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Interventions to support patient decision making about taking part in health research: A systematic review

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ABSTRACT

Objectives: An important, albeit challenging, aspect of conducting clinical research is achieving informed consent. We systematically reviewed the literature to characterise existing interventions designed to support communication and decision making about participating in health research.
Methods: We searched five databases (1990–2025) for peer-reviewed studies about intervention development and/or evaluation, reporting data on acceptability and/or efficacy. Eligible interventions addressed decisions about research participation and aimed to improve decision quality by enabling adult patients to address their information needs (e.g., question prompt list) and/or incorporate their values into decision making (e.g., decision aid). We conducted a narrative synthesis to describe the interventions, summarising findings on their effects where applicable.
Results: Eighteen studies met inclusion criteria. In seven studies, interventions targeted a specific clinical study; 11 covered clinical trials generally. Eight tools were printed; ten were digital, incorporating various interactive features. Four interventions addressed racial, ethnic, or cultural diversity. Thirteen papers cited relevant theories or frameworks that informed intervention development. Evidence from controlled studies (n = 11) showed that interventions generally increased knowledge, with little effect on participation rates.
Conclusions and practice implications: This review highlights the potential utility of tools for patients considering health research participation, providing an overview of resources available and synthesising key principles for intervention developers. However, most interventions targeted decisions about participation in cancer clinical trials. Future interventions should address other clinical settings and research designs, and emerging areas like genomics and precision medicine. Digital technology can offer opportunities to tailor content, enhance interactivity, and optimise support for diverse communities.

1. Background

Clinical research studies are critical for generating evidence to support the delivery and ongoing refinement of evidence-based care. Informed consent is a cornerstone of ethical healthcare research [1], but achieving it can be complex and challenging for researchers and participants alike. Depending on the type of research, fully understanding the study methods may require patients to grasp unfamiliar concepts like randomisation and blinding. A clinical research invitation is a novel situation for many patients, and the associated cognitive burden can be confounded by a range of important affective factors that may influence participation decisions [2,3]. For example, the attention of a prospective study participant may be strongly directed by their eagerness to access a perceived health benefit by participating [4], leading them to overlook limitations and potential harms [2]. Although the concept of equipoise is often central to a study's rationale, patients may find this clinical

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uncertainty difficult to accept. Misunderstandings and discomfort around such issues, plus patient hopes or fears, may result in poor-quality decisions to either accept or decline a study invitation [1,3,5]. This in turn may contribute to problems with recruitment and/or retention of participants and thus compromise the validity of the research and its capacity to ultimately improve patient health outcomes.

Extensive evidence demonstrates frequent limitations in participants' understanding of studies in which they take part [6–8], alongside a commonly reported perception that study information is confusing [3]. Considering this evidence and the challenges outlined above, efforts have been made to improve the ways in which consent information is conveyed to prospective participants. Prior systematic reviews evaluated diverse interventions [9], or focused on multimedia and/or audio-visual presentation of information [10,11], finding mixed or partial success in improving comprehension. However, much of this empirical work focused on the content, structure and delivery of consent documents, and their capacity to impart knowledge, rather than addressing the decision making process broadly [1].

Taking a somewhat different approach, clinical researchers have begun drawing on techniques from the health communication and decision science empirical literature to try to facilitate and address key issues in the research consent process. Tools such as question prompt lists and decision aids have been designed to support patients to gather and consider information and attributes important to them in relation to a specific healthcare situation or decision [12,13]. Question prompt lists are structured lists of questions for patients to consider asking a healthcare provider. They aim to provide an opportunity for two-way exchange in which patients gain information tailored to their needs and share their own thoughts as part of the discussion. Decision aids are resources that communicate balanced, evidence-based information about benefits and harms of different healthcare options while helping people to consider what is important to them personally and choose the best option for them. Substantial evidence shows that both types of tools effectively improve patients' knowledge of their situation and options in a range of clinical contexts for treatment and screening decisions [12,13]. They may also have the potential to support dialogue with family members and healthcare professionals, addressing patients' broader psychological and decision support needs alongside their informational needs [3]. However, the use of these tools for decisions about research participation is relatively recent.

