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5 **Decision aids for randomised controlled trials: a qualitative exploration of stakeholders'**
6 **views.**
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ABSTRACT**Word count 228**

Objectives To explore stakeholders' perceptions of decision aids designed to support the informed consent decision making process for randomised controlled trials.

Design Qualitative semi-structured interviews that included participants being provided with prototype trial decision aids in advance to stimulate discussion. Interviews were analysed using an established interpretive approach.

Participants 23 stakeholders: trialists (n=5); research nurses (n=5); ethics committee chairs (n=5); patients (n=4) and clinical principal investigators (n=4).

Setting Embedded within two ongoing randomised controlled trials. All interviews conducted with UK based participants.

Results Certain key aspects (e.g. values clarification exercises, presentation of probabilities, experiences of others and balance of options) in the prototype decision aids were perceived by all stakeholders as having a significant advantage (over existing patient information leaflets) in terms of supporting well informed appropriate decisions. More generally the stakeholders believed trial decision aids have the potential to better engage potential participants in the decision making process and allow them to make more personally relevant decisions about their participation. Interestingly, stakeholder views did differ on specific content and design aspects of the trial decision aids (such as length of information and mode of delivery).

Conclusion Compared to existing patient information leaflets, stakeholders perceived decision aids for trial participation to have the potential to promote a more 'informed' decision making process. Further efforts to develop, refine and formally evaluate trial decision aids should be explored.

Article Summary

Strengths and limitations of this study

- This study is the first to explore, and evidence, the potential of a decision aid to support decision making for participating in a randomised controlled trial from the perspectives of a range of stakeholders, including: patients; trialists; research nurses; clinician researchers; and ethics committee chairs.
- Compared to existing patient information leaflets, this study has shown that trial decision aids have the potential to better engage potential participants in the decision making process and allow them to make more personally relevant decisions about their participation.
- All the participants in our study were UK based and a self-selecting sample and therefore may hold different views to those in other countries with different social norms and cultures. However, these participants can offer thoughtful and reflective insights into decision aids for trial participation when reflecting on their own trial experience including reflection on existing PILs.

INTRODUCTION

There is an ethical requirement to obtain informed consent from potential participants before they are enrolled in a randomised controlled trial (RCT) [1, 2]. As part of the informed consent process, potential trial participants are provided with written information about the trial often in the form of a participant information leaflet (PIL) [3]. The information included in PILs is largely guided by the Declaration of Helsinki, the international Conference on Harmonisation and Good Clinical Practice (ICH GCP) and, in the UK, by national guidance such as the National Research Ethics Service (NRES) [2, 3, 4]. As outlined by this guidance the PIL should include largely fact-based information about: the purpose of the trial; procedures; interventions; possible risks and benefits; sources of finance; conflicts of interest; and the researcher's affiliation [3, 4].

Existing PILs may be sub-optimal; research has shown that some trial participants (both those considering participation and those actively enrolled) fail to understand key aspects of trial rationale or process [5, 6]. A range of studies have tested ways to improve information provision in the context of trials [6]. These have tended to focus on the content and structure of the information and measured outcomes such as understanding, recall and trial recruitment [6]. Whilst improving understanding of the trial is important, informed decision making about trial participation is complex and likely to require more than just greater understanding of fact-based information [6]. Furthermore, it has been argued that PILs are 'institutionally scripted' as a means to obtain ethical approval rather than functioning as a tool to support potential participants' decision making [7]. As such, the current conceptualisation of 'informed consent' (largely as understanding of information) and how it is enacted (through signing of a consent form) may be overly narrow and require broadening to consider the importance of deliberation and determination in the decision making process for trial participation [8, 9].

Evidence from the treatment and screening decision making literature has highlighted that certain key items are important for making 'good' decisions [10, 11]. For example, being able to consider alternative options (in the context of trial participation this may be another intervention or may be usual care), making trade-offs and evaluating potential outcomes of

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3 the decision and consideration of what those outcomes mean personally for that individual.
4 These items, and others, are often included in decision aids, which actively encourage
5 people to participate in decisions about treatment that involve weighing up associated
6 benefits and harms often when there is clinical uncertainty [10]. Decision aids have been
7 developed for a variety of treatment and screening decisions and have been shown to
8 positively influence several aspects of decision making [10]. The items identified as being
9 important for good decision making are largely lacking from existing PILs for trial
10 participation [12], further supporting the contention that existing PILs do not function well
11 as decision making tools [12].
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21 The very few published studies that have explored the use of decision aids, or components
22 of them, in the context of trial participation decisions have shown some promise [13, 14,
23 15]. However, these studies have solely focused on trial participants' perceptions and have
24 not explored other stakeholders' opinions. Whilst trial participants perspectives are
25 important, replacement of, or any amendments to existing PILs would require buy-in from
26 an additional range of stakeholders, such as: developers (e.g. trial managers); deliverers
27 (e.g. research nurses and clinician researchers); and approvers (e.g. ethics committees).
28 This buy-in is critical to ensuring that trial decision aids are as effective as they can be (i.e.
29 act as a decision support tool to facilitate meaningful conversations that encourage
30 informed decision making), are implementable and used as intended. Although treatment
31 and screening decision aids have been shown to be efficacious, the main barriers to their
32 effectiveness in a real world setting are a lack of implementation and fidelity of use often as
33 a result of a lack of buy-in at inception from stakeholders [16, 17]. Furthermore, previous
34 studies have not explicitly explored perceptions of the 'new' content (i.e. features to
35 improve decision making), which define decision aids as different to existing PILs.
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49 The study reported in this manuscript forms part of a larger programme of work that aimed
50 to systematically develop and pilot (through interviews reported here) prototype trial
51 decision aids. The prototype decision aids were developed through an iterative process
52 informed by the MRCs framework on development of complex interventions [18]. The
53 process began with establishing the current evidence on the effectiveness of decision aids
54 for supporting decisions about RCT participation [19]. Next a Delphi study was conducted,
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3 with a range of stakeholders, to identify key items for inclusion [20], followed by an
4 evaluation of existing PILs using a tool (that contains items assessing key features of 'good'
5 decision making) to identify areas that were lacking [12], drafting of prototype decision aids
6 (informed by previous stages), followed by rounds of revision within the study team. We
7 then undertook an in-depth qualitative study to explore stakeholders' views and
8 perspectives on the specific content of the prototype decision aids and their potential to
9 improve the informed consent process for RCTs (it is this qualitative study that is reported
10 here).

11 12 13 14 15 16 17 18 19 **METHODS**

20 **Development of the prototype trial participation decision aids**

21
22 Prototype decision aids were developed for two on-going RCTs (one surgical; one drug trial)
23 identified from the portfolio of RCTs managed by the Centre of Healthcare Randomised
24 Trials (CHaRT) at the University of Aberdeen. The content of the prototype decision aids
25 was developed through the iterative process outlined above. The prototype decision aids
26 were enhanced by a Graphic Designer, at the University of Aberdeen, to improve the visual
27 impact of the tools. The tools were presented as A5 booklets which could be printed or
28 read as a PDF document.

29 **Exploration of stakeholders' perceptions of trial decision aids.**

30
31 Semi-structured interviews were conducted with different stakeholder groups (including
32 patients, trialists, research nurses, ethics committee chairs and lead clinicians involved with
33 both trials) to explore perspectives about the use of decision aids in a trials context.

34 35 36 **Sampling and recruitment**

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38 Potential participants from the trialist, research nurse and ethics committee chair
39 stakeholder groups were identified through email list serves (trialists: UK Clinical Research
40 Collaboration Trial Managers listserv; research nurses: Scottish Research Nurse and
41 Coordinators Network listserv; ethics committee chairs: National Research Ethics Service
42 committee chair listserv). Patients who would be eligible for each RCT were identified and
43 contacted by a research nurse working at the lead site for each of the RCTs. Prospective
44 participants were sent a letter of invite with a slip to return, or email response, to express
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3 interest. Interested participants were then sent full information about the study, and a
4 consent form. Ethics committee chairs, Principal Investigators, Research Nurses and trialists
5 who were recruited for interview were sent a copy of both decision aids to review.
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7 Recruited patients were only sent the decision aid relevant for their condition. Recruited
8
9 participants were given the choice of a face-to-face or telephone interview. All participants
10 provided written consent.
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13 14 15 **Data collection**

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17 One author (KG) conducted the interviews between April 2012 and July 2012. Only one
18 patient participant chose a face-to-face interview. Interviews were audio-recorded,
19 transcribed verbatim and anonymised. At the start of the interviews, participants were
20 encouraged to provide their views and perspectives on existing patient information leaflets
21 for clinical trials and discuss their experiences of participating in clinical trials or reviewing
22 clinical trial information, as appropriate. All participants were then asked about their views
23 of the prototype decision aids and how they might, or might not, support a decision about
24 trial participation.
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32 33 **Data management and analysis**

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35 A thematic content analysis of the transcripts was conducted. An established interpretive
36 approach was used whereby following familiarisation with the transcripts, *a priori* and
37 emergent themes were identified, discussed and agreed by the research team [21]. Two
38 authors (KG & ZS) independently reviewed transcripts and documented the major emerging
39 themes. A thematic framework was subsequently generated, and agreed through
40 discussion with all authors, which detailed codes for labelling textual data related to the
41 major themes and sub-themes. Codes with specific relevance to decision aids (and items
42 which define them as being distinct from existing PILs) were used as *a priori* codes for key
43 parts of the interview transcripts. Transcripts were subsequently coded by one author (KG),
44 in which the thematic framework was applied systematically to the textual data. This
45 process was managed through the use of text management software (NVivo 10). This
46 facilitated data organisation which promoted further analytic consideration through
47 constant comparison of data both within and across the stakeholder groups. Relevant
48 quotes representing interviewees' considerations were selected to illustrate the results.
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RESULTS

Sample characteristics

Fifty individuals contacted the researcher (23 trialists; 10 research nurses; 8 ethics committee chairs; 5 patients and 4 lead clinicians) and 23 were interviewed. In those stakeholder groups where more participants responded than were required for interview, participants were sampled purposively based on affiliation with registered UKCRC clinical trials units and further stratified for geographic location. The number of participants in each group was decided on a predetermined judgement that each group should contain a similar number and be informed by the numbers in the patient group (n=4). The interviews ranged from 40-80 minutes. We deemed this sample size to be sufficient to identify a range of experiences and views that would generate a manageable amount of data for in-depth analysis within the timescale of this project [22].

A brief description of the participants is provided in Table 1. They included 12 women and 11 men, aged from 35 to 80, who were from the following stakeholder groups: trialists (n=5); research nurses (n=5); ethics committee chairs (n=5); patients (n=4) and lead clinicians (n=4). Twelve of the sample had experience of working for an NHS organisation and 7 worked within Universities. Experience of working in clinical trials (which could be as a recruiter, a trial manager, a reviewer of ethical applications of trials) ranged from 3 to 20 years. The majority of the group (n=21) had no previous experience of decision aids but all stakeholders had previous exposure to PILs for trials.

General impressions of the trial decision aids compared to existing information leaflets

The majority of stakeholders perceived that, in principle, trial decision aids were beneficial and an improvement on existing PILs. There was a perception that they provided a 'balanced', unbiased picture, that they were uncomplicated and that they could proactively facilitate more engagement in the decision, compared to existing PILs.

'it's very well balanced and I think that's really important because it's not leading anybody in any one direction. And I think that's an excellent part of the whole booklet itself.' (Patient 3)

'I think that they [decision aids] are very, very straight forward actually, that as I've said before the patient information leaflets are very wordy things and they have a lot of

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3 *information to impart to patients and sometimes they will switch off after the third*
4 *paragraph.’ (Research Nurse 1)*
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8 *‘there’s not just an information sheet; there’s a decision making tool to help the patient*
9 *make decisions, rather than it just being a passive thing of read the information leaflet ...*
10 *whereas this is actually making them work through and think about it, and this is obviously*
11 *the biggest change and I do think this would be of a benefit.’ (Trialist 2)*
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17 Although most of the initial perceptions of the decision aids were positive, some
18 respondents did feel that the use of a decision aid could potentially over-complicate the
19 decision process in this context by providing more information and potentially raising
20 concerns.
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23
24 *‘My concerns were that sometimes people feel that the patient information sheet alone is*
25 *onerous, so adding something else on might actually put some people off..... just that it*
26 *might increase fear or uncertainty. It almost makes the decision bigger, by adding in this*
27 *decision making tool.’ (Research Nurse 5)*
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32 33 **Perception of trial decision aid content**

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35 This section of the paper reports the findings relating to specific aspects of the decision aids
36 which are not routinely included in patient information leaflets for trial participation.
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38 ***Provision of information about positive and negative features of taking part in the trial.***

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40 The trial decision aids included information on both the advantages and disadvantages of
41 both options (participating in the trial or not) whereas existing PILs generally only cover
42 issues relating to trial participation [12]. There were varied views expressed when
43 participants reflected on whether the information included about positive and negative
44 features of participating in the trial or not was balanced. Some recognised this was a new
45 addition to the standard information and felt the section was well balanced and would be
46 helpful for potential participants to make an informed choice about participation.
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54 *‘I think this does just outline the different variables really that, you know, there are*
55 *disadvantages about taking part in clinical studies and there are disadvantages about not.*
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3 *It's an interesting new thing as far as I can see, I've not see anything quite that descriptive*
4 *before.'* (Research Nurse 1)
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8 Other participants felt that whilst the overall concept of providing information about both
9 options was advantageous, some of the included information about advantages and
10 disadvantages of options could be deemed as being potentially coercive.

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13 *'And I thought that they [sections on advantages and disadvantages participating in the trial*
14 *or not participating] were quite helpful.... I did think that one of the sentences [You will*
15 *receive extra personalised care and attention from research nurses by taking part in the*
16 *trial] possibly was a bit over-emotive.'* (Trialist 4)
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22 Even though many participants agreed that advantages and disadvantages about both
23 options should be included, all of the ethics committee chairs reported some of the
24 language as potentially inappropriate and stated that ethics committees would be
25 uncomfortable with some statements. For example:
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29 *'I think that there's quite a lot of emphasis on saying to people one of the advantages of*
30 *taking part is that you'll get some extra care and attention... Now, in a sense that's true*
31 *given that that is built in to the research procedure, but certainly the committee, we're*
32 *very... we're very sensitive to anything that could be taken as an extra inducement to take*
33 *part. And I felt that one or both of these was a bit more emphatic about that and if we'd be*
34 *reviewing these as a committee I think we wouldn't have been very comfortable with that.'*
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40 (Ethics Committee Chair 2)
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43 **Presentation of probabilities**

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45 Methods used to present probabilities of outcomes associated with interventions across the
46 two prototype trial decision aids were varied according to reported methods of good
47 practice for decision aids [11](see Box 1). Participants were asked to compare where
48 appropriate. There was recognition amongst participants that presenting complex
49 probabilistic information to potential trial participants is challenging and that individuals
50 have varied preferences and understandings of this type of information, especially within
51 the context of clinical trials and the interventions they are testing.
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3 *'I think it's a good way of presenting it [risks] in a different way. I think presenting risk as*
4 *words and as numbers and as something visual is going to help. I think in the end it's still a*
5 *very hard thing for people to understand, as I said, at a personal level.'* (Ethics Committee
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Chair 3).

A couple of participants raised the importance of placing risk within the context of familiar activities as an effective way to allow potential participants to make judgements about the risks they are willing to take.

'you could say, "This list does look long and worrying but actually these side-effects don't occur very often. By comparison if we listed all the side-effects of paracetamol these are the things you would be told about" and you could say very commonly without any problem at all.' (Principal Investigator 2)

Methods for clarifying and expressing values.

The majority felt that values clarification exercises included in the trial decision aids (see Box 2), which allow patients to trade-off positive and negative features of the decision to facilitate personally meaningful decision making, were helpful and that they had the potential to facilitate the decision making process.

'I mentioned that the pros and cons is very, very good, I think that that would help a lot of people make decisions and it talks about what would happen to me if I didn't take part in this study as well so that's something that we don't, well we say "Oh well that's Ok, you'll just get the standard course of treatment" is there anything negative about me not taking part, that's important to emphasise that as well.' (Research Nurse 4)

A significant potential benefit of values clarification exercises that was highlighted by participants was their potential to allow potential trial participants to make personally relevant decisions by weighing up what matters most to them, within the context of the clinical trial.

