PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	Development of a patient decision aid for children and adolescents following anterior cruciate ligament rupture: an international mixed-methods study
AUTHORS	Gamble, Andrew; McKay, Marnee; Anderson, David; Pappas, Evangelos; Alvarez Cooper, Ignatius; Macpherson, Sophie; Harris, Ian; Filbay, Stephanie; McCaffery, Kirsten; Thompson, Rachel; Hoffmann, Tammy; Maher, Christopher; Zadro, Joshua

VERSION 1 – REVIEW

REVIEWER	Smith, Benjamin Derby Teaching Hospitals NHS Foundation Trust, Physiotherapy Outpatients
REVIEW RETURNED	09-Jan-2024

GENERAL COMMENTS	Thank you for inviting me to review this mixed methods study developing a patient decision aid for children and adolescents following anterior cruciate ligament rupture.
	I congratulate the authors for conducting a novel and interesting study. The writing is clear and accurate. The methods described sufficiently. Results and outcomes clearly defined. Discussion and conclusion appropriate.
	Before I can recommend for publication, I have a few questions/concerns that might be useful to address. Points below.
	Abstract: The phrase '7 were adolescents and 9 were now adults' is hard to read. Everyone ages, does it matter that 9 of your participants are now adults? At time of writing? Or analysis? Or publication?
	Why weren't patients involved in the design, or conduct, or reporting, or dissemination plans of this research?
	Background: Reads well. Clear justification for the need for a decision aid tool.
	Methods: The participants age statement reads better in this section.
	Purposive sampling by country is an interesting decision. Would it not have been better to focus on one country with one healthcare system. To get a diverse range of views from different countries you would nee a large sample, you only have 6 countries represented for patients; one African country and only one European country. Similar for professionals. In your discussion

section you talk about this as a strength, but it seems a major flaw to me.

Why were patients not included in the design of the initial draft of the tool? Some of the feedback on psychological concerns/support could have been addressed from the outset. A lack of patients in the draft phase isn't mentioned in the limitations.

How did you control for bias in the development of the first draft?

Why did you not use a consensus method, to ensure the process was systematic? This isn't mentioned in the limitations section.

Discussion:
In your limitation section you say "there is a lack of high-quality evidence comparing rehabilitation only to ACL reconstruction followed by rehabilitation in children and adolescents". If there is no evidence, can a decision aid tool developed at all? Does it not reduce any reliable and validity of the information given in the tool?

I think your limitation sections needs to be expanded with more discussion on pros and cons of the methods.

Thanks again for inviting me to review. I hope my comments are constructive and useful.
Ben Smith
University Hospitals of Derby and Burton NHS Foundation Trust, UK.

REVIEWER	Carter, Hayley University Hospitals of Derby and Burton NHS Foundation Trust, Department of Physiotherapy
REVIEW RETURNED	10-Jan-2024

| GENERAL COMMENTS | Comments for the Author
Thank you for the opportunity to review this manuscript. This paper is an interesting contribution to the literature, considering evidence in the management of adolescent/child ACL injuries is sparse. The manuscript is well written and the processes followed within the study are clear. I have made some suggestions for areas where I feel further justification would offer greater insight into decisions made within the study and implications of the work.

Abstract

Introduction
    1st paragraph: I feel it would help the reader if context were added to the statements about increasing rates of ACL injuries & ACLRs in children & adolescents e.g. over what time period, by how much

2nd paragraph: There have been three RCTs to date comparing rehab to ACLR. This section would be strengthened by including the results from ACL SNNAP (https://doi.org/10.1016/S0140-6736(22)01424-6)

Method
    Missing information: There is no information as to where ethical approval was sought/gained. |

1st paragraph: Could you add some detail as to why patients & parents were not included in the initial development of the patient decision aid?

Participants paragraph: the justification for the inclusion of adult-participants who had ruptured their ACL when under 18 isn't clear here or why this was necessary in addition to adolescents and their parents.

Semi structured interviews, 2nd paragraph: "At the end of each interview, participants were given the opportunity to provide any additional feedback or comments", justification as to why this was necessary in addition to the interview and acceptability questionnaire would be beneficial for the reader, I'm not clear why this was needed.

Results
1st paragraph: you mention not meeting 3 quality criteria from IPDASi including readability levels and evaluating the decision aid. Could you add some justification as to why readability levels are not included?

Table 2: Is there data missing for years of experience?

Discussion
4th paragraph: You mention a recommended age limit for use of the decision aid, but this isn't clear on the decision aid itself or within the manuscript.

5th paragraph: "Some parents suggested the decision aid would save them time (e.g., "would have saved me hours of googling") but one parent withdrew their adolescent from an interview due to concerns (e.g., "seeing potential harms could disrupt focus on rehabilitation"). Parents and health professionals should consider encouraging children and adolescents to be involved in shared decision-making9,37,38 and informing them of potential risks."
I think further discussion is needed here. Was involving children in shared decision-making conversations discussed in the interviews to offer insight on this comment? What were clinicians/parents/children's thought? Motivation to be involved in SDM is multi-factorial, for example, some do not wish to be responsible for a decision made about treatment and so do not want to engage. If a parent has expressed concern before using the decision aid, how might this impact implementation in clinical practice?

Strengths and Limitations
You mentioned in the methods aiming for diversity of profession but 75% of health professionals interviewed were physiotherapists. Could you add acknowledgement of this to your limitations in addition to consideration as to how the results may have been influenced by the physiotherapy profession more so than orthopaedic surgeons/other professions & what implications this may have? In addition, over 50% of your patient participants were adults at the time of interview. I'm not clear on the benefit of interviewing adults (particularly given the upper age of 33) on a decision aid for use with adolescents and children? The age range of the adolescents interviewed was also high given the decision aid could be used with someone younger. Although you mention

	not interviewing children, I feel further discussion on this would be beneficial. In addition, most of the patient participants you interviewed had private health insurance, it would be useful to consider how a patient without this would may offer different insight on the decision aid. Although you described in the methods that there was no restriction on country of practice for health professionals & that you set to achieve diversity in this demographic, a large proportion of the therapists trained in Australia. It would be useful to add this to the limitations section & consider the implications of this. It is also unclear as to whether they also continue to practice in the country they trained or whether all the health professions now practice in Australia? Conclusion 1st sentence: I feel 'valuable' should be changed to 'acceptable' to make it clearer that the effectiveness of the decision aid is currently unknown.