In 2015, Gillies et al. [1] conducted a Cochrane systematic review of decision aids for people considering taking part in clinical trials. Although it addressed a broad range of study outcomes, the review's inclusion criteria for study design were restricted to randomised controlled trials (RCTs) or quasi-RCTs. Moreover, eligible interventions were decision aids, strictly defined using an established checklist of key qualifying items, that supported decisions about participation in clinical trials [1]. With these restrictions in place, the Cochrane review found only one publication eligible for inclusion.

The present review was done in the context of increasing interest in application of shared decision making tools in research informed consent [3,14] and the potential of evolving technology in this space [2]. We sought studies of any design, focusing on development and/or evaluation of an intervention designed to support adult patients deciding whether to take part in any type of health research. Eligible interventions comprised interactive resources promoting consideration of the patient's needs or preferences while working towards a decision. Our primary goal was to collate the literature and describe the characteristics of identified interventions, in order to understand the work done so far in what is a relatively new research area. A secondary goal was to collate evidence of interventions' efficacy in supporting decision making in the context of informed consent for research participation and to explore potential differences in efficacy by intervention type.

2. Methods

We prospectively registered the review protocol via PROSPERO (CRD42022320771) and report it in accordance with the PRISMA statement [15].

2.1. Criteria for considering studies for this review

2.1.1. Types of studies

Published studies, reported in peer-reviewed journal articles, were eligible for inclusion. Aiming to comprehensively describe relevant interventions in the literature, we placed no restrictions on study design, as long as the primary focus was development and/or evaluation of an eligible intervention. Data on acceptability, feasibility and/or preliminary efficacy of the intervention were sufficient for a study to contribute to the primary aim of the review – describing relevant interventions. To also contribute to our secondary question around intervention efficacy, studies had to include inferential statistical analysis comparing intervention and control conditions. We excluded conference abstracts, reviews, and discussion papers.

2.1.2. Types of participants

Eligible studies included patients able to consider and make their own decisions about taking part in health research. Study samples could also include other participants (e.g., healthcare professionals) alongside patients. We excluded studies whose participants were people unable to provide their own informed consent (e.g., children under 16 years or adults with impaired cognitive capacity) or caregivers consenting on another person's behalf. We placed no further limitations on participants' demographic or clinical characteristics.

2.1.3. Types of interventions

Eligible interventions aimed to support patients during the informed consent process for participation in health research (e.g., clinical trials or other studies) – that is, to help patients make well-informed decisions about whether to take part. Interventions could address research participation generically or could relate to a specific study. Interventions had to involve direct engagement between patient and tool to facilitate decision making that addressed or incorporated the individual's information needs, preferences and/or circumstances (e.g., question prompt lists, decision aids). We excluded interventions (a) focusing on a decision about treatment or screening (outside of research), (b) designed solely to (passively) convey educational information, (c) directed solely towards healthcare professionals rather than patients, or (d) explicitly aiming to increase recruitment rather than support patients to make the best choice for them, according to the publication. We excluded studies if we could not find sufficient detail about the intervention to assess eligibility.

2.1.4. Types of outcome measures

Eligible studies reported data collected from patients relating to the intervention and its potential to support aspects of decision making and consent about research participation. The context could be an actual clinical study open to the patient at the time or a hypothetical/future opportunity for research participation. We excluded studies only reporting an intervention's effect on the number of patients giving (actual/hypothetical) consent, without assessing any decision making variables.

2.2. Search methods for identification of studies

2.2.1. Electronic databases

We searched these databases (last update February 2025): Medline, Embase, CINAHL, PsycINFO, and the Cochrane Central Register of Controlled Trials. We based the search strategy on that used in a Cochrane review of RCTs of clinical trial decision aids [1] and modified

it to reflect our broader inclusion criteria regarding study design and types of intervention. The search encompassed the intersection of three key concepts – research participation; informed consent; and interventions to support communication and/or decision making – each addressed via a range of keywords (see supplement for search strategies). We limited results to items published since 1990 (the 1990s being the period in which the first decision aids and question prompt lists were developed) and to those written in English or other languages understood by members of the review team (German, Czech, or Chinese).