'I think it would probably be quite useful just to have that let them weigh that up, whether they want to take part or not.' (Principal Investigator 3)

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3 *'And that's very powerful, they're making a decision that feels to them very fair because*
4 *they've done a weighting process around it. So I really, really liked this.'* (Research Nurse 5)
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8 However, some other participants felt that the exercises themselves, or aspects of them
9 (such as the term 'worksheets' and the lengthy instructions for completion), would not be
10 helpful and would be perceived negatively.
11

12 *'... I don't know, it just made me think you know patients thinks, "Ah worksheets, am I going*
13 *to have to fill in loads of stuff?''* (Trialist 1)
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17 18 19 **Structured guidance in deliberation.**

20 Decision aids should provide steps to assist the patient in making a decision, which may
21 include suggesting ways to talk through the decision with health professionals and including
22 tools (worksheets or question lists) that would allow discussion with others [11]. Several of
23 the participants stated that the identified steps for making a decision (a list of 6 items
24 outlining the process) that were highlighted in the decision aid (see Box 3) were a helpful
25 addition.
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27

28 *'I think putting out how somebody might make a decision. You know, the six points [decision*
29 *guidance]. And I think setting all of this... I was pleased that when I read it through.'* (Ethics
30 *Committee Chair 4)*
31
32

33 *'I do think that's good; rather than giving them all the information and then saying "Right,*
34 *now it's up to you to make a decision." it almost leads them through to actually think:*
35 *right...it's like making it a much more active decision rather than just reading the leaflet and*
36 *chucking it away; their actually having to think about the questions in their head.'* Trialist 1)
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47 There were also positive reactions to the 'notes' page (included as a way to promote
48 question asking and deliberation, which was a blank page titled 'notes'). Participants felt
49 this would facilitate the decision making process by enabling potential trial participants to
50 ask questions, highlight areas where they need more support to make their decision and
51 reflect on following their decision making.
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55 *'And what I thought was excellent, and really this is great, was that you gave room for notes,*
56 *you know for patients to make notes. It just gives permission for them to be able to do that.*
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3 *And what I thought was, at every time point where you're maybe asking them to go through*
4 *their decision, put in a blank page which says 'notes', because I just think that is really*
5 *helpful and it facilitates them actually making notes that they can return back to – “What*
6 *was my thinking around this?” ’ (Research Nurse 2)*
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10 11 **Experiences of other potential trial participants.**

12 Experiences of others (or patient stories) are sometimes included in treatment decision aids
13 and, if included, should represent a range of experiences, both positive and negative [11].
14 Although there were mixed views expressed, most thought the inclusion of other
15 participants' experiences was a helpful addition as the general perception was that people
16 are often interested in what their peers have done and that this could help to normalise trial
17 participation.
18

19 *'It is like a big Expedia or a trip adviser thing, you are always interested in the other people's*
20 *experiences. Yes actually I think its something that we've not really thought about before,*
21 *that you are not alone here, that there are hundreds and thousands and millions of people*
22 *participating in clinical trials all the time so to get a wee bit of feedback from them, yes, yes*
23 *no I like that.'* (Research Nurse 1)
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35 Some of the respondents reported that trial participants already ask them what other
36 patients have done and that usually there is some dialogue around those experiences.

37 *'Yeah, it's [being asked what others think] not infrequent. “What do your other patients*
38 *think, Mr X?” I usually say, “They often want to get involved.” “Oh, well okay then.” It's*
39 *slightly interesting, and a bit bizarre, but there is a bit of team play in that I think.'* (Principal
40 Investigator 4)
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47 *'They say, “What's the uptake of others? Are they all taking part or not?” And I say, “The*
48 *majority take part in a study; some don't for various reasons. And some of those reasons are*
49 *personal to that patient: they're too far away, they don't want to come back to the follow-*
50 *up, they hate hospitals, they don't want to ever come back after this – that type of thing.”'*
51 (Research Nurse 4)
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3 It was also highlighted that experiences of others may enable participants to ask questions
4 by highlighting aspects they may not have previously been considered.

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6 *'but what it at least does is it encourages them to ask questions because these guys have*
7 *already identified experiences that they have had.'* (Research Nurse 1)
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11 Despite generally positive views about the inclusion of others' experiences, there were
12 some queries raised however, around how the experiences from other trial participants
13 would be generated for inclusion in a trial decision aid given that information leaflets are
14 developed before any participants have entered, or refused, the trial.

15
16 *'So I was a bit unsure how that was all going to work because either you make it generic and*
17 *it's just about patients who have participated in other trials, or you wouldn't be able to*
18 *implement this for any trial until after you've already got some patients in.'* (Trialist 4)
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25 There was a concern from one respondent who perceived there to be no additional value by
26 including experiences of others and that it complicated the process by introducing the
27 perspectives of others when ultimately the decision lies with that individual and should be
28 based on their own values and preferences.

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30 *'[I'm] Not sure it doesn't... just that it doesn't cloud the water, it was their decision at the*
31 *end of the day.'* (Ethics Committee Chair 5)
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38 **Amount of information**

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40 There was variation in participants' perceptions about the amount of information and the
41 length of the trial decision aids, with some saying there was too much information and
42 others feeling all of the information included was important. There was recognition that the
43 length could be partially attributed to the pre-specified regulatory requirements. However,
44 none of the patients felt there was too much information or that the trial decision aids were
45 too long. For example:

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47 *'I can't say that I found anything in the book unhelpful.'* (Patient 3)
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56 **Method of delivery**

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3 The stakeholders in this study had varying preferences for how the trial decision aids should
4 be delivered. Some felt that there should be a move towards presenting this type of
5 information online or using other electronic media such as DVDs. However, others felt that
6 providing the information in a booklet format was the best option as this allows people to
7 take it away with them and discuss with others.
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13 *'You know, if there were a DVD of somebody talking me through this with the diagrams, the*
14 *presentation, which they could look at in the research room, that would be much better. I'm*
15 *sure that would be more acceptable to most of them [trial participants].'* (Principal
16 Investigator 4)
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22 *'I read it quite thoroughly from page to page, and I think that's what it's designed to do, you*
23 *can take time to read it and make some notes and then consult with somebody else about it,*
24 *you know? I think the paper document is the best way; the old-fashioned way is the best*
25 *way, really.'* (Patient 2)
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31 However, some reported that the specific method of delivery is less important and more
32 emphasis should be placed on accessibility.
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34 *'I think it's important that whatever you use people can access it easily and that if they*
35 *choose to they can show it to other people outside the place or the room where they made*
36 *the decision, so they can go over it again.'* (Ethics Committee Chair 4).
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40 41 42 **The untapped potential of trial participation decision aids**

43 The interviews also focussed on respondents perceptions of the future potential of decision
44 aids to support decisions about participation. Participants' reflections on this were varied,
45 ranging from improving consent through to increasing recruitment and retention in the trial.
46 However, stakeholders highlighted a focus on the biggest potential gains to be from
47 improving aspects of the decision making process such as informedness (which includes an
48 understanding of their involvement and commitment to the trial over time) and
49 opportunities for discussion with others.
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3 *'To me, it was still open [the decision] right the way through.... But reading this here, right*
4 *the way through the whole thing you're still feeling, "Well there's still an option, they're still*
5 *making sure it's ok.'* (Patient 1).
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10 *'So I think a tool like this ought and should help people make a better decision, fully informed*
11 *decision that they can also explain to perhaps their own clinician, certainly to family and*
12 *friends.'* (Ethics Committee Chair 3)
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17 *'I think it's probably making the patient more aware of what's actually involved, and what*
18 *the commitment will be from the patient.'* (Trialist 1)
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22 There was also recognition that these trial decision aids have the potential to actively
23 engage potential participants in their decision making process and allow them to make
24 personally relevant decisions that they are able to discuss with others.
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29 *' it makes it a bit more personalised, it makes them think about how they would cope with*
30 *this trial in their life at the time, then I think that would be useful, it would maybe help them*
31 *think, 'Am I really going to manage this?'. (Trialist 5)*
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36 *'To empower for decision making, to enfranchise them to make a decision, and to not just*
37 *get people on study, but to care for people when they're on study, in that this is more helpful*
38 *to know that they have made a truly well informed decision. And it's something about giving*
39 *patients the ownership of what they're doing, and I think this is helpful in that.'* (Research
40 *Nurse 5)*
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46 **DISCUSSION**

47 **Principal findings**

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49 This is the first study to explore perceptions about the potential of decision aids to support
50 decisions about trial participation from the perspective of all key stakeholder groups and
51 provides empirical data on a range of relevant stakeholder perspectives. Furthermore, this
52 is the first study to explicitly investigate stakeholders' views about key content items of
53 decision aids and their appropriateness for decisions about trial participation. Overall,
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3 stakeholders felt that the decision aids were an improvement on existing PILs in that they
4 explicitly highlighted that there was a decision to be made about participation in the trial. In
5 addition to this, stakeholders believed that the decision aids also provided ways for
6 potential participants to engage with the decision making process and make personally
7 appropriate decisions for them as individuals.
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10 This study explored views about the specific content items that differ between decision aids
11 and existing PILs namely: provision of information about positive and negative features of
12 options; presenting probabilities; methods for clarifying and values; structured guidance in
13 deliberation; and experiences of other potential trial participants.
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20 In principle, providing information about positive and negative features of options (i.e. to
21 participate or not) was received positively and was felt to provide balance to the decision by
22 highlighting all features. However, some respondents expressed views that some of the
23 language was weighted, or may allow participants to attach value to, and could be deemed
24 as potentially coercive. Therefore, it would be important in future decision aids for trial
25 participation to ensure that neutral statements are incorporated. A recent study has
26 illustrated the potential bias that can be introduced into trial participants' decision making
27 when the framing effects of language are not addressed [23].
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36 The section on presenting probabilities was well received by all stakeholders and was stated
37 to be an improvement on current PILs. However, it served to further highlight that
38 individuals have preferences for the way probabilistic information is presented and that
39 there is no 'one size fits all' approach. This is of particular importance when considering
40 that understanding and perception of risk within clinical trials can be a significant influence
41 on the decision to take part or not [24]. Although there is a wealth of literature on how best
42 to communicate probabilistic information in a treatment and screening context, this does
43 not exist for decisions about trial participation where often due to the inherent nature of
44 trials, much of this information is not known and the layers of risk are greater (e.g. risk of
45 the trial vs. risk of treatment, risk of outcomes associated with both interventions, risk of
46 randomisation, etc). Therefore, further research to identify how this can be undertaken
47 effectively, in different trial contexts, are of importance.
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3 The values clarification exercise was reported as a positive addition and provided a way to
4 engage potential participants in their decision making by making them weigh up what
5 matters most to them. One study has measured the extent to which the use of values
6 clarification exercises support (hypothetical) decisions about trial participation and found
7 they lowered ambivalence and decisional uncertainty whilst improving the clarity of
8 personal values [15]. Therefore, there is merit in further exploring this type of exercise to
9 support decisions with potential trial participants facing real decisions.
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17 The section on experiences of others was well received by most stakeholders, with several
18 saying that potential participants already ask for this type of information. Participant stories
19 about trial participation are already available through public websites such as
20 healthtalkonline and the NIH clinical trials website [25, 26]. However, as yet there is no
21 evidence as to the benefit or harm of including this type of information on people's decision
22 making. Whilst patient stories may be an effective way to increase engagement with the
23 information, there are concerns that people will make decisions based on others values
24 rather than their own [27]. As such, further research is required to determine whether and
25 how they can be used in this context.
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35 None of the patient group expressed the view that there was too much information
36 incorporated. However, most of the other stakeholder groups thought the decision aids
37 might be too long. Some stakeholders attributed the amount of information to the
38 guidance requirements for content of informed consent information and recognised this as
39 a barrier against keeping information materials concise. A recent review highlighted the lack
40 of evidence, from a participant's perspective, to support inclusion of many of these
41 prerequisite items in trial information [28]. However, within the context of a decision aid,
42 stakeholders have agreed that many items required for informed consent (as defined by the
43 regulatory guidance) and items required for informed decision making (as defined by the
44 International patient decision aid standards) are important and should be included [20].
45 Therefore, ways of presenting this information more succinctly need to be explored
46 alongside real-time decision making by real patients to explore which information is most
47 valued.
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3 The Ottawa Decision Support Framework (ODSF) recommends that during the development
4 and piloting process for decision aids, end users are engaged and their preferences for
5 delivery of the intervention are incorporated [29]. During this study we elicited
6 respondents' views with regard to the most appropriate method of delivery. Stakeholders'
7 perceptions varied in this regard, with some believing that online or electronic methods
8 were best and others believing paper based was optimal. Other studies have shown that
9 patients deliberating informed consent for elective surgery had preferences for methods of
10 information provision, with younger patients preferring internet based information and
11 older patients preferring paper based information [30] providing further justification for
12 engaging with users at the outset. However, it should be highlighted that a recent
13 systematic review found equivocal evidence with regard to effectiveness of audio-visual
14 interventions to enhance trial knowledge (during informed consent) but the authors
15 highlight the need to involve consumers in intervention development [31]. These findings
16 are important for development of decision aids but also for PILs more generally. As such,
17 trial participants and trial staff (e.g. research nurses, clinical investigators) should be
18 engaged during development of trial decision aids to ascertain the best mode of delivery in
19 the trial population. Moreover, if the mode of delivery is novel it may also be worth
20 engaging with ethics committees early in the process.
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37 **Strengths and weaknesses**

38 A significant strength of this study was the elicitation of views from a diverse stakeholder
39 group, including: patients; research nurses; trialists; clinician researchers; and ethics
40 committee chairs. This forms of multi-stakeholder engagement is promoted as international
41 best practice by the Ottawa Decision Support Framework. Two other studies have explored
42 perceptions of decision aids for trial participation and highlighted their potential benefit, but
43 this previous work has focussed only on patients [13, 14]. Whilst patient perceptions are
44 important, as they are the decision makers, it is important to explore the views of others
45 involved in the informed consent process who would be responsible for developing,
46 endorsing, reviewing and delivering these decision aids. Many of the barriers to
47 implementation of decision aids for treatment decisions relate to 'process' aspects, which
48 may be less relevant for trial decision aids due to a regulatory requirement to provide
49 information in the informed consent process. As such, decision aids for trials would slot in to
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3 the existing informed consent process but would require additional training of those
4 delivering to ensure fidelity of use. However, if there is a lack of buy-in and endorsement
5 from those involved in the informed consent process, the decision aids may not be
6 implemented as intended i.e. tools to support decision making that also enable
7 conversations about treatment (and in this context trial participation) to be created and
8 discussed in a meaningful way. Therefore, it is critical to engage with end-users during
9 development.

10
11 A further strength of this study was the decision to explore stakeholders' perceptions of key
12 decision aid content items *a priori*, rather than exploring only general perceptions. This is of
13 particular importance when considering that it is these items which define decision aids as
14 being different to existing PILs.

15
16 All the participants in our study were UK based and therefore may hold different views to
17 those in other countries with different social norms and cultures. However, it was felt that
18 focusing on the UK was appropriate due to the differences in regulatory requirements and
19 structure of PILs across countries i.e. consent forms for American and Canadian studies tend
20 to be longer than UK forms and contain much of the information being found within UK PILs.
21 Another potential limitation of our study is that the sample were a self-selecting group of
22 individuals and, especially for the patients, may be different from those in the general
23 population. However, these participants can offer thoughtful and reflective insights into
24 decision aids for trial participation when reflecting on their own trial experience including
25 reflection on existing PILs.

41 **Implications for researchers**

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43 Decision aids for trial participation should be developed with meaningful stakeholder
44 involvement. All aspects of the information should be balanced. Attention to language is
45 critical to ensure it is not deemed coercive or value laden. Developers should be mindful of
46 the target audience, especially when considering presenting probabilistic information and
47 considering method of delivery. If patient stories are included, how these will be generated
48 and included must be considered. Finally, decision aids for trial participation should be
49 developed and used in ways that allow all users to engage effectively with the information
50 and provide support to decision makers.
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Future research

Given the limitations of the current conceptualisation of informed consent, it is important to think about how decision aids would be evaluated. For example, if tested in an RCT against existing PILs what outcomes should be measured, how do these outcomes compare to others in existing studies of interventions to improve consent, and what do potential participants think should be measured?

Further research regarding how decisions about trial participation are discussed, engaged with, deliberated over, participated in, supported and executed is required to inform the design of interventions to better support the process. In addition, where much of the previous literature has focussed on participants' understanding of trial concepts such as randomisation and blinding, exploration of what participants believe taking part means for them as individuals could also help to develop more tailored approaches to informed consent.

CONCLUSIONS

Compared to existing PILs, decision aids for trial participation have the potential to promote a more 'informed' decision making process with regard to consent. It is vital that research efforts continue to understand how to support potential trial participants' decisions about trial participation (whether it be to enrol or not); how to ensure these decisions are in line with individuals values and preferences and to determine optimal methods to support informed decision making in this context.

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Competing interests

All authors have completed the Unified Competing Interest form at www.icmje.org/coi_disclosure.pdf (available on request from the corresponding author) and declare that (1) No authors have support from any company for the submitted work; (2) No authors have relationships with companies that might have an interest in the submitted work in the previous 3 years; (3) their spouses, partners, or children have no financial relationships that may be relevant to the submitted work; and (4) The authors have no non-financial interests that may be relevant to the submitted work.

Authors' contributions

KG conceived the study idea. KG, ZS and MC were involved in designing the study and developing the methods. KG applied for ethics approval and collected the interview data. KG and ZS conducted the initial analysis and development of the thematic framework, with additional input from MC. KG directed the full analysis. All authors had full access to all of the data and participated in the discussion and interpretation of the results. KG wrote the initial manuscript draft. All authors critically revised the manuscript and approved the final version.

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Ethical approval

The study was approved by the North of Scotland Research Ethics Committee 1 (REC Reference Number 09/S0802/105) and NHS Grampian Research and Development department (Reference Number 2009HS002). All interview participants provided their signed consent, which included consent for anonymised quotes from their interviews to be published.

Provenance and peer review

Not commissioned; externally peer reviewed.

Transparency declaration

KG (the manuscript's guarantor) affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned have been explained.