VERSION 1 – AUTHOR RESPONSE

REVIEWER 1 COMMENTS

Mr. Benjamin Smith, Derby Teaching Hospitals NHS Foundation Trust, University of Nottingham School of Medicine

1. Comment
Thank you for inviting me to review this mixed methods study developing a patient decision aid for children and adolescents following anterior cruciate ligament rupture.

I congratulate the authors for conducting a novel and interesting study. The writing is clear and accurate. The methods described sufficiently. Results and outcomes clearly defined. Discussion and conclusion appropriate.

Response
We thank the reviewer for their positive comments. Below is our response to each specific point raised.

2. Comment
Abstract:
The phrase '7 were adolescents and 9 were now adults' is hard to read. Everyone ages, does it matter that 9 of your participants are now adults? At time of writing? Or analysis? Or publication?

Response
We have edited the phrase about participants' age to improve clarity.

Abstract:
Results: We conducted 32 interviews; 16 health professionals (12 physiotherapists, 4 orthopaedic surgeons) and 16 people who ruptured their ACL when they were under 18 years old (7 were adolescents and 9 were adults at the time of the interview). Parents participated in 8 interviews. Most

4

health professionals, patients, and parents rated the aid's acceptability as good or excellent. Health professionals and patients agreed on most aspects of the decision aid, but some health professionals had differing views on non-surgical management (rehabilitation only) in children and adolescents, the risk of harms, treatment protocols and evidence on benefits and harms.

3. Comment
Abstract
Why weren't patients involved in the design, or conduct, or reporting, or dissemination plans of this research?

Response
Thank you for raising this important aspect of our study. Four people with lived experience of an ACL rupture were included in our steering group and therefore involved in all aspects of study design. Patients were also heavily involved in the design of the decision aid via iterative piloting and feedback during online interviews and questionnaires to guide its design and acceptability. This method is widely employed to develop other decision aids. This project also sits within Wiser Healthcare that has a consumer committee that comments on all aspects of Wiser research.

Gan, J. F. L., McKay, M. J., Jones, C. M. P., Harris, I. A., McCaffery, K., Thompson, R., Hoffmann, T. C., Adie, S., Maher, C. G., & Zadro, J. R. (2023, Jun 14). Developing a patient decision aid for Achilles tendon rupture management: a mixed-methods study. *BMJ Open, 13*(6), e072553. https://doi.org/10.1136/bmjopen-2023-072553

Zadro, J., Jones, C., Harris, I., Buchbinder, R., O'Connor, D. A., McCaffery, K., Thompson, R. E., Karunaratne, S., Teng, M. J., Maher, C., & Hoffmann, T. (2021, Aug 30). Development of a patient decision aid on subacromial decompression surgery and rotator cuff repair surgery: an international mixed-methods study. *BMJ Open, 11*(8), e054032. https://doi.org/10.1136/bmjopen-2021-054032).

Page 5 (1st paragraph)
1. **Methods**
Initial design of the decision aid
We developed a patient decision aid informed by the International Patient Decision Aid Standards (IPDAS) checklist and Collaboration Evidence Update 2.0[20]. A multidisciplinary steering group was assembled (study authors), including topic experts on ACL injury and physiotherapists with experience managing ACL ruptures (AG, JZ, MM, DA, EP, CM, SF, SM), people who have experienced an ACL rupture (SF, MM, EP, IAC) and one who was 18 years old when they ruptured their ACL (SF), an orthopaedic surgeon (IH) and patient decision aid and shared decision-making experts (KM, TH and RT). The first draft of the decision aid was informed by a template used for previous decision aids (for Achilles rupture[21], shoulder pain[22] , antibiotics[23] and knee arthroscopy[24]) developed by some authors in the steering group (JZ, MM, KM, TH, RT, CM, and IH). Key features adopted from these decision aids included questions to consider when talking to health professionals, icon arrays to present statistics, and a table comparing the potential benefits and harms of each management option. Decision science evidence suggests these features improve patient decision making[25-28]. We also included statements of the quality of evidence, study participants demographic information and a reference list to give further context to statistics used in the decision aid.

4. Comment
Background:
Reads well. Clear justification for the need for a decision aid tool.

Response

We thank the reviewer for their positive comment.

5. Comment

The participants age statement reads better in this section.

Response

We thank the reviewer for their positive comment. We adjusted this statement in the abstract to closely match the wording here.

6. Comment

Purposive sampling by country is an interesting decision. Would it not have been better to focus on one country with one healthcare system. To get a diverse range of views from different countries you would need a large sample, you only have 6 countries represented for patients; one African country and only one European country. Similar for professionals. In your discussion section you talk about this as a strength, but it seems a major flaw to me.

Response

We agree not having a larger sample size of participants from each country is a limitation and we have added this to the discussion. We removed 'diverse range' from the strength and limitations of the study and discuss the pros and cons of interviewing participants from different countries with respect to our sample size in the discussion.

Page 2 (1st paragraph)
Strengths and limitations of this study:

- We developed a decision aid that satisfies the International Patient Decision Aid Standards criteria and used mixed methods to evaluate acceptability of the decision aid.
- One-on-one interviews conducted with participants from different countries allowed for rich feedback to be gathered on the decision aid, but the generalisability of the decision aid may be limited by the number of interviews with participants from each country.
- We were able to interview health professionals who manage children who have ruptured their anterior cruciate ligament but were unable to recruit children-participants to interview with their parents.
- Our patient decision aid was limited by the lack of high-quality evidence comparing rehabilitation only to ACL reconstruction followed by rehabilitation in children and adolescents.
- The systematic review used to inform estimates of benefits and harms included older studies that did not always report details of rehabilitation and may not reflect advances in treatment.