2.2.2. Searching other resources

We searched Google Scholar (last update February 2025) using terms adapted from the database search terms, aiming to identify additional studies not captured by database searching. We screened titles and abstracts of the first 100 results and obtained full texts where relevant. We posted a request for suggestions of relevant papers via Twitter and a Shared Decision Making group on Facebook (October 2022). Finally, we manually screened reference lists of included papers, and those of relevant reviews, to identify additional studies.

2.3. Data collection and analysis

2.3.1. Selection of studies

We conducted searches in the prespecified databases, then imported the results into the Covidence systematic review software platform (www.covidence.org), combined results and removed duplicates. Titles and abstracts of all retrieved records were screened for relevance by two reviewers independently. Where there was disagreement or uncertainty regarding the potential relevance of an abstract, it was discussed with two other reviewers to reach consensus on which records should progress to full-text screening. We retrieved the full text for all potentially relevant studies, including those where the description (usually relating to the intervention) was insufficient to determine eligibility.

Two authors independently assessed full texts against the eligibility criteria. In case of disagreement, consensus was reached by discussion and if necessary, other reviewers were consulted. When we found multiple reports about the same intervention, we selected for inclusion whichever study we thought would contribute the most valuable evaluation data for the review. This was generally the most recent and/or rigorous evaluation. We retained additional articles to help clarify details of interventions.

2.3.2. Data extraction and management

Two reviewers independently extracted data from each eligible study into a pilot-tested, standard form. Extracted variables included: study design, methods, setting, sample size, participant characteristics, intervention characteristics (e.g., type, format, context, features), outcomes, measures (including all relevant outcomes measured at any time point), results, conclusions, and limitations. Extracted data were compared, with any discrepancies resolved through discussion to reach consensus (consulting a third reviewer if necessary).

2.3.3. Assessment of methodological quality of included studies

Two reviewers independently assessed the methodological quality of each included study using a critical appraisal tool appropriate to the study design (i.e., RCT, quasi-experimental, mixed methods, qualitative) from the JBI Reviewers' Manual [16]. Any disagreements were resolved by discussion (consulting a third reviewer if necessary).

2.3.4. Data synthesis

The focus of this review was to document the characteristics of existing interventions. Due to expected heterogeneity between studies, we did not anticipate that meta-analysis would be possible but instead planned to describe and summarise findings via narrative synthesis. To facilitate comparisons across studies, we constructed tables presenting key study data including characteristics of participants, interventions, main outcomes assessed (with a focus on the outcomes shared by multiple studies), and effects reported in the included studies. In order to explore any differences in efficacy by type of intervention, we grouped studies according to whether the intervention was a decision aid, a question prompt list, or an eligible resource incorporating multiple elements.

3. Results

3.1. Description of studies

3.1.1. Results of the search

Fig. 1 outlines the study selection process. Database searching identified 8120 records. Removing duplicates left 6416 records for title and abstract screening. We retrieved full text for 108 records and found 14 eligible studies [17–30]. Where our search identified records that were ineligible (e.g., conference abstracts or secondary analyses) but appeared to relate to a potentially eligible study, we sought and evaluated any appropriate publication reporting on the intervention described. Two additional papers [31,32] were identified this way. Two further papers [33,34] were found through checking reference lists of included papers or relevant reviews. No additional papers were found through Google Scholar or social media. This resulted in a total of 18 included studies, all published in English.

3.1.2. Characteristics of included studies

Of the 18 included studies, nine were RCTs, three used quasi-experimental methods with a control group, one was cross-sectional, three used mixed methods including both a questionnaire/survey and interviews, and two involved qualitative interviews only (Table 1). Publication year ranged from 2002 to 2024. Most studies took place in the USA (n = 8) or Australia (n = 7). The total number of patients across all studies was over 3200, with additional stakeholders (doctors, researchers, carers) also participating across four studies. Cancer was the predominant clinical context (n = 15), with participants in most studies having a cancer diagnosis or, in one study, being at elevated risk (Table 1). Among the seven studies that reported participants' age range, this varied from 18 to 87 years [23].

