes. • Heterogeneity in the effect estimates of the individual studies will be assessed using the I2 statistic. I2 values of greater than 50% and 80% will be considered as serious and very serious heterogeneity, respectively. Heterogeneity will be explored as appropriate using sensitivity analyses and pre-specified subgroup analyses. If heterogeneity cannot be explained through subgroup analysis then a random effects model will be used for meta-analysis, or the data will not be pooled. • The confidence in the findings across all available evidence will be evaluated for each outcome using an adaptation of the 'Grading of Recommendations Assessment, Development and Evaluation (GRADE) toolbox' developed by the international GRADE working group: http://www.gradeworkinggroup.org/
Analysis of sub-groups	If there is sufficient data, views and experiences will be analysed separately by the following age ranges: • <1 year-old (i.e. 364 days-old or less) • ≥1 to <12 years-old (i.e. 365 days-old to 11 years and 364 days-old

Field	Content			
	• ≥12 to <18 years-old (i.e. 12 years and 0 days-old to 17 years and 364 days-old) The committee are aware that children can experience substantial cognitive and developmental change during the ages of 1 and 12, and that there may be (though not necessarily) substantive differences between children in this group depending on the topic about which they are being asked. The committee will therefore be consulted regarding whether data regarding further subgroups within this age range (e.g. 1-5, 6-11) should be used. Subgroup analysis according to any of the groups listed in the Equality Considerations section of the scope will be conducted if there is sufficient data.			
Type and method of review	☒	Intervention		
	☐	Diagnostic		
	☐	Prognostic		
	☐	Qualitative		
	☐	Epidemiologic		
	☐	Service Delivery		
	☐	Other (please specify)		
Language	English			
Country	England			
Anticipated or actual start date				
Anticipated completion date	07 April 2021			
Stage of review at time of this submission	Review stage		Started	Completed
	Preliminary searches			☒
	Piloting of the study selection process			☒
	Formal screening of search results against eligibility criteria			☒
	Data extraction			☒
	Risk of bias (quality) assessment			☒

Field	Content		
	Data analysis		☒
Named contact	**5a. Named contact** National Guideline Alliance **5b. Named contact e-mail** Infant&younghealth@nice.org.uk **5c. Organisational affiliation of the review** National Institute for Health and Care Excellence (NICE) and National Guideline Alliance		
Review team members	NGA Technical Team		
Funding sources/sponsor	This systematic review is being completed by the National Guideline Alliance, which receives funding from NICE.		
Conflicts of interest	All guideline committee members and anyone who has direct input into NICE guidelines (including the evidence review team and expert witnesses) must declare any potential conflicts of interest in line with NICE's code of practice for declaring and dealing with conflicts of interest. Any relevant interests, or changes to interests, will also be declared publicly at the start of each guideline committee meeting. Before each meeting, any potential conflicts of interest will be considered by the guideline committee Chair and a senior member of the development team. Any decisions to exclude a person from all or part of a meeting will be documented. Any changes to a member's declaration of interests will be recorded in the minutes of the meeting. Declarations of interests will be published with the final guideline.		
Collaborators	Development of this systematic review will be overseen by an advisory committee who will use the review to inform the development of evidence-based recommendations in line with section 3 of Developing NICE guidelines: the manual. Members of the guideline committee are available on the NICE website: https://www.nice.org.uk/guidance/indevelopment/gid-ng10119/documents		
Other registration details	-		
URL for published protocol	https://www.crd.york.ac.uk/prospero/display_record.php?RecordID=159594		
Dissemination plans	NICE may use a range of different methods to raise awareness of the guideline. These include standard approaches such as: • notifying registered stakeholders of publication • publicising the guideline through NICE's newsletter and alerts • issuing a press release or briefing as appropriate, posting news articles on the NICE website, using social media channels, and publicising the guideline within NICE.		

Field	Content	
Keywords	Babies; benefit; children; communication; informed decision making; experience; harm; healthcare; infants; information; risk; understanding; young people.	
Details of existing review of same topic by same authors	Not applicable	
Current review status	☒	Ongoing
	☐	Completed but not published
	☐	Completed and published
	☐	Completed, published and being updated
	☐	Discontinued
Additional information	[Provide any other information the review team feel is relevant to the registration of the review.]	
Details of final publication	www.nice.org.uk	

CDSR: Cochrane Database of Systematic Reviews; CENTRAL: Cochrane Central Register of Controlled Trials; GRADE: Grading of Recommendations Assessment, Development and Evaluation; NGA: National Guideline Alliance; NHS: National health service; NICE: National Institute for Health and Care Excellence; PRESS: peer review of electronic search strategies; RCT: randomised controlled trial; RoB: risk of bias; ROBIS: risk of bias in systematic reviews; ROBINS-I: risk of bias in non-randomized studies of interventions

Appendix B – Literature search strategies

Literature search strategies for review question: What are the best ways to help children and young people and the parents and carers of babies and young children understand the risks and benefits of healthcare decisions?

Databases: Embase/Medline/PsycINFO

Last searched on:31/07/2020

#	Searches
1	(ADOLESCENT/ or MINORS/) use ppez
2	exp ADOLESCENT/ use emez
3	(adolescen$ or teen$ or youth$ or young or juvenile? or minors or highschool$).ti,ab,jw,nw.
4	exp CHILD/
5	(child$ or schoolchild$ or "school age" or "school aged" or preschool$ or toddler$ or kid? or kindergar$ or boy? or girl?).ti,ab,jw,nw.
6	exp INFANT/
7	(infan$ or neonat$ or newborn$ or baby or babies).ti,ab,jw,nw.
8	exp PEDIATRICS/ or exp PUBERTY/
9	(p?ediatric$ or pubert$ or prepubert$ or pubescen$ or prepubescen$).ti,ab,jx,ec.
10	or/1-9
11	(Ambulance/ or Ambulance Transportation/ or Child Health Care/ or Community Care/ or Day Care/ or Dentist/ or Dental Facility/ or Pediatric Dentist/ or Dietitian/ or Emergency Care/ or Emergency Health Service/ or Emergency Ward/ or General Practice/ or Health Care/ or Health Care Delivery/ or Health Care Facility/ or Health Service/ or exp Home Care/ or Home Mental Health Care/ or Hospice/ or Hospice Care/ or exp Hospital/ or Hospital Care/ or Intensive Care Unit/ or Mental Health Care/ or Mental Health Service/ or Nursing Care/ or Newborn Care/ or Newborn Intensive Care/ or Neonatal Intensive Care Unit/ or Occupational Therapy/ or Ophthalmology/ or Orthodontics/ or exp pediatrics/ or Pediatric Intensive Care Unit/ or Pharmacy/ or exp Primary Health Care/ or Physiotherapy/ or Respite Care/ or School Health Nursing/ or exp School Health Service/ or Secondary Care Center/ or Secondary Health Care/ or "Speech and Language Rehabilitation"/ or Telemedicine/ or Tertiary Care Center/ or Tertiary Health Care/) use emez
12	(Ambulances/ or Adolescent Health Services/ or exp Child Health Services/ or Community Health Services/ or Community Pharmacy Services/ or Community Health Centers/ or Community Mental Health Centers/ or "Delivery of Health Care"/ or Dental Care for Children/ or exp Dental Health Services/ or Dentists/ or Dental Facilities/ or Emergency Medical Services/ or Emergency Service, Hospital/ or General Practice/ or Health Facilities/ or Health Services/ or Home Care Services/ or Home Care Services, Hospital-Based/ or Home Nursing/ or Hospice Care/ or Hospices/ or exp Hospitals/ or Intensive Care Units/ or Intensive Care Units, Pediatric/ or Intensive Care Units, Neonatal/ or exp Mental Health Services/ or Nutritionists/ or Occupational Therapy/ or Orthodontists/ or exp pediatrics/ or Pediatric Nursing/ or Pharmacies/ or Primary Health Care/ or Respite Care/ or exp School Health Services/ or School Nursing/ or Secondary Care/ or Telemedicine/ or Tertiary Healthcare/ or "Transportation of Patients"/) use ppez
13	(Adolescent Psychiatry/ or Community Health/ or Community Services/ or Dentists/ or Dental Health/ or Educational Psychology/ or Health Care Delivery/ or Health Care Services/ or Home Care/ or Home Visiting Programes/ or Hospice/ or exp Hospitals/ or Intensive Care/ or Language Therapy/ or exp Mental Health Services/ or Neonatal Intensive Care/ or Occupational Therapy/ or Outreach Programs/ or exp pediatrics/ or Pharmacy/ or Physical Therapy/ or Primary Health Care/ or Psychiatric Clinics/ or Psychiatric Units/ or Respite Care/ or Speech Therapy/ or Telemedicine/ or Telepsychiatry/ or Telepsychology/ or Walk In Clinics/) use psyh
14	(hospital patient/ or hospitalized adolescent/ or hospitalized child/ or hospitalized infant/ or hospitalization/ or hospital patient/ or outpatient/) use emez
15	(adolescent, hospitalized/ or child, hospitalized/ or Hospitalization/ or inpatients/ or outpatients/) use ppez
16	(hospitalized patients/ or exp hospitalization/ or outpatients/) use psyh
17	(hospital* or inpatient* or outpatient*).tw.
18	(health* adj3 (care or center* or centre* or clinic* or facility or facilities or service* or setting* or specialist*)).tw.
19	((dental or communit* or emergency or hospital* or home or intensive or high-dependen* or mental* or primary or secondary or tertiary) adj3 (care or health*)).tw.
20	(emergency adj2 room*).tw.

#	Searches
21	(ambulance* or CAMHS or dentist* or dietics or dieti?ian or hospice* or NICU or nutritionist* or orthodont* or ophthalmolog* or (outreach adj2 team*) or pharmacy or pharmacies or physio* or SCBU or SENCO or telemedicine*).tw.
22	((virtual* or online) adj2 (physician* or clinician* or doctor*)).tw.
23	(communit* adj3 (p?ediatric* or nurs*)).tw.
24	(home adj3 visit*).tw.
25	((walk-in or "urgent care") adj2 (centre* or center* or clinic* or service*)).tw.
26	"speech and language therap*".tw.
27	general practice*.tw.
28	(health* and (nursery or nurseries or school*)).tw.
29	(respite adj2 care).tw.
30	(foster care or "looked after children" or "children in care").tw.
31	or/11-30
32	exp *decision making/ use emez
33	Clinical decision making/ use emez
34	exp decision support system/ use emez
35	(Family decision making/ or Medical decision making/ or Patient decision making/ or Shared decision making/ or Ethical decision making/) use emez
36	(Clinical Decision-Making/ or decision making/ or choice behavior/ or Decision Support Systems, Clinical/ or decision support techniques/) use ppez
37	(decision making/ or decision support systems/ or choice behavior/) use psyh
38	Decision* making.tw.
39	Choice process*.tw.
40	(Choice adj2 satisfaction).tw.
41	(Decision* adj2 (model* or aid* or tool*)).tw.
42	Decisional conflict.tw.
43	(Family involvement adj2 decision*).tw.
44	Patient partnership.tw.
45	Decision* counselling.tw.
46	((shar* or inform*) adj2 (choice* or decision*)).tw.
47	(sdm and decision*).tw.
48	(Decision* adj (analys*s or support)).tw.
49	((decision* or choice*) adj3 (making* or support* or behavio?r*)).ti.
50	((patient-focused or patient-cent?red) adj2 (decision* or choice*)).tw.
51	((adolescen* or baby or babies or child* or infant* or patient* or teen* or young person*) adj3 ((attitude* or choice* or dissatisf* or expectation* or experienc* or opinion* or perceive* or perception* or perspective* or preferen* or priorit* or satisf* or thought* or view*) adj3 (Risk* or benefit*))).tw.
52	((risk* or benefit*) adj3 (communicat* or convey* or inform* or "bar chart" or "cates plot" or "crowd figure" or "icon array" or pictogram or "risk ladder" or "risk scale" or "thermometer scale")).tw.
53	((risk* or benefit*) adj3 (health* or treatment* or therap* or procedure* or medication* or surgery or surgeries) adj3 (booklet* or pamphlet* or leaflet* or book* or online* or webpage*)).tw.
54	(patient adj understanding).tw.
55	((check or clarify) adj3 understanding).tw.
56	or/32-55
57	10 and 31 and 56
58	clinical Trials as topic.sh. or (controlled clinical trial or pragmatic clinical trial or randomized controlled trial).pt. or (placebo or randomi#ed or randomly).ab. or trial.ti.
59	58 use ppez
60	crossover procedure/ or double blind procedure/ or randomized controlled trial/ or single blind procedure/ or (assign* or allocat* or crossover* or cross over* or ((doubl* or singl*) adj blind*) or factorial* or placebo* or random* or volunteer*).ti,ab.
61	60 use emez
62	clinical trials/ or randomized controlled trials/