Data sharing statement

No additional data available

For peer review only

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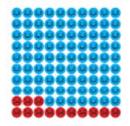
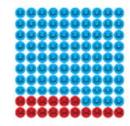
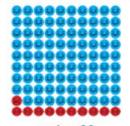
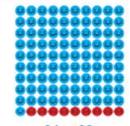
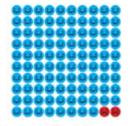
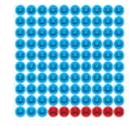
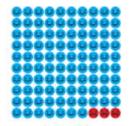
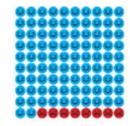
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Table 1. Characteristics of interviewees

	N (%)
Stakeholder group	
Trialist	5 (22)
Research Nurse	5 (22)
Research Ethics Committee (REC) Chair	5 (22)
Principal Investigator – Clinician	4 (17)
Patient	4 (17)
Gender	
Male	11 (48)
Female	12 (52)
Age (yrs)	
40 and under	8 (35)
41 –60	10 (43)
61 and above	5 (22)
Experience of working in clinical trials (yrs)*	
< 10	7 (37)
≥ 10	12 (63)
Location (University or NHS)*	
University	7 (37)
NHS	12 (63)
Previous experience with decision aids	
None	21 (91)
Limited	2 (9)
Experienced	0 (0)

*Patients (n=4) not included in this category

Box 1. Example of content items from prototype trial decision aids: Presenting probabilities section

	symptom	number of people affected	% of people affected	treatment group	
				traditional surgery	stapled surgery
COMMON	<ul style="list-style-type: none"> dizziness headache constipation 	less than 1 in 10 but more than 1 in 100	1-10%	 13 in 100	 16 in 100
UNCOMMON	<ul style="list-style-type: none"> rapid heartbeat runny itchy nose diarrhea nausea vomiting indigestion itching rash abnormal ejaculation increased urination fainting mood changes. 	less than 1 in 100 but more than 1 in 1000	0.1-1%	 11 in 100	 9 in 100
RARE	<ul style="list-style-type: none"> pins and needles swollen gums impotence 	less than 1 in 1000 but more than 1 in 10000	0.01-0.1%	 2 in 100	 7 in 100
VERY RARE	<ul style="list-style-type: none"> feeling of weakness, lethargy eye pain shortness of breath prolonged painful erection, swelling of lips, face and neck 	Less than 1 in 10000 or rate unknown	Less than 0.01%	 3 in 100	 8 in 100

review only

Box 2. Example of content items from prototype trial decision aids: Methods for clarifying and expressing values

“Will the study suit me?”

Pros of the study	Cons of the study
<p>You may have access to treatment that is not otherwise available for your condition. The treatment may be more effective and safer than your current treatment options.</p> <p style="text-align: center;">No Benefit Small Benefit Big Benefit</p>	<p>You will be allocated to group 1, 2 or 3 at random. There will be an equal chance that you will receive either of the treatments. This means that neither you nor your doctor can choose which treatment you receive.</p> <p style="text-align: center;">No Concern Small Concern Big Concern</p>
<p>By taking part in the trial, you may help others who have the same condition in the future.</p> <p style="text-align: center;">No Benefit Small Benefit Big Benefit</p>	<p>If you decide to take part in the trial, you will have to complete questionnaires that you would not normally complete if you decide not to take part.</p> <p style="text-align: center;">No Concern Small Concern Big Concern</p>
<p>Your progress will be monitored carefully over a number of years. You will likely receive more attention from your health care team and more careful monitoring of your condition and the possible side effects of treatment.</p> <p style="text-align: center;">No Benefit Small Benefit Big Benefit</p>	<p>It is not known which treatment is best. There is a chance that there may be no differences between the treatments in terms of benefits.</p> <p style="text-align: center;">No Concern Small Concern Big Concern</p>
<p>Some people may think it is an advantage to have their treatment chosen randomly when the doctors do not know which treatment is best.</p> <p style="text-align: center;">No Benefit Small Benefit Big Benefit</p>	<p>It is important to note that the trial is testing these drugs compared to a non-active control (placebo). You may get allocated the placebo.</p> <p style="text-align: center;">No Concern Small Concern Big Concern</p>
Participating in the study	Not participating in the study

Any further questions?

What are you leaning towards?

Participating in the study
★ ★ ★ ★ ★
Not participating in the study

Review only

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3 **Box 3. Example of content items from prototype trial decision aids: Structured guidance**
4 **in deliberation: Decision making steps**
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8 **MAKING A DECISION**

9 The previous pages have outlined the main options available to you. The following steps may help you to make a decision about whether or not to participate in the Study.

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11 The decision making process can be helped by following these 6 steps:

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1. Understand your diagnosis of haemorrhoids as fully as you can
 2. Understand your options for treatment and the risks and benefits of these options
 3. Review the pros and cons of these options
 4. Assess how important the pros and cons are to you
 5. Prioritise the pros and cons of the study for you (and your family)
 6. Get more information/clarification about any uncertain areas

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The information in this booklet has already taken you through steps 1-3. To help you complete steps 4-6 and come to a decision that suits you best, we have provided some experiences of others who did or did not take part in the trial and a worksheet for you to think through and complete if you wish (see overleaf).

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5 **Decision aids for randomised controlled trials: a qualitative exploration of stakeholders'**
6 **views.**

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29 **Keywords**

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ABSTRACT**Word count 263**

Objectives To explore stakeholders' perceptions of decision aids designed to support the informed consent decision making process for randomised controlled trials.

Design Qualitative semi-structured interviews. Participants were provided with prototype trial decision aids in advance to stimulate discussion. Interviews were analysed using an established interpretive approach.

Participants 23 stakeholders: trial managers (n=5); research nurses (n=5); ethics committee chairs (n=5); patients (n=4) and clinical principal investigators (n=4).

Setting Embedded within two ongoing randomised controlled trials. All interviews conducted with UK based participants.

Results Certain key aspects (e.g. values clarification exercises, presentation of probabilities, experiences of others and balance of options) in the prototype decision aids were perceived by all stakeholders as having a significant advantage (over existing patient information leaflets) in terms of supporting well informed appropriate decisions. However, there were some important differences between the stakeholder groups on specific content (e.g. language used in the section on positive and negative features of taking part in a trial and the overall length of the trial decision aids). Generally the stakeholders believed trial decision aids have the potential to better engage potential participants in the decision making process and allow them to make more personally relevant decisions about their participation. Interestingly, stakeholder views did differ on specific content and design aspects of the trial decision aids (such as length of information and mode of delivery).

Conclusion Compared to existing patient information leaflets, stakeholders perceived decision aids for trial participation to have the potential to promote a more 'informed' decision making process. Further efforts to develop, refine and formally evaluate trial decision aids should be explored.

Article Summary

Strengths and limitations of this study

- This study is the first to explore, and evidence, the potential of a decision aid to support decision making for participating in a randomised controlled trial from the perspectives of a range of stakeholders, including: patients; trial managers; research nurses; clinician researchers; and ethics committee chairs.
- Compared to existing patient information leaflets, this study has shown that trial decision aids have the potential to better engage potential participants in the decision making process and allow them to make more personally relevant decisions about their participation.
- All the participants in our study were UK based and a self-selecting sample and therefore may hold different views to those in other countries with different social norms and cultures. However, these participants can offer thoughtful and reflective insights into decision aids for trial participation when reflecting on their own trial experience including reflection on existing Patient Information Leaflets.

INTRODUCTION

There is an ethical requirement to obtain informed consent from potential participants before they are enrolled in a randomised controlled trial (RCT) [1, 2]. As part of the informed consent process, potential trial participants are provided with written information about the trial often in the form of a participant information leaflet (PIL) [3]. The information included in PILs is largely guided by the Declaration of Helsinki, the international Conference on Harmonisation and Good Clinical Practice (ICH GCP) and, in the UK, by national guidance such as the National Research Ethics Service (NRES) [2, 3, 4]. As outlined by this guidance the PIL should include largely fact-based information about: the purpose of the trial; procedures; interventions; possible risks and benefits; sources of finance; conflicts of interest; and the researcher's affiliation [3, 4].

Existing PILs may be sub-optimal; research has shown that some trial participants (both those considering participation and those actively enrolled) fail to understand key aspects of trial rationale or process [5, 6]. A range of studies have tested ways to improve information provision in the context of trials [6]. These have tended to focus on the content and structure of the information and measured outcomes such as understanding, recall and trial recruitment [6]. Whilst improving understanding of the trial is important, informed decision making about trial participation is complex and likely to require more than just greater understanding of fact-based information [6]. Furthermore, it has been argued that PILs are 'institutionally scripted' as a means to obtain ethical approval rather than functioning as a tool to support potential participants' decision making [7]. As such, the current conceptualisation of 'informed consent' (largely as understanding of information) and how it is enacted (through signing of a consent form) may be overly narrow and require broadening to consider the importance of deliberation and determination in the decision making process for trial participation [8, 9].

Evidence from the treatment and screening decision making literature has highlighted that certain key items are important for making 'good' decisions [10, 11]. For example, being able to consider alternative options (in the context of trial participation this may be another intervention or may be usual care), making trade-offs and evaluating potential outcomes of

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3 the decision and consideration of what those outcomes mean personally for that individual.
4 These items, and others, are often included in decision aids, which actively encourage
5 people to participate in decisions about treatment that involve weighing up associated
6 benefits and harms often when there is clinical uncertainty [10]. Decision aids have been
7 developed for a variety of treatment and screening decisions and have been shown to
8 positively influence several aspects of decision making [10]. The items identified as being
9 important for good decision making are largely lacking from existing PILs for trial
10 participation [12], further supporting the contention that existing PILs do not function well
11 as decision making tools [12].
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21 The very few published studies that have explored the use of decision aids, or components
22 of them, in the context of trial participation decisions have shown some promise [13, 14,
23 15]. For example, compared to existing PILs, decision aids for trial participation have been
24 shown to improve understanding whilst not increasing anxiety [13] and resulted in low
25 levels of decisional conflict and high levels of satisfaction [14]. Although encouraging, these
26 studies have solely focused on trial participants' perceptions and have not explored other
27 stakeholders' opinions. Whilst trial participants perspectives remain key, replacement of, or
28 any amendments to existing PILs would require buy-in from an additional range of
29 stakeholders, such as: developers (e.g. trial managers); deliverers (e.g. research nurses and
30 clinician researchers); and approvers (e.g. ethics committees). This buy-in is critical to
31 ensuring that trial decision aids are as effective as they can be (i.e. act as a decision support
32 tool to facilitate meaningful conversations that encourage informed decision making), are
33 implementable and used as intended. Although treatment and screening decision aids have
34 been shown to be efficacious, the main barriers to their effectiveness in a real world setting
35 are a lack of implementation and fidelity of use often as a result of a lack of buy-in at
36 inception from stakeholders [16, 17]. Furthermore, previous studies on trial decision aids
37 have not explicitly explored perceptions of the 'new' content (i.e. features to improve
38 decision making), which define decision aids as different to existing PILs.
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54 The study reported in this manuscript forms part of a larger programme of work that aimed
55 to systematically develop and pilot (through interviews reported here) prototype trial
56 decision aids. The prototype decision aids were developed through an iterative process
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3 informed by the MRCs framework on development of complex interventions [18]. The
4 process began with establishing the current evidence on the effectiveness of decision aids
5 for supporting decisions about RCT participation [19]. Next a Delphi study was conducted,
6 with a range of stakeholders, to identify key items for inclusion [20], followed by an
7 evaluation of existing PILs using a tool (that contains items assessing key features of 'good'
8 decision making) to identify areas that were lacking [12], drafting of prototype decision aids
9 (informed by previous stages), followed by rounds of revision within the study team. We
10 then undertook an in-depth qualitative study to explore stakeholders' views and
11 perspectives on the specific content of the prototype decision aids and their potential to
12 improve the informed consent process for RCTs (it is this qualitative study that is reported
13 here).

24 METHODS

25 Development of the prototype trial participation decision aids

26 Prototype decision aids were developed for two on-going RCTs. The first was a trial
27 comparing two surgical procedures for treatment of haemorrhoids (ISRCTN [8006172](#), [date](#)
28 [of registration 08/03/2010](#)); and the other a drug trial comparing 2 active drugs and a
29 placebo for treatment of ureteric stones (ISRCTN [69423238](#), [date of registration](#)
30 [18/11/2010](#)). These RCTs were identified from the portfolio of RCTs managed by the Centre
31 of Healthcare Randomised Trials (CHaRT) at the University of Aberdeen. The content of the
32 prototype decision aids was developed through the iterative process outlined above. The
33 prototype decision aids were enhanced by a Graphic Designer, at the University of
34 Aberdeen, to improve the visual impact of the tools. The tools were presented as A5
35 booklets which could be printed or read as a PDF document.

36 Exploration of stakeholders' perceptions of trial decision aids.

37 An open-ended topic guide was developed to elicit accounts of participant's view of the
38 prototype decision aids (see Additional file 1). The topic guide was informed by literature
39 on content items for decision aids and explored the key differences between decision aids
40 and existing PILs [11, 12]. Moreover, items identified as contentious in earlier work [20]
41 were also further explored (e.g. use of experiences of others). The guide, and subsequent
42 analysis, were organised around views of existing patient information leaflets; views about
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3 the prototype decision aids with specific exploration of their potential to support the
4 decision making process. Semi-structured interviews were conducted with different
5 stakeholder groups (including patients, trial managers, research nurses, ethics committee
6 chairs and Principal Investigator involved with both trials) to explore perspectives about the
7 use of decision aids in a trials context.
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11 12 13 **Sampling and recruitment**

14 Potential participants from the trial manager, research nurse and ethics committee chair
15 stakeholder groups were identified through email list serves (trial managers: UK Clinical
16 Research Collaboration Trial Managers listserv (n=501); research nurses: Scottish Research
17 Nurse and Coordinators Network listserv (n=198); ethics committee chairs: National
18 Research Ethics Service committee chair listserv (n=88)). Patients who would be eligible for
19 each RCT were identified and contacted by a research nurse working at the lead site for
20 each of the RCTs (n=20). Principal Investigators for both of the RCTs were sent an email
21 invite and asked to respond to the lead researcher (KG) to express interest (n=40).
22 Prospective participants were sent a letter of invite with a slip to return, or email response,
23 to express interest. Interested participants were sent full information about the study (in
24 the form of a participant information leaflet), and a consent form and were provided with
25 an opportunity to discuss the research project and have any questions answered before
26 making a decision. Ethics committee chairs, Principal Investigators, Research Nurses and
27 trial managers who were recruited for interview were sent a copy of both decision aids to
28 review. Recruited patients were only sent the decision aid relevant for their condition.
29 Recruited participants were given the choice of a face-to-face or telephone interview. All
30 participants provided written consent.
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47 **Data collection**

48 One author (KG) conducted the interviews between April 2012 and July 2012. Only one
49 patient participant chose a face-to-face interview, which was conducted at the University of
50 Aberdeen as agreed by the participant and the researcher, all other participants requested
51 telephone interviews. Interviews were audio-recorded, transcribed verbatim and
52 anonymised. At the start of the interviews, participants were encouraged to provide their
53 views and perspectives on existing patient information leaflets for clinical trials and discuss
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3 their experiences of participating in clinical trials or reviewing clinical trial information, as
4 appropriate. All participants were then asked about their views of the prototype decision
5 aids and how they might, or might not, support a decision about trial participation (see
6 Additional file 1).
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10 11 12 **Data management and analysis**

13 A thematic content analysis of the transcripts was conducted. An established interpretive
14 approach was used whereby following familiarisation with the transcripts, *a priori* and
15 emergent themes were identified, discussed and agreed by the research team [21]. As
16 many of the interview questions were developed around pre-determined themes of interest
17 (i.e. those relating to specific content and purpose of trial decision aids [11]) there were not
18 many emergent themes identified. However, the meaning and importance attached to each
19 of the pre-determined themes was emergent. Two authors (KG & ZS) independently
20 reviewed transcripts and documented the major emerging themes. A thematic framework
21 was subsequently generated, and agreed through discussion with all authors, which detailed
22 codes for labelling textual data related to the major themes and sub-themes. Codes with
23 specific relevance to decision aids (and items which define them as being distinct from
24 existing PILs) were used as *a priori* codes for key parts of the interview transcripts [11].
25 Transcripts were subsequently coded by one author (KG), in which the thematic framework
26 was applied systematically to the textual data. This process was managed through the use
27 of text management software (NVivo 10). This facilitated data organisation which promoted
28 further analytic consideration through constant comparison of data both within and across
29 the stakeholder groups, this was conducted by two authors (KG and ZS) and identified key
30 differences between the groups and identified consensus on the importance of the potential
31 of decision aids across all groups. Relevant quotes representing interviewees'
32 considerations were selected to illustrate the results.
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50 51 **Ethical approval**

52 The study was approved by the North of Scotland Research Ethics Committee 1 (REC
53 Reference Number 09/S0802/105) and NHS Grampian Research and Development
54 department (Reference Number 2009HS002). All interview participants provided their
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3 signed consent, which included consent for anonymised quotes from their interviews to be
4 published.
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8 **RESULTS**

9 **Sample characteristics**

10 Fifty individuals contacted the researcher (23 trial managers; 10 research nurses; 8 ethics
11 committee chairs; 5 patients and 4 lead clinicians) and 23 were interviewed. Response rates
12 varied across the groups: 5% for trial managers; 7% for Research Nurses; 9% for ethics
13 committee chairs; 25% for patients (1 subsequently declined participation); and 10% for
14 Principal Investigators. In those stakeholder groups where more participants responded
15 than were required for interview, participants were sampled purposively based on affiliation
16 with registered UKCRC clinical trials units and further stratified for geographic location. The
17 number of participants in each group was decided based on a predetermined judgement
18 that each group should contain a similar number and be informed by the numbers
19 interviewed in the patient group (n=4). The interviews ranged from 40-80 minutes. We
20 deemed this sample size to be sufficient to identify a range of experiences and views that
21 would generate a manageable amount of data for in-depth analysis within the timescale of
22 this project [22].
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35 A brief description of the participants is provided in Table 1. They included 12 women and
36 11 men, aged from 35 to 80, who were from the following stakeholder groups: trial
37 managers (n=5); research nurses (n=5); ethics committee chairs (n=5); patients (n=4) and
38 lead clinicians (n=4). Twelve of the sample had experience of working for an NHS
39 organisation and 7 worked within Universities. Experience of working in clinical trials (which
40 could be as a recruiter, a trial manager, a reviewer of ethical applications of trials) ranged
41 from 3 to 20 years. The majority of the group (n=21) had no previous experience of decision
42 aids but all stakeholders had previous exposure to PILs for trials. The themes described
43 below were largely identified *a priori* so as to provide a predetermined exploration of the
44 key content items that differ between existing PILs and decision aids for trial participation.
45 Due to the pre-defined areas of importance for investigation informing the topic guide, all
46 themes were discussed by all stakeholder groups but the extent to which their opinions
47 converged differed between groups and across themes.
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General impressions of the trial decision aids compared to existing information leaflets

The majority of stakeholders across all groups perceived that, in principle, trial decision aids were beneficial and an improvement on existing PILs. There was a perception that they provided a 'balanced', unbiased picture, that they were uncomplicated and that they could proactively facilitate more engagement in the decision, compared to existing PILs.