3.1.3. Characteristics of interventions

Table 2 presents intervention characteristics. In ten studies, we judged that interventions could best be described as decision aids, two of which [24,27] also included a question prompt list. Other interventions included one stand-alone question prompt list [21], a dynamic consent platform [25], and a value clarification tool [30], while the other five interventions consisted of educational resources or communication tools incorporating question prompt lists. Eight studies utilised printed interventions, whereas ten used digital tools that in five cases incorporated video content (Table 2).

The vast majority of studies (n = 16) involved interventions addressing decisions about taking part in clinical trials, of which two focused on early-phase trials [30,34] while the remainder covered phase III trials or applied across phases. One recent study intervention centred on clinical trials involving precision oncology [27]. The only interventions not about clinical trial participation pertained to genetic carrier testing [22] and whole genome sequencing [25] offered through research projects. In five papers, the interventions (all printed decision aids) were custom designed to use during the informed consent process for specific clinical studies, with content directly addressing the named studies. These studies involved chemoprevention of breast cancer in women at elevated risk [17], surgery for breast cancer [26], radiotherapy for prostate cancer [31], genetic testing in women at risk of carrying a haemophilia-related mutation [22], surgery for haemorrhoids, and drug treatments for ureteric stones [29]. In two further papers [24,25], the interventions were also designed for use during the informed consent process, with some content addressing specific studies,