Page 18 (2nd and 3rd paragraph)
Strengths and Limitations

Our development process (Supplementary file 16) had several strengths. The steering group includes people who experienced an ACL rupture and one who was 18 years old when they ruptured their ACL, the manuscript is transparent about the authors' professional backgrounds, the design, conduct and reporting of this study were guided by the IPDAS criteria, we conducted one-on-one interviews with participants which allowed for rich feedback to be gathered on the decision aid, and used mixed methods to evaluate acceptability of the decision aid. The readability of our tool measured higher (Grade 9 to 11) than recommendations (Grade 8) but contains multiple features to support understanding and readability that aligns with best practice[45] including bullet points, white space, images, and sub-headers. The tool therefore performs well relative to existing decision aids in terms

of its attention to health literacy[45]. We also included justification of the evidence used to inform numeric estimates of benefits and harms in the decision aid and used the highest quality evidence available comparing rehabilitation only and ACL reconstruction followed by rehabilitation for children and adolescents[13].

Our patient decision aid was limited by the lack of high-quality evidence comparing rehabilitation only to ACL reconstruction followed by rehabilitation in children and adolescents. Emergence of future studies related to this topic will likely warrant an update of the evidence used in the decision aid. Another limitation is that evidence from older studies did not always report details of rehabilitation or consider advances in treatment to know if they reflect current recommended practice. We were unable to recruit any children-participants to interview and adolescent-participants were aged between 15-17 years old. We did interview health professionals who treat children and younger adolescents, but not being able to recruit children-participants means the decision aid was not directly influenced by children's feedback. Most authors are physiotherapists, and most health professional-participants were physiotherapists (75%), trained in Australia (69%) and worked in private practice (63%) which may impact the themes that emerged from interviews (e.g., views on costs and waiting time for ACL reconstruction). Recruitment of participants was difficult which was expected without offering incentives for their time. We didn't directly involve children or adolescents in all stages of the study as consumers, and stakeholder involvement heavily influenced the design of the decision aid via feedback during online interviews and questionnaires on the acceptability of the decision aid. Our aim was to interview participants until we achieved data saturation, but we acknowledge that the majority of participants were Australian (60%). Including participants from several different countries may have made the decision aid more globally acceptable (e.g., feedback was influenced by different cultures and healthcare systems) but the sample size of participants from each country may limit the generalisability of the decision aid for use in different countries. Future work includes adapting this decision aid for culturally and linguistically diverse populations as it is only presented in English.

7. Comment
Why were patients not included in the design of the initial draft of the tool? Some of the feedback on psychological concerns/support could have been addressed from the outset. A lack of patients in the draft phase isn't mentioned in the limitations.

Response
In the revised version, we are acknowledging that the steering group includes four people who experienced an ACL rupture and we have updated the patient involvement statement at the beginning of the manuscript accordingly. Given the large amount of misinformation about the management of ACL injuries online and common misconceptions among the public we thought it was appropriate to use the best available evidence to inform the initial draft of the tool before consulting patients for their feedback. We also based the initial draft off previous decision aids which were developed via numerous interviews with patients.

Page 2 (3rd paragraph)
Patient and Public involvement:

People who experienced an ACL rupture were part of the authorship group (SF, MM, EP, IAC). One was 18 years old when they ruptured their ACL (SF).

Page 5 (1st paragraph)

1. Methods
Initial design of the decision aid

We developed a patient decision aid informed by the International Patient Decision Aid Standards (IPDAS) checklist and Collaboration Evidence Update 2.0[20]. A multidisciplinary steering group was assembled (study authors), including topic experts on ACL injury and physiotherapists with experience managing ACL ruptures (AG, JZ, MM, DA, EP, CM, SF, SM), people who have experienced an ACL rupture (SF, MM, EP, IAC) and one who was 18 years old when they ruptured their ACL (SF), an orthopaedic surgeon (IH) and patient decision aid and shared decision-making experts (KM, TH and RT). The first draft of the decision aid was informed by a template used for previous decision aids (for Achilles rupture[21], shoulder pain[22], antibiotics[23] and knee arthroscopy[24]) developed by some authors in the steering group (JZ, MM, KM, TH, RT, CM, and IH). Key features adopted from these decision aids included questions to consider when talking to health professionals, icon arrays to present statistics, and a table comparing the potential benefits and harms of each management option. Decision science evidence suggests these features improve patient decision making[25-28]. We also included statements of the quality of evidence, study participants demographic information and a reference list to give further context to statistics used in the decision aid.

Please also see changes to strengths and limitations in response to comment 6 above.

8. Comment
How did you control for bias in the development of the first draft?

Response
We have included the professional background of each member of the steering group for transparency as well as the history of authors who have experienced an ACL rupture themselves (see response to comment 7). We have also acknowledged in the limitations that most authors (steering group members) and health professionals we interviewed were physiotherapists. Furthermore, the author team includes experts on ACL injuries whose publication record demonstrates that their research is committed to improving treatment outcomes for patients. The first draft of the decision aid was also informed by existing rigorously developed decision aids which may have limited bias as these previous decision aids were rated by most participants as 'balanced' via acceptability questionnaires.

Gan, J. F. L., McKay, M. J., Jones, C. M. P., Harris, I. A., McCaffery, K., Thompson, R., Hoffmann, T. C., Adie, S., Maher, C. G., & Zadro, J. R. (2023, Jun 14). Developing a patient decision aid for Achilles tendon rupture management: a mixed-methods study. *BMJ Open, 13*(6), e072553. https://doi.org/10.1136/bmjopen-2023-072553

Zadro, J., Jones, C., Harris, I., Buchbinder, R., O'Connor, D. A., McCaffery, K., Thompson, R. E., Karunaratne, S., Teng, M. J., Maher, C., & Hoffmann, T. (2021, Aug 30). Development of a patient decision aid on subacromial decompression surgery and rotator cuff repair surgery: an international mixed-methods study. *BMJ Open, 11*(8), e054032. https://doi.org/10.1136/bmjopen-2021-054032).