'it's very well balanced and I think that's really important because it's not leading anybody in any one direction. And I think that's an excellent part of the whole booklet itself.' (Patient 3)

'I think that they [decision aids] are very, very straight forward actually, that as I've said before the patient information leaflets are very wordy things and they have a lot of information to impart to patients and sometimes they will switch off after the third paragraph.' (Research Nurse 1)

'there's not just an information sheet; there's a decision making tool to help the patient make decisions, rather than it just being a passive thing of read the information leaflet ... whereas this is actually making them work through and think about it, and this is obviously the biggest change and I do think this would be of a benefit.' (Trial manager 2)

Although most of the initial perceptions of the decision aids were positive, some participants, from the Research Nurse and Principal Investigator groups, did feel that the use of a decision aid could potentially over-complicate the decision process in this context by providing more information and potentially raising concerns.

'My concerns were that sometimes people feel that the patient information sheet alone is onerous, so adding something else on might actually put some people off..... just that it might increase fear or uncertainty. It almost makes the decision bigger, by adding in this decision making tool.' (Research Nurse 5)

However, these perceptions were from the minority of participants within these stakeholder groups, with most of the group expressing agreement of the improvement of these decision aids compared to existing methods.

Perception of trial decision aid content

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3 This section of the paper reports the findings relating to specific aspects of the decision aids
4 which are not routinely included in patient information leaflets for trial participation.

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6 ***Provision of information about positive and negative features of taking part in the trial.***

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8 The trial decision aids included information on both the advantages and disadvantages of
9 both options (participating in the trial or not) whereas existing PILs generally only cover
10 issues relating to trial participation [12]. There were varied views (largely across and within
11 the Research Nurse, Trial Manager and Ethics Committee Chair groups) expressed when
12 participants reflected on whether the information included about positive and negative
13 features of participating in the trial or not was balanced. Some recognised this was a new
14 addition to the standard information and felt the section was well balanced and would be
15 helpful for potential participants to make an informed choice about participation.
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24 *'I think this does just outline the different variables really that, you know, there are*
25 *disadvantages about taking part in clinical studies and there are disadvantages about not.*
26 *It's an interesting new thing as far as I can see, I've not see anything quite that descriptive*
27 *before.'* (Research Nurse 1)
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33 Other participants felt that whilst the overall concept of providing information about both
34 options was advantageous, some of the included information about advantages and
35 disadvantages of options could be deemed as being potentially coercive. This was a view
36 held by most of the Trial Managers, Research Nurses and Ethics Committee Chairs.
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40 *'And I thought that they [sections on advantages and disadvantages participating in the trial*
41 *or not participating] were quite helpful.... I did think that one of the sentences [You will*
42 *receive extra personalised care and attention from research nurses by taking part in the*
43 *trial] possibly was a bit over-emotive.'* (Trial manager 4)
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49 Even though many participants agreed that advantages and disadvantages about both
50 options should be included, all of the ethics committee chairs reported some of the
51 language as potentially inappropriate and stated that ethics committees would be
52 uncomfortable with some statements. For example:
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56 *'I think that there's quite a lot of emphasis on saying to people one of the advantages of*
57 *taking part is that you'll get some extra care and attention... Now, in a sense that's true*
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3 given that that is built in to the research procedure, but certainly the committee, we're
4 very... we're very sensitive to anything that could be taken as an extra inducement to take
5 part. And I felt that one or both of these was a bit more emphatic about that and if we'd be
6 reviewing these as a committee I think we wouldn't have been very comfortable with that.'
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8 (Ethics Committee Chair 2)
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13 However, patients reported this section to be well balanced and felt that this section
14 provided information to illustrate that participating in a clinical trial may provide access to
15 services (whether treatment or follow up) that would not be available outside of the trial.
16 For example:
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20 'it was honest, it was upfront and I was like...yeah, okay, you won't have to do the
21 questionnaires but yeah, you will get additional care. So there was a little bit of a "We
22 provide you with a luxury service" or you just get the MOT when we're ready for it. So, it
23 was quite a good inducement to take part.' (Patient 3)
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31 **Presentation of probabilities**

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33 Methods used to present probabilities of outcomes associated with interventions across the
34 two prototype trial decision aids were varied according to reported methods of good
35 practice for decision aids [11](see Figure 1). Participants were asked to compare where
36 appropriate. There was recognition amongst participants in all stakeholder groups that
37 presenting complex probabilistic information to potential trial participants is challenging
38 and that individuals have varied preferences and understandings of this type of information,
39 especially within the context of clinical trials and the interventions they are testing.
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43 'I think it's a good way of presenting it [risks] in a different way. I think presenting risk as
44 words and as numbers and as something visual is going to help. I think in the end it's still a
45 very hard thing for people to understand, as I said, at a personal level.' (Ethics Committee
46 Chair 3).
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54 A couple of participants, from the Principal Investigator and Ethics Committee Chair groups,
55 raised the importance of placing risk within the context of familiar activities as an effective
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3 way to allow potential participants to make judgements about the risks they are willing to
4 take.

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6 *'you could say, "This list does look long and worrying but actually these side-effects don't*
7 *occur very often. By comparison if we listed all the side-effects of paracetamol these are the*
8 *things you would be told about" and you could say very commonly without any problem at*
9 *all.'* (Principal Investigator 2)

14 15 **Methods for clarifying and expressing values.**

16
17 The majority of stakeholders across all groups felt that values clarification exercises included
18 in the trial decision aids (see Figure 2), which allow patients to trade-off positive and
19 negative features of the decision to facilitate personally meaningful decision making, were
20 helpful and that they had the potential to facilitate the decision making process.

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22 *'I mentioned that the pros and cons is very, very good, I think that that would help a lot of*
23 *people make decisions and it talks about what would happen to me if I didn't take part in*
24 *this study as well so that's something that we don't, well we say "Oh well that's Ok, you'll*
25 *just get the standard course of treatment" is there anything negative about me not taking*
26 *part, that's important to emphasise that as well.'* (Research Nurse 4)

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29 A significant potential benefit of values clarification exercises that was highlighted by
30 participants was their potential to allow potential trial participants to make personally
31 relevant decisions by weighing up what matters most to them, within the context of the
32 clinical trial.

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35 *'I think it would probably be quite useful just to have that let them weigh that up, whether*
36 *they want to take part or not.'* (Principal Investigator 3)

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39 *'And that's very powerful, they're making a decision that feels to them very fair because*
40 *they've done a weighting process around it. So I really, really liked this.'* (Research Nurse 5)

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52 However, a minority of participants (mainly Trial Managers) felt that the exercises
53 themselves, or aspects of them (such as the term 'worksheets' and the lengthy instructions
54 for completion), would not be helpful and could be perceived negatively.
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3 *'... I don't know, it just made me think you know patients thinks, "Ah worksheets, am I going*
4 *to have to fill in loads of stuff?">' (Trial manager 1)*
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9 Yet the patient group all perceived these exercises as being helpful and beneficial for their
10 decision making, acting as a guide to take them through the advantages and disadvantages
11 of trial participation.

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13 *'I find the little piece at the back, the pros and cons table, or pros and cons balance graphic,*
14 *quite useful. It did help me come to my conclusion, the pros and cons one, because I*
15 *answered all the questions and highlighted my answers. I found that really quite*
16 *interesting.'* (Patient 2)
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22 However, one of the patients and participants across the other stakeholder groups did
23 highlight that there may be a need for the values clarification exercise to provide a 'score' or
24 objective decision with regard to trial participation.

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26 *'It's like...there's not a scoring system, so...big benefit, no benefit, so I don't know actually*
27 *where that would come out. There's no - what's my weighting?'* (Patient 3).
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33 **Structured guidance in deliberation.**

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35 Decision aids should provide steps to assist the patient in making a decision, which may
36 include suggesting ways to talk through the decision with health professionals and including
37 tools (worksheets or question lists) that would allow discussion with others [11].
38 Participants across all groups stated that the identified steps for making a decision (a list of
39 6 items outlining the process) that were highlighted in the decision aid (see Figure 3) were a
40 helpful addition.
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45 *'I think putting out how somebody might make a decision. You know, the six points [decision*
46 *guidance]. And I think setting all of this... I was pleased that when I read it through.'* (Ethics
47 *Committee Chair 4)*
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52 *'I do think that's good; rather than giving them all the information and then saying "Right,*
53 *now it's up to you to make a decision." it almost leads them through to actually think:*
54 *right...it's like making it a much more active decision rather than just reading the leaflet and*
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3 *chucking it away; their actually having to think about the questions in their head.’ Trial*
4 *manager 1)*
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8 There were also positive reactions to the ‘notes’ page (included as a way to promote
9 question asking and deliberation, which was a blank page titled ‘notes’). Participants felt
10 this would facilitate the decision making process by enabling potential trial participants to
11 ask questions, highlight areas where they need more support to make their decision and
12 reflect on following their decision making.
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15 *‘And what I thought was excellent, and really this is great, was that you gave room for notes,*
16 *you know for patients to make notes. It just gives permission for them to be able to do that.*
17 *And what I thought was, at every time point where you’re maybe asking them to go through*
18 *their decision, put in a blank page which says ‘notes’, because I just think that is really*
19 *helpful and it facilitates them actually making notes that they can return back to – “What*
20 *was my thinking around this?” ’ (Research Nurse 2)*
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29 In addition, members of all groups apart from the Principal Investigators commented on
30 aspects of the decision aid being repetitive. One of the patients stated the following with
31 regard to the structured guidance for decision making:
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34 *‘It’s very clear. I would, the only comment I would make on that is it’s probably repetitive of*
35 *what’s gone on throughout the whole book.....But I wouldn’t say it would drive me to take*
36 *that away, not take it out. I just felt that, you know, I’d read most of that and understood*
37 *most of 1 to 6 in the preceding narrative.’ (Patient 1)*
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43 ***Experiences of other potential trial participants.***

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45 Experiences of others (or patient stories) are sometimes included in treatment decision aids
46 and, if included, should represent a range of experiences, both positive and negative [11].
47 Although there were mixed views expressed, most thought the inclusion of other
48 participants’ experiences was a helpful addition as the general perception was that people
49 are often interested in what their peers have done and that this could help to normalise trial
50 participation.
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53 *‘It is like a big Expedia or a trip adviser thing, you are always interested in the other people’s*
54 *experiences. Yes actually I think its something that we’ve not really thought about before,*
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3 *that you are not alone here, that there are hundreds and thousands and millions of people*
4 *participating in clinical trials all the time so to get a wee bit of feedback from them, yes, yes*
5 *no I like that.’ (Research Nurse 1)*
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10 Some of the Research Nurse and Principal Investigator participants reported that trial
11 participants often ask them what other patients have done and that usually there is some
12 dialogue around those experiences.
13

14 *‘Yeah, it’s [being asked what others think] not infrequent. “What do your other patients*
15 *think, Mr X?” I usually say, “They often want to get involved.” “Oh, well okay then.” It’s*
16 *slightly interesting, and a bit bizarre, but there is a bit of team play in that I think.’ (Principal*
17 *Investigator 4)*
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24 *‘They say, “What’s the uptake of others? Are they all taking part or not?” And I say, “The*
25 *majority take part in a study; some don’t for various reasons. And some of those reasons are*
26 *personal to that patient: they’re too far away, they don’t want to come back to the follow-*
27 *up, they hate hospitals, they don’t want to ever come back after this – that type of thing.”’*
28 *(Research Nurse 4)*
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35 It was also highlighted that experiences of others may enable participants to ask questions
36 by highlighting aspects they may not have previously been considered.
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38 *‘but what it at least does is it encourages them to ask questions because these guys have*
39 *already identified experiences that they have had.’ (Research Nurse 1)*
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43 Despite generally positive views about the inclusion of others’ experiences, there were
44 some queries raised from Trial Managers and Research Nurses, with regard to how the
45 experiences from other trial participants would be generated for inclusion in a trial decision
46 aid given that information leaflets are developed before any participants have entered, or
47 refused, the trial.
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52 *‘So I was a bit unsure how that was all going to work because either you make it generic and*
53 *it’s just about patients who have participated in other trials, or you wouldn’t be able to*
54 *implement this for any trial until after you’ve already got some patients in.’ (Trial manager*
55 *4)*
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5 There was a concern from one respondent (an Ethics Committee Chair) who perceived there
6 to be no additional value by including experiences of others and that it complicated the
7 process by introducing the perspectives of others when ultimately the decision lies with that
8 individual and should be based on their own values and preferences.
9

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11 *'[I'm] Not sure it doesn't... just that it doesn't cloud the water, it was their decision at the*
12 *end of the day.'* (Ethics Committee Chair 5)
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14

15 16 17 **Amount of information**

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19 There was variation in participants' perceptions about the amount of information and the
20 length of the trial decision aids, with the majority of stakeholders (largely Trial Managers,
21 Ethics Committee Chairs, and Principal Investigators agreeing there was too much
22 information and others (patients and Research Nurses) feeling all of the information
23 included was important. There was recognition that the length could be partially attributed
24 to the pre-specified regulatory requirements. None of the patients felt there was too much
25 information or that the trial decision aids were too long. For example:
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29 *'I can't say that I found anything in the book unhelpful.'* (Patient 3)
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35 *'Its difficult because there is so much stuff that is legislated that has to be in, so it is difficult*
36 *to condense them any less.'* (Research Nurse 2)
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40 41 **Method of delivery**

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43 The stakeholders in this study had varying preferences, which diverged between and within
44 groups, for how the trial decision aids should be delivered. Some felt that there should be a
45 move towards presenting this type of information online or using other electronic media
46 such as DVDs. However, others felt that providing the information in a booklet format was
47 the best option as this allows people to take it away with them and discuss with others.
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52 *'You know, if there were a DVD of somebody talking me through this with the diagrams, the*
53 *presentation, which they could look at in the research room, that would be much better. I'm*
54 *sure that would be more acceptable to most of them [trial participants].'* (Principal
55 Investigator 4)
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5 *'I read it quite thoroughly from page to page, and I think that's what it's designed to do, you*
6 *can take time to read it and make some notes and then consult with somebody else about it,*
7 *you know? I think the paper document is the best way; the old-fashioned way is the best*
8 *way, really.'* (Patient 2)
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14 Some reported that the specific method of delivery is less important and more emphasis
15 should be placed on accessibility.