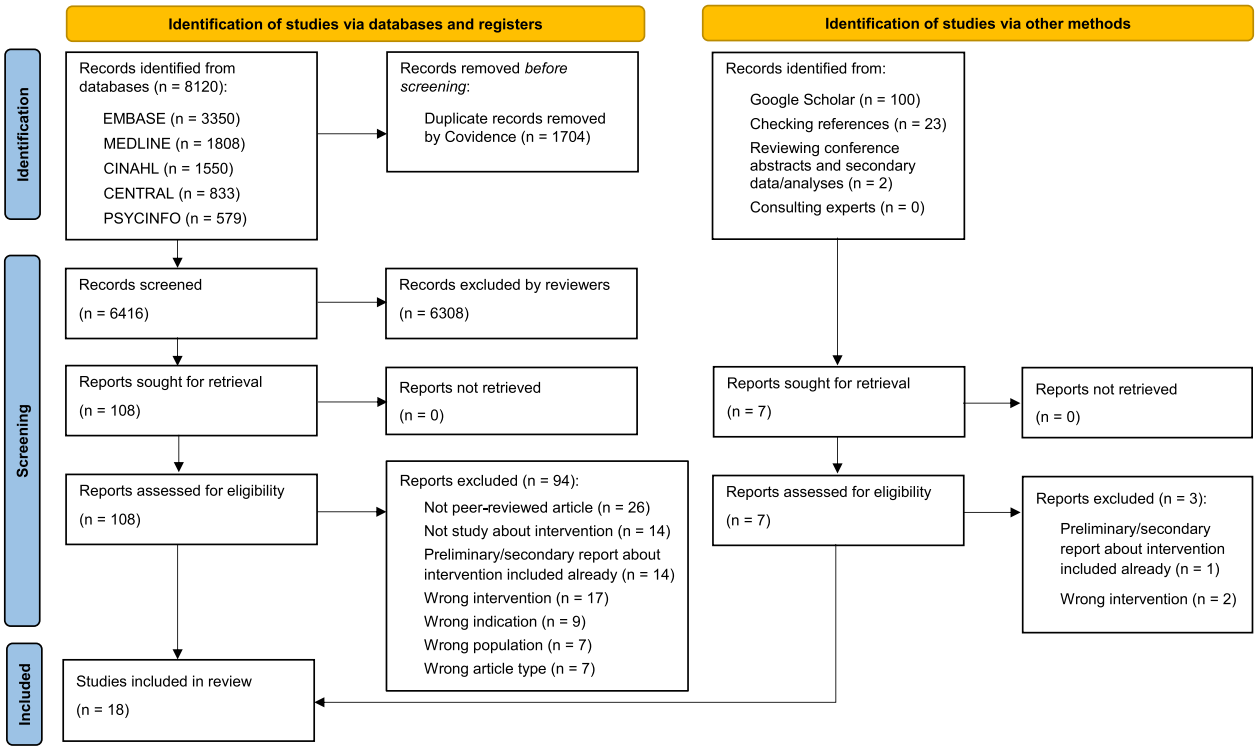

Fig. 1. Study identification and selection.

but they also incorporated more general content and were intended to be easily adaptable for other studies. The other 11 interventions were about clinical trials generically. Two of these were provided to cancer patients who were, at the time, considering whether to enrol in an actual clinical trial [21,34]. The remaining nine were intended to prepare patients for informed discussions and decision making about whether to take part in a trial, should doing so be an option for them in the (near) future [18–20,23,27,28,30,32,33]. Although these 11 interventions were 'generic', seven of them included a question prompt list as a means through which patients could obtain information specific to them and their circumstances.

In line with our inclusion criteria, all interventions involved direct engagement between patient and tool. Question prompt lists facilitated patient-provider communication addressing personal information needs or circumstances, enabling patients to review a range of potentially relevant topics and identify questions they considered important to ask clinical or research staff. Decision aids facilitated decisions incorporating individual values or preferences, by helping patients consider reasons for and against research participation and weigh up the personal importance of each. This could occur in various ways (Table 2). For example, the five studies using printed decision aids included conventional 'values clarification exercises' to complete in a 'worksheet' format [17,22,26,29,31] – an approach that could also be adapted to an online format [18]. Web-based materials took advantage of the digital format to offer additional interactivity or personalisation. For example, two resources tailored content based on details the patient entered beforehand to indicate their circumstances, knowledge, or attitudes [23,32]. One of these then produced a personalised report outlining the compatibility between the patient's circumstances or values and the prospect of research participation [23]. Other examples of interactivity included quizzes for the patient to check their understanding while progressing through the material [24,27], a 'virtual walk' with a character guiding the patient through an exploration of their values [30], a chatbot to help navigate content or direct patients to resources [27], and a consumer-friendly database of registered trials that the patient could search to find details of study participation opportunities that may be personally relevant [20].

In outlining the background behind interventions (in the included paper itself or others relating to the same intervention), seven papers cited underlying theories or models and eight cited relevant standards or guiding frameworks – most often (n = 5) the International Patient Decision Aid Standards [35] (Table 2). Although some papers mentioned health literacy considerations (e.g., plain language, lay terms) [17,26], they were rarely explicit about how health literacy was taken into account. One paper described iterative review and editing of content by patient educators with health literacy expertise [28], and in two digital interventions users could tap on a medical term to make an explanation of the term pop up [24,27]. Four USA studies [18,19,27,28] addressed racial, ethnic, or cultural diversity in the development and/or evaluation of their interventions, paying particular attention to cultural appropriateness and the needs of minority populations. They did so by, for example, working with Hispanic and/or black patients or survivors to develop and pilot the intervention, or by including text, images, graphics, or videos designed to portray the inclusion of Hispanic and/or black patients or survivors [19,27]. Interestingly, one study started out designing a communication tool for black patients and then pivoted to instead produce a 'multi-cultural' resource because some participants in user testing felt uncomfortable being 'singled out' [28].

3.1.4. *Outcome assessment*

Four studies reported primarily qualitative data on views about intervention usability, acceptability, and/or potential to support decisions [27–30]. The other 14 studies reported quantitative efficacy data collected from patients, post-intervention. Studies addressed a range of outcomes using varied measurement instruments.

Knowledge was the most commonly reported outcome (n = 13 studies, explicitly named as primary outcome in two [18,21]). All 13 studies measured knowledge objectively; five [17,18,21,26,31] also collected a subjective self-assessment from participants. Measurement instruments assessed general understanding around clinical research and/or study-specific knowledge, as appropriate to the intervention's focus. Most papers (n = 10) reported effects on choice about whether to

Table 1
Study design, setting, sample size and population.