Please also see changes to strengths and limitations in response to comment 6 above.

9. Comment
Why did you not use a consensus method, to ensure the process was systematic? This isn't mentioned in the limitations section.

Response
We have added further information to clarify that we did use a consensus method and following each interview we identified potential minor and major changes in a table. New versions of the decision aid

were circulated to the steering group to gain consensus and interviews involved asking participants their views on changes (to reach consensus). We also included reasons for not implementing some feedback (Supplementary file 15) which is referenced in the results section of the manuscript with justification based on the best available evidence and author consensus.

(Page 7, 4th paragraph)

All interview data were analysed using thematic analysis; a method for identifying, analysing and reporting patterns within data[5]. Grounded theory using an inductive approach underpinned how data were collected and analysed. Two researchers (AG and SM) independently familiarised themselves with the interviews (via audio recordings or transcripts), recorded initial observations and identified concepts relevant to the questions asked. The two researchers developed a framework to organise concepts into broader themes and subthemes in Excel. Any disagreements in categorising concepts into themes and subthemes were discussed and resolved with a third author (JZ). The mapping of themes and subthemes (figure 1) was iterative as new data emerged so that the decision aid was continually updated before new interviews were conducted. Multiple iterative cycles of revisions were performed, and new versions of the decision aid were circulated to the steering group to reach consensus following changes from interviews. In some cases, revisions were very minor changes (e.g., correcting typos, rewording a sentence). No further interviews were conducted once data saturation was achieved (no new feedback emerged) and participants had an overall positive impression of the decision aid.

10. Comment

Discussion:

In your limitation section you say "there is a lack of high-quality evidence comparing rehabilitation only to ACL reconstruction followed by rehabilitation in children and adolescents". If there is no evidence, can a decision aid tool developed at all? Does it not reduce any reliable and validity of the information given in the tool?

Response:

We acknowledge that the lack of high-quality evidence comparing rehabilitation only to ACL reconstruction followed by rehabilitation in children and adolescents limits the quality of information in the decision aid. However, as per the recent update from the International Patient Decision Aid Standards, a decision aid is often most helpful when a single most appropriate option cannot be decided based on high-certainty evidence or professional knowledge alone. Particularly, when decisions may differ between patients depending on their preference and life situation and there is greater uncertainty in management choices. Given there is evidence available, we believe it should be included in the decision-making process if the quality of evidence is transparent. We have highlighted that the quality of the evidence is low in the manuscript and the decision aid is to be used with a health professional. We believe that making a management decision with low quality evidence (the best available) and guidance from a health professional (expert opinion) is better than expert opinion alone. Our acceptability questionnaire suggested that 87% of patients thought our decision aid would have made their decision easier but we also state there is a need to test the effectiveness of the decision aid in an adequately powered randomised control trial. The decision aid also includes a date when an update will be required so new, higher-quality evidence can be incorporated to further support patients' decision-making.

Martin, R. W., Brogård Andersen, S., O'Brien, M. A., Bravo, P., Hoffmann, T., Olling, K., Shepherd, H. L., Dankl, K., Stacey, D., & Dahl Steffensen, K. 2021. Providing Balanced Information about Options in Patient Decision Aids: An Update from the International Patient Decision Aid Standards. *Medical Decision Making, 41*(7), 780-800. https://doi.org/10.1177/0272989X211021397

11. Comment

I think your limitation sections needs to be expanded with more discussion on pros and cons of the methods.

Response

We agree that it would be appropriate to expand on the pro and cons of our methods and have made significant changes to the limitations section.

Please see changes to strengths and limitations in response to comment 6 above.

REVIEWER 2 COMMENTS
Miss Hayley Carter, University Hospitals of Derby and Burton NHS Foundation Trust

1. Comment

Thank you for the opportunity to review this manuscript. This paper is an interesting contribution to the literature, considering evidence in the management of adolescent/child ACL injuries is sparse. The manuscript is well written and the processes followed within the study are clear. I have made some suggestions for areas where I feel further justification would offer greater insight into decisions made within the study and implications of the work.

Response

We thank the reviewer for their positive comments. Below is our response to each specific point raised.

2. Comment

Abstract

Introduction 1st paragraph: I feel it would help the reader if context were added to the statements about increasing rates of ACL injuries & ACLRs in children & adolescents e.g. over what time period, by how much

Response

We have added further context to the statement about the increasing rates of ACL injuries and ACLR in children and adolescents.

Page 3 (1st paragraph)
The incidence of anterior cruciate ligament (ACL) ruptures continues to increase[1]. ==The total annual incidence of ACL ruptures in children and adolescents rose by 46% between 1994 to 2013 in the United States and the overall annual rate increased by 147.8% between 2005 to 2015 in Australia==[2,3]. This increase has been linked to more children and adolescents participating in organised sport, increased intensity of training, and==, potentially,== a focus on single-sport specialisation at an earlier age[4-6]. The number of ACL reconstruction surgeries in children and adolescents is also increasing globally[1,6-8] despite non-surgical treatment (rehabilitation only) being an option[9].

3. Comment

2nd paragraph: There have been three RCTs to date comparing rehab to ACLR. This section would be strengthened by including the results from ACL SNNAP (https://doi.org/10.1016/S0140-6736(22)01424-6)

Response
We have added the SNNAP RCT trial to strengthen this section.

Page 3 (2nd paragraph)
Recommended management options following ACL rupture include rehabilitation only, rehabilitation with the choice to undergo ACL reconstruction at a later time==, or early ACL reconstruction==[10,11]. Research comparing ==these options== is scarce, particularly in children and adolescents[9]. Two randomised control trials (RCT) (n=167[11]; n=121,[10]) have shown that early ACL reconstruction in adults does not result in superior knee function, sports participation and quality of life compared to rehabilitation only with the option for delayed ACL reconstruction. ==A third RCT (n=316[12]) found that ACL reconstruction was clinically superior to rehabilitation alone for adults with ACL injury and long-term knee instability who had not trialled rehabilitation previously.== However, there are no RCT's directly comparing these treatment options in children or adolescents[13].