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17 *'I think it's important that whatever you use people can access it easily and that if they*
18 *choose to they can show it to other people outside the place or the room where they made*
19 *the decision, so they can go over it again.'* (Ethics Committee Chair 4).
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24 However, participants in the Research Nurse, Trial Manager and Ethics Committee Chair
25 groups identified the importance of context with regard to the trial population being
26 recruited.
27

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29 *'Some people were put off by it [computer tablet], but that is just my client group [elderly].*
30 *Obviously it is going to really depend on you client group, if it is children, teenagers, people*
31 *in their twenties, thirties, forties, that's how we live our lives, that is how we expect to*
32 *receive information nowadays. We certainly don't expect to get it in a paper format.'*
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37 (Research nurse 2)
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42 **The untapped potential of trial participation decision aids**

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44 The interviews also focussed on participants perceptions of the future potential of decision
45 aids to support decisions about participation. Participants' reflections on this were varied,
46 ranging from improving consent (across all stakeholders) through to increasing recruitment
47 (mentioned by Principal Investigators and Research Nurses) and retention (highlighted by
48 Research Nurses, Principal Investigators and Trial Managers) in the trial. However,
49 stakeholders across all groups highlighted a focus on the biggest potential gains to be from
50 improving aspects of the decision making process such as informedness (which includes an
51 understanding of their involvement and commitment to the trial over time) and
52 opportunities for discussion with others.
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3 *'To me, it was still open [the decision] right the way through.... But reading this here, right*
4 *the way through the whole thing you're still feeling, "Well there's still an option, they're still*
5 *making sure it's ok.'* (Patient 1).
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10 *'So I think a tool like this ought and should help people make a better decision, fully informed*
11 *decision that they can also explain to perhaps their own clinician, certainly to family and*
12 *friends.'* (Ethics Committee Chair 3)
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17 *'I think it's probably making the patient more aware of what's actually involved, and what*
18 *the commitment will be from the patient.'* (Trial manager 1)
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22 There was also recognition, largely by Trial Managers and Research Nurses, that these trial
23 decision aids have the potential to actively engage potential participants in their decision
24 making process and allow them to make personally relevant decisions that they are able to
25 discuss with others.
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31 *' it makes it a bit more personalised, it makes them think about how they would cope with*
32 *this trial in their life at the time, then I think that would be useful, it would maybe help them*
33 *think, 'Am I really going to manage this?'. (Trial manager 5)*
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38 *'To empower for decision making, to enfranchise them to make a decision, and to not just*
39 *get people on study, but to care for people when they're on study, in that this is more helpful*
40 *to know that they have made a truly well informed decision. And it's something about giving*
41 *patients the ownership of what they're doing, and I think this is helpful in that.'* (Research
42 *Nurse 5)*
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46 47 48 **DISCUSSION**

49 **Principal findings**

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52 This is one of the first studies to explore perceptions about the potential of decision aids to
53 support decisions about trial participation from the perspective of all key stakeholder
54 groups and provides empirical data on a range of relevant stakeholder perspectives.
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56 Furthermore, this is the first study to explicitly investigate stakeholders' views about key
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3 content items of decision aids and their appropriateness for decisions about trial
4 participation. Overall, stakeholders felt that the decision aids were an improvement on
5 existing PILs in that they explicitly highlighted that there was a decision to be made about
6 participation in the trial. In addition to this, stakeholders believed that the decision aids also
7 provided ways for potential participants to engage with the decision making process and
8 make personally appropriate decisions for them as individuals.
9

10 This study explored views about the specific content items that differ between decision aids
11 and existing PILs namely: provision of information about positive and negative features of
12 options; presenting probabilities; methods for clarifying and values; structured guidance in
13 deliberation; and experiences of other potential trial participants. It is important to highlight
14 that whilst the majority of the stakeholders agreed on specific aspects there were some key
15 differences between the patient group versus the others. For example, patients views
16 differed to the majority of other stakeholders groups with regard to provision of
17 information about positive and negative features of taking part in a trial (specifically with
18 regard to the exacting information contained within the section) in that patients felt it to be
19 balanced but others reported worries about coercive language. In addition, many of the
20 stakeholders felt that the decision aids were too long, but none of the patients reported this
21 with all of them saying that all of the information was important. These findings (which
22 must be considered within the context of this study i.e. patients may be different the
23 general population) should serve as a reminder that when developing decision aids for trial
24 participation, whilst all stakeholder views are important, patients views must be placed at
25 the core.
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43 In principle, the general concept of providing information about positive and negative
44 features of options (i.e. to participate or not) was received positively and was felt to provide
45 balance to the decision by highlighting all features. However, some participants expressed
46 views that some of the language was weighted, or may allow participants to attach value to,
47 and could be deemed as potentially coercive. Therefore, it would be important in future
48 decision aids for trial participation to ensure that neutral statements are incorporated. A
49 recent study has illustrated the potential bias that can be introduced into trial participants'
50 decision making when the framing effects of language are not addressed [23].
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3 The section on presenting probabilities was well received by all stakeholders and was stated
4 to be an improvement on current PILs. However, it served to further highlight that
5 individuals have preferences for the way probabilistic information is presented and that
6 there is no 'one size fits all' approach. This is of particular importance when considering
7 that understanding and perception of risk within clinical trials can be a significant influence
8 on the decision to take part or not [24]. Although there is a wealth of literature on how best
9 to communicate probabilistic information in a treatment and screening context, this does
10 not exist for decisions about trial participation where often due to the inherent nature of
11 trials, much of this information is not known and the layers of risk are greater (e.g. risk of
12 the trial vs. risk of treatment, risk of outcomes associated with both interventions, risk of
13 randomisation, etc). Therefore, further research to identify how this can be undertaken
14 effectively, in different trial contexts, are of importance.
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26 The values clarification exercise was reported as a positive addition and provided a way to
27 engage potential participants in their decision making by making them weigh up what
28 matters most to them. One study has measured the extent to which the use of values
29 clarification exercises support (hypothetical) decisions about trial participation and found
30 they lowered ambivalence and decisional uncertainty whilst improving the clarity of
31 personal values [15]. Therefore, there is merit in further exploring this type of exercise to
32 support decisions with potential trial participants facing real decisions.
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40 The section on experiences of others was well received by most stakeholders, with several
41 saying that potential participants already ask for this type of information. Participant stories
42 about trial participation are already available through public websites such as
43 healthtalkonline and the NIH clinical trials website [25, 26]. However, as yet there is no
44 evidence as to the benefit or harm of including this type of information on people's decision
45 making. Whilst patient stories may be an effective way to increase engagement with the
46 information, there are concerns that people will make decisions based on others values
47 rather than their own [27]. As such, further research is required to determine whether and
48 how they can be used in this context.
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3 None of the patient group expressed the view that there was too much information
4 incorporated, a finding mirrored by an earlier study exploring patients perceptions of a trial
5 decision aid for radiotherapy for prostate cancer [14]. However, most of the other
6 stakeholder groups thought the decision aids might be too long. Some stakeholders
7 attributed the amount of information to the guidance requirements for content of informed
8 consent information and recognised this as a barrier against keeping information materials
9 concise. A recent review highlighted the lack of evidence, from a participant's perspective,
10 to support inclusion of many of these prerequisite items in trial information [28]. However,
11 within the context of a decision aid, stakeholders have agreed that many items required for
12 informed consent (as defined by the regulatory guidance) and items required for informed
13 decision making (as defined by the International patient decision aid standards) are
14 important and should be included [20]. Therefore, ways of presenting this information
15 more succinctly need to be explored alongside real-time decision making by real patients to
16 explore which information is most valued.
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30 The Ottawa Decision Support Framework (ODSF) recommends that during the development
31 and piloting process for decision aids, end users are engaged and their preferences for
32 delivery of the intervention are incorporated [29]. During this study we elicited participants'
33 views with regard to the most appropriate method of delivery. Stakeholders' perceptions
34 varied in this regard, with some believing that online or electronic methods were best and
35 others believing paper based was optimal but certainly the context and preferences of the
36 end users should be considered. Other studies have shown that patients deliberating
37 informed consent for elective surgery had preferences for methods of information
38 provision, with younger patients preferring internet based information and older patients
39 preferring paper based information [30] providing further justification for engaging with
40 users at the outset. However, it should be highlighted that a recent systematic review
41 found equivocal evidence with regard to effectiveness of audio-visual interventions to
42 enhance trial knowledge (during informed consent) but the authors highlight the need to
43 involve consumers in intervention development [31]. These findings are important for
44 development of decision aids but also for PILs more generally. As such, trial participants and
45 trial staff (e.g. research nurses, clinical investigators) should be engaged during
46 development of trial decision aids to ascertain the best mode of delivery in the trial
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3 population. Moreover, if the mode of delivery is novel it may also be worth engaging with
4 ethics committees early in the process.
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8 Overall, these findings complement the previous preliminary work on decision aids for trial
9 participation in that they show that patients perceive these tools as useful and more helpful
10 (compared to existing PILs) in terms of making a well-informed, balanced, personally
11 relevant decision [13, 14]. However, our results also contribute additional insights through
12 the involvement of a wide range of stakeholders, which include perspectives from those
13 involved in developing, delivering and reviewing information for patients considering trial
14 participation. Moreover, these findings contribute to the wider literature on participants
15 and stakeholders sense-making of research participation with respect to what it means for
16 them as individuals. For example, a study by Townsend and Cox identifies the importance of
17 the 'meaning' of research participation (including trials) for participants, implicitly
18 underpinned by their individualised context and which transcend the entire participation
19 trajectory, not just the point of consent [32].
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22 **Strengths and weaknesses**

23 A significant strength of this study was the elicitation of views from a diverse stakeholder
24 group, including: patients; research nurses; trial managers; clinician researchers; and ethics
25 committee chairs. This forms of multi-stakeholder engagement is promoted as international
26 best practice by the Ottawa Decision Support Framework. Two other studies have explored
27 perceptions of decision aids for trial participation and highlighted their potential benefit, but
28 this previous work has focussed only on patients [13, 14]. Whilst patient perceptions are
29 key, as they are the decision makers, it is important to explore the views of others involved
30 in the informed consent process who would be responsible for developing, endorsing,
31 reviewing and delivering these decision aids. Many of the barriers to implementation of
32 decision aids for treatment decisions relate to 'process' aspects, which may be less relevant
33 for trial decision aids due to a regulatory requirement to provide information in the
34 informed consent process. As such, decision aids for trials would slot in to the existing
35 informed consent process but would require additional training of those delivering to
36 ensure fidelity of use. However, if there is a lack of buy-in and endorsement from those
37 involved in the informed consent process, the decision aids may not be implemented as
38 intended i.e. tools to support decision making that also enable conversations about
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3 treatment (and in this context trial participation) to be created and discussed in a
4 meaningful way. Therefore, it is critical to engage with end-users during development.

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6 A further strength of this study was the decision to explore stakeholders' perceptions of key
7 decision aid content items *a priori*, rather than exploring only general perceptions. This is of
8 particular importance when considering that it is these items which define decision aids as
9 being different to existing PILs.

10
11 It may be that the specific trial contexts may have influenced participants' perceptions of
12 the decision aids. However, several sections were written from a generic perspective and
13 were not specific for the individual trial context, which included both a chronic and an acute
14 condition. Moreover, the majority of the stakeholder groups (research nurses, trial
15 managers and ethics committee chairs) were not directly involved with the trials in which
16 the decision aids were set and the data suggest that their perceptions were being
17 considered commonly across decision aids more widely rather than the exacting information
18 for each trial pilot decision aid presented. All the participants in our study were UK based
19 and therefore may hold different views to those in other countries with different social
20 norms and cultures. However, it was felt that focusing on the UK was appropriate due to
21 the differences in regulatory requirements and structure of PILs across countries i.e. consent
22 forms for American and Canadian studies tend to be longer than UK forms and contain
23 much of the information being found within UK PILs. In addition, there was an assumption
24 that these decision aids were for adults who had capacity to consent for themselves. It
25 would also be important to explore the usefulness of these tools in other contexts with
26 proxy decision makers, including parent of children who are consenting on their behalf.
27 Another potential limitation of our study is that the sample were a self-selecting group of
28 individuals and, especially for the patients, may be different from those in the general
29 population. Indeed the size of each of the stakeholder groups was relatively small.
30 However, it is important to highlight that the participants included in this study can offer
31 thoughtful and reflective insights into decision aids for trial participation when reflecting on
32 their own trial experience including reflection on existing PILs.
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53 54 **Implications for researchers**

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56 Decision aids for trial participation should be developed with meaningful stakeholder
57 involvement. All aspects of the information should be balanced. Attention to language is
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3 critical to ensure it is not deemed coercive or value laden. Developers should be mindful of
4 the target audience, especially when considering presenting probabilistic information and
5 considering method of delivery. If patient stories are included, how these will be generated
6 and included must be considered. Finally, decision aids for trial participation should be
7 developed and used in ways that allow all users to engage effectively with the information
8 and provide support to decision makers.
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13 14 15 **Future research**

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17 Whilst the decision aids explored in this study were perceived as being potentially helpful, it
18 should be noted that these types of interventions (or certainly the aids developed in this
19 study) may be more appropriate to support some RCT decisions than others, we are not
20 proposing a 'one size fits all' model. It is likely that decision aids could be more effective for
21 some trial decisions rather than others e.g. where interventions being trialled are very
22 different (like medical management vs. surgery), which is also the case for treatment
23 decision aids [10]. It may also be that the decision aid could be broken up into component
24 parts (values clarification exercises, experiences of others, etc) and used as appropriate
25 (defined by individuals preferences for information) in different contexts to facilitate and
26 support the informed decision making process. However, this requires further evaluation
27 before recommendations can be made.
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31 In addition, given the limitations of the current conceptualisation of informed consent, it is
32 important to think about how decision aids would be evaluated. For example, if tested in an
33 RCT against existing PILs what outcomes should be measured, how do these outcomes
34 compare to others in existing studies of interventions to improve consent, and what do
35 potential participants think should be measured?
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39 Further research regarding how decisions about trial participation are discussed, engaged
40 with, deliberated over, participated in, supported and executed is required to inform the
41 design of interventions to better support the process. In addition, where much of the
42 previous literature has focussed on participants' understanding of trial concepts such as
43 randomisation and blinding, exploration of what participants believe taking part means for
44 them as individuals could also help to develop more tailored approaches to informed
45 consent.
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CONCLUSIONS

Compared to existing PILs, decision aids for trial participation have the potential to promote a more 'informed' decision making process with regard to consent. It is vital that research efforts, inclusive of all stakeholders, continue to understand how to support potential trial participants' decisions about trial participation (whether it be to enrol or not); how to ensure these decisions are in line with individuals values and preferences and to determine optimal methods to support informed decision making in this context.

For peer review only

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Competing interests

All authors have completed the Unified Competing Interest form at www.icmje.org/coi_disclosure.pdf (available on request from the corresponding author) and declare that (1) No authors have support from any company for the submitted work; (2) No authors have relationships with companies that might have an interest in the submitted work in the previous 3 years; (3) their spouses, partners, or children have no financial relationships that may be relevant to the submitted work; and (4) The authors have no non-financial interests that may be relevant to the submitted work.

Authors' contributions

KG conceived the study idea. KG, ZS and MC were involved in designing the study and developing the methods. KG applied for ethics approval and collected the interview data. KG and ZS conducted the initial analysis and development of the thematic framework, with additional input from MC. KG directed the full analysis. All authors had full access to all of the data and participated in the discussion and interpretation of the results. KG wrote the initial manuscript draft. All authors critically revised the manuscript and approved the final version.

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Transparency declaration

KG (the manuscript's guarantor) affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned have been explained.

Data sharing statement

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No additional data available

For peer review only

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Table 1. Characteristics of interviewees

	N (%)
Stakeholder group	
Trialist	5 (22)
Research Nurse	5 (22)
Research Ethics Committee (REC) Chair	5 (22)
Principal Investigator – Clinician	4 (17)
Patient	4 (17)
Gender	
Male	11 (48)
Female	12 (52)
Age (yrs)	
40 and under	8 (35)
41 –60	10 (43)
61 and above	5 (22)
Experience of working in clinical trials (yrs)*	
< 10	7 (37)
≥ 10	12 (63)
Location (University or NHS)*	
University	7 (37)
NHS	12 (63)
Previous experience with decision aids	
None	21 (91)
Limited	2 (9)
Experienced	0 (0)

*Patients (n=4) not included in this category

Figure legends

Figure 1. Example of content items from prototype trial decision aids:

Presenting probabilities section

Figure 2. Example of content items from prototype trial decision aids:

Methods for clarifying and expressing values

Figure 3. Example of content items from prototype trial decision aids:

Structured guidance in deliberation: Decision making steps

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8 **Decision aids for randomised controlled trials: a qualitative exploration of stakeholders'**
9 **views.**

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30 [Key words](#)

31 [Decision Aids](#)

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35 [Randomised Controlled Trials](#)
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ABSTRACT**Word count ~~26328~~**

Objectives To explore stakeholders' perceptions of decision aids designed to support the informed consent decision making process for randomised controlled trials.

Design Qualitative semi-structured interviews. ~~that included~~ participants ~~were being~~ provided with prototype trial decision aids in advance to stimulate discussion. Interviews were analysed using an established interpretive approach.

Participants 23 stakeholders: ~~trial~~ trial managers (n=5); research nurses (n=5); ethics committee chairs (n=5); patients (n=4) and clinical principal investigators (n=4).

Setting Embedded within two ongoing randomised controlled trials. All interviews conducted with UK based participants.

Results Certain key aspects (e.g. values clarification exercises, presentation of probabilities, experiences of others and balance of options) in the prototype decision aids were perceived by all stakeholders as having a significant advantage (over existing patient information leaflets) in terms of supporting well informed appropriate decisions. However, there were some important differences between the stakeholder groups on specific content (e.g. language used in the section on positive and negative features of taking part in a trial and the overall length of the trial decision aids). ~~More g~~Generally the stakeholders believed trial decision aids have the potential to better engage potential participants in the decision making process and allow them to make more personally relevant decisions about their participation. Interestingly, stakeholder views did differ on specific content and design aspects of the trial decision aids (such as length of information and mode of delivery).

Conclusion Compared to existing patient information leaflets, stakeholders perceived decision aids for trial participation to have the potential to promote a more 'informed' decision making process. Further efforts to develop, refine and formally evaluate trial

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decision aids should be explored.

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Article Summary

Strengths and limitations of this study

- This study is the first to explore, and evidence, the potential of a decision aid to support decision making for participating in a randomised controlled trial from the perspectives of a range of stakeholders, including: patients; ~~trial~~[trial manager](#); research nurses; clinician researchers; and ethics committee chairs.
- Compared to existing patient information leaflets, this study has shown that trial decision aids have the potential to better engage potential participants in the decision making process and allow them to make more personally relevant decisions about their participation.
- All the participants in our study were UK based and a self-selecting sample and therefore may hold different views to those in other countries with different social norms and cultures. However, these participants can offer thoughtful and reflective insights into decision aids for trial participation when reflecting on their own trial experience including reflection on existing [Patient Information Leaflets](#).