#	Searches
63	(placebo or randomi#ed or randomly).ab. or trial.ti.
64	(assign* or allocat* or crossover* or cross over* or ((doubl* or singl*) adj blind*) or factorial* or placebo* or random* or volunteer*).ti,ab.
65	(or/62-64) use psyh
66	59 or 61 or 65
67	meta-analysis/
68	meta-analysis as topic/
69	systematic review/
70	meta-analysis/
71	(meta analy* or metanaly* or metaanaly*).ti,ab.
72	((systematic or evidence) adj2 (review* or overview*)).ti,ab.
73	((systematic* or evidence*) adj2 (review* or overview*)).ti,ab.
74	(reference list* or bibliograph* or hand search* or manual search* or relevant journals).ab.
75	(search strategy or search criteria or systematic search or study selection or data extraction).ab.
76	(search* adj4 literature).ab.
77	(medline or pubmed or cochrane or embase or psychlit or psyclit or psychinfo or psycinfo or cinahl or science citation index or bids or cancerlit).ab.
78	cochrane.jw.
79	((pool* or combined) adj2 (data or trials or studies or results)).ab.
80	((comprehensive* or integrative or systematic*) adj3 (bibliographic* or review* or literature)).ti,ab,id.
81	(meta-analy* or metaanaly* or "research synthesis").ti,ab,id.
82	(((information or data) adj3 synthesis) or (data adj2 extract*)).ti,ab,id.
83	(review adj5 (rationale or evidence)).ti,ab,id. and "Literature Review".md.
84	(cinahl or (cochrane adj3 trial*) or embase or medline or psyclit or pubmed or scopus or "sociological abstracts" or "web of science").ab.
85	("systematic review" or "meta analysis").md.
86	(or/67-68,71,73-78) use ppez
87	(or/69-72,74-79) use emez
88	(or/80-85) use psyh
89	86 or 87 or 88
90	exp United Kingdom/
91	(national health service* or nhs*).ti,ab,in,ad,cq.
92	(english not ((published or publication* or translat* or written or language* or speak* or literature or citation*) adj5 english)).ti,ab.
93	(gb or "g.b." or britain* or (british* not "british columbia") or uk or "u.k." or united kingdom* or (england* not "new england") or northern ireland* or northern irish* or scotland* or scottish* or ((wales or "south wales") not "new south wales") or welsh*).ti,ab,jx,in,ad,cq.
94	(bath or "bath's" or ((birmingham not alabama*) or ("birmingham's" not alabama*) or bradford or "bradford's" or brighton or "brighton's" or bristol or "bristol's" or carlisle* or "carlisle's" or (cambridge not (massachusetts* or boston* or harvard*)) or ("cambridge's" not (massachusetts* or boston* or harvard*)) or (canterbury not zealand*) or ("canterbury's" not zealand*) or chelmsford or "chelmsford's" or chester or "chester's" or chichester or "chichester's" or coventry or "coventry's" or derby or "derby's" or (durham not (carolina* or nc)) or ("durham's" not (carolina* or nc)) or ely or "ely's" or exeter or "exeter's" or gloucester or "gloucester's" or hereford or "hereford's" or hull or "hull's" or lancaster or "lancaster's" or leeds* or leicester or "leicester's" or (lincoln not nebraska*) or ("lincoln's" not nebraska*) or (liverpool not (new south wales* or nsw)) or ("liverpool's" not (new south wales* or nsw)) or ((london not (ontario* or ont or toronto*)) or ("london's" not (ontario* or ont or toronto*)) or manchester or "manchester's" or (newcastle not (new south wales* or nsw)) or ("newcastle's" not (new south wales* or nsw)) or norwich or "norwich's" or nottingham or "nottingham's" or oxford or "oxford's" or peterborough or "peterborough's" or plymouth or "plymouth's" or portsmouth or "portsmouth's" or preston or "preston's" or ripon or "ripon's" or salford or "salford's" or salisbury or "salisbury's" or sheffield or "sheffield's" or southampton or "southampton's" or st albans or stoke or "stoke's" or sunderland or "sunderland's" or truro or "truro's" or wakefield or "wakefield's" or wells or westminster or "westminster's" or winchester or "winchester's" or wolverhampton or "wolverhampton's" or (worcester not (massachusetts* or boston* or harvard*)) or ("worcester's" not (massachusetts* or boston* or harvard*)) or (york not ("new york*" or ny or ontario* or ont or toronto*)) or ("york's" not ("new york*" or ny or ontario* or ont or toronto*))))).ti,ab,in,ad,cq.
95	(bangor or "bangor's" or cardiff or "cardiff's" or newport or "newport's" or st asaph or "st asaph's" or st davids or swansea or "swansea's").ti,ab,in,ad,cq.

#	Searches
96	(aberdeen or "aberdeen's" or dundee or "dundee's" or edinburgh or "edinburgh's" or glasgow or "glasgow's" or inverness or (perth not australia*) or ("perth's" not australia*) or stirling or "stirling's").ti,ab,in,ad,cq.
97	(armagh or "armagh's" or belfast or "belfast's" or lisburn or "lisburn's" or londonderry or "londonderry's" or derry or "derry's" or newry or "newry's").ti,ab,in,ad,cq.
98	or/90-97
99	((exp africa/ or exp americas/ or exp antarctic regions/ or exp arctic regions/ or exp asia/ or exp oceania/) not (exp united kingdom/ or europe/)) use ppez
100	((exp "arctic and antarctic"/ or exp oceanic regions/ or exp western hemisphere/ or exp africa/ or exp asia/ or exp "australia and new zealand"/) not (exp united kingdom/ or europe/)) use emez
101	99 or 100
102	98 not 101
103	57 and 66 and 102
104	57 and 89
105	103 or 104
106	Letter/ use ppez
107	letter.pt. or letter/ use emez
108	note.pt.
109	editorial.pt.
110	Editorial/ use ppez
111	News/ use ppez
112	news media/ use psyh
113	exp Historical Article/ use ppez
114	Anecdotes as Topic/ use ppez
115	Comment/ use ppez
116	Case Report/ use ppez
117	case report/ or case study/ use emez
118	Case report/ use psyh
119	(letter or comment*).ti.
120	or/106-119
121	randomized controlled trial/ use ppez
122	randomized controlled trial/ use emez
123	random*.ti,ab.
124	cohort studies/ use ppez
125	cohort analysis/ use emez
126	cohort analysis/ use psyh
127	case-control studies/ use ppez
128	case control study/ use emez
129	or/121-128
130	120 not 129
131	animals/ not humans/ use ppez
132	animal/ not human/ use emez
133	nonhuman/ use emez
134	"primates (nonhuman)"/
135	exp Animals, Laboratory/ use ppez
136	exp Animal Experimentation/ use ppez
137	exp Animal Experiment/ use emez
138	exp Experimental Animal/ use emez
139	animal research/ use psyh
140	exp Models, Animal/ use ppez
141	animal model/ use emez
142	animal models/ use psyh

#	Searches
143	exp Rodentia/ use ppez
144	exp Rodent/ use emez
145	rodents/ use psyh
146	(rat or rats or mouse or mice).ti.
147	or/130-146
148	105 not 147
149	remove duplicates from 148

1 **Database: Cochrane Library**

2 Last searched on: 31/07/2020

#	Searches
1	MeSH descriptor: [Adolescent] this term only
2	MeSH descriptor: [Minors] this term only
3	(adolescen* or teen* or youth* or young or juvenile* or minors or highschool*):ti,ab
4	MeSH descriptor: [Child] explode all trees
5	(child* or schoolchild* or "school age" or "school aged" or preschool* or toddler* or kid* or kindergar* or boy* or girl*):ti,ab
6	MeSH descriptor: [Infant] explode all trees
7	(infan* or neonat* or newborn* or baby or babies):ti,ab
8	MeSH descriptor: [Pediatrics] explode all trees
9	MeSH descriptor: [Puberty] explode all trees
10	(p*ediatric* or pubert* or prepubert* or pubescen* or prepubescen*):ti,ab
11	#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10
12	MeSH descriptor: [Ambulances] this term only
13	MeSH descriptor: [Adolescent Health Services] this term only
14	MeSH descriptor: [Child Health Services] this term only
15	MeSH descriptor: [Community Health Services] this term only
16	MeSH descriptor: [Community Pharmacy Services] this term only
17	MeSH descriptor: [Community Health Centers] this term only
18	MeSH descriptor: [Community Mental Health Centers] this term only
19	MeSH descriptor: [Delivery of Health Care] this term only
20	MeSH descriptor: [Dental Care for Children] this term only
21	MeSH descriptor: [Dental Health Services] explode all trees
22	MeSH descriptor: [Dentists] this term only
23	MeSH descriptor: [Dental Facilities] this term only
24	MeSH descriptor: [Emergency Medical Services] this term only
25	MeSH descriptor: [Emergency Service, Hospital] this term only
26	MeSH descriptor: [General Practice] this term only
27	MeSH descriptor: [Health Facilities] this term only
28	MeSH descriptor: [Health Services] this term only
29	MeSH descriptor: [Home Care Services] this term only
30	MeSH descriptor: [Home Care Services, Hospital-Based] this term only
31	MeSH descriptor: [Home Nursing] this term only
32	MeSH descriptor: [Hospice Care] this term only
33	MeSH descriptor: [Hospices] this term only
34	MeSH descriptor: [Hospitals] explode all trees
35	MeSH descriptor: [Intensive Care Units] this term only
36	MeSH descriptor: [Intensive Care Units, Pediatric] this term only
37	MeSH descriptor: [Intensive Care Units, Neonatal] this term only

#	Searches
38	MeSH descriptor: [Mental Health Services] explode all trees
39	MeSH descriptor: [Nutritionists] this term only
40	MeSH descriptor: [Occupational Therapy] this term only
41	MeSH descriptor: [Orthodontists] this term only
42	MeSH descriptor: [Pediatrics] explode all trees
43	MeSH descriptor: [Pediatric Nursing] this term only
44	MeSH descriptor: [Pharmacies] this term only
45	MeSH descriptor: [Primary Health Care] this term only
46	MeSH descriptor: [Respite Care] this term only
47	MeSH descriptor: [School Health Services] explode all trees
48	MeSH descriptor: [School Nursing] this term only
49	MeSH descriptor: [Secondary Care] this term only
50	MeSH descriptor: [Telemedicine] this term only
51	MeSH descriptor: [Tertiary Healthcare] this term only
52	MeSH descriptor: [Transportation of Patients] this term only
53	MeSH descriptor: [Adolescent, Hospitalized] this term only
54	MeSH descriptor: [Child, Hospitalized] this term only
55	MeSH descriptor: [Hospitalization] this term only
56	MeSH descriptor: [Inpatients] this term only
57	MeSH descriptor: [Outpatients] this term only
58	(hospital* or inpatient* or outpatient*):ti,ab
59	(health* near/3 (care or center* or centre* or clinic* or facility or facilities or service* or setting* or specialist*)):ti,ab
60	((dental or communit* or emergency or hospital* or home or intensive or high-dependen* or mental* or primary or secondary or tertiary) near/3 (care or health*)):ti,ab
61	(emergency near/2 room*):ti,ab
62	(ambulance* or CAMHS or dentist* or dietics or dieti*ian or hospice* or NICU or nutritionist* or orthodont* or ophthalmolog* or (outreach near/2 team*) or pharmacy or pharmacies or physio* or SCBU or SENCO or telemedicine*):ti,ab
63	((virtual* or online) near/2 (physician* or clinician* or doctor*)):ti,ab
64	(communit* near/3 (p?ediatric* or nurs*)):ti,ab
65	(home near/3 visit*):ti,ab
66	((walk-in or "urgent care") near/2 (centre* or center* or clinic* or service*)):ti,ab
67	("speech and language therap*"):ti,ab
68	(general practice*):ti,ab
69	health* and (nursery or nurseries or school*):ti,ab
70	(respite near/2 care):ti,ab
71	(foster care or looked after children or children in care):ti,ab
72	#12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22 OR #23 OR #24 OR #25 OR #26 OR #27 OR #28 OR #29 OR #30 OR #31 OR #32 OR #33 OR #34 OR #35 OR #36 OR #37 OR #38 OR #39 OR #40 OR #41 OR #42 OR #43 OR #44 OR #45 OR #46 OR #47 OR #48 OR #49 OR #50 OR #51 OR #52 OR #53 OR #54 OR #55 OR #56 OR #57 OR #58 OR #59 OR #60 OR #61 OR #62 OR #63 OR #64 OR #65 OR #66 OR #67 OR #68 OR #69 OR #70 OR #71
73	MeSH descriptor: [Clinical Decision-Making] this term only
74	MeSH descriptor: [Decision Making] this term only
75	MeSH descriptor: [Choice Behavior] this term only
76	MeSH descriptor: [Decision Support Systems, Clinical] this term only
77	MeSH descriptor: [Decision Support Techniques] this term only
78	(Decision* making):ti,ab
79	(Choice process*):ti,ab
80	(Choice near/2 satisfaction):ti,ab
81	(Decision* near/2 (model* or aid* or tool*)):ti,ab
82	(Decisional conflict):ti,ab