4. Comment
Method
Missing information: There is no information as to where ethical approval was sought/gained.

Response
We have now added where ethical approval was gained in the manuscript.

Page 1 (4th paragraph)
==Ethics approval:==
==Sydney University Human Research Ethics Committee (HRECs) approval 2022/008.==

5. Comment
1st paragraph: Could you add some detail as to why patients & parents were not included in the initial development of the patient decision aid?

Response
We have acknowledged it is a limitation that children and adolescents were not involved in all stages of the study. However, the steering group includes four people with lived experience of ACL rupture and patients and parents were heavily involved in the design of the decision aid via feedback during online interviews and questionnaires on the acceptability of the decision aid. This method has previously been employed to develop other decision aids. The first draft of our decision aid was informed by existing rigorously developed decision aids which were the result of interviews with patients.

Gan, J. F. L., McKay, M. J., Jones, C. M. P., Harris, I. A., McCaffery, K., Thompson, R., Hoffmann, T. C., Adie, S., Maher, C. G., & Zadro, J. R. (2023, Jun 14). Developing a patient decision aid for Achilles tendon rupture management: a mixed-methods study. *BMJ Open, 13*(6), e072553. https://doi.org/10.1136/bmjopen-2023-072553

Zadro, J., Jones, C., Harris, I., Buchbinder, R., O'Connor, D. A., McCaffery, K., Thompson, R. E., Karunaratne, S., Teng, M. J., Maher, C., & Hoffmann, T. (2021, Aug 30). Development of a patient decision aid on subacromial decompression surgery and rotator cuff repair surgery: an international mixed-methods study. *BMJ Open, 11*(8), e054032. https://doi.org/10.1136/bmjopen-2021-054032).

Page 2 (3rd paragraph)
Patient and Public involvement:

People who experienced an ACL rupture were part of the authorship group (SF, MM, EP, IAC). One was 18 years old when they ruptured their ACL (SF).

Page 5 (1st paragraph)

1. Methods
Initial design of the decision aid
We developed a patient decision aid informed by the International Patient Decision Aid Standards (IPDAS) checklist and Collaboration Evidence Update 2.0[20]. A multidisciplinary steering group was assembled (study authors), including topic experts on ACL injury and physiotherapists with experience managing ACL ruptures (AG, JZ, MM, DA, EP, CM, SF, SM), people who have experienced an ACL rupture (SF, MM, EP, IAC) and one who was 18 years old when they ruptured their ACL (SF), an orthopaedic surgeon (IH) and patient decision aid and shared decision-making experts (KM, TH and RT). The first draft of the decision aid was informed by a template used for previous decision aids (for Achilles rupture[21], shoulder pain[22], antibiotics[23] and knee arthroscopy[24]) developed by some authors in the steering group (JZ, MM, KM, TH, RT, CM, and IH). Key features adopted from these decision aids included questions to consider when talking to health professionals, icon arrays to present statistics, and a table comparing the potential benefits and harms of each management option. Decision science evidence suggests these features improve patient decision making[25-28]. We also included statements of the quality of evidence, study participants demographic information and a reference list to give further context to statistics used in the decision aid.

Page 18 (2nd and 3rd paragraph)
Strengths and Limitations
Our development process (Supplementary file 17) had several strengths. The steering group includes people who experienced an ACL rupture and one who was 18 years old when they ruptured their ACL, the manuscript is transparent about the authors' professional backgrounds, the design, conduct and reporting of this study were guided by the IPDAS criteria, we conducted one-on-one interviews with participants which allowed for rich feedback to be gathered on the decision aid, and used mixed methods to evaluate acceptability of the decision aid. The readability of our tool measured higher (Grade 9 to 11) than recommendations (Grade 8) but contains multiple features to support understanding and readability that aligns with best practice[45] including bullet points, white space, images, and sub-headers. The tool therefore performs well relative to existing decision aids in terms of its attention to health literacy[45]. We also included justification of the evidence used to inform numeric estimates of benefits and harms in the decision aid and used the highest quality evidence available comparing rehabilitation only and ACL reconstruction followed by rehabilitation for children and adolescents[13].

Our patient decision aid was limited by the lack of high-quality evidence comparing rehabilitation only to ACL reconstruction followed by rehabilitation in children and adolescents. Emergence of future studies related to this topic will likely warrant an update of the evidence used in the decision aid. Another limitation is that evidence from older studies did not always report details of rehabilitation or consider advances in treatment to know if they reflect current recommended practice. We were unable to recruit any children-participants to interview and adolescent-participants were aged between 15-17 years old. We did interview health professionals who treat children and younger adolescents, but not being able to recruit children-participants means the decision aid was not directly influenced by children's feedback. Most authors are physiotherapists, and most health professional-participants were physiotherapists (75%), trained in Australia (69%) and worked in private practice (63%) which may impact the themes that emerged from interviews (e.g., views on costs and waiting time for ACL reconstruction). Recruitment of participants was difficult which was expected without

offering incentives for their time. We didn't directly involve children or adolescents in all stages of the study as consumers, and stakeholder involvement heavily influenced the design of the decision aid via feedback during online interviews and questionnaires on the acceptability of the decision aid. Our aim was to interview participants until we achieved data saturation, but we acknowledge that the majority of participants were Australian (60%). Including participants from several different countries may have made the decision aid more globally acceptable (e.g., feedback was influenced by different cultures and healthcare systems) but the sample size of participants from each country may limit the generalisability of the decision aid for use in different countries. Future work includes adapting this decision aid for culturally and linguistically diverse populations as it is only presented in English.

6. Comment

Participants paragraph: the justification for the inclusion of adult participants who had ruptured their ACL when under 18 isn't clear here or why this was necessary in addition to adolescents and their parents.

Response

We have added a sentence to justify why we included adult participants.