INTRODUCTION

There is an ethical requirement to obtain informed consent from potential participants before they are enrolled in a randomised controlled trial (RCT) [1, 2]. As part of the informed consent process, potential trial participants are provided with written information about the trial often in the form of a participant information leaflet (PIL) [3]. The information included in PILs is largely guided by the Declaration of Helsinki, the international Conference on Harmonisation and Good Clinical Practice (ICH GCP) and, in the UK, by national guidance such as the National Research Ethics Service (NRES) [2, 3, 4]. As outlined by this guidance the PIL should include largely fact-based information about: the purpose of the trial; procedures; interventions; possible risks and benefits; sources of finance; conflicts of interest; and the researcher's affiliation [3, 4].

Existing PILs may be sub-optimal; research has shown that some trial participants (both those considering participation and those actively enrolled) fail to understand key aspects of trial rationale or process [5, 6]. A range of studies have tested ways to improve information provision in the context of trials [6]. These have tended to focus on the content and structure of the information and measured outcomes such as understanding, recall and trial recruitment [6]. Whilst improving understanding of the trial is important, informed decision making about trial participation is complex and likely to require more than just greater understanding of fact-based information [6]. Furthermore, it has been argued that PILs are 'institutionally scripted' as a means to obtain ethical approval rather than functioning as a tool to support potential participants' decision making [7]. As such, the current conceptualisation of 'informed consent' (largely as understanding of information) and how it is enacted (through signing of a consent form) may be overly narrow and require broadening to consider the importance of deliberation and determination in the decision making process for trial participation [8, 9].

Evidence from the treatment and screening decision making literature has highlighted that certain key items are important for making 'good' decisions [10, 11]. For example, being able to consider alternative options (in the context of trial participation this may be another intervention or may be usual care), making trade-offs and evaluating potential outcomes of

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7 the decision and consideration of what those outcomes mean personally for that individual.
8 These items, and others, are often included in decision aids, which actively encourage
9 people to participate in decisions about treatment that involve weighing up associated
10 benefits and harms often when there is clinical uncertainty [10]. Decision aids have been
11 developed for a variety of treatment and screening decisions and have been shown to
12 positively influence several aspects of decision making [10]. The items identified as being
13 important for good decision making are largely lacking from existing PILs for trial
14 participation [12], further supporting the contention that existing PILs do not function well
15 as decision making tools [12].
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22 The very few published studies that have explored the use of decision aids, or components
23 of them, in the context of trial participation decisions have shown some promise [13, 14,
24 15]. For example, compared to existing PILs, decision aids for trial participation have been
25 shown to improve understanding whilst not increasing anxiety [13] and resulted in low
26 levels of decisional conflict and high levels of satisfaction [14]. ~~However~~Although
27 encouraging, these studies have solely focused on trial participants' perceptions and have
28 not explored other stakeholders' opinions. Whilst trial participants perspectives remain
29 keyare important, replacement of, or any amendments to existing PILs would require buy-in
30 from an additional range of stakeholders, such as: developers (e.g. trial managers);
31 deliverers (e.g. research nurses and clinician researchers); and approvers (e.g. ethics
32 committees). This buy-in is critical to ensuring that trial decision aids are as effective as they
33 can be (i.e. act as a decision support tool to facilitate meaningful conversations that
34 encourage informed decision making), are implementable and used as intended. Although
35 treatment and screening decision aids have been shown to be efficacious, the main barriers
36 to their effectiveness in a real world setting are a lack of implementation and fidelity of use
37 often as a result of a lack of buy-in at inception from stakeholders [16, 17]. Furthermore,
38 previous studies on trial decision aids have not explicitly explored perceptions of the 'new'
39 content (i.e. features to improve decision making), which define decision aids as different to
40 existing PILs.
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52 The study reported in this manuscript forms part of a larger programme of work that aimed
53 to systematically develop and pilot (through interviews reported here) prototype trial
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7 decision aids. The prototype decision aids were developed through an iterative process
8 informed by the MRCs framework on development of complex interventions [18]. The
9 process began with establishing the current evidence on the effectiveness of decision aids
10 for supporting decisions about RCT participation [19]. Next a Delphi study was conducted,
11 with a range of stakeholders, to identify key items for inclusion [20], followed by an
12 evaluation of existing PILs using a tool (that contains items assessing key features of 'good'
13 decision making) to identify areas that were lacking [12], drafting of prototype decision aids
14 (informed by previous stages), followed by rounds of revision within the study team. We
15 then undertook an in-depth qualitative study to explore stakeholders' views and
16 perspectives on the specific content of the prototype decision aids and their potential to
17 improve the informed consent process for RCTs (it is this qualitative study that is reported
18 here).

26 METHODS

27 Development of the prototype trial participation decision aids

28
29 Prototype decision aids were developed for two on-going RCTs. The first was a trial
30 comparing two surgical procedures for treatment of haemorrhoids ~~one surgical~~ (ISRCTN
31 8006172, date of registration 08/03/2010); and the other a one drug trial comparing 2
32 active drugs and a placebo for treatment of ureteric stones (ISRCTN 69423238, date of
33 registration 18/11/2010). These RCTs were identified from the portfolio of RCTs managed
34 by the Centre of Healthcare Randomised Trials (CHaRT) at the University of Aberdeen. The
35 content of the prototype decision aids was developed through the iterative process outlined
36 above. The prototype decision aids were enhanced by a Graphic Designer, at the University
37 of Aberdeen, to improve the visual impact of the tools. The tools were presented as A5
38 booklets which could be printed or read as a PDF document.

46 Exploration of stakeholders' perceptions of trial decision aids.

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48 An open-ended topic guide was developed to elicit accounts of participant's view of the
49 prototype decision aids (see Additional file 1). The topic guide was informed by literature
50 on content items for decision aids and explored the key differences between decision aids
51 and existing PILs [11, 12]. Moreover, items identified as contentious in earlier work [20]
52 were also further explored (e.g. use of experiences of others). The guide, and subsequent
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7 analysis, were organised around views of existing patient information leaflets; views about
8 the prototype decision aids with specific exploration of their potential to support the
9 decision making process. Semi-structured interviews were conducted with different
10 stakeholder groups (including patients, ~~trial~~trial managers, research nurses, ethics
11 committee chairs and Principal Investigator~~lead clinicians~~ involved with both trials) to
12 explore perspectives about the use of decision aids in a trials context.
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16 17 18 **Sampling and recruitment**

19 Potential participants from the ~~trial~~trial manager, research nurse and ethics committee
20 chair stakeholder groups were identified through email list serves (~~trial~~trial managers: UK
21 Clinical Research Collaboration Trial Managers listserv (n=501); research nurses: Scottish
22 Research Nurse and Coordinators Network listserv (n=198); ethics committee chairs:
23 National Research Ethics Service committee chair listserv (n=88)). Patients who would be
24 eligible for each RCT were identified and contacted by a research nurse working at the lead
25 site for each of the RCTs (n=20). Principal Investigators for both of the RCTs were sent an
26 email invite and asked to respond to the lead researcher (KG) to express interest (n=40).
27 Prospective participants were sent a letter of invite with a slip to return, or email response,
28 to express interest. Interested participants were ~~then~~ sent full information about the study
29 (in the form of a participant information leaflet), and a consent form and were provided
30 with an opportunity to discuss the research project and have any questions answered
31 before making a decision. Ethics committee chairs, Principal Investigators, Research Nurses
32 and ~~trial~~trial managers who were recruited for interview were sent a copy of both
33 decision aids to review. Recruited patients were only sent the decision aid relevant for their
34 condition. Recruited participants were given the choice of a face-to-face or telephone
35 interview. All participants provided written consent.
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46 47 **Data collection**

48 One author (KG) conducted the interviews between April 2012 and July 2012. Only one
49 patient participant chose a face-to-face interview, which was conducted at the University of
50 Aberdeen as agreed by the participant and the researcher, all other participants requested
51 telephone interviews. Interviews were audio-recorded, transcribed verbatim and
52 anonymised. At the start of the interviews, participants were encouraged to provide their
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7 views and perspectives on existing patient information leaflets for clinical trials and discuss
8 their experiences of participating in clinical trials or reviewing clinical trial information, as
9 appropriate. All participants were then asked about their views of the prototype decision
10 aids and how they might, or might not, support a decision about trial participation [\(see](#)
11 [Additional file 1\)](#).

16 **Data management and analysis**

17 A thematic content analysis of the transcripts was conducted. [—An established interpretive](#)
18 [approach was used whereby following familiarisation with the transcripts, *a priori* and](#)
19 [emergent themes were identified, discussed and agreed by the research team \[21\].](#) [As](#)
20 [many of the interview questions were developed around pre-determined themes of interest](#)
21 [\(i.e. those relating to specific content and purpose of trial decision aids \[11\]\) there were not](#)
22 [many emergent themes identified. However, the meaning and importance attached to each](#)
23 [of the pre-determined themes was emergent.](#) Two authors (KG & ZS) independently
24 reviewed transcripts and documented the major emerging themes. A thematic framework
25 was subsequently generated, and agreed through discussion with all authors, which detailed
26 codes for labelling textual data related to the major themes and sub-themes. Codes with
27 specific relevance to decision aids (and items which define them as being distinct from
28 existing PILs) were used as *a priori* codes for key parts of the interview transcripts [\[11\]](#).
29 Transcripts were subsequently coded by one author (KG), in which the thematic framework
30 was applied systematically to the textual data. This process was managed through the use
31 of text management software (NVivo 10). This facilitated data organisation which promoted
32 further analytic consideration through constant comparison of data both within and across
33 the stakeholder groups, [this was conducted by two authors \(KG and ZS\) and identified key](#)
34 [differences between the groups and identified consensus on the importance of the potential](#)
35 [of decision aids across all groups.](#) Relevant quotes representing interviewees'
36 considerations were selected to illustrate the results.

49 **Ethical approval**

50 [The study was approved by the North of Scotland Research Ethics Committee 1 \(REC](#)
51 [Reference Number 09/S0802/105\) and NHS Grampian Research and Development](#)
52 [department \(Reference Number 2009HS002\). All interview participants provided their](#)
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7 signed consent, which included consent for anonymised quotes from their interviews to be
8 published.
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11 RESULTS

13 Sample characteristics

14 Fifty individuals contacted the researcher (23 ~~trialist~~trial managers; 10 research nurses; 8
15 ethics committee chairs; 5 patients and 4 lead clinicians) and 23 were interviewed.

16 Response rates varied across the groups: 5% for trial managers; 7% for Research Nurses; 9%
17 for ethics committee chairs; 25% for patients (1 subsequently declined participation); and
18 10% for Principal Investigators. In those stakeholder groups where more participants
19 responded than were required for interview, participants were sampled purposively based

20 on affiliation with registered UKCRC clinical trials units and further stratified for geographic
21 location. The number of participants in each group was decided based on a predetermined
22 judgement that each group should contain a similar number and be informed by the
23 numbers interviewed in the patient group (n=4). The interviews ranged from 40-80 minutes.
24 We deemed this sample size to be sufficient to identify a range of experiences and views
25 that would generate a manageable amount of data for in-depth analysis within the
26 timescale of this project [22].
27

28 A brief description of the participants is provided in Table 1. They included 12 women and
29 11 men, aged from 35 to 80, who were from the following stakeholder groups: ~~trialist~~trial
30 managers (n=5); research nurses (n=5); ethics committee chairs (n=5); patients (n=4) and
31 lead clinicians (n=4). Twelve of the sample had experience of working for an NHS
32 organisation and 7 worked within Universities. Experience of working in clinical trials (which
33 could be as a recruiter, a trial manager, a reviewer of ethical applications of trials) ranged
34 from 3 to 20 years. The majority of the group (n=21) had no previous experience of decision
35 aids but all stakeholders had previous exposure to PILs for trials. The themes described
36 below were largely identified a priori so as to provide a predetermined exploration of the
37 key content items that differ between existing PILs and decision aids for trial participation.
38 Due to the pre-defined areas of importance for investigation informing the topic guide, all
39 themes were discussed by all stakeholder groups but the extent to which their opinions
40 converged differed between groups and across themes.
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General impressions of the trial decision aids compared to existing information leaflets

The majority of stakeholders [across all groups](#) perceived that, in principle, trial decision aids were beneficial and an improvement on existing PILs. There was a perception that they provided a 'balanced', unbiased picture, that they were uncomplicated and that they could proactively facilitate more engagement in the decision, compared to existing PILs.

'it's very well balanced and I think that's really important because it's not leading anybody in any one direction. And I think that's an excellent part of the whole booklet itself.' (Patient 3)

'I think that they [decision aids] are very, very straight forward actually, that as I've said before the patient information leaflets are very wordy things and they have a lot of information to impart to patients and sometimes they will switch off after the third paragraph.' (Research Nurse 1)

'there's not just an information sheet; there's a decision making tool to help the patient make decisions, rather than it just being a passive thing of read the information leaflet ... whereas this is actually making them work through and think about it, and this is obviously the biggest change and I do think this would be of a benefit.' (~~Trialist~~Trial manager 2)

Although most of the initial perceptions of the decision aids were positive, some [respondents/participants, from the Research Nurse and Principal Investigator groups](#), did feel that the use of a decision aid could potentially over-complicate the decision process in this context by providing more information and potentially raising concerns.

'My concerns were that sometimes people feel that the patient information sheet alone is onerous, so adding something else on might actually put some people off..... just that it might increase fear or uncertainty. It almost makes the decision bigger, by adding in this decision making tool.' (Research Nurse 5)

[However, these perceptions were from the minority of participants within these stakeholder groups, with most of the group expressing agreement of the improvement of these decision aids compared to existing methods.](#)

Perception of trial decision aid content

This section of the paper reports the findings relating to specific aspects of the decision aids which are not routinely included in patient information leaflets for trial participation.

Provision of information about positive and negative features of taking part in the trial.

The trial decision aids included information on both the advantages and disadvantages of both options (participating in the trial or not) whereas existing PILs generally only cover issues relating to trial participation [12]. There were varied views (largely across and within the Research Nurse, Trial Manager and Ethics Committee Chair groups) expressed when participants reflected on whether the information included about positive and negative features of participating in the trial or not was balanced. Some recognised this was a new addition to the standard information and felt the section was well balanced and would be helpful for potential participants to make an informed choice about participation.

'I think this does just outline the different variables really that, you know, there are disadvantages about taking part in clinical studies and there are disadvantages about not. It's an interesting new thing as far as I can see, I've not see anything quite that descriptive before.' (Research Nurse 1)

Other participants felt that whilst the overall concept of providing information about both options was advantageous, some of the included information about advantages and disadvantages of options could be deemed as being potentially coercive. This was a view held by most of the Trial Managers, Research Nurses and Ethics Committee Chairs.

'And I thought that they [sections on advantages and disadvantages participating in the trial or not participating] were quite helpful.... I did think that one of the sentences [You will receive extra personalised care and attention from research nurses by taking part in the trial] possibly was a bit over-emotive.' (~~Tri~~alist Trial manager 4)

Even though many participants agreed that advantages and disadvantages about both options should be included, all of the ethics committee chairs reported some of the language as potentially inappropriate and stated that ethics committees would be uncomfortable with some statements. For example:

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'I think that there's quite a lot of emphasis on saying to people one of the advantages of taking part is that you'll get some extra care and attention... Now, in a sense that's true given that that is built in to the research procedure, but certainly the committee, we're very... we're very sensitive to anything that could be taken as an extra inducement to take part. And I felt that one or both of these was a bit more emphatic about that and if we'd be reviewing these as a committee I think we wouldn't have been very comfortable with that.'

(Ethics Committee Chair 2)

However, patients reported this section to be well balanced and felt that this section provided information to illustrate that participating in a clinical trial may provide access to services (whether treatment or follow up) that would not be available outside of the trial.

For example:

'it was honest, it was upfront and I was like...yeah, okay, you won't have to do the questionnaires but yeah, you will get additional care. So there was a little bit of a "We provide you with a luxury service" or you just get the MOT when we're ready for it. So, it was quite a good inducement to take part.' (Patient 3)

Presentation of probabilities

Methods used to present probabilities of outcomes associated with interventions across the two prototype trial decision aids were varied according to reported methods of good practice for decision aids [11](see [FigureBox 1](#)). Participants were asked to compare where appropriate. There was recognition amongst participants in all stakeholder groups that presenting complex probabilistic information to potential trial participants is challenging and that individuals have varied preferences and understandings of this type of information, especially within the context of clinical trials and the interventions they are testing.

'I think it's a good way of presenting it [risks] in a different way. I think presenting risk as words and as numbers and as something visual is going to help. I think in the end it's still a very hard thing for people to understand, as I said, at a personal level.' (Ethics Committee Chair 3).

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7 A couple of participants, [from the Principal Investigator and Ethics Committee Chair groups](#),
8 raised the importance of placing risk within the context of familiar activities as an effective
9 way to allow potential participants to make judgements about the risks they are willing to
10 take.