#	Searches
83	(Family involvement near/2 decision*):ti,ab
84	(Patient partnership):ti,ab
85	(Decision* counselling):ti,ab
86	((shar* or inform*) near/2 (choice* or decision*)):ti,ab
87	(sdm and decision*):ti,ab
88	(Decision* near (analys*s or support)):ti,ab
89	((decision* or choice*) near/3 (making* or support* or behavio?r*)):ti
90	((patient-focused or patient-cent?red) near/2 (decision* or choice*)):ti,ab
91	((adolescen* or baby or babies or child* or infant* or patient* or teen* or young person*) near/3 ((attitude* or choice* or dissatisf* or expectation* or experienc* or opinion* or perceive* or perception* or perspective* or preferen* or priorit* or satisf* or thought* or view*) near/3 (Risk* or benefit*))):ti,ab
92	((risk* or benefit*) near/3 (communicat* or present* or convey* or inform* or "bar chart" or "cates plot" or "crowd figure" or "icon array" or pictogram or "risk ladder" or "risk scale" or "thermometer scale")):ti,ab
93	((risk* or benefit*) near/3 (health* or treatment* or therap* or procedure* or medication* or surgery or surgeries) near/3 (booklet* or pamphlet* or leaflet* or book* or online* or webpage*)):ti,ab
94	(patient near understanding):ti,ab
95	((check or clarify) near/3 understanding):ti,ab
96	#73 OR #74 OR #75 OR #76 OR #77 OR #78 OR #79 OR #80 OR #81 OR #82 OR #83 OR #84 OR #85 OR #86 OR #87 OR #88 OR #89 OR #90 OR #91 OR #92 OR #93 OR #94 OR #95
97	#11 AND #72 AND #96
98	MeSH descriptor: [United Kingdom] explode all trees
99	national health service* or nhs*:ti,ab,kw
100	(english not ((published or publication* or translat* or written or language* or speak* or literature or citation*) near/5 english)):ti,ab,kw
101	(gb or "g.b." or britain* or (british* not "british columbia") or uk or "u.k." or united kingdom* or (england* not "new england") or northern ireland* or northern irish* or scotland* or scottish* or ((wales or "south wales") not "new south wales") or welsh*):ti,ab,kw
102	(gb or "g.b." or britain* or (british* not "british columbia") or uk or "u.k." or united kingdom* or (england* not "new england") or northern ireland* or northern irish* or scotland* or scottish* or ((wales or "south wales") not "new south wales") or welsh*):so
103	(bath or "bath's" or ((birmingham not alabama*) or ("birmingham's" not alabama*) or bradford or "bradford's" or brighton or "brighton's" or bristol or "bristol's" or carlisle* or "carlisle's" or (cambridge not (massachusetts* or boston* or harvard*)) or ("cambridge's" not (massachusetts* or boston* or harvard*)) or (canterbury not zealand*) or ("canterbury's" not zealand*) or chelmsford or "chelmsford's" or chester or "chester's" or chichester or "chichester's" or coventry or "coventry's" or derby or "derby's" or (durham not (carolina* or nc)) or ("durham's" not (carolina* or nc)) or ely or "ely's" or exeter or "exeter's" or gloucester or "gloucester's" or hereford or "hereford's" or hull or "hull's" or lancaster or "lancaster's" or leeds* or leicester or "leicester's" or (lincoln not nebraska*) or ("lincoln's" not nebraska*) or (liverpool not (new south wales* or nsw)) or ("liverpool's" not (new south wales* or nsw)) or ((london not (ontario* or ont or toronto*)) or ("london's" not (ontario* or ont or toronto*)) or manchester or "manchester's" or (newcastle not (new south wales* or nsw)) or ("newcastle's" not (new south wales* or nsw)) or norwich or "norwich's" or nottingham or "nottingham's" or oxford or "oxford's" or peterborough or "peterborough's" or plymouth or "plymouth's" or portsmouth or "portsmouth's" or preston or "preston's" or ripon or "ripon's" or salford or "salford's" or salisbury or "salisbury's" or sheffield or "sheffield's" or southampton or "southampton's" or st albans or stoke or "stoke's" or sunderland or "sunderland's" or truro or "truro's" or wakefield or "wakefield's" or wells or westminster or "westminster's" or winchester or "winchester's" or wolverhampton or "wolverhampton's" or (worcester not (massachusetts* or boston* or harvard*)) or ("worcester's" not (massachusetts* or boston* or harvard*)) or (york not ("new york*" or ny or ontario* or ont or toronto*)) or ("york's" not ("new york*" or ny or ontario* or ont or toronto*))))):ti,ab,kw
104	(bangor or "bangor's" or cardiff or "cardiff's" or newport or "newport's" or st asaph or "st asaph's" or st davids or swansea or "swansea's"):ti,ab,kw
105	(aberdeen or "aberdeen's" or dundee or "dundee's" or edinburgh or "edinburgh's" or glasgow or "glasgow's" or inverness or (perth not australia*) or ("perth's" not australia*) or stirling or "stirling's"):ti,ab,kw
106	armagh or "armagh's" or belfast or "belfast's" or lisburn or "lisburn's" or londonderry or "londonderry's" or derry or "derry's" or newry or "newry's":ti,ab,kw
107	#99 OR #100 OR #101 OR #102 OR #103 OR #104 OR #105 OR #106
108	MeSH descriptor: [Africa] explode all trees
109	MeSH descriptor: [Americas] explode all trees
110	MeSH descriptor: [Antarctic Regions] explode all trees
111	MeSH descriptor: [Arctic Regions] explode all trees

#	Searches
112	MeSH descriptor: [Asia] explode all trees
113	MeSH descriptor: [Oceania] explode all trees
114	#108 OR #109 OR #110 OR #111 OR #112 OR #113
115	MeSH descriptor: [United Kingdom] explode all trees
116	MeSH descriptor: [Europe] explode all trees
117	#115 OR #116
118	#114 not #117
119	#107 not #118
120	#97 AND #119

1

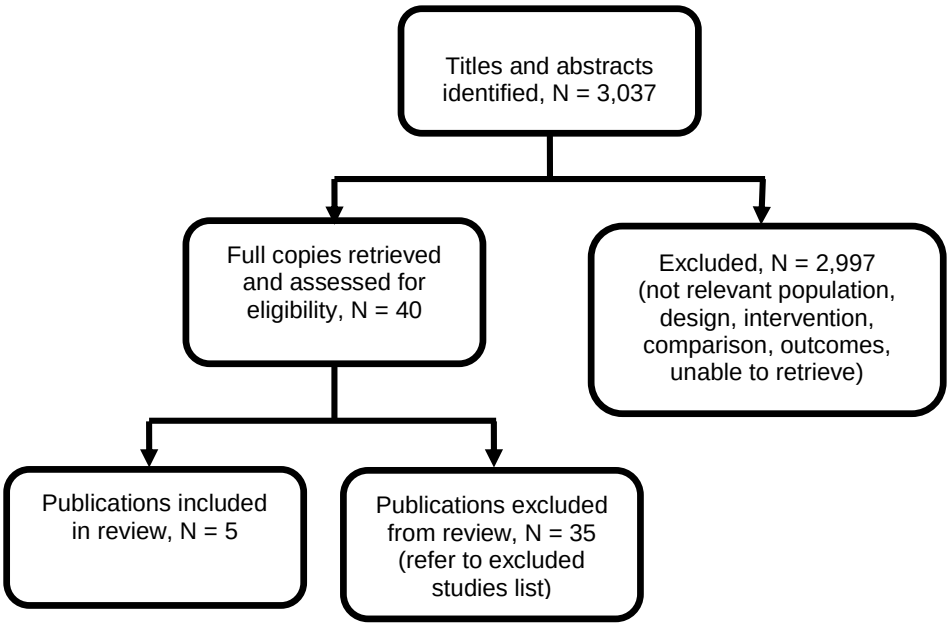
2

3

Appendix C – Clinical evidence study selection

Study selection for: What are the best ways to help children and young people and the parents and carers of babies and young children understand the risks and benefits of healthcare decisions?

Figure 1: Study selection flow chart



Appendix D – Clinical evidence tables

Evidence tables for review question: What are the best ways to help children and young people and the parents and carers of babies and young children understand the risks and benefits of healthcare decisions?

Table 5: Evidence tables

Study details	Participants	Interventions	Outcomes and Results	Limitations
Full citation Hulin, J., Baker, S. R., Marshman, Z., Albadri, S., Rodd, H. D., Development of a decision aid for children faced with the decision to undergo dental treatment with sedation or general anaesthesia, International journal of paediatric dentistry, 27, 344-355, 2017 **Ref Id** 989815 **Country/ies where the study was carried out** UK **Study type** RCT **Aim of the study**	**Sample size** N (randomised)=32 children and young people Decision aid: 16 * Conventional counselling: 16 * * Not explicitly reported but assuming equal distribution N (analysed): not explicitly stated but assuming same as number randomised. **Characteristics** *Characteristics only reported for total study population rather than per group.* Age in years [Mean (SD)]: 13 (1.71)	**Interventions** • *Intervention group: Decision aid + conventional clinical counselling*. Conventional clinical counselling as per control group. The decision aid was an A4 paper booklet designed using the Ottawa Personal Decision Guide as a template and with content informed by qualitative interviews and focus groups with babies, children and young people, parents/guardians and dental professionals. The booklet contained a description of the surgery relating to the decision of anaesthesia and the options available before going on to describe the advantages and disadvantages of the options. An explicit values clarification exercise to help patients identify their individual values attached to each option and a short multiple-choice quiz to help re-enforce some key-	**Results** *Knowledge [mean (SD)]* Scale 0 (worst) – 15 (better). At follow-up: • Decision aid + counselling: 9.93 (2.97) • Counselling: 6.59 (3.18) • Significantly higher (better) in intervention group (p=0.01, independent t-test) *Decisional conflict: total [mean (SD)]* Scale 0 (no decisional conflict) – 100 (high decision conflict). At follow-up: • Decision aid + counselling: 13.00 (18.01) • Counselling: 20.00 (18.71) • No significant difference between groups (p=0.15, Mann-Whitney U-test)	**Limitations** **Risk of bias assessed using the revised Cochrane risk of bias tool (RoB 2)** Domain 1: Risk of bias arising from the randomization process 1.1 Was the allocation sequence random? NI - Study simply states participants were randomised. 1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions? NI. 1.3 Did baseline differences between intervention groups suggest a problem with the randomization process? NI - Brief details of characteristics given but not compared statistically or presented. *Risk-of-bias judgement:* Some concerns. Domain 2: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention) 2.1. Were participants aware of their assigned intervention

Study details	Participants	Interventions	Outcomes and Results	Limitations
To develop and pilot a decision aid to assist young people and their parents with the anaesthetic decisions (inhalation sedation, intravenous sedation or general anaesthetic) while undergoing dental treatment. **Study dates** May 2014 - January 2015 **Source of funding** This study received funding from the Society for the Advancement of Anaesthesia in Dentistry.	• Age range in years: 10-16. Gender (M/F): 16/16 Ethnicity (White British/White Irish/Other): 31/1/0 **Inclusion criteria** Not reported. • However, article does mention that participants were recruited from sample of new patients being referred to study dental hospital and are potentially needing sedation. The hospital does not accept patients below 10 years old. **Exclusion criteria** Not reported.	features of options and allow patients to determine their level of knowledge was also included. This aid was primarily designed to be used by babies, children and young people and their parents in their home, but it was encouraged for them to bring it with them to consultations as a discussion aid. • *Control group: Conventional clinical counselling.* Given to patients and their parents/guardians after initial assessment at a pre-sedation or pre-general anaesthetic assessment clinic as part of the paediatric sedation service at the study hospital. Counselling clinics provide a forum to further discuss treatments and anaesthesia with a healthcare professional prior to babies, children and young people giving their choice of anaesthesia.	*Decisional conflict: informed sub-scale [mean (SD)]* Scale 0 (no decisional conflict) – 100 (high decision conflict). At follow-up: • Decision aid + counselling: 20.00 (31.62) • Counselling: 29.41 (36.58) • No significant difference between groups (p=0.44, Mann-Whitney U-test) *Decisional conflict: values clarity sub-scale [mean (SD)]* Scale 0 (no decisional conflict) – 100 (high decision conflict). At follow-up: • Decision aid + counselling: 20.00 (33.00) • Counselling: 26.47 (25.72) • No significant difference between groups (p=0.33, Mann-Whitney U-test) *Decisional conflict: support sub-scale [mean (SD)]* Scale 0 (no decisional conflict) – 100 (high decision conflict).	during the trial? NI. 2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial? NI. 2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the experimental context? PN - No deviations from protocol and no adverse effects reported. 2.4. If Y/PY to 2.3: Were these deviations from intended intervention balanced between groups? NA. 2.5 If No/PN/NI to 2.4: Were these deviations likely to have affected the outcome? NA. 2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention? Y - Intention to treat. 2.7 If No/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized? NA. *Risk-of-bias judgement:* Some concerns. <u>Domain 3: Missing outcome data</u> 3.1 Were data for this outcome available for all, or nearly all, participants randomized? PY - Not explicitly stated but

Study details	Participants	Interventions	Outcomes and Results	Limitations
			At follow-up: • Decision aid + counselling: 6.67 (12.28) • Counselling: 7.84 (13.33) • No significant difference between groups (p=0.90, Mann-Whitney U-test) *Decisional conflict: uncertainty sub-scale [mean (SD)]* Scale 0 (no decisional conflict) – 100 (high decision conflict). At follow-up: • Decision aid + counselling: 5 (10.35) • Counselling: 17.65 (30.32) • No significant difference between groups (p=0.28, Mann-Whitney U-test)	assumed data available for all participants and no follow-up period. 3.2 If No/PN/NI to 3.1: Is there evidence that the result was not biased by missing outcome data? NA. 3.3 If No/PN to 3.2: Could missingness in the outcome depend on its true value? NA. 3.4 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value? NA. *Risk-of-bias judgement:* Low risk. <u>Domain 4: Risk of bias in measurement of the outcome</u> 4.1 Was the method of measuring the outcome inappropriate? N. 4.2 Could measurement or ascertainment of the outcome have differed between intervention groups? PN - All patients completed and returned their questionnaires prior to appointment to discuss anaesthesia. 4.3 If No/PN/NI to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants? NI - Self-reported outcomes. 4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention

Study details	Participants	Interventions	Outcomes and Results	Limitations
				received? Y - Subjective measurement. 4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received? PN - High levels of belief in decision aid may influence responses but each group received some level of face-to-face information with a healthcare professional. *Risk-of-bias judgement:* Some concerns. <u>Domain 5: Risk of bias in selection of the reported result</u> 5.1 Were the data that produced this result analysed in accordance with a pre-specified analysis plan that was finalized before unblinded outcome data were available for analysis? NI. Is the numerical result being assessed likely to have been selected, on the basis of the results, from... 5.2. ... multiple outcome measurements (e.g. scales, definitions, time points) within the outcome domain? PN. 5.3 ... multiple analyses of the data? PN. *Risk-of-bias judgement*: Some concerns. <u>Overall risk of bias</u> *High risk.* **Other information**