Page 5 (3rd paragraph)

Participants

We interviewed people who ruptured their ACL when they were under 18 years old, their parents, and health professionals who manage patients following an ACL rupture. Some participants who ruptured their ACL when they were under 18 years old were adolescents at the time of interview (adolescent-participants) and some were adults (adult-participants). We included both adolescent-participants and adult-participants as we thought they would give a different perspective on what information is important when considering the best management approach following ACL rupture. For example, adult-participants could provide hindsight influenced by longer-term impacts of their decision. Participants were required to have had their ACL rupture verified previously by an MRI. Participants who were under 18 years old at the time of interview were accompanied by a parent (who we also interviewed). Health professionals needed to review ≥5 patients (including some who are under 18 years old) with ACL rupture per year and there was no restriction on type (e.g., orthopaedic surgeon, physiotherapist, general practitioner), work setting, country of practice, or years of experience. All participants needed to be able to understand written and verbal English. There was no restriction on participant country of birth.

7. Comment

Semi structured interviews, 2nd paragraph: "At the end of each interview, participants were given the opportunity to provide any additional feedback or comments", justification as to why this was necessary in addition to the interview and acceptability questionnaire would be beneficial for the reader, I'm not clear why this was needed.

Response

This was a continuation of the interview to gain further feedback, but we have removed this sentence to avoid confusion.

8. Comment

Results

1st paragraph: you mention not meeting 3 quality criteria from IPDASi including readability levels and evaluating the decision aid. Could you add some justification as to why readability levels are not included?

Response

We conducted the readability evaluation of the decision aid using the SHeLL Editor tool as recommended in the IPDASi checklist.

Page 8 (1st paragraph)

Results:

Adherence to the IPDAS criteria and user-centredness

The decision aid (supplementary file 12) met all 6 of the criteria to be considered a decision aid, all 6 of the criteria to reduce the risk of harmful bias, and <mark>21</mark> of the 23 quality criteria according to the IPDASi checklist (V.4.0)[34] (supplementary file 13). The <mark>two</mark> IPDASi criteria that were not met involved evaluating the decision aid. <mark>Readability was assessed including all the decision aid text (Grade 11.8) and without necessary complex words (Grade 9.7) using the SHeLL Editor (https://shell.techlab.works)</mark>. Our decision aid also met 10 of the 11 criteria for user-centredness (supplementary file 14) as assessed by the User-Centred Design 11-item measure[35].

9. Comment

Table 2: Is there data missing for years of experience?

Response

There are no data missing for years of experience (11.5 (7.3)). There is a gap due to work setting being a separate sub-heading.

10. Comment

Discussion

4th paragraph: You mention a recommended age limit for use of the decision aid, but this isn't clear on the decision aid itself or within the manuscript.

Response

We have removed this statement and made minor edits to the following sentence to clarify this as we did not include an age limit for the decision aid but state it is for children and adolescents.

Page 16 (5th paragraph)

Some physiotherapists and orthopaedic surgeons had conflicting views on using evidence from research that had included participants over 18 years old. <mark>Given the decision aid is not for adults with an ACL rupture, we</mark> decided not to present data from studies in people over 18 years to avoid children and adolescents having to consider multiple data sources and potentially becoming confused[37]. <mark>The decision aid is designed for children and adolescents and includes prompts to encourage management that considers individual circumstances and different rates of child development (e.g., questions to consider when talking to a health professional and key points).</mark>

11. Comment

5th paragraph: "Some parents suggested the decision aid would save them time (e.g., "would have saved me hours of googling") but one parent withdrew their adolescent from an interview due to concerns (e.g., "seeing potential harms could disrupt focus on rehabilitation"). Parents and health professionals should consider encouraging children and adolescents to be involved in shared decision-making[9,37,38] and informing them of potential risks." I think further discussion is needed here. Was involving children in shared decision-making conversations discussed in the interviews to offer

insight on this comment? What were clinicians/parents/children's thought? Motivation to be involved in SDM is multi-factorial, for example, some do not wish to be responsible for a decision made about treatment and so do not want to engage. If a parent has expressed concern before using the decision aid, how might this impact implementation in clinical practice?

Response

Involving children and adolescents in shared decision-making was discussed in the interviews. We have modified the discussion to highlight that shared decision making was discussed during interviews and the potential implications for implementing this decision aid in clinical practice.

Page 17 (2nd and 3rd paragraph)

Although children and adolescents should be encouraged to take an active role in the decision-making process, interviews with parents suggested that individual circumstances may dictate how the decision aid is best used. Some parents suggested the decision aid would save them time when researching information to help with making treatment choices (e.g., *"getting this handout instead of me having to go home and Google, I Googled many, many nights trying to find you know, something like this"* (F, 41-50 years old, parent)). One parent withdrew their adolescent child before the interview due to concerns that discussion of potential harms could disrupt their child's focus on rehabilitation. This adolescent recently had ACL reconstruction and was not given the option to have non-surgical management based on their injuries. Overall, parents and health professionals should consider encouraging children and adolescents to be involved in shared decision-making[9,38,39] and consider that the decision aid is designed to be used before making the management decision. Once a decision is made, particularly an irreversible decision, parents and health professionals may have an important role in guiding focus and promoting optimism.

The decision aid can facilitate parents discussing their child's treatment preference, sport choice and potential harms of participation. Parents and health professionals should acknowledge their supporting role in treatment decisions (e.g., *"it's important that we listen to the kids and what they have to say, it's their body"* (F, 41-50 years old, parent)). Discussions of sporting choice may solidify a decision or lead to diversifying sporting participation that has been shown to encourage the development of resilient self-identities[37]. Parental anxiety or pain catastrophising has been shown to negatively influence children's anxiety, postoperative pain and ability to perform rehabilitation[40]. While potential harms and uncertainty of returning to sport can be a sensitive topic, their acknowledgment could also provide reassurance to children and adolescences if something goes wrong (e.g., *"as a parent you're trying to make sure they understand the decision they're making"* (F, 41-50 years old, parent)).