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12 *'you could say, "This list does look long and worrying but actually these side-effects don't*
13 *occur very often. By comparison if we listed all the side-effects of paracetamol these are the*
14 *things you would be told about" and you could say very commonly without any problem at*
15 *all.'* (Principal Investigator 2)
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20 **Methods for clarifying and expressing values.**

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22 The majority [of stakeholders across all groups](#) felt that values clarification exercises included
23 in the trial decision aids (see [FigureBox-2](#)), which allow patients to trade-off positive and
24 negative features of the decision to facilitate personally meaningful decision making, were
25 helpful and that they had the potential to facilitate the decision making process.

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28 *'I mentioned that the pros and cons is very, very good, I think that that would help a lot of*
29 *people make decisions and it talks about what would happen to me if I didn't take part in*
30 *this study as well so that's something that we don't, well we say "Oh well that's Ok, you'll*
31 *just get the standard course of treatment" is there anything negative about me not taking*
32 *part, that's important to emphasise that as well.'* (Research Nurse 4)
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37 A significant potential benefit of values clarification exercises that was highlighted by
38 participants was their potential to allow potential trial participants to make personally
39 relevant decisions by weighing up what matters most to them, within the context of the
40 clinical trial.

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43 *'I think it would probably be quite useful just to have that let them weigh that up, whether*
44 *they want to take part or not.'* (Principal Investigator 3)
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48 *'And that's very powerful, they're making a decision that feels to them very fair because*
49 *they've done a weighting process around it. So I really, really liked this.'* (Research Nurse 5)
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7 However, ~~a minority of some other~~ participants (mainly Trial Managers) felt that the
8 exercises themselves, or aspects of them (such as the term 'worksheets' and the lengthy
9 instructions for completion), would not be helpful and ~~would~~ be perceived negatively.

10
11 *'... I don't know, it just made me think you know patients thinks, "Ah worksheets, am I going
12 to have to fill in loads of stuff?">' (Trialist/Trial manager 1)*

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15
16 Yet the patient group all perceived these exercises as being helpful and beneficial for their
17 decision making, acting as a guide to take them through the advantages and disadvantages
18 of trial participation.

19
20 *'I find the little piece at the back, the pros and cons table, or pros and cons balance graphic,
21 quite useful. It did help me come to my conclusion, the pros and cons one, because I
22 answered all the questions and highlighted my answers. I found that really quite
23 interesting.'* (Patient 2)

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28 However, one of the patients and participants across the other stakeholder groups did
29 highlight that there may be a need for the values clarification exercise to provide a 'score' or
30 objective decision with regard to trial participation.

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32 *'It's like...there's not a scoring system, so...big benefit, no benefit, so I don't know actually
33 where that would come out. There's no - what's my weighting?'* (Patient 3).

34 35 36 37 **Structured guidance in deliberation.**

38
39 Decision aids should provide steps to assist the patient in making a decision, which may
40 include suggesting ways to talk through the decision with health professionals and including
41 tools (worksheets or question lists) that would allow discussion with others [11]. ~~Several of~~
42 ~~the p~~Participants across all groups stated that the identified steps for making a decision (a
43 list of 6 items outlining the process) that were highlighted in the decision aid (see ~~FigureBox~~
44 3) were a helpful addition.

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48 *'I think putting out how somebody might make a decision. You know, the six points [decision
49 guidance]. And I think setting all of this... I was pleased that when I read it through.'* (Ethics
50 Committee Chair 4)

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7 | *'I do think that's good; rather than giving them all the information and then saying "Right, now it's up to you to make a decision." it almost leads them through to actually think: right...it's like making it a much more active decision rather than just reading the leaflet and chucking it away; their actually having to think about the questions in their head.'*

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12 | *~~Trialist~~ Trial manager 1)*

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16 There were also positive reactions to the 'notes' page (included as a way to promote
17 question asking and deliberation, which was a blank page titled 'notes'). Participants felt
18 this would facilitate the decision making process by enabling potential trial participants to
19 ask questions, highlight areas where they need more support to make their decision and
20 reflect on following their decision making.
21

22
23 *'And what I thought was excellent, and really this is great, was that you gave room for notes,*
24 *you know for patients to make notes. It just gives permission for them to be able to do that.*
25 *And what I thought was, at every time point where you're maybe asking them to go through*
26 *their decision, put in a blank page which says 'notes', because I just think that is really*
27 *helpful and it facilitates them actually making notes that they can return back to – "What*
28 *was my thinking around this?"' (Research Nurse 2)*
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34 In addition, members of all groups apart from the Principal Investigators commented on
35 aspects of the decision aid being repetitive. One of the patients stated the following with
36 regard to the structured guidance for decision making:
37

38 *'It's very clear. I would, the only comment I would make on that is it's probably repetitive of*
39 *what's gone on throughout the whole book.....But I wouldn't say it would drive me to take*
40 *that away, not take it out. I just felt that, you know, I'd read most of that and understood*
41 *most of 1 to 6 in the preceding narrative.'* (Patient 1)
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45 46 **Experiences of other potential trial participants.**

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48 Experiences of others (or patient stories) are sometimes included in treatment decision aids
49 and, if included, should represent a range of experiences, both positive and negative [11].
50 Although there were mixed views expressed, most thought the inclusion of other
51 participants' experiences was a helpful addition as the general perception was that people
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7 are often interested in what their peers have done and that this could help to normalise trial
8 participation.
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10 *'It is like a big Expedia or a trip adviser thing, you are always interested in the other people's*
11 *experiences. Yes actually I think its something that we've not really thought about before,*
12 *that you are not alone here, that there are hundreds and thousands and millions of people*
13 *participating in clinical trials all the time so to get a wee bit of feedback from them, yes, yes*
14 *no I like that.'* (Research Nurse 1)
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18
19 Some of the ~~respondents~~ Research Nurse and Principal Investigator participants reported
20 that trial participants ~~often~~already ask them what other patients have done and that usually
21 there is some dialogue around those experiences.
22

23 *'Yeah, it's [being asked what others think] not infrequent. "What do your other patients*
24 *think, Mr X?" I usually say, "They often want to get involved." "Oh, well okay then." It's*
25 *slightly interesting, and a bit bizarre, but there is a bit of team play in that I think.'* (Principal
26 Investigator 4)
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31 *'They say, "What's the uptake of others? Are they all taking part or not?" And I say, "The*
32 *majority take part in a study; some don't for various reasons. And some of those reasons are*
33 *personal to that patient: they're too far away, they don't want to come back to the follow-*
34 *up, they hate hospitals, they don't want to ever come back after this – that type of thing."*
35
36
37 (Research Nurse 4)
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39

40 It was also highlighted that experiences of others may enable participants to ask questions
41 by highlighting aspects they may not have previously been considered.

42 *'but what it at least does is it encourages them to ask questions because these guys have*
43 *already identified experiences that they have had.'* (Research Nurse 1)
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48 Despite generally positive views about the inclusion of others' experiences, there were
49 some queries raised from Trial Managers and Research Nurses~~however,~~ around with regard
50 to how the experiences from other trial participants would be generated for inclusion in a
51 trial decision aid given that information leaflets are developed before any participants have
52 entered, or refused, the trial.
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7 *'So I was a bit unsure how that was all going to work because either you make it generic and*
8 *it's just about patients who have participated in other trials, or you wouldn't be able to*
9 *implement this for any trial until after you've already got some patients in.'* (~~Trialist~~Trial
10 manager 4)
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14 There was a concern from one respondent (an Ethics Committee Chair) who perceived there
15 to be no additional value by including experiences of others and that it complicated the
16 process by introducing the perspectives of others when ultimately the decision lies with that
17 individual and should be based on their own values and preferences.
18

19
20 *'[I'm] Not sure it doesn't... just that it doesn't cloud the water, it was their decision at the*
21 *end of the day.'* (Ethics Committee Chair 5)
22
23

24 25 **Amount of information**

26 There was variation in participants' perceptions about the amount of information and the
27 length of the trial decision aids, with the majority of stakeholders (largely Trial Managers,
28 Ethics Committee Chairs, and Principal Investigators~~some agreeingsaying~~ there was too
29 much information and others (patients and Research Nurses)-feeling all of the information
30 included was important. There was recognition that the length could be partially attributed
31 to the pre-specified regulatory requirements. ~~However, n~~One of the patients felt there
32 was too much information or that the trial decision aids were too long. For example:
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37 *'I can't say that I found anything in the book unhelpful.'* (Patient 3)
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40 *'Its difficult because there is so much stuff that is legislated that has to be in, so it is difficult*
41 *to condense them any less.'* (Research Nurse 2)
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47 48 **Method of delivery**

49 The stakeholders in this study had varying preferences, which diverged between and within
50 groups, for how the trial decision aids should be delivered. Some felt that there should be a
51 move towards presenting this type of information online or using other electronic media
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7 such as DVDs. However, others felt that providing the information in a booklet format was
8 the best option as this allows people to take it away with them and discuss with others.
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11 *'You know, if there were a DVD of somebody talking me through this with the diagrams, the*
12 *presentation, which they could look at in the research room, that would be much better. I'm*
13 *sure that would be more acceptable to most of them [trial participants].'* (Principal
14 Investigator 4)
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19 *'I read it quite thoroughly from page to page, and I think that's what it's designed to do, you*
20 *can take time to read it and make some notes and then consult with somebody else about it,*
21 *you know? I think the paper document is the best way; the old-fashioned way is the best*
22 *way, really.'* (Patient 2)
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27 ~~However, s~~Some reported that the specific method of delivery is less important and more
28 emphasis should be placed on accessibility.

29
30 *'I think it's important that whatever you use people can access it easily and that if they*
31 *choose to they can show it to other people outside the place or the room where they made*
32 *the decision, so they can go over it again.'* (Ethics Committee Chair 4).
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36 However, participants in the Research Nurse, Trial Manager and Ethics Committee Chair
37 groups identified the importance of context with regard to the trial population being
38 recruited.

39
40 *'Some people were put off by it [computer tablet], but that is just my client group [elderly].*
41 *Obviously it is going to really depend on you client group, if it is children, teenagers, people*
42 *in their twenties, thirties, forties, that's how we live our lives, that is how we expect to*
43 *receive information nowadays. We certainly don't expect to get it in a paper format.'*
44 *(Research nurse 2)*
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51 **The untapped potential of trial participation decision aids**

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53 The interviews also focussed on ~~respondents~~participants perceptions of the future potential
54 of decision aids to support decisions about participation. Participants' reflections on this
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7 were varied, ranging from improving consent (across all stakeholders) through to increasing
8 recruitment (mentioned by Principal Investigators and Research Nurses) and retention
9 (highlighted by Research Nurses, Principal Investigators and Trial Managers) in the trial.
10
11 However, stakeholders across all groups highlighted a focus on the biggest potential gains to
12 be from improving aspects of the decision making process such as informedness (which
13 includes an understanding of their involvement and commitment to the trial over time) and
14 opportunities for discussion with others.

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17 *'To me, it was still open [the decision] right the way through.... But reading this here, right*
18 *the way through the whole thing you're still feeling, "Well there's still an option, they're still*
19 *making sure it's ok.'* (Patient 1).
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22
23 *'So I think a tool like this ought and should help people make a better decision, fully informed*
24 *decision that they can also explain to perhaps their own clinician, certainly to family and*
25 *friends.'* (Ethics Committee Chair 3)
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29 *'I think it's probably making the patient more aware of what's actually involved, and what*
30 *the commitment will be from the patient.'* (~~Trialist~~Trial manager 1)
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34 There was also recognition, largely by Trial Managers and Research Nurses, that these trial
35 decision aids have the potential to actively engage potential participants in their decision
36 making process and allow them to make personally relevant decisions that they are able to
37 discuss with others.
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41 *' it makes it a bit more personalised, it makes them think about how they would cope with*
42 *this trial in their life at the time, then I think that would be useful, it would maybe help them*
43 *think, 'Am I really going to manage this?'. (~~Trialist~~Trial manager 5)*
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47 *'To empower for decision making, to enfranchise them to make a decision, and to not just*
48 *get people on study, but to care for people when they're on study, in that this is more helpful*
49 *to know that they have made a truly well informed decision. And it's something about giving*
50 *patients the ownership of what they're doing, and I think this is helpful in that.'* (Research
51 Nurse 5)
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DISCUSSION

Principal findings

This is one of the first studies to explore perceptions about the potential of decision aids to support decisions about trial participation from the perspective of all key stakeholder groups and provides empirical data on a range of relevant stakeholder perspectives. Furthermore, this is the first study to explicitly investigate stakeholders' views about key content items of decision aids and their appropriateness for decisions about trial participation. Overall, stakeholders felt that the decision aids were an improvement on existing PILs in that they explicitly highlighted that there was a decision to be made about participation in the trial. In addition to this, stakeholders believed that the decision aids also provided ways for potential participants to engage with the decision making process and make personally appropriate decisions for them as individuals.

This study explored views about the specific content items that differ between decision aids and existing PILs namely: provision of information about positive and negative features of options; presenting probabilities; methods for clarifying and values; structured guidance in deliberation; and experiences of other potential trial participants. It is important to highlight that whilst the majority of the stakeholders agreed on specific aspects there were some key differences between the patient group versus the others. For example, patients views differed to the majority of other stakeholders groups with regard to provision of information about positive and negative features of taking part in a trial (specifically with regard to the exacting information contained within the section) in that patients felt it to be balanced but others reported worries about coercive language. In addition, many of the stakeholders felt that the decision aids were too long, but none of the patients reported this with all of them saying that all of the information was important. These findings (which must be considered within the context of this study i.e. patients may be different the general population) should serve as a reminder that when developing decision aids for trial participation, whilst all stakeholder views are important, patients views must be placed at the core.

In principle, the general concept of providing information about positive and negative features of options (i.e. to participate or not) was received positively and was felt to provide

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7 | balance to the decision by highlighting all features. However, some ~~respondents~~ participants
8 expressed views that some of the language was weighted, or may allow participants to
9 attach value to, and could be deemed as potentially coercive. Therefore, it would be
10 important in future decision aids for trial participation to ensure that neutral statements are
11 incorporated. A recent study has illustrated the potential bias that can be introduced into
12 trial participants' decision making when the framing effects of language are not addressed
13 [23].
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19 The section on presenting probabilities was well received by all stakeholders and was stated
20 to be an improvement on current PILs. However, it served to further highlight that
21 individuals have preferences for the way probabilistic information is presented and that
22 there is no 'one size fits all' approach. This is of particular importance when considering
23 that understanding and perception of risk within clinical trials can be a significant influence
24 on the decision to take part or not [24]. Although there is a wealth of literature on how best
25 to communicate probabilistic information in a treatment and screening context, this does
26 not exist for decisions about trial participation where often due to the inherent nature of
27 trials, much of this information is not known and the layers of risk are greater (e.g. risk of
28 the trial vs. risk of treatment, risk of outcomes associated with both interventions, risk of
29 randomisation, etc). Therefore, further research to identify how this can be undertaken
30 effectively, in different trial contexts, are of importance.
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39 The values clarification exercise was reported as a positive addition and provided a way to
40 engage potential participants in their decision making by making them weigh up what
41 matters most to them. One study has measured the extent to which the use of values
42 clarification exercises support (hypothetical) decisions about trial participation and found
43 they lowered ambivalence and decisional uncertainty whilst improving the clarity of
44 personal values [15]. Therefore, there is merit in further exploring this type of exercise to
45 support decisions with potential trial participants facing real decisions.
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51 The section on experiences of others was well received by most stakeholders, with several
52 saying that potential participants already ask for this type of information. Participant stories
53 about trial participation are already available through public websites such as
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7 healthtalkonline and the NIH clinical trials website [25, 26]. However, as yet there is no
8 evidence as to the benefit or harm of including this type of information on people's decision
9 making. Whilst patient stories may be an effective way to increase engagement with the
10 information, there are concerns that people will make decisions based on others values
11 rather than their own [27]. As such, further research is required to determine whether and
12 how they can be used in this context.
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17 None of the patient group expressed the view that there was too much information
18 incorporated, a finding mirrored by an earlier study exploring patients perceptions of a trial
19 decision aid for radiotherapy for prostate cancer [14]. However, most of the other
20 stakeholder groups thought the decision aids might be too long. Some stakeholders
21 attributed the amount of information to the guidance requirements for content of informed
22 consent information and recognised this as a barrier against keeping information materials
23 concise. A recent review highlighted the lack of evidence, from a participant's perspective,
24 to support inclusion of many of these prerequisite items in trial information [28]. However,
25 within the context of a decision aid, stakeholders have agreed that many items required for
26 informed consent (as defined by the regulatory guidance) and items required for informed
27 decision making (as defined by the International patient decision aid standards) are
28 important and should be included [20]. Therefore, ways of presenting this information
29 more succinctly need to be explored alongside real-time decision making by real patients to
30 explore which information is most valued.
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40 The Ottawa Decision Support Framework (ODSF) recommends that during the development
41 and piloting process for decision aids, end users are engaged and their preferences for
42 delivery of the intervention are incorporated [29]. During this study we elicited
43 respondentsparticipants' views with regard to the most appropriate method of delivery.
44 Stakeholders' perceptions varied in this regard, with some believing that online or electronic
45 methods were best and others believing paper based was optimal but certainly the context
46 and preferences of the end users should be considered. Other studies have shown that
47 patients deliberating informed consent for elective surgery had preferences for methods of
48 information provision, with younger patients preferring internet based information and
49 older patients preferring paper based information [30] providing further justification for
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7 engaging with users at the outset. However, it should be highlighted that a recent
8 systematic review found equivocal evidence with regard to effectiveness of audio-visual
9 interventions to enhance trial knowledge (during informed consent) but the authors
10 highlight the need to involve consumers in intervention development [31]. These findings
11 are important for development of decision aids but also for PILs more generally. As such,
12 trial participants and trial staff (e.g. research nurses, clinical investigators) should be
13 engaged during development of trial decision aids to ascertain the best mode of delivery in
14 the trial population. Moreover, if the mode of delivery is novel it may also be worth
15 engaging with ethics committees early in the process.
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22 Overall, these findings complement the previous preliminary work on decision aids for trial
23 participation in that they show that patients perceive these tools as useful and more helpful
24 (compared to existing PILs) in terms of making a well-informed, balanced, personally
25 relevant decision [13, 14]. However, our results also contribute additional insights through
26 the involvement of a wide range of stakeholders, which include perspectives from those
27 involved in developing, delivering and reviewing information for patients considering trial
28 participation. Moreover, these findings contribute to the wider literature on participants
29 and stakeholders sense-making of research participation with respect to what it means for
30 them as individuals. For example, a study by Townsend and Cox identifies the importance of
31 the 'meaning' of research participation (including trials) for participants, implicitly
32 underpinned by their individualised context and which transcend the entire participation
33 trajectory, not just the point of consent [32].
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42 **Strengths and weaknesses**

43 A significant strength of this study was the elicitation of views from a diverse stakeholder
44 group, including: patients; research nurses; ~~trialist~~ trial manager; clinician researchers; and
45 ethics committee chairs. This forms of multi-stakeholder engagement is promoted as
46 international best practice by the Ottawa Decision Support Framework. Two other studies
47 have explored perceptions of decision aids for trial participation and highlighted their
48 potential benefit, but this previous work has focussed only on patients [13, 14]. Whilst
49 patient perceptions are key ~~important~~, as they are the decision makers, it is important to
50 explore the views of others involved in the informed consent process who would be
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7 responsible for developing, endorsing, reviewing and delivering these decision aids. Many of
8 the barriers to implementation of decision aids for treatment decisions relate to 'process'
9 aspects, which may be less relevant for trial decision aids due to a regulatory requirement to
10 provide information in the informed consent process. As such, decision aids for trials would
11 slot in to the existing informed consent process but would require additional training of
12 those delivering to ensure fidelity of use. However, if there is a lack of buy-in and
13 endorsement from those involved in the informed consent process, the decision aids may
14 not be implemented as intended i.e. tools to support decision making that also enable
15 conversations about treatment (and in this context trial participation) to be created and
16 discussed in a meaningful way. Therefore, it is critical to engage with end-users during
17 development.