Study details	Participants	Interventions	Outcomes and Results	Limitations
				None.
Full citation Parker, K., Cunningham, S. J., Petrie, A., Ryan, F. S., Randomized controlled trial of a patient decision-making aid for orthodontics, American journal of orthodontics and dentofacial orthopedics : official publication of the American Association of Orthodontists, its constituent societies, and the American Board of Orthodontics, 152, 154-160, 2017 **Ref Id** 1168398 **Country/ies where the study was carried out** UK **Study type** RCT **Aim of the study** To investigate the effectiveness of a	**Sample size** N (randomised)=72 children and young people • Decision aid (n): 36 • Standard information (n): 36 N (analysed)=71 children and young people • Decision aid (n): 35 • Standard information (n): 36 **Characteristics** Age in years [Mean (SD)]: • Decision aid: 13.1 (1.7) ○ 10-13 [n (%)]: 22 (61.1) ○ 14-16 [n (%)]: 21 (38.9) • Standard information: 13.0 (1.8) ○ 10-13 [n (%)]: 21 (60.0) ○ 14-16 [n (%)]: 14 (40.0) Gender (M/F):	**Interventions** • *Intervention group: Decision aid + standard information.* Standard information as per the control group plus a patient decision aid which participants were able to discuss with the researcher. The decision aid was a 4-sided A4 booklet which included information on what fixed appliances are, what they are used for and what the patient can expect from them and the overall risk and benefits. A decision-making tree was also included to aid decision-making and questions to aid the process. Information was collected from evidence-based literature and interviews with babies, children and young people undergoing/recently undergone fixed appliance treatment. Particularly, interviewees were asked about their knowledge of fixed appliance treatment risk and benefits, and which were the most important to them. • *Control group: Standard information.* Participants received verbal information and patients leaflets as per their clinicians standard care.	**Results** *Decisional conflict: total [median (range)]* Scale 0 (no decisional conflict) – 100 (high decision conflict). At follow-up: • Decision aid: 15.63 (0.00-37.50) • Standard information: 19.53 (0.00-40.60) • No significant difference between 2 groups [median (95% CI)]: 3.90 (-4.30 to 12.11) (p=0.32, Mann-Whitney U-test) *Decisional conflict: uncertainty sub-scale [median (range)]* Scale 0 (no decisional conflict) – 100 (high decision conflict). At follow-up: • Decision aid: 16.67 (0.00-58.30) • Standard information: 25.00 (0.00-50.00) • No significant difference between 2 groups [median (95% CI)]: 8.33 (-8.08 to	**Limitations** **Risk of bias assessed using the revised Cochrane risk of bias tool (RoB 2)** Domain 1: Risk of bias arising from the randomization process 1.1 Was the allocation sequence random? Y - Using random number table. 1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions? Y - Used sequentially numbered, sealed, opaque envelopes. 1.3 Did baseline differences between intervention groups suggest a problem with the randomization process? N - No significant differences between groups at baseline. *Risk-of-bias judgement:* Low risk. Domain 2: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention) 2.1. Were participants aware of their assigned intervention during the trial? N - Study states that participants were unblinded. 2.2. Were carers and people delivering the interventions aware of participants' assigned

Study details	Participants	Interventions	Outcomes and Results	Limitations
patient decision-making aid in patients considering fixed appliance orthodontic treatment when compared to traditional information provision. **Study dates** July 2015 - February 2016 **Source of funding** Not reported.	• Decision aid (n): 16/20 • Standard information (n): 11/24 Ethnicity (White British or Irish/Other): • Decision aid (n): 15/21 • Standard information (n): 21/14 **Inclusion criteria** Participants had to: • Be aged 10-16 years old • Have not undergone prior orthodontic treatment • Have no craniofacial abnormalities **Exclusion criteria** Not reported.	Patients also received standardised verbal information from a research involved in the study regarding risks and benefits of fixed appliance orthodontic treatment.	24.74) (p=0.36, Mann-Whitney U-test) *Decisional conflict: informed sub-scale [median (range)]* Scale 0 (no decisional conflict) – 100 (high decision conflict). At follow-up: • Decision aid: 16.67 (0.00-50.00) • Standard information: 20.83 (0.00-50.00) • No significant difference between 2 groups [median (95% CI)]: 4.16 (-4.65 to 12.99) (p=0.38, Mann-Whitney U-test) *Decisional conflict: values clarity sub-scale [median (range)]* Scale 0 (no decisional conflict) – 100 (high decision conflict). At follow-up: • Decision aid: 16.67 (0.00-41.70) • Standard information: 20.83 (0.00-50.00) • No significant difference between 2 groups [median (95% CI)]: 4.16 (-6.77 to	intervention during the trial? N - Study states that researchers were unblinded to group allocation. 2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the experimental context? PN - Paper states that there were no changes to the trial after it started. 2.4. If Y/PY to 2.3: Were these deviations from intended intervention balanced between groups? NA. 2.5 If No/PN/NI to 2.4: Were these deviations likely to have affected the outcome? NA. 2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention? Y - Intention to treat. 2.7 If No/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized? NA. *Risk-of-bias judgement:* Low risk. <u>Domain 3: Missing outcome data</u> 3.1 Were data for this outcome available for all, or nearly all, participants randomized? Y - Data available for 35/36

Study details	Participants	Interventions	Outcomes and Results	Limitations
			15.11) (p=0.47, Mann-Whitney U-test) *Decisional conflict: support sub-scale [median (range)]* Scale 0 (no decisional conflict) – 100 (high decision conflict). At follow-up: • Decision aid: 8.33 (0.00-50.00) • Standard information: 8.33 (0.00-41.70) • No significant difference between 2 groups [median (95% CI)]: 0.00 (-10.94 to 10.94) (p=0.27, Mann-Whitney U-test) *Decisional conflict: effective decision sub-scale [median (range)]* Scale 0 (no decisional conflict) – 100 (high decision conflict). At follow-up: • Decision aid: 12.50 (0.00-43.80) • Standard information: 15.63 (0.00-50.00) • No significant difference between 2 groups [median (95% CI)]: 3.13 (-9.18 to	intervention participants and all control participants. 3.2 If No/PN/NI to 3.1: Is there evidence that the result was not biased by missing outcome data? NA. 3.3 If No/PN to 3.2: Could missingness in the outcome depend on its true value? NA. 3.4 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value? NA. *Risk-of-bias judgement:* Low risk. <u>Domain 4: Risk of bias in measurement of the outcome</u> 4.1 Was the method of measuring the outcome inappropriate? N. 4.2 Could measurement or ascertainment of the outcome have differed between intervention groups? N - Outcome measured once, after the intervention was given. 4.3 If No/PN/NI to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants? Y - Decisional Conflict Scale is patient reported. 4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received? Y.

Study details	Participants	Interventions	Outcomes and Results	Limitations
			15.43) (p=0.39, Mann-Whitney U-test)	4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received? PN - Decisional Conflict Scale is a validated tool with food reliability and high test-retest correlation. *Risk-of-bias judgement:* Some concerns. Domain 5: Risk of bias in selection of the reported result 5.1 Were the data that produced this result analysed in accordance with a pre-specified analysis plan that was finalized before unblinded outcome data were available for analysis? NI. Is the numerical result being assessed likely to have been selected, on the basis of the results, from... 5.2. ... multiple outcome measurements (e.g. scales, definitions, time points) within the outcome domain? PN. 5.3 ... multiple analyses of the data? PN. *Risk-of-bias judgement:* Some concerns. Overall risk of bias *Some concerns.* **Other information** None.

Study details	Participants	Interventions	Outcomes and Results	Limitations
Full citation Robbins, H., Hundley, V., Osman, L. M., Minor illness education for parents of young children, Journal of advanced nursing, 44, 238-47, 2003 **Ref Id** 992570 **Country/ies where the study was carried out** UK **Study type** RCT **Aim of the study** To investigate the effectiveness of a home visit and minor illnesses decision aid booklet for parents of infants compared to standard care. **Study dates** 1999 **Source of funding**	**Sample size** N (randomised)=103 parental proxies • Decision aid (n): 54 • Standard care (n): 49 N (analysed)=92 parental proxies • Decision aid (n): 49 • Standard care (n): 43 **Characteristics** Age: not reported but intervention visit coincided with babies being 6 weeks old. Gender (M/F): • Decision aid (n): 25/29 • Standard care (n): 27/22 • Ethnicity: not reported. **Inclusion criteria** Parents were eligible if: • They had a child born in a specific 6-month cohort	**Interventions** • *Intervention group: Information booklet + home visit.* The booklet was posted to participants at the beginning of the intervention and a home visit date was set for when the infant was 6 weeks old. The visit was designed to fit in with current minor illness service and consisted of discussing childhood illnesses, information on usual illnesses and details of how to contact the health centre services. The researcher also re-enforced the care option for minor illnesses presented in the posted booklet. • *Control group: Standard care.* Parents received standard care offered by health visitors. They were sent the informational booklet at the end of the study period.	**Results** *Parental knowledge of how care for their child in each scenario (percentages)* High temperature At baseline: • Decision aid: 76.0 • Standard care: 67.3 7 months follow-up: • Decision aid: 98.0 • Standard care: 100.0 • Percentage difference (if data from both questionnaires available, n=87): 2.1 • No significant difference between 2 group (p=0.9, unable to determine statistical test) Crying At baseline: • Decision aid: 66.7 • Standard care: 63.2 7 months follow-up: • Decision aid: 87.7 • Standard care: 93.0	**Limitations** **Risk of bias assessed using the revised Cochrane risk of bias tool (RoB 2)** Domain 1: Risk of bias arising from the randomization process 1.1 Was the allocation sequence random? NI - Study simpy states participants were randomised. 1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions? NI. 1.3 Did baseline differences between intervention groups suggest a problem with the randomization process? N - No significant difference between groups at baseline. *Risk-of-bias judgement:* Some concerns. Domain 2: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention) 2.1. Were participants aware of their assigned intervention during the trial? NI. 2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial? N - Paper states that researchers and health visitors were blinded to group allocation.

Study details	Participants	Interventions	Outcomes and Results	Limitations
This study received funding from the Chief Scientist Office.	identified from the birth registry of the study medical practice • Their baby was going to live with them **Exclusion criteria** Not reported.		• Percentage difference at 7 months (if data from both questionnaires available, N=87): 4.0 • No significant difference between 2 group (p=0.5, unable to determine statistical test) Spots At baseline: • Decision aid: 59.2 • Standard care: 53.1 7 months follow-up: • Decision aid: 87.8 • Standard care: 86.0 • Percentage difference at 7 months (if data from both questionnaires available, n=87): 5 • No significant difference between 2 group (p=0.5, unable to determine statistical test) Diarrhoea and vomiting At baseline: • Decision aid: 64.9 • Standard care: 51 7 months:	2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the experimental context? NI. 2.4. If Y/PY to 2.3: Were these deviations from intended intervention balanced between groups? NA. 2.5 If No/PN/NI to 2.4: Were these deviations likely to have affected the outcome? NA. 2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention? Y - Intention to treat. 2.7 If No/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized? NA. *Risk-of-bias judgement:* Some concerns. <u>Domain 3: Missing outcome data</u> 3.1 Were data for this outcome available for all, or nearly all, participants randomized? N - Data available for 49/54 in intervention group and 43/49 n control group. 3.2 If No/PN/NI to 3.1: Is there evidence that the result was not biased by missing outcome data? N. 3.3 If No/PN to 3.2: Could

Study details	Participants	Interventions	Outcomes and Results	Limitations
			• Decision aid: 77.6 • Standard care: 90.7 • Percentage difference at 7 months (if data from both questionnaires available, N=87): 10.2 • No significant difference between 2 group (p=0.2, unable to determine statistical test) Snuffles At baseline: • Decision aid: 79.6 • Standard care: 75.6 7 months follow-up: • Decision aid: 98.0 • Standard care: 100.0 • Percentage difference at 7 months (if data from both questionnaires available, n=87): 2.1 • No significant difference between 2 group (p=0.9, unable to determine statistical test) *Parental knowledge of which home care option to use in each scenario (median percentages)* High temperature	missingness in the outcome depend on its true value? PY - Reasons not presented to loss to follow up. 3.4 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value? PN - Drop out similar between 2 groups and no adverse effects reported in the rest of the study. *Risk-of-bias judgement:* Some concerns. <u>Domain 4: Risk of bias in measurement of the outcome</u> 4.1 Was the method of measuring the outcome inappropriate? N. 4.2 Could measurement or ascertainment of the outcome have differed between intervention groups? N - Questionnaire given at baseline (6 weeks) and after the intervention (7 months) by researchers (intervention) or health visitors (control). 4.3 If No/PN/NI to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants? NI - Self-reported assessment. 4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received? Y - Subjective component to knowledge

Study details	Participants	Interventions	Outcomes and Results	Limitations
			At baseline: • Decision aid: 74.1 • Standard care: 67.4 7 months at follow-up: • Decision aid: 94.9 • Standard care: 91.9 • Significance not reported Crying At baseline: • Decision aid: 67.8 • Standard care: 51.1 7 months follow-up: • Decision aid: 93.4 • Standard care: 83.7 • Significance not reported Spots At baseline: • Decision aid: 63.9 • Standard care: 49 7 months follow-up: • Decision aid: 97.0 • Standard care: 89.6 • Significance not reported	questionnaire. 4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received? PN - Parents of both intervention and control group received some form of education from healthcare professionals. *Risk-of-bias judgement:* Some concerns. <u>Domain 5: Risk of bias in selection of the reported result</u> 5.1 Were the data that produced this result analysed in accordance with a pre-specified analysis plan that was finalized before unblinded outcome data were available for analysis? NI. Is the numerical result being assessed likely to have been selected, on the basis of the results, from... 5.2. ... multiple outcome measurements (e.g. scales, definitions, time points) within the outcome domain? PN. 5.3 ... multiple analyses of the data? PN. *Risk-of-bias judgement:* Some concerns. <u>Overall risk of bias</u> *High risk.* **Other information** None.

Study details	Participants	Interventions	Outcomes and Results	Limitations
			Diarrhoea and vomiting At baseline: • Decision aid: 69.5 • Standard care: 53.1 7 months follow-up: • Decision aid: 90.9 • Standard care: 89.6 • Significance not reported Snuffles At baseline: • Decision aid: 71.3 • Standard care: 58.2 7 months follow-up: • Decision aid: 98.0 • Standard care: 94.2 • Significance not reported	
Full citation Rowe, Sarah L., Patel, Krisna, French, Rebecca S., Henderson, Claire, Ougrin, Dennis, Slade, Mike, Moran, Paul, Web-Based Decision Aid to Assist Help-Seeking Choices for Young People Who Self-Harm: Outcomes	**Sample size** N (randomised)=23 young people • Decision aid (n): 10 • Childline webpage (n): 13 N (analysed) = 23 young people • Decision aid (n): 10	**Interventions** • *Intervention group: Decision aid (My Self-Help Tool).* Designed to help young people find out about different help-seeking avenues for self-harm, such as family, general practitioners, or helplines. Participants were also asked to identify important help-seeking concerns, including	**Results** *Decisional conflict: uncertainty sub-scale [Mean (SD)]* Scale 0 (no decisional conflict) – 100 (high decision conflict). Baseline: • Decision aid: 31.7 (32.8)	**Limitations** **Risk of bias assessed using the revised Cochrane risk of bias tool (RoB 2)** Domain 1: Risk of bias arising from the randomization process 1.1 Was the allocation sequence random? Y - Using randomisation tokens and a permuted block algorithm.