12. Comment

Strengths and limitations

You mentioned in the methods aiming for diversity of profession but 75% of health professionals interviewed were physiotherapists. Could you add acknowledgement of this to your limitations in addition to consideration as to how the results may have been influenced by the physiotherapy profession more so than orthopaedic surgeons/other professions & what implications this may have? In addition, over 50% of your patient participants were adults at the time of interview. I'm not clear on the benefit of interviewing adults (particularly given the upper age of 33) on a decision aid for use with adolescents and children? The age range of the adolescents interviewed was also high given the decision aid could be used with someone younger. Although you mention not interviewing children, I feel further discussion on this would be beneficial. In addition, most of the patient participants you interviewed had private health insurance, it would be useful to consider how a patient without this would may offer different insight on the decision aid.

Response

We have acknowledged that 75% of the health professionals interviewed were physiotherapists in the limitations and have discussed the potential implications of this. We added a sentence to justify why we thought it would be helpful to interview adults who ruptured their ACL when they were under the age of 18 years old and the difficulty of recruiting younger patients. We have also added a sentence to acknowledge that most of the patients we interviewed had private health insurance and how this may affect views including costs and potential waiting times for ACL reconstruction.

Please also see the updated limitations section in the response to comment 5.

13. Comment

Although you described in the methods that there was no restriction on country of practice for health professionals & that you set to achieve diversity in this demographic, a large proportion of the therapists trained in Australia. It would be useful to add this to the limitations section & consider the implications of this. It is also unclear as to whether they also continue to practice in the country they trained or whether all the health professions now practice in Australia?

Response

We have added that a large portion of health professionals interviewed were trained in Australia and added that all health professionals interviewed were currently practising in their country of training at the time of interviews.

Please see the updated limitations section in the response to comment 5.

Table 2: Characteristics of health professionals that manage patients with ACL ruptures.

Participant groups pre interview questionnaire responses (All statistics are reported as Mean (SD) or N (%), unless specified otherwise)		Health Professionals (n=16)
Age (years) range		39 (8.6) 23-54
Female		3 (19%)
Country of health professional training*	Australia	11 (69%)
	Germany	1 (6%)
	Switzerland	1 (6%)
	United Kingdom	1 (6%)
	United States of America (USA)	2 (13%)
Role	Physiotherapist	12 (75%)
	Orthopaedic surgeon	4 (25%)
Years of experience		11.5 (7.3)
Work setting	Private practice	11 (63%)
	Private hospital	1 (6%)
	Public hospital	4 (25%)
	Other	1 (6%)
Average number of patients with ACL rupture managed per year	5	1 (6%)
	5-10	5 (31%)
	10-20	2 (13%)
	20-30	3 (19%)
	>50	5 (31%)
The percentage of patients recommended to have ACL reconstruction following ACL rupture		67 (20.3)

N, number of health professionals that manage patients with ACL ruptures. *All health professional-participants were practicing in their country of training at the time of interviews.

14. Comment

Conclusion

1st sentence: I feel 'valuable' should be changed to 'acceptable' to make it clearer that the effectiveness of the decision aid is currently unknown.

Response

We have changed 'valuable' to 'acceptable' to make it clearer that the effectiveness of the decision aid is currently unknown.

Page 19 (4th paragraph)

Conclusion

Our patient decision aid appears to be ==an acceptable== tool to help children and adolescents following ACL rupture choose between surgical and non-surgical management, with support from their parents and health professionals. Feedback from adolescents frequently suggested the importance of planning to include psychological and social support during rehabilitation. Feedback also suggested that health professionals should use positive messaging despite uncertainty of outcomes, while avoiding the creation of unrealistic expectations. Our patient decision aid is a user-friendly tool that could improve decision making in children and adolescents following ACL rupture. A randomised controlled trial evaluating its impact is the next important step.

VERSION 2 – REVIEW

REVIEWER	Smith, Benjamin Derby Teaching Hospitals NHS Foundation Trust, Physiotherapy Outpatients
REVIEW RETURNED	26-Mar-2024

GENERAL COMMENTS	Thank you for inviting me to review the revised manuscript. I congratulate the authors on an improved document, and I feel my points have been addressed adequately.

REVIEWER	Carter, Hayley University Hospitals of Derby and Burton NHS Foundation Trust, Department of Physiotherapy
REVIEW RETURNED	07-Mar-2024

GENERAL COMMENTS	I thank the authors for a clear and thorough response to peer review comments adding further clarity and justification to study procedures. I have a few final suggestions. Abstract Setting: would the authors consider detailing who was present as part of the multidisciplinary steering group? I feel this would be beneficial to be included in the abstract. Strengths and limitations: I'm not sure the description of the one-to-one interviews as rich is accurate. I would agree it allowed for different perspectives of healthcare professionals working in different settings. I'm also unsure whether it limits generalisability of the PDA, perhaps usability might be a better description? Introduction The addition of ACL SNNAP strengthens the introduction of the literature however I'm not sure the statement of its results is quite

	accurate. Some patients who had ACLR had rehabilitation first & crossed over to the surgical arm of the trial. The sentence "who had not trialled rehabilitation previously" is therefore not representative of the results of ACL SNNAP. Methods Page 9, 2nd paragraph You've added that "new versions of the decision aid were circulated to the steering group to reach consensus following changes from interviews". How was consensus reached?

VERSION 2 – AUTHOR RESPONSE

REVIEWER 1 COMMENTS
Mr. Benjamin Smith, Derby Teaching Hospitals NHS Foundation Trust, University of Nottingham School of Medicine

1. Comment
Thank you for inviting me to review the revised manuscript.
I congratulate the authors on an improved document, and I feel my points have been addressed adequately.

Response
We thank the reviewer for their positive comments.

REVIEWER 2 COMMENTS
Miss Hayley Carter, University Hospitals of Derby and Burton NHS Foundation Trust

1. Comment
I thank the authors for a clear and thorough response to peer review comments adding further clarity and justification to study procedures. I have a few final suggestions.

Response
We thank the reviewer for their positive comments. Below is our response to each specific point raised.

2. Comment
Abstract
Setting: would the authors consider detailing who was present as part of the multidisciplinary steering group? I feel this would be beneficial to be included in the abstract.

Response
We have made a change to include detailing who was part of the multidisciplinary steering group in the abstract.