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23 A further strength of this study was the decision to explore stakeholders' perceptions of key
24 decision aid content items *a priori*, rather than exploring only general perceptions. This is of
25 particular importance when considering that it is these items which define decision aids as
26 being different to existing PILs.
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30 It may be that the specific trial contexts may have influenced participants' perceptions of
31 the decision aids. However, several sections were written from a generic perspective and
32 were not specific for the individual trial context, which included both a chronic and an acute
33 condition. Moreover, the majority of the stakeholder groups (research nurses, trial
34 managers and ethics committee chairs) were not directly involved with the trials in which
35 the decision aids were set and the data suggest that their perceptions were being
36 considered commonly across decision aids more widely rather than the exacting information
37 for each trial pilot decision aid presented. All the participants in our study were UK based
38 and therefore may hold different views to those in other countries with different social
39 norms and cultures. However, it was felt that focusing on the UK was appropriate due to
40 the differences in regulatory requirements and structure of PILs across countries i.e. consent
41 forms for American and Canadian studies tend to be longer than UK forms and contain
42 much of the information being found within UK PILs. In addition, there was an assumption
43 that these decision aids were for adults who had capacity to consent for themselves. It
44 would also be important to explore the usefulness of these tools in other contexts with
45 proxy decision makers, including parent of children who are consenting on their behalf.
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54 Another potential limitation of our study is that the sample were a self-selecting group of
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7 individuals and, especially for the patients, may be different from those in the general
8 population. Indeed the size of each of the stakeholder groups was relatively small.
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10 However, it is important to highlight that these participants included in this study can offer
11 thoughtful and reflective insights into decision aids for trial participation when reflecting on
12 their own trial experience including reflection on existing PILs.
13

14 15 16 **Implications for researchers**

17 Decision aids for trial participation should be developed with meaningful stakeholder
18 involvement. All aspects of the information should be balanced. Attention to language is
19 critical to ensure it is not deemed coercive or value laden. Developers should be mindful of
20 the target audience, especially when considering presenting probabilistic information and
21 considering method of delivery. If patient stories are included, how these will be generated
22 and included must be considered. –Finally, decision aids for trial participation should be
23 developed and used in ways that allow all users to engage effectively with the information
24 and provide support to decision makers.
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30 31 **Future research**

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33 Whilst the decision aids explored in this study were perceived as being potentially helpful, it
34 should be noted that these types of interventions (or certainly the aids developed in this
35 study) may be more appropriate to support some RCT decisions than others, we are not
36 proposing a 'one size fits all' model. It is likely that decision aids could be more effective for
37 some trial decisions rather than others e.g. where interventions being trialled are very
38 different (like medical management vs. surgery), which is also the case for treatment
39 decision aids [10]. It may also be that the decision aid could be broken up into component
40 parts (values clarification exercises, experiences of others, etc) and used as appropriate
41 (defined by individuals preferences for information) in different contexts to facilitate and
42 support the informed decision making process. However, this requires further evaluation
43 before recommendations can be made.
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50 In addition, given the limitations of the current conceptualisation of informed consent, it is
51 important to think about how decision aids would be evaluated. For example, if tested in an
52 RCT against existing PILs what outcomes should be measured, how do these outcomes
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7 compare to others in existing studies of interventions to improve consent, and what do
8 potential participants think should be measured?
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10 Further research regarding how decisions about trial participation are discussed, engaged
11 with, deliberated over, participated in, supported and executed is required to inform the
12 design of interventions to better support the process. In addition, where much of the
13 previous literature has focussed on participants' understanding of trial concepts such as
14 randomisation and blinding, exploration of what participants believe taking part means for
15 them as individuals could also help to develop more tailored approaches to informed
16 consent.
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20 21 22 **CONCLUSIONS**

23 Compared to existing PILs, decision aids for trial participation have the potential to promote
24 a more 'informed' decision making process with regard to consent. It is vital that research
25 efforts, inclusive of all stakeholders, continue to understand how to support potential trial
26 participants' decisions about trial participation (whether it be to enrol or not); how to
27 ensure these decisions are in line with individuals values and preferences and to determine
28 optimal methods to support informed decision making in this context.
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Competing interests

All authors have completed the Unified Competing Interest form at www.icmje.org/coi_disclosure.pdf (available on request from the corresponding author) and declare that (1) No authors have support from any company for the submitted work; (2) No authors have relationships with companies that might have an interest in the submitted work in the previous 3 years; (3) their spouses, partners, or children have no financial relationships that may be relevant to the submitted work; and (4) The authors have no non-financial interests that may be relevant to the submitted work.

Authors' contributions

KG conceived the study idea. KG, ZS and MC were involved in designing the study and developing the methods. KG applied for ethics approval and collected the interview data. KG and ZS conducted the initial analysis and development of the thematic framework, with additional input from MC. KG directed the full analysis. All authors had full access to all of the data and participated in the discussion and interpretation of the results. KG wrote the initial manuscript draft. All authors critically revised the manuscript and approved the final version.

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~~Ethical approval~~

~~The study was approved by the North of Scotland Research Ethics Committee 1 (REC Reference Number 09/S0802/105) and NHS Grampian Research and Development department (Reference Number 2009HS002). All interview participants provided their signed consent, which included consent for anonymised quotes from their interviews to be published.~~

Provenance and peer review

Not commissioned; externally peer reviewed.

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Transparency declaration

KG (the manuscript's guarantor) affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned have been explained.

Data sharing statement

No additional data available

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Figure legends

Figure 1. Example of content items from prototype trial decision aids:

Presenting probabilities section

Figure 2. Example of content items from prototype trial decision aids:

Methods for clarifying and expressing values

Figure 3. Example of content items from prototype trial decision aids:

Structured guidance in deliberation: Decision making steps

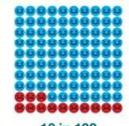
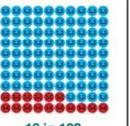
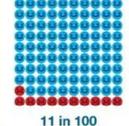
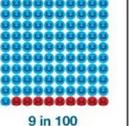
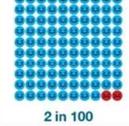
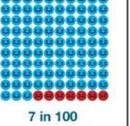
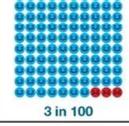
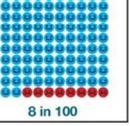
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	symptom	number of people affected	% of people affected
COMMON	<ul style="list-style-type: none"> dizziness headache constipation 	less than 1 in 10 but more than 1 in 100	1-10%
UNCOMMON	<ul style="list-style-type: none"> rapid heartbeat runny itchy nose diarrhea nausea vomiting indigestion itching rash abnormal ejaculation increased urination fainting mood changes. 	less than 1 in 100 but more than 1 in 1000	0.1-1%
RARE	<ul style="list-style-type: none"> pins and needles swollen gums impotence 	less than 1 in 1000 but more than 1 in 10000	0.01-0.1%
VERY RARE	<ul style="list-style-type: none"> feeling of weakness, lethargy eye pain shortness of breath prolonged painful erection, swelling of lips, face and neck 	Less than 1 in 10000 or rate unknown	Less than 0.01%

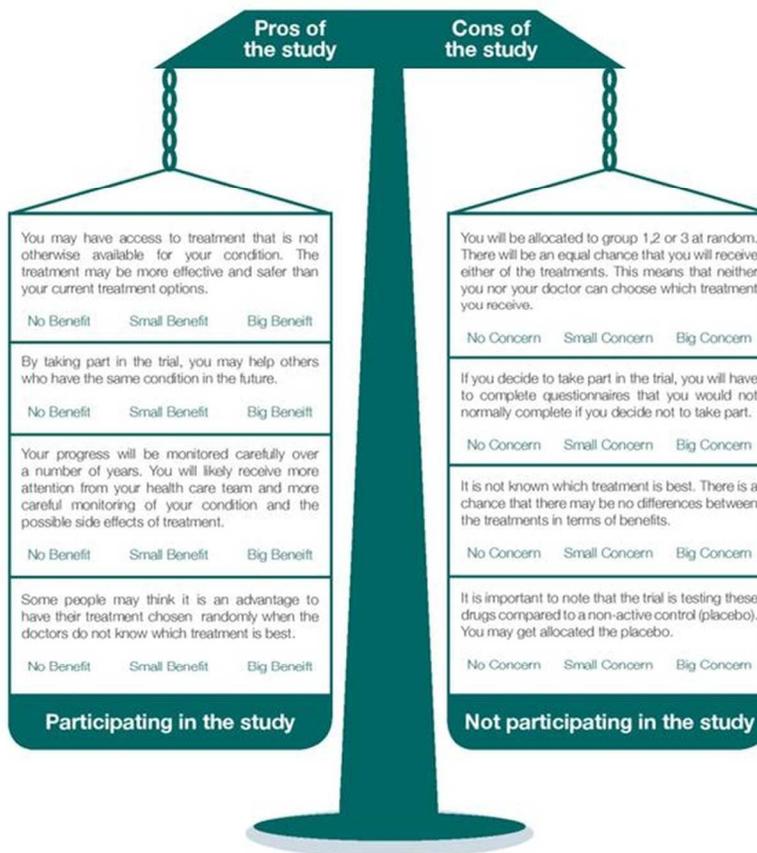
side effect	treatment group	
	traditional surgery	stapled surgery
bleeding	 13 in 100	 16 in 100
pain	 11 in 100	 9 in 100
recurrence	 2 in 100	 7 in 100
additional operation	 3 in 100	 8 in 100

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“Will the SUSPEND study suit me?”



Any further questions?

What are you leaning towards?

Participating in the study ★★★★★ Not participating in the study

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MAKING A DECISION

The previous pages have outlined the main options available to you. The following steps may help you to make a decision about whether or not to participate in the eTHoS Study.

The decision making process can be helped by following these 6 steps:

1. Understand your diagnosis of haemorrhoids as fully as you can
2. Understand your options for treatment and the risks and benefits of these options
3. Review the pros and cons of these options
4. Assess how important the pros and cons are to you
5. Prioritise the pros and cons of the study for you (and your family)
6. Get more information/clarification about any uncertain areas

The information in this booklet has already taken you through steps 1-3. To help you complete steps 4-6 and come to a decision that suits you best, we have provided some experiences of others who did or did not take part in the trial and a worksheet for you to think through and complete if you wish (see overleaf).

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Additional file 1**Topic guide for interviews with decision aid stakeholders.****Discussion and ensure signing of consent form**

- Check the participant has read the participant information leaflet and understands what the interview entails;
- Ask if there are any questions;
- Ensure they are aware that confidentiality will be ensured at all times and their anonymity should direct quotes be used in publication;
- Request verbal consent and completion and return of paper copy of consent form in post.

Recording to commence.

- Present background to the study

Please tell me about your experience of clinical trials.*Patients*

- How was the trial introduced to you?
- Did you feel you understood what was expected of you as a participant?

Research nurses, trial managers and principal investigators

- Can you tell me about where you work?
- What is your role in the clinical trials that you run ?
 - How long have you worked in clinical trials?
 - Is it an NHS or University setting?
- What kind of trials do you work on? How are they mainly funded?
- Do the trials that you run have a focus? E.g. cancer trials, paediatric trials...
- Can you tell me a little bit about who does the recruiting in your trials?

Ethics committee chairs

- What is your role at the ethics committee?
 - How long have you been the chair of this REC?
 - Does your REC focus on any particular types of research studies?

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7 **Please can you tell me about your views on existing patient information leaflets for clinical**
8 **trials.**

9
10
11 *Patients not asked this question.*

12
13 *Research nurses, trial managers and principal investigators.*

- 14 ○ Can you tell me a little bit about how you develop the patient information
15 leaflets you currently use in your trials.
 - 16
17
18 ▪ For example do you have a skeleton template that you use or do you
19 have team discussions, who do you involve?
- 20 ○ How effective do you think existing patient information leaflets are at helping
21 patients make a decision about trial participation?
- 22 ○ Do you think they facilitate discussion between the recruiter and the participant?
23 Why or why not?
- 24
- 25
- 26
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- 29

30 *Ethics committee chairs*

- 31 ○ How effective do you think existing patient information leaflets are at helping
32 patients make a decision about trial participation? Are they fit for purpose? Why
33 or why not?
- 34 ○ And do you think they facilitate discussion between the recruiter and the
35 participant? Why or why not?
- 36 ○ What do you think about the NRES guidance on information leaflets and consent
37 forms?
- 38 ○ Do you think researchers follow this when developing information leaflets? Why
39 or why not?
- 40 ○ How does your REC review information leaflets? E.g. do you use a template?
41 How often do they come up in the discussion?
- 42
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54 ***Views about the prototype trial decision aids***

55 **Please can you tell me a little bit about what you think about using these tools to help**
56 **people make a decision about trial participation?**

- 57 ○ In general, what were your impressions of these tools?
- 58
- 59
- 60

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2
3 ○ How do you think they compare to existing patient information leaflets?
4 *(patients not asked this probe)*
5
6
7

8
9 **Please can you tell me what you thought were the most useful components of the tool?**

- 10
11 ○ Why?
12
13

14
15 **And can you tell me if you felt any aspects of the tool weren't helpful?**

- 16 ○ Why?
17
18

19
20 **What do you think about the sections on possible benefits and disadvantages of taking**
21 **part and NOT taking part?**
22

- 23 ○ Do you think this will influence decision making? Why or why not?
24
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26

27
28 **Can you tell me what you thought about the section covering experiences of others?**

- 29 ○ Do you think this will influence decision making? Why or why not?
30
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32

33 **What do you think about the risk information that is presented?**

- 34 ○ Do you think this will influence decision making? Why or why not?
35
36 ○ Do you have a preference? Why?
37
38 ○ More generally, do you think participants have trouble understanding risk
39 information?
40
41 ○ Do you think this influences their decision to participate?
42
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45
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47 **Can you tell me what you think about the worksheets at end?**

- 48 ○ What do you think the best way to utilise these would be?
49
50 ○ Again, do you think they would support potential participant's decision making?
51 Why or why not?
52
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56 **Can you tell me what you thought about the length of the tool?**

- 57 ○ If too much, how do you think we can reduce the amount of information
58 presented?
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5 **When thinking about using these tools within recruitment consultations, how do you**
6 **think they should be delivered?**
7

- 8
9 ○ Why?
10

11 **What do you think the objective of a trial participation decision aid should be?**
12

- 13
14 ○ For example, there could be a variety of outcome researchers may want these
15 tools to influence. What do you think is most important? Why?
16
17

18
19 **Thinking about current practice, do you think the decision support tools would better**
20 **support potential participants when faced with a decision about trial participation?**
21

- 22
23 ○ Think specifically about the decision to participate and the decision to continue
24 to participate.
25
26

27
28 **Thank the participant for their contribution and ask whether they have any additional**
29 **questions.**
30

- 31
32 ○ Complete demographic data questions;
33 ○ Ask if wish to receive a summary of the results.
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