Study details	Participants	Interventions	Outcomes and Results	Limitations
From a Randomized Controlled Feasibility Trial, JMIR mental health, 5, e10, 2018 **Ref Id** 1168752 **Country/ies where the study was carried out** UK **Study type** RCT **Aim of the study** To investigate the feasibility and acceptability of a RCT of self-harm decision aid in a school setting. **Study dates** Not reported. **Source of funding** This study received funding from Guy's and St Thomas' charity.	• Childline webpage (n): 13 **Characteristics** Age in years [n (%)]: • Decision aid: ○ 12-15: 8 (80) ○ 16-18: 2 (20) • Childline webpage: ○ 12-15: 12 (92) ○ 16-18: 1 (8) Gender (M/F): • Decision aid (n): 4/6 • Childline webpage (n): 5/8 Ethnicity (White British /Mixed/Other): • Decision aid (n): 10/0/0 • Childline webpage (n): 11/1/1 **Inclusion criteria** Participants had to: • Be aged 12-18 years old • Currently attending the study school • Able to speak and understand English language	confidentiality and not wanting to be labelled as attention seeking. Each of these factors was rate with the importance individuals attached. For example, confidentiality could be rated from very important to not important. After this questionnaire, a personalised set of help-seeking options were presented, ranked according to acceptability to participants. • *Control group: Childline webpage.* Participants were presented with the Childline webpage consisting of general information on feelings and emotions but no decision aid component. This page was a non-interactive page within the questionnaire, rather than a link to the live Childline webpage.	• Childline webpage: 35.9 (33.9) Post-intervention: • Decision aid: 31.7 (33.7) • Childline webpage: 37.2 (35.5) • No significant difference between groups (p=0.78, linear regression adjusted for baseline scores) 4-week follow-up: • Decision aid: 40.0 (42.5) • Childline webpage: 30.8 (27.9) • No significant difference between groups (p=0.94, linear regression adjusted for baseline scores) *Decisional conflict: support sub-scale (Mean (SD)]* Scale 0 (no decisional conflict) – 100 (high decision conflict). Baseline: • Decision aid: 15.0 (18.3) • Childline webpage: 19.2 (23.4) Post-intervention: • Decision aid: 15.0 (24.2)	1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions? NI. 1.3 Did baseline differences between intervention groups suggest a problem with the randomization process? PN - Statistical analysis not presented but groups appear visibly similar. *Risk-of-bias judgement:* Some concerns. <u>Domain 2: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)</u> 2.1. Were participants aware of their assigned intervention during the trial? PY - Described as a single-blind trial and article notes that researchers were blinded. 2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial? N - Study states researchers were blinded. 2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the experimental context? PN - Study carried out a per published protocol. 2.4. If Y/PY to 2.3: Were these deviations from intended

Study details	Participants	Interventions	Outcomes and Results	Limitations
	• Have self-harmed in the last 12 months **Exclusion criteria** • Unable to provide informed consent (either due to cognitive or language difficulties)		• Childline webpage: 11.5 (19.7) • No significant difference between groups (p=0.26, linear regression adjusted for baseline scores) 4-week follow-up: • Decision aid: 21.7 (26.1) • Childline webpage: 15.4 (18.6) • No significant difference between groups (p=0.55, linear regression adjusted for baseline scores).	intervention balanced between groups? NA. 2.5 If No/PN/NI to 2.4: Were these deviations likely to have affected the outcome? NA. 2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention? Y - Intention to treat. 2.7 If No/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized? NA. *Risk-of-bias judgement:* Low risk. <u>Domain 3: Missing outcome data</u> 3.1 Were data for this outcome available for all, or nearly all, participants randomized? Y - No data missing. 3.2 If No/PN/NI to 3.1: Is there evidence that the result was not biased by missing outcome data? NA. 3.3 If No/PN to 3.2: Could missingness in the outcome depend on its true value? NA. 3.4 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value? NA. *Risk-of-bias judgement:* Low risk.

Study details	Participants	Interventions	Outcomes and Results	Limitations
				Domain 4: Risk of bias in measurement of the outcome 4.1 Was the method of measuring the outcome inappropriate? N. 4.2 Could measurement or ascertainment of the outcome have differed between intervention groups? N - Baseline and 4 weeks follow-up. 4.3 If No/PN/NI to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants? PY - Self-report. 4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received? PY. 4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received? PN - Each group received some sort of information and control group had access to Childline webpage outside of the study. *Risk-of-bias judgement:* Some concerns. Domain 5: Risk of bias in selection of the reported result 5.1 Were the data that produced this result analysed in accordance with a pre-

Study details	Participants	Interventions	Outcomes and Results	Limitations
				specified analysis plan that was finalized before unblinded outcome data were available for analysis? PY - Outcomes measures and time points match up with published protocol. Is the numerical result being assessed likely to have been selected, on the basis of the results, from... 5.2. ... multiple outcome measurements (e.g. scales, definitions, time points) within the outcome domain? PN. 5.3 ... multiple analyses of the data? PN. *Risk-of-bias judgement:* Low risk. Overall risk of bias *Some concerns.* **Other information** None.
Full citation Wyatt, K. D., List, B., Brinkman, W. B., Prutsky Lopez, G., Asi, N., Erwin, P., Wang, Z., Domecq Garces, J. P., Montori, V. M., LeBlanc, A., Shared Decision Making in Pediatrics: A Systematic Review and Meta-analysis,	**Sample size** Included studies (K)=61 Studies included in meta-analysis (K)=15 • RCT=11 • Non-RCT=2 • Pre-post=2	**Interventions** • *Intervention groups*: *Decision aids.* Tools and methods designed to facilitate medical shared-decision making, broadly defined as the process of involving paediatric patients (and their parents/caregivers) in medical decision making with healthcare professionals.	**Results** *Details of individual studies* • **Study 1** *Topic:* Autism spectrum disorder. *Intervention:* Medical home intervention including care plans, monitoring tools, longer visits and techniques to improve appointments versus usual care. *Aimed at:*	**Limitations** **Risk of bias assessed using the ROBIS tool** Domain 1: Study eligibility criteria 1.1 Did the review adhere to pre-defined objectives and eligibility criteria? Y – previously published protocol.

Study details	Participants	Interventions	Outcomes and Results	Limitations
Academic pediatrics, 15, 573-583, 2015 **Ref Id** 1168533 **Country/ies where the study was carried out** Various **Study type** Systematic review **Aim of the study** To investigate the various tools and techniques available to assist with implementing shared decision making in paediatric care and collate their reported effects on satisfaction, decisional conflict and knowledge using meta-analysis. **Study dates** Not reported. **Source of funding** Not reported.	**Characteristics** Range of sample size: N = 22 – 509 Target population: • Babies, children and young people k=2 • Parents/guardians k=13 • Clinicians k=5 Format: • Electronic k=37 • Paper k=13 • Live sessions k=7 • Other k=2 Area of healthcare: • Vaccination k=5 • Acute respiratory illness k=3 • Mental health k=1 • Autism spectrum disorder k=1 • Attention deficit hyperactivity disorder (ADHD) k=1 • Intellectual disability k=1 • Palliative care k=1 Study country: • United States k=5	• *Control groups.* Included studies were not limited by comparator groups. No further details reported.	babies, children and young people, parents/guardians, clinicians. *Outcomes measured:* Satisfaction • **Study 2** *Topic:* End-of-life care. *Intervention:* Personalised written information documenting end-of-life care plan (plus provider education and flexible administration of insurance plans) versus usual care. *Aimed at:* babies, children and young people, parents/guardians, clinicians. *Outcomes measured:* Satisfaction. • **Study 3** *Topic:* Immunisation. *Intervention:* 15-minute polio vaccination video and written vaccine information versus written vaccine information only. *Aimed at:* Parents/guardians. *Outcomes measured:* Knowledge. • **Study 4** *Topic:* Immunisation. *Intervention:* 2 hour parent education meeting with written vaccine leaflet versus written vaccine leaflet only. *Aimed at:* Parents/guardians. *Outcomes measured:* Knowledge, decisional conflict. • **Study 5** *Topic:* Immunisation. *Intervention:* Web-based MMR decision aid with usual	1.2 Were the eligibility criteria appropriate for the review question? Y. 1.3 Were eligibility criteria unambiguous? PY – Broad definition of decision making tool applied but consistent with broad topic area. 1.4 Were any restrictions in eligibility criteria based on study characteristics appropriate (e.g. date, sample size, study quality, outcomes measured)? NA - No restrictions were placed on study design, outcomes or comparator groups. 1.5 Were any restrictions in eligibility criteria based on sources of information appropriate (e.g. publication status or format, language, availability of data)? PY – Original protocol detailed contacting all authors to verify data extraction but this was but this was discarded due to high levels of agreement between data extractors and the resource intensity of contacting authors. Studies restricted to English language papers due to lack of translation capacity. *Concerns regarding specification of study eligibility criteria:* Low. <u>Domain 2: Identification and selection of studies</u>

Study details	Participants	Interventions	Outcomes and Results	Limitations
	• Netherlands k=3 • Canada k=2 • UK k=2 • Australia k=1 • New Zealand k=1 **Inclusion criteria** Studies had to: • Investigate methods and tools designed to facilitate medical shared-decision making • Focus on patients < 18 years old, their parents or both • Be reported in English **Exclusion criteria** Not reported.		care versus MMR leaflet with usual care versus usual care only. *Aimed at:* Parents/guardians. *Outcomes measured:* Decisional conflict. • **Study 6** *Topic:* Immunisation. *Intervention:* Written information booklet covering risks and benefits of each immunisation option versus different immunisation booklet. *Aimed at:* Parents/guardians. *Outcomes measured:* Satisfaction • **Study 7** *Topic:* Intellectual disability. *Intervention:* Web-based individual counselling sessions, group support meetings, published information and chat room versus usual care. *Aimed at:* Parents/guardians. *Outcomes measured:* Knowledge, satisfaction, decisional conflict. • **Study 8** *Topic:* ADHD. *Intervention:* Website containing ADHD information and discussion surrounding treatment options versus usual care. *Aimed at:* Parents/guardians, clinicians. *Outcomes measured:* Knowledge, decisional conflict.	2.1 Did the search include an appropriate range of databases/electronic sources for published and unpublished reports? Y. 2.2 Were methods additional to database searching used to identify relevant reports? Y – Reference lists of included studies were checked for relevant studies and an environmental scan was performed (including contact with experts in shared decision making). 2.3 Were the terms and structure of the search strategy likely to retrieve as many eligible studies as possible? PY - Search strategy was devised in collaboration with a librarian from experiences in conducting systematic reviews on methods of patient engagement. 2.4 Were restrictions based on date, publication format, or language appropriate? PY – Standard exclusions. 2.5 Were efforts made to minimise error in selection of studies? Y – Titles and abstracts reviewed in independently and in duplicate. Any studies marked as possible inclusions by 1 reviewer were requested. Full texts were assessed independently and in duplicate

Study details	Participants	Interventions	Outcomes and Results	Limitations
			• **Study 9** *Topic:* Mental health. *Intervention:* Parental counselling session including information on empowerment, treatment options and final treatment plans versus usual care. *Aimed at:* Parents/guardians. *Outcomes measured:* Satisfaction, decisional conflict. • **Study 10** *Topic:* ADHD. *Intervention:* Pre-consultation cards and booklet on ADHD treatment modalities versus usual care. *Aimed at:* Parents/guardians, clinicians. *Outcomes measured:* Knowledge, decisional conflict. • **Study 11** *Topic:* Acute respiratory infection. *Intervention:* Written pamphlet on respiratory tract symptoms and treatments versus usual care. *Aimed at:* Parents/guardians, clinicians. *Outcomes measured:* Satisfaction. • **Study 12** *Topic:* Acute respiratory infection. *Intervention:* 3 x 3-hour clinician workshops including toolkit and training on involving patients in decision making process versus usual care. *Aimed at:* Clinicians.	and any disagreements were resolved by consensus of 5 reviewers. *Concerns regarding methods used to identify and/or select studies:* Low. <u>Domain 3: Data collection and study appraisal</u> 3.1 Were efforts made to minimise error in data collection? PY – Extraction performed independently and in duplicate using a pre-designed electronic extraction form. Conflicts were resolved by consensus. However, no description of piloting of form. 3.2 Were sufficient study characteristics available for both review authors and readers to be able to interpret the results? PY – Although some of the characteristics of the pre-post studies were not able to be assessed due to design. 3.3 Were all relevant study results collected for use in the synthesis? NI – Studies not limited due to outcomes and appears as though all have been extraction. Reviewers contacted study authors for paediatric specific results. However, only the 3 results that were able to be meta-analysed have been presented in the paper.