ABSTRACT

Aim: To develop and user test an evidence-based patient decision aid for children and adolescents who are considering anterior cruciate ligament (ACL) reconstruction.

Design: Mixed-methods study describing the development of a patient decision aid.

Setting: A draft decision aid was developed by a multidisciplinary steering group (including various types of health professionals and researchers, and consumers) informed by the best available evidence and existing patient decision aids.

Participants: People who ruptured their ACL when they were under 18 years old (i.e. adolescents), their parents, and health professionals who manage these patients. Participants were recruited through social media and the network outreach of the steering group.

Primary and secondary outcomes: Semi-structured interviews and questionnaires were used to gather feedback on the decision aid. The feedback was used to refine the decision aid and assess acceptability. An iterative cycle of interviews, refining the aid according to feedback and further interviews, was used. Interviews were analysed using reflexive thematic analysis.

Results: We conducted 32 interviews; 16 health professionals (12 physiotherapists, 4 orthopaedic surgeons) and 16 people who ruptured their ACL when they were under 18 years old (7 were adolescents and 9 were adults at the time of the interview). Parents participated in 8 interviews. Most health professionals, patients, and parents rated the aid's acceptability as good-to-excellent. Health professionals and patients agreed on most aspects of the decision aid, but some health professionals had differing views on non-surgical management, risk of harms, treatment protocols and evidence on benefits and harms.

Conclusion: Our patient decision aid is an acceptable tool to help children and adolescents choose an appropriate management option following ACL rupture with their parents and health professionals. A clinical trial evaluating the potential benefit of this tool for children and adolescents considering ACL reconstruction is warranted.

3. Comment

Strengths and limitations: I'm not sure the description of the one-to-one interviews as rich is accurate. I would agree it allowed for different perspectives of healthcare professionals working in different settings. I'm also unsure whether it limits generalisability of the PDA, perhaps usability might be a better description?

Response

We have changed 'rich' to 'in-depth' to be more accurate. We feel this term better reflects that one-to-one interviews allowed more focused time to explore each participant's feedback. We have also changed the term 'generalisability' to 'usability'.

Strengths and limitations of this study:
- We developed a decision aid that satisfies the International Patient Decision Aid Standards criteria and used mixed methods to evaluate acceptability of the decision aid.
- One-on-one interviews conducted with participants from different countries allowed for in-depth feedback to be gathered on the decision aid, but the usability of the decision aid may be limited by the number of interviews with participants from each country.
- We were able to interview health professionals who manage children who have ruptured their anterior cruciate ligament but were unable to recruit children-participants to interview with their parents.
- Our patient decision aid was limited by the lack of high-quality evidence comparing rehabilitation only to ACL reconstruction followed by rehabilitation in children and adolescents.

- The systematic review used to inform estimates of benefits and harms included older studies that did not always report details of rehabilitation and may not reflect advances in treatment.

Page 17 (2nd paragraph) and page 18 (1st paragraph)
Strengths and Limitations
Our development process (Supplementary file 17) had several strengths. The steering group includes people who experienced an ACL rupture and one who was 18 years old when they ruptured their ACL, the manuscript is transparent about the authors' professional backgrounds, the design, conduct and reporting of this study were guided by the IPDAS criteria, we conducted one-on-one interviews with participants which allowed for in-depth feedback to be gathered on the decision aid, and used mixed methods to evaluate acceptability of the decision aid. ….

Including participants from several different countries may have made the decision aid more globally acceptable (e.g., feedback was influenced by different cultures and healthcare systems) but the sample size of participants from each country may limit the usability of the decision aid for use in different countries. Future work includes adapting this decision aid for culturally and linguistically diverse populations as it is only presented in English.

4. Comment
Introduction
The addition of ACL SNNAP strengthens the introduction of the literature however I'm not sure the statement of its results is quite accurate. Some patients who had ACLR had rehabilitation first & crossed over to the surgical arm of the trial. The sentence "who had not trialled rehabilitation previously" is therefore not representative of the results of ACL SNNAP.

Response
We have removed 'who had not trialled rehabilitation previously' and added 'non-acute'.

Page 4 (2nd paragraph)
Recommended management options following ACL rupture include rehabilitation only, rehabilitation with the choice to undergo ACL reconstruction at a later time, or early ACL reconstruction[10,11]. Research comparing these options is scarce, particularly in children and adolescents[9]. Two randomised control trials (RCT) (n=167[11]; n=121,[10]) have shown that early ACL reconstruction in adults does not result in superior knee function, sports participation and quality of life compared to rehabilitation only with the option for delayed ACL reconstruction. A third RCT (n=316[12]) found that ACL reconstruction was clinically superior to rehabilitation alone for adults with non-acute ACL injury and long-term knee instability. However, there are no RCT's directly comparing these treatment options in children or adolescents[13].

5. Comment
Methods
Page 9, 2nd paragraph
You've added that "new versions of the decision aid were circulated to the steering group to reach consensus following changes from interviews". How was consensus reached?

Response
We have added a sentence to outline that consensus was reached when the majority of the steering group agreed with proposed changes.

Page 7 (3rd paragraph)
All interview data were analysed using thematic analysis; a method for identifying, analysing and reporting patterns within data[33]. Grounded theory using an inductive approach underpinned how

data were collected and analysed. Two researchers (AG and SM) independently familiarised themselves with the interviews (via audio recordings or transcripts), recorded initial observations and identified concepts relevant to the questions asked. The two researchers developed a framework to organise concepts into broader themes and subthemes in Excel. Any disagreements in categorising concepts into themes and subthemes were discussed and resolved with a third author (JZ). The mapping of themes and subthemes (figure 1) was iterative as new data emerged so that the decision aid was continually updated before new interviews were conducted. Multiple iterative cycles of revisions were performed, and new versions of the decision aid were circulated to the steering group to reach consensus following changes from interviews. Consensus was reached by the majority of the steering group agreeing with proposed changes. In some cases, revisions were very minor changes (e.g., correcting typos, rewording a sentence). No further interviews were conducted once data saturation was achieved (no new feedback emerged) and participants had an overall positive impression of the decision aid.