Study details	Participants	Interventions	Outcomes and Results	Limitations
			Outcomes measured: Decisional conflict. • **Study 13** *Topic:* Acute respiratory infection. *Intervention:* 2-hour web-based tutorial and 2-hour in-person interactive session on shared-decision making versus usual care. *Aimed at:* Clinicians. *Outcomes measured:* Decisional conflict. • **Study 14** *Topic:* Immunisation. *Intervention:* No information provided. *Aimed at:* no information provided. *Outcomes measured:* Knowledge, decisional conflict NB. Due to the heterogeneity observed in the meta-analysed studies and reflected in I^2 statistics, results should be interpreted carefully. *Satisfaction (measured using a variety of non-standardised scales)* Number of papers in meta-analysis = 6 • Non-RCT = 1, Pre-post = 1, RCTs = 4	3.4 Was risk of bias (or methodological quality) formally assessed using appropriate criteria? Y – expanded 9-item Cochrane Risk of Bias tool used to aid comparisons between groups and allow inclusion of the non-RCTs and pre/post studies. 3.5 Were efforts made to minimise error in risk of bias assessment? Y – Risk of bias assessed independently and in duplicate by 2 reviewers. Any discrepancies were resolved using a third senior member of the research team. *Concerns regarding methods used to collect data and appraise studies:* Unclear. <u>Domain 4: Synthesis and findings</u> 4.1 Did the synthesis include all studies that it should? PY – All studies included in the meta-analysis are presented in the forest plot. 4.2 Were all pre-defined analyses reported or departures explained? Y – Outcomes match with pre-defined protocol. 4.3 Was the synthesis appropriate given the nature and similarity in the research questions, study designs and outcomes across included studies? PN - DerSimonian and

Study details	Participants	Interventions	Outcomes and Results	Limitations
			• Standardised mean difference (95% CI): 0.37 (-0.04 to 0.78) • No significant difference between group (p=0.08, random effects model). • Considerable heterogeneity (I^2 = 77.3%) *Knowledge (measurement tools not reported)* Number of papers in meta-analysis = 6 • Non-RCT = 1, Pre-post = 4, RCTs = 1 • Standardised mean difference (95% CI): 1.21 (0.26 to 2.17) • Significantly higher (better) in intervention groups (p=0.013, random effects model). • Considerable heterogeneity (I^2 = 95.0%) *Decisional conflict (measured using Decisional Conflict Scale)* Number of papers in meta-analysis = 9 • Non-RCT = 1, Pre-post = 4, RCTs = 6*	Laird random-effects model was used to collate the standardised mean differences of 3 most commonly reported outcomes. However, studies were very different in terms to study design, description of decision aid, target of decision aid. 4.4 Was between-study variation (heterogeneity) minimal or addressed in the synthesis? N – Random-effects model was used but authors note that heterogeneity was high between studies and that the I^2 value was used in conjunction with researcher's clinical judgement to decide which studies to include in the analysis. This could lead to studies being included when it was not appropriate to. 4.5 Were the findings robust, e.g. as demonstrated through funnel plot or sensitivity analyses? NI – Sensitivity analysis was conducted for decisional conflict as 1 study showed very different results than the others and results presented for both analyses. No information presented for other outcomes. 4.6 Were biases in primary studies minimal or addressed in the synthesis? N – Risk of bias is presented separately in

Study details	Participants	Interventions	Outcomes and Results	Limitations
			• Standardised mean difference (95% CI): -1.20 (-2.01 to -0.40) • Significantly lower (better) in intervention groups (p=0.003, random effects model). • Considerable heterogeneity (I^2 = 95.2%) * Adds up to 11 due to some studies contributing separate sample populations.	online appendices and not integrated into the results of the review. Some of the characteristics of the pre-post studies were not able to be assessed due to design. Again, this does not appear to be taken into account in the results or discussion. *Concerns regarding the synthesis and findings:* High. Overall risk of bias *High risk.* **Other information** 61 studies were included in the full systematic review. Data has only been extracted for studies included in the meta-analyses as only these contributed to the extracted outcomes.

CI: Confidence interval; F: Female; M: Male; N: Number; RCT: Randomised controlled trials; SD: Standard deviation

Appendix E – Forest plots

Forest plots for review question: What are the best ways to help children and young people and the parents and carers of babies and young children understand the risks and benefits of healthcare decisions?

This section includes forest plots only for outcomes that are meta-analysed. Outcomes from single studies are not presented here, but the quality assessment for these outcomes is provided in the GRADE profiles in appendix F.

Comparison 5: decision aid interventions versus control

Figure 2: Satisfaction

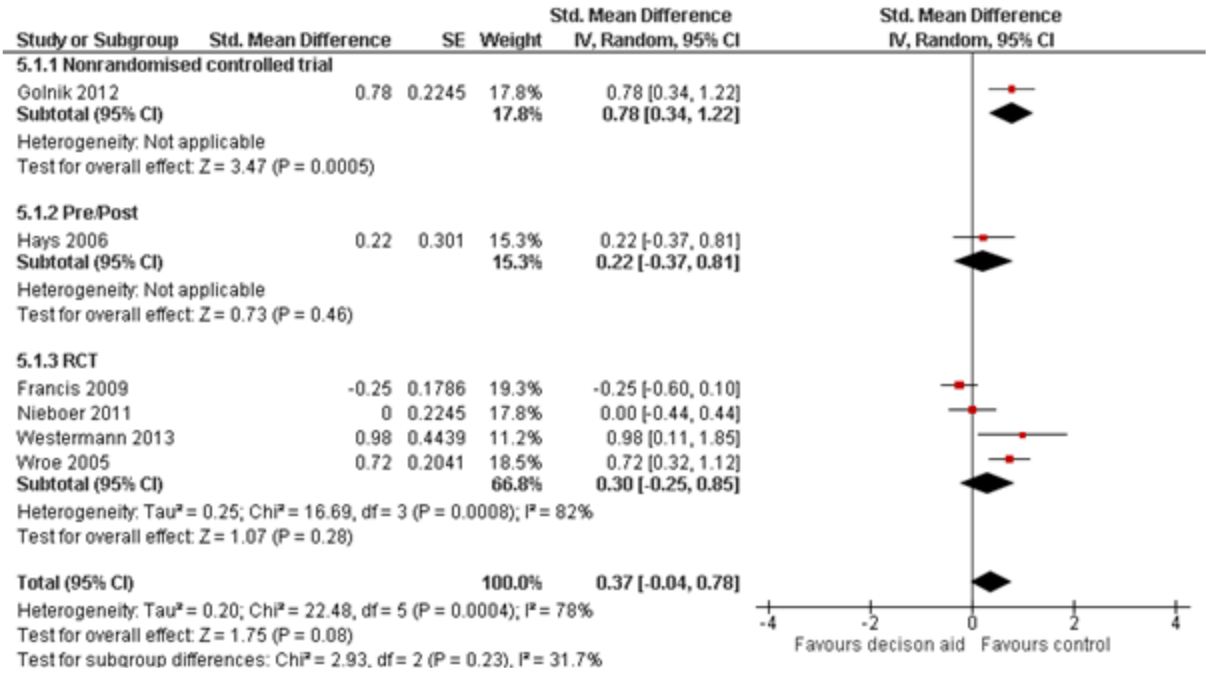


Figure 3: Knowledge

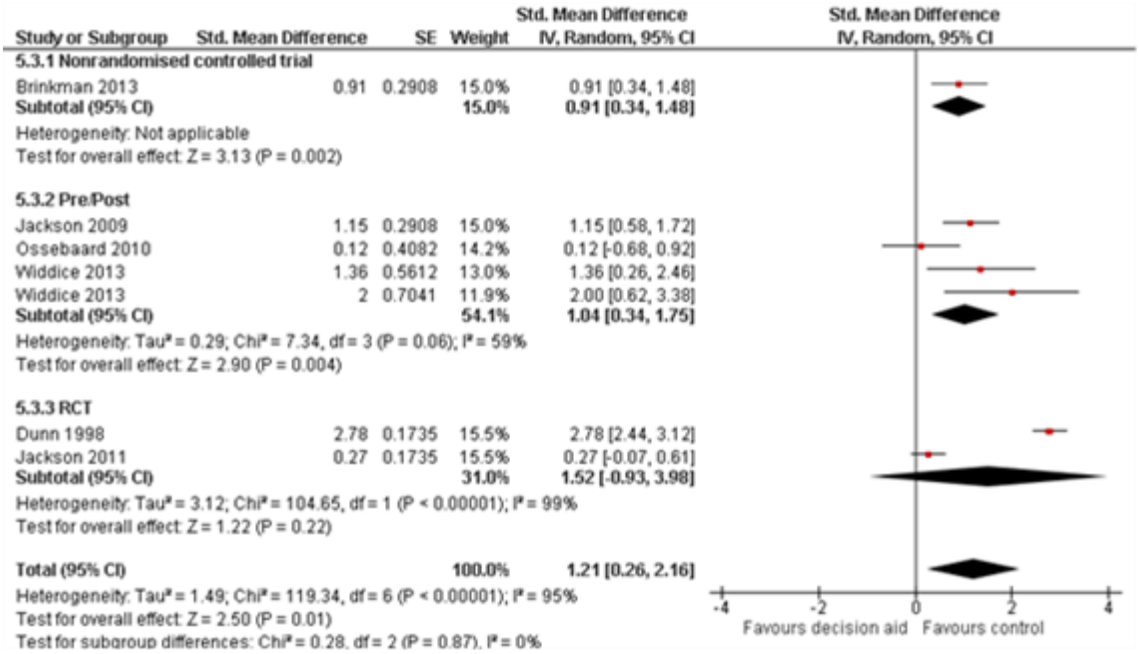
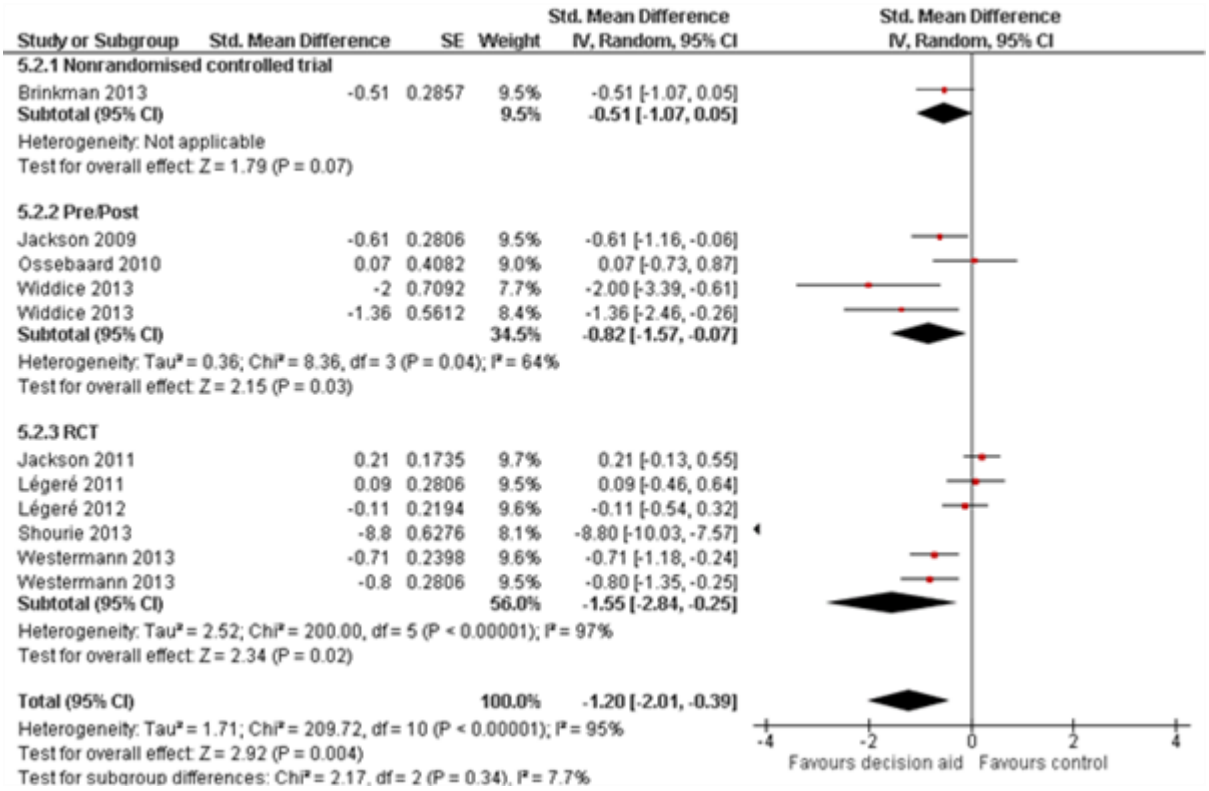


Figure 4: Decisional conflict



Appendix F – GRADE tables

GRADE tables for review question: What are the best ways to help children and young people and the parents and carers of babies and young children understand the risks and benefits of healthcare decisions?

Table 6: Clinical evidence profile for comparison 1: decision aid plus conventional clinical counselling versus conventional clinical counselling only

Quality assessment							Number of patients		Effect		Quality	Importance
Number of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Decision aid + conventional clinical counselling	Conventional clinical counselling only	Relative (95% CI)	Absolute		
Knowledge - At follow-up (Better indicated by higher values)												
1 (Hulin 2017)	RCT	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	16	16	-	MD 3.34 higher (1.21 to 5.47 higher)	VERY LOW	CRITICAL
Overall Decisional Conflict Scale - At follow-up (Better indicated by lower values)												
1 (Hulin 2017)	RCT	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	16	16	-	MD 7 lower (19.72 lower to 5.72 higher)	VERY LOW	IMPORTANT
Decisional Conflict Scale: informed sub-scale - At follow-up (Better indicated by lower values)												
1 (Hulin 2017)	RCT	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	16	16	-	MD 9.41 lower (33.1 lower to 14.28 higher)	VERY LOW	IMPORTANT
Decisional Conflict Scale: values clarity sub-scale - At follow-up (Better indicated by lower values)												

Quality assessment							Number of patients		Effect		Quality	Importance
Number of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Decision aid + conventional clinical counselling	Conventional clinical counselling only	Relative (95% CI)	Absolute		
1 (Hulin 2017)	RCT	very serious[1]	no serious inconsistency	no serious indirectness	very serious[3]	none	16	16	-	MD 6.47 lower (26.97 lower to 14.03 higher)	VERY LOW	IMPORTANT
Decisional Conflict Scale: support sub-scale - At follow-up (Better indicated by lower values)												
1 (Hulin 2017)	RCT	very serious[1]	no serious inconsistency	no serious indirectness	very serious[3]	none	16	16	-	MD 1.17 lower (10.05 lower to 7.71 higher)	VERY LOW	IMPORTANT
Decisional Conflict Scale: uncertainty sub-scale - At follow-up (Better indicated by lower values)												
1 (Hulin 2017)	RCT	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	16	16	-	MD 12.65 lower (28.35 lower to 3.05 higher)	VERY LOW	IMPORTANT

1 Very serious risk of bias in the evidence contributing to the outcomes as per RoB 2
2 95% CI crosses 1 MID (for knowledge +/-1.59; for total decisional conflict +/-9.35; for decisional conflict: informed +/-18.29; for decisional conflict: uncertainty +/-15.16)
3 95% CI crosses 2 MIDs (for decisional conflict: values clarity +/-12.86; for decisional conflict: support +/-6.66)

Table 7: Clinical evidence profile for comparison 2: decision aid plus standard information versus standard information only

Quality assessment							Number of patients		Effect		Quality	Importance
Number of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Decision aid + standard care	Standard care only	Relative (95% CI)	Absolute		
Overall Decisional Conflict Scale - At follow-up (Better indicated by lower values)												
1 (Parker 2017)	RCT	serious[1]	no serious inconsistency	no serious indirectness	very serious[2]	none	35	36	-	Median (95% CI) 3.9 (-4.3 to 12.11)	VERY LOW	IMPORTANT
Decisional Conflict Scale: uncertainty sub-scale - At follow-up (Better indicated by lower values)												
1 (Parker 2017)	RCT	serious[1]	no serious inconsistency	no serious indirectness	very serious[2]	none	35	36	-	Median (95% CI 8.33 (-8.08 to 24.75))	VERY LOW	IMPORTANT
Decisional Conflict Scale: informed sub-scale - At follow-up (Better indicated by lower values)												
1 (Parker 2017)	RCT	serious[1]	no serious inconsistency	no serious indirectness	very serious[2]	none	35	36	-	Median (95% CI 4.16 (-4.65 to 12.99)	VERY LOW	IMPORTANT
Decisional Conflict Scale: values clarity sub-scale - At follow-up (Better indicated by lower values)												
1 (Parker 2017)	RCT	serious[1]	no serious inconsistency	no serious indirectness	very serious[2]	none	35	36	-	Median (95% CI) 4.16 (-6.77 to 15.11)	VERY LOW	IMPORTANT
Decisional Conflict Scale: support sub-scale - At follow-up (Better indicated by lower values)												
1 (Parker 2017)	RCT	serious[1]	no serious inconsistency	no serious indirectness	very serious[2]	none	35	36	-	Median (95% CI) 0 (-10.94 to 10.94)	VERY LOW	IMPORTANT
Decisional Conflict Scale: effective decision sub-scale - At follow-up (Better indicated by lower values)												
1 (Parker 2017)	RCT	serious[1]	no serious inconsistency	no serious indirectness	very serious[2]	none	35	36	-	Median (95% CI) 3.13 (-9.18 to 15.43)	VERY LOW	IMPORTANT

1 Serious risk of bias in the evidence contributing to the outcomes as per RoB 2
2 The result was not downgraded if N≥400, if N=399-200, the result was downgraded 1 level, and if N<200 the result was downgraded by 2 levels.

Table 8: Clinical evidence profile for comparison 3: information booklet plus home visit versus standard care

Quality assessment							Number of patients		Effect		Quality	Importance
Number of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Information booklet + home visit	Standard care	Relative (95% CI)	Absolute		
Parental knowledge of how care for their child in each scenario - High temperature												
1 (Robbins 2003)	RCT	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	48/49 (98%)	43/43 (100%)	RR 0.98 (0.93 to 1.04)	20 fewer per 1000 (from 70 fewer to 40 more)	LOW	CRITICAL
Parental knowledge of how care for their child in each scenario - Crying												
1 (Robbins 2003)	RCT	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	43/49 (87.8%)	40/43 (93%)	RR 0.94 (0.83 to 1.08)	56 fewer per 1000 (from 158 fewer to 74 more)	LOW	CRITICAL
Parental knowledge of how care for their child in each scenario - Spots												
1 (Robbins 2003)	RCT	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	43/49 (87.8%)	37/43 (86%)	RR 1.02 (0.87 to 1.2)	17 more per 1000 (from 112 fewer to 172 more)	LOW	CRITICAL
Parental knowledge of how care for their child in each scenario - Diarrhoea and vomiting												
1 (Robbins 2003)	RCT	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	38/49 (77.6%)	39/43 (90.7%)	RR 0.86 (0.72 to 1.02)	127 fewer per 1000 (from 254 fewer to 18 more)	VERY LOW	CRITICAL
Parental knowledge of how care for their child in each scenario - Snuffles												

Quality assessment							Number of patients		Effect		Quality	Importance
Number of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Information booklet + home visit	Standard care	Relative (95% CI)	Absolute		
1 (Robbins 2003)	RCT	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	48/49 (98%)	43/43 (100%)	RR 0.98 (0.93 to 1.04)	20 fewer per 1000 (from 70 fewer to 40 more)	LOW	CRITICAL
Parental knowledge of which home care option to use in each scenario - High temperature												
1 (Robbins 2003)	RCT	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	47/49 (95.9%)	40/43 (93%)	RR 1.03 (0.93 to 1.14)	28 more per 1000 (from 65 fewer to 130 more)	LOW	CRITICAL
Parental knowledge of which home care option to use in each scenario - Crying												
1 (Robbins 2003)	RCT	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	46/49 (93.9%)	36/43 (83.7%)	RR 1.12 (0.97 to 1.3)	100 more per 1000 (from 25 fewer to 251 more)	VERY LOW	CRITICAL
Parental knowledge of which home care option to use in each scenario - Spots												
1 (Robbins 2003)	RCT	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	48/49 (98%)	39/43 (90.7%)	RR 1.08 (0.97 to 1.2)	73 more per 1000 (from 27 fewer to 181 more)	LOW	CRITICAL
Parental knowledge of which home care option to use in each scenario - Diarrhoea and vomiting												
1 (Robbins 2003)	RCT	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	45/49 (91.8%)	39/43 (90.7%)	RR 1.01 (0.89 to 1.15)	9 more per 1000 (from 100 fewer to 136 more)	LOW	CRITICAL
Parental knowledge of which home care option to use in each scenario - Snuffles												
1 (Robbins 2003)	RCT	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	48/49 (98%)	41/43 (95.3%)	RR 1.03 (0.95 to 1.11)	29 more per 1000 (from 48	LOW	CRITICAL

Quality assessment							Number of patients		Effect		Quality	Importance
Number of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Information booklet + home visit	Standard care	Relative (95% CI)	Absolute		
										fewer to 105 more)		

1 Very serious risk of bias in the evidence contributing to the outcomes as per RoB 2
2 95% CI crosses 1 MID (for all outcomes 0.8 and 1.25)

Table 9: Clinical evidence profile for comparison 4: My Self-Help Tool versus Childline webpage

Quality assessment							Number of patients		Effect		Quality	Importance
Number of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	My Self-Help Tool	Childline webpage	Relative (95% CI)	Absolute		
Decisional Conflict Scale: uncertainty sub-scale - Post-intervention (Better indicated by lower values)												
1 (Rowe 2018)	RCT	serious[1]	no serious inconsistency	no serious indirectness	very serious[2]	none	10	13	-	MD 5.5 lower (33.94 lower to 22.94 higher)	VERY LOW	IMPORTANT
Decisional Conflict Scale: uncertainty sub-scale - 4-week follow-up (Better indicated by lower values)												
1 (Rowe 2018)	RCT	serious[1]	no serious inconsistency	no serious indirectness	very serious[2]	none	10	13	-	MD 9.2 higher (21.2 lower to 39.6 higher)	VERY LOW	IMPORTANT
Decisional Conflict Scale: support sub-scale - Post-intervention (Better indicated by lower values)												
1 (Rowe 2018)	RCT	serious[1]	no serious inconsistency	no serious indirectness	serious[3]	none	10	13	-	MD 3.5 higher (14.93 lower to 21.93 higher)	LOW	IMPORTANT
Decisional Conflict Scale: support sub-scale - 4-week follow-up (Better indicated by lower values)												

Quality assessment							Number of patients		Effect		Quality	Importance
Number of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	My Self-Help Tool	Childline webpage	Relative (95% CI)	Absolute		
1 (Rowe 2018)	RCT	serious[1]	no serious inconsistency	no serious indirectness	very serious[2]	none	10	13	-	MD 6.3 higher (12.78 lower to 25.38 higher)	VERY LOW	IMPORTANT

1 Serious risk of bias in the evidence contributing to the outcomes as per RoB 2
2 95% CI crosses 2 MIDs (for decisional conflict: uncertainty +/-16.95; for decisional conflict: support +/-11.7)
3 95% CI crosses 1 MID (for decisional conflict: uncertainty +/-16.95; for decisional conflict: support +/-11.7)

Table 10: Clinical evidence profile for comparison 5: decision aid interventions versus control

Quality assessment							Number of patients		Effect		Quality	Importance
Number of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Decision aid	Control	Relative (95% CI)	Absolute		
Satisfaction (measured using a variety of non-standardised scales) (Better indicated by higher values)												
1 (Wyatt 2015)	systematic review	very serious[1]	very serious[2]	serious[3]	no serious imprecision	none	NR	NR	-	SMD 0.37 higher (0.04 lower to 0.78 higher)	VERY LOW	CRITICAL
Knowledge (percentage of questions correctly answered) (Better indicated by higher values)												
1 (Wyatt 2015)	systematic review	very serious[1]	very serious[2]	serious[3]	no serious imprecision	none	NR	NR	-	SMD 1.21 higher (0.26 to 2.17 higher)	VERY LOW	CRITICAL

Quality assessment							Number of patients		Effect		Quality	Importance
Number of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Decision aid	Control	Relative (95% CI)	Absolute		
Decisional conflict (measured using Decisional Conflict Scale) (Better indicated by lower values)												
1 (Wyatt 2015)	systematic review	very serious[1]	very serious[2]	serious[3]	no serious imprecision	none	NR	NR	-	SMD 1.2 lower (2.01 to 0.4 lower)	VERY LOW	IMPORTANT

1 Very serious risk of bias in the evidence contributing to the outcomes as per ROBIS tool
2 Considerable heterogeneity observed in the included studies (for satisfaction: I^2 = 77.3%, for knowledge: I^2 = 95.0%; for decisional conflict: I^2 = 95.2%)
3 Population is indirect - contains evidence from children, parents/carers and clinicians

Appendix G – Economic evidence study selection

Economic evidence study selection for review question: What are the best ways to help children and young people and the parents and carers of babies and young children understand the risks and benefits of healthcare decisions?

No economic evidence was identified which was applicable to this review question.

Appendix H – Economic evidence tables

Economic evidence tables for review question: What are the best ways to help children and young people and the parents and carers of babies and young children understand the risks and benefits of healthcare decisions?

No evidence was identified which was applicable to this review question.

Appendix I – Economic evidence profiles

Economic evidence profiles for review question: What are the best ways to help children and young people and the parents and carers of babies and young children understand the risks and benefits of healthcare decisions?

No economic evidence was identified which was applicable to this review question.

Appendix J – Economic analysis

Economic evidence analysis for review question: What are the best ways to help children and young people and the parents and carers of babies and young children understand the risks and benefits of healthcare decisions?

No economic analysis was conducted for this review question.

Appendix K – Excluded studies

Excluded studies for review question: What are the best ways to help children and young people and the parents and carers of babies and young children understand the risks and benefits of healthcare decisions?

Clinical studies

Table 11: Excluded studies and reasons for their exclusion

Study	Reason for Exclusion
Ahn, J. H., Power, S., Thickett, E., Andiappan, M., Newton, T., Information retention of orthodontic patients and parents: a randomized controlled trial, American journal of orthodontics and dentofacial orthopedics, 156, 169-177.e2, 2019	Intervention not in protocol – Education on orthodontic treatment only. No decision component.
Alvarez, Kiara, Wang, Ye, Alegria, Margarita, Ault-Brutus, Andrea, Ramanayake, Natasha, Yeh, Yi-Hui, Jeffries, Julia R., Shrout, Patrick E., Psychometrics of shared decision making and communication as patient centered measures for two language groups, Psychological assessment, 28, 1074-86, 2016	Country not in protocol - USA
Anzinger, H., Elliott, S. A., Hartling, L., Comparative Usability Analysis and Parental Preferences of Three Web-Based Knowledge Translation Tools: Multimethod Study, Journal of medical Internet research, 22, e14562, 2020	Population not in protocol - Parents of children under 18 years old, with no further information on ages of children
Aronson, P. L., Shapiro, E. D., Niccolai, L. M., Fraenkel, L., Shared Decision-Making with Parents of Acutely Ill Children: A Narrative Review, Academic pediatrics, 18, 3-7, 2018	Outcomes not in protocol - No quantitative data presented. Included studies checked for relevance.
Aventin, A., French, R., Young, H., McDaid, L., Lewis, R., Warren, E., McConnon, L., Lohan, M., Acceptability of an interactive film-based intervention targeting adolescent boys to prevent sexual risk-taking: findings from the JACK cluster randomised controlled trial process evaluation, The Lancet, 394, S5, 2019	Conference abstract
Barber, S., Bekker, H., Marti, J., Pavitt, S., Khambay, B., Meads, D., Development of a Discrete-Choice Experiment (DCE) to Elicit Adolescent and Parent Preferences for Hypodontia Treatment, Patient, 12, 137-148, 2019	Study design not in protocol - Cross-sectional
Bekker, H. L., Luther, F., Buchanan, H., Developments in making patients' orthodontic choices better, Journal of Orthodontics, 37, 217-24, 2010	Narrative review. Included studies checked for relevance.
Bekker, H., Thornton, J. G., Airey, C. M., Connelly, J. B., Hewison, J., Robinson, M. B., Lilleyman, J., MacIntosh, M., Maule, A. J., Michie, S., Pearman, A. D., Informed decision making: An annotated bibliography and systematic review, Health technology assessment, 3, iii-150, 1999	Population not in protocol - Mixture of adults and children with results not presented separately for target population.
Boland, L., Graham, I. D., Legare, F., Lewis, K., Jull, J., Shephard, A., Lawson, M. L., Davis, A., Yameogo, A., Stacey, D., Barriers and facilitators of pediatric shared decision-making: a systematic review, Implementation science : IS, 14, 7, 2019	Systematic review. Included studies checked for relevance.
Boland, Laura, Legare, France, McIsaac, Daniel I., Graham, Ian D., Monica, Taljaard, Decary, Simon, Stacey, Dawn, SURE Test Accuracy for Decisional Conflict Screening among Parents Making	Country not in protocol - Canada

Study	Reason for Exclusion
Decisions for Their Child, Medical decision making : an international journal of the Society for Medical Decision Making, 272989X19884541, 2019	
Boland, Laura, Legare, France, McIsaac, Daniel I., Graham, Ian D., Taljaard, Monica, Decary, Simon, Stacey, Dawn, SURE Test Accuracy for Decisional Conflict Screening among Parents Making Decisions for Their Child, Medical decision making : an international journal of the Society for Medical Decision Making, 39, 1010-1018, 2019	Country not in protocol - Canada
Chi, N. C., Demiris, G., A systematic review of telehealth tools and interventions to support family caregivers, Journal of Telemedicine & Telecare, 21, 37-44, 2015	Systematic review. Included studies checked for relevance.
Coronado-Vazquez, Valle, Navarro-Abal, Yolanda, Magallon-Botaya, Rosa, Cerezo Espinosa de Los Monteros, Javier, Cruz-Salgado, Oscar, Gomez-Salgado, Juan, Ramirez Duran, M. Del Valle, [Applicability of decision aids in emergency departments: an exploratory review], Aplicabilidad de las herramientas de ayuda a la toma de decisiones compartidas en los servicios de Urgencias: una revision exploratoria., 93, 2019	Non-English language paper
Coyne, I., O'Mathúna, D. P., Gibson, F., Shields, L., Leclercq, E., Sheaf, G., Interventions for promoting participation in shared decisionâ€• making for children with cancer, Cochrane Database of Systematic Reviews, 2016	Empty systematic review - no included studies.
Donovan, E., Little, P., Willcox, M. L., Wilcox, C. R., Patel, S., Hay, A. D., Digital interventions for parents of acutely ill children and their treatment-seeking behaviour: A systematic review, British Journal of General Practice, 70, E172-E178, 2020	Systematic review. Included studies checked for relevance.
Edbrooke-Childs, Julian, Edridge, Chloe, Averill, Phoebe, Delane, Louise, Hollis, Chris, Craven, Michael P., Martin, Kate, Feltham, Amy, Jeremy, Grace, Deighton, Jessica, Wolpert, Miranda, A Feasibility Trial of Power Up: Smartphone App to Support Patient Activation and Shared Decision Making for Mental Health in Young People, JMIR mHealth and uHealth, 7, e11677, 2019	Outcomes not in protocol - No quantitative data presented.
Feinstein, M. M., Adegboye, J., Niforatos, J. D., Pescatore, R. M., Informed consent for invasive procedures in the emergency department, American Journal of Emergency Medicine, 2020	Systematic review. Included studies checked for relevance.
Flynn,D., Knoedler,M.A., Hess,E.P., Murad,M.H., Erwin,P.J., Montori,V.M., Thomson,R.G., Engaging patients in health care decisions in the emergency department through shared decision-making: A systematic review, Academic Emergency Medicine, 19, 959-967, 2012	Systematic review. Included studies checked for relevance.
Garanito, Marlene Pereira, Zaher-Rutherford, Vera Lucia, ADOLESCENT PATIENTS AND THE CLINICAL DECISION ABOUT THEIR HEALTH, Revista paulista de pediatria : orgao oficial da Sociedade de Pediatria de Sao Paulo, 37, 503-509, 2019	Systematic review. Included studies checked for relevance.
Geerards, D., Pusic, A., Hoogbergen, M., van der Hulst, R., Sidey-Gibbons, C., Computerized Quality of Life Assessment: A Randomized Experiment to Determine the Impact of Individualized Feedback on Assessment Experience, Journal of medical Internet research, 21, e12212, 2019	Country not in protocol - USA

Study	Reason for Exclusion
Gurung, G., Richardson, A., Wyeth, E., Edmonds, L., Derrett, S., Child/youth, family and public engagement in paediatric services in high-income countries: A systematic scoping review, Health expectations : an international journal of public participation in health care and health policy, 23, 261-273, 2020	Systematic review. Included studies checked for relevance.
Liverpool, S., Pereira, B., Hayes, D., Wolpert, M., Edbrooke-Childs, J., A scoping review and assessment of essential elements of shared decision-making of parent-involved interventions in child and adolescent mental health, European Child and Adolescent Psychiatry, 2020	Scoping review. Included studies checked for relevance.
Muller, K., Tao, R., Goring, S., Lane, S., Use of discrete choice experiments designed with a single scenario and two or more choices: A systematic review, Value in health, 19, A92, 2016	Conference abstract.
Neill, S., Roland, D., Jones, C. H. D., Thompson, M., Lakhanpaul, M., Information resources to aid parental decision-making on when to seek medical care for their acutely sick child: A narrative systematic review, BMJ open, 5 (12) (no pagination), 2015	Systematic review. Included studies checked for relevance.
Nicholson, E., McDonnell, T., De Brun, A., Barrett, M., Bury, G., Collins, C., Hensey, C., McAuliffe, E., Factors that influence family and parental preferences and decision making for unscheduled paediatric healthcare - systematic review, BMC health services research, 20, 663, 2020	Systematic review. Included studies checked for relevance.
Reilly, S., Competency to consent to research and treatment: Methods for assessing capacity and improving patient understanding, World Journal for Pediatric and Congenital Heart Surgery, 10, NP47, 2019	Conference abstract.
Robles, N., Carrion, C., Ribas, I., Pamias, M., Parra, I., Conesa, J., Perez-Navarro, A., Alabert, M., Aymerich, M., A mobile clinical decision support system for autism spectrum disorder, International Journal of Technology Assessment in Health Care, 35, 68-69, 2019	Poster presentation.
Sarrami-Foroushani, P., Travaglia, J., Debono, D., Braithwaite, J., Implementing strategies in consumer and community engagement in health care: results of a large-scale, scoping meta-review, BMC health services research, 14, 402, 2014	Scoping review. Included studies checked for relevance.
Schmidtke, K. A., Watson, D. G., Vlaev, I., The use of control charts by laypeople and hospital decision-makers for guiding decision making, Quarterly journal of experimental psychology (2006), 70, 1114-1128, 2017	Population not in protocol - Health professionals and people >18 years old.
Scott, J. T., Harmsen, M., Prictor, M. J., Sowden, A. J., Watt, I., Interventions for improving communication with children and adolescents about their cancer, Cochrane database of systematic reviews (Online), CD002969, 2003	Systematic review. Included studies checked for relevance.
Steciuk, K., Wang, X., Holch, P., Incidence, risks and information and support needs of patients and their carers experiencing cancer and stroke: A scoping review, Psycho-Oncology, 29, 23, 2020	Poster presentation
Stephenson, Judith, Bailey, Julia V., Gubijev, Ana, D'Souza, Preethy, Oliver, Sandy, Blandford, Ann, Hunter, Rachael, Shawe, Jill, Rait, Greta, Brima, Nataliya, Copas, Andrew, An interactive website for informed contraception choice: randomised evaluation of Contraception Choices, Digital health, 6, 2055207620936435, 2020	Population not in protocol - Women aged 15-30 with results not presented separately for target population.
Talen, Mary R., Muller-Held, Christine F., Eshleman, Kate Grampp, Stephens, Lorraine, Patients' communication with doctors: a	Population not in protocol - People >18 years old.

Study	Reason for Exclusion
randomized control study of a brief patient communication intervention, Families, systems & health : the journal of collaborative family healthcare, 29, 171-83, 2011	
Teela, L., Verhagen, L., Grootenhuis, M., Haverman, L., Participation of pediatric patients in hospital care, research and intervention development: A systematic review, Quality of Life Research, 27, S149-S150, 2018	Conference abstract.
Triantafyllidis, Andreas, Polychronidou, Eleftheria, Alexiadis, Anastasios, Rocha, Cleilton Lima, Oliveira, Douglas Nogueira, da Silva, Amanda S., Freire, Ananda Lima, Macedo, Crislanio, Sousa, Igor Farias, Werbet, Eriko, Lillo, Elena Arredondo, Luengo, Henar Gonzalez, Ellacuria, Macarena Torrego, Votis, Konstantinos, Tzovaras, Dimitrios, Abdullah, Ahmed Armijo-Olivo Ben-Zvi Blum Butler Cruz Donsa Dugan Dyrstad Falagas Fergus Fiechtner Gance-Cleveland Gance-Cleveland Gultepe Hastie Hendrix Kornman Lamboglia Lau Lazarou LeBlanc Lim Lingren Martinez-Perez Mirzaei Moher Moja Murdoch Nguyen Nguyen Nguyen Obermeyer Pakarinen Peng Polacsek Price Rios-Julian Roshanov Salvatore Schmiege Shaikh Shields Simmonds Smith Song Staiano Tate Taveras Taveras Taveras Taveras Triantafyllidis Triantafyllidis Triantafyllidis Tripicchio Turner Vucenik Wiechmann Witten Yacef Yoong Zheng Ziauddeen, Computerized decision support and machine learning applications for the prevention and treatment of childhood obesity: A systematic review of the literature, Artificial Intelligence in Medicine, 104, 2020	Systematic review. Included studies checked for relevance.

1

2 **Economic studies**

3 No economic evidence was identified for this review. See supplementary material 6 for
4 details.

5

Appendix L – Research recommendations

Research recommendations for review question: What are the best ways to help children and young people and the parents and carers of babies and young children understand the risks and benefits of healthcare decisions?

Research question

What decision aids are the most cost-effective and acceptable when explaining the risks and benefits of healthcare interventions to children and young people?

Why this is important

Shared decision-making is an approach that has a large number of potential benefits, including promoting patient-centred care, improving motivation and engagement with treatment, empowering patients, and reducing anxiety. An understanding of risks and benefits of any healthcare intervention is a fundamental pre-requisite for effective shared decision making. The purpose of a decision aid is to facilitate such understanding by providing accurate information in such a way that it is comprehensible to those involved. There is currently very limited evidence available on the most effective types of decision aids available for children and young people.

Table 12: Research recommendation rationale

Research question	What decision aids are the most cost-effective and acceptable when explaining the risks and benefits of healthcare interventions to children and young people?
Importance to 'patients' or the population	Improved shared decision making resulting from effective decision aids would have a range of potential benefits including greater empowerment of children and young people, increased satisfaction with care, improved adherence with treatment regimes
Relevance to NICE guidance	The purpose of the research is to improve the healthcare experiences of children and young people by increasing their involvement in their own care by informed decision making
Relevance to the NHS	Multiple healthcare interventions and procedures for children and young people are undertaken within the NHS, ranging from those which are low risk such as immunisations and dental treatment to much higher risk ones such as major surgical procedures. Effective decision aids could therefore have widespread benefits.
National priorities	The findings from this research would support the priorities of the NHS Long Term Plan with respect to children and young people by supporting the workforce to listen, respond and meet their needs.
Current evidence base	There is a paucity of published research relating to decision aids for children and young people relevant to a UK NHS setting, and none relating

Research question	What decision aids are the most cost-effective and acceptable when explaining the risks and benefits of healthcare interventions to children and young people?
	to younger children. As summarised in the evidence review, the three UK based studies targeting children and young people only included children over the age of ten: two of these evaluated provision of written booklets for dental anaesthesia or orthodontic treatment; and one study evaluated an interactive decision aid for young people who had self-harmed. A systematic review included only two non-UK studies evaluating decision aids aimed at children and young people.
Equality	Need to ensure that decision aids are appropriate for whole population of children and young people with particular reference to marginalised groups.
Feasibility	Recruitment should be feasible as children and young people's healthcare treatment will not change, it will just be the way the decision is discussed with them that is under investigation.

Table 13: Research recommendation modified PICO table

Criterion	Explanation
Population	Children and young people aged 5-17 who are due to undergo a common medical or surgical intervention or procedure (e.g. immunisation) with stratification by age group and particularly focussing on younger children.
Intervention	Up to three different age / developmentally appropriate decision aids identified from literature review.
Comparator	Usual standard information, advice and care
Outcomes	Knowledge Satisfaction Decisional conflict Decisional congruence with parents or carers Adverse impact Cost benefit
Study design	Randomised controlled trial
Timeframe	Three years

Appendix M – Evidence from reference groups and focus groups

Reference and focus group evidence for review question: What are the best ways to help children and young people and the parents and carers of babies and young children understand the risks and benefits of healthcare decisions?

Methods for the reference and focus groups and details of how input was obtained from the children and young people are described in Supplement 4.

Table 14: Evidence from reference groups and focus groups

Age < 7 years	Age 7-11 Years	Age 11-14 years	Overall quality of the evidence

There was no evidence from this group for this question.	Would you want to know all the risks in advance [having a tooth out] or not be told?
	• Some would want to know:
	  ○ 'So it isn't a bad big, surprise'
	  ○ 'If I know the risks it would make me feel better'
	  ○ 'I'd like to be told at least 1 week before to prepare for it'
	• Some were unsure:
	  ○ 'I want to know the risks but don't want to get scared, so could say what the risks are but then say all the things they were doing to stop the risks'
	• Some would not want to know:
	  ○ 'Could be really bad, if it's a surprise you might be more worried'
	  ○ 'If they told you, you would be in pain you would be really worried and wouldn't want your teeth pulled out so might try to fix it yourself and not go in'
	  ○ 'If I hear that, I'd get really scared and say to my dad I didn't want to do this anymore'
	  ○ 'If it was serious, I'd be scared so prefer not to know'
		• How should risks and benefits of having a filling be explained?
		  ○ 'Talk to us about the things you are concerned about'
		  ○ 'Eat healthy'
		  ○ 'It will reduce pain'
		  ○ 'Don't worry it is quick'
		  ○ 'Rating'
		  ○ 'Don't worry, talk to us if you are concerned. These are risks but they are very rare'
		  ○ 'It prevents infections to tooth'
		• How should risks and benefits of having a vaccine be explained?
		  ○ 'A side effect is that you may feel sick after'
		  ○ 'When you're done you get stickers'
		  ○ 'There may be temporary side effects but I'm much more protected now'
		  ○ '3 in 1 booster vaccine for teenagers'
		  ○ 'The jab projects you from illnesses'
		  ○ 'Is it safe? Sure?'
		  ○ 'It helps your immune systems'
		  ○ 'That vaccine means that I can't get them'
		  ○ 'You can have an allergic reaction but 1 in 100 people get that'
		  ○ 'Sometimes, some people may have side-effects. But don't worry, it's rare'
			• Low

Appendix N – Evidence from national surveys

Evidence from national surveys for review question: What are the best ways to help children and young people and the parents and carers of babies and young children understand the risks and benefits of healthcare decisions?

Methods for the grey literature review of national surveys and details of the surveys included are described in Supplement 5.

No evidence from the grey literature review of national surveys of children and young people's experience was identified for this review question.