Study ID	Study design	Setting	Sample size (no. of patients)	Patient population (diagnosis)
Juraskova 2014 [17]	RCT	Australia	146	Elevated risk of breast cancer
Sundaresan 2017 [31]	RCT	Australia	129	Prostate cancer
Politi 2016 [18]	RCT	USA	200	Cancer
Meropol 2016 [32]	RCT	USA	1255	Cancer
Ellis 2002 [33]	RCT	Australia	83	Breast cancer
Eggly 2023 [19]	RCT	USA	44	Prostate cancer
Kass 2009 [34]	RCT	USA	130	Cancer
Dear 2012 [20]	RCT	Australia	398 patients, 28 oncologists	Cancer
Tattersall 2017 [21]	RCT	Australia	88	Cancer
Sorenson 2004 [22]	Quasi-experimental	USA	139	At risk of carrying haemophilia mutation
Morgan 2022 [23]	Quasi-experimental	USA	302	Cancer
Okada 2021 [24]	Quasi-experimental	Japan	54	Breast cancer
Haas 2024 [25]	Cross-sectional	Australia	91	Cardiovascular disorders
Juraskova 2015 [26]	Mixed methods	Australia & New Zealand	45	Breast cancer
An 2024 [27]	Mixed methods	USA	50 patients, 15 relatives, 13 healthcare providers	Cancer
Fleisher 2020 [28]	Mixed methods	USA	57	Cancer
Gillies 2014 [29]	Qualitative	UK	4 patients, 19 researchers	Haemorrhoids or ureteric stones
van Gurp 2024 [30]	Qualitative	Netherlands	23 patients/ relatives, 11 oncologists	Cancer

Note. RCT = randomised controlled trial

participate in research, measured as actual choice made and/or intentions regarding a potential future decision. Other common outcomes were decisional conflict (n = 7 studies, primary outcome in three [17,18,31]), attitudes to research participation (n = 7), and satisfaction (with decision, intervention, consultation, study and/or consent process; n = 6). Less common were self-efficacy (n = 3), decision readiness and/or preparation for decision making (n = 2), reasons for choosing to accept or decline study participation (n = 3), anxiety (n = 4), regret (n = 3), whether trial participation was discussed during a consultation (n = 1) and whether the patient was invited to a trial (n = 2).

3.2. Critical appraisal of included studies

Results of critical appraisal for included studies, by study design, are presented in Supplementary tables 1–4. Across studies, relatively common sources of potential risk of bias were attrition (bias related to participant retention) and lack of blinding (bias related to administration of intervention). Other study limitations included small samples

Table 2
Intervention characteristics.

Study ID	Type	Format	Theory/model and standards/ framework	Interactive aspects/features
van Gurp 2024 [30]	Value clarification tool	Web-based	Moral education and value theories; MRC framework for complex interventions	Virtual conversation with chosen characters who share stories or contemplations and ask questions to engage user into own reflection
Juraskova 2014 [17]	DAs*	Printed booklet	ODSF; IPDAS	VCE: rate importance of pros/cons and weigh up (worksheets)
Sundaresan 2017 [31]	DA	Printed booklet	IPDAS	VCE: rate importance of pros/cons and weigh up (worksheets)
Sorenson 2004 [22]	DA	Printed	Decision conflict theory	VCE: identify consequences and classify as reasons for/against, then select which are most important
Juraskova 2015 [26]	DA	Printed booklet	IPDAS	VCE: rate importance of pros/cons and weigh up (worksheets)
Gillies 2014 [29]	DAs*	Printed booklet	MRC framework for complex interventions	VCE: rate importance of pros/cons and weigh up (worksheets)
Politi 2016 [18]	DA	Web-based	Knowledge, empowerment, and values clarification model of decision making	VCE: indicate perceived importance of pros/cons (sliding toolbar)
Meropol 2016 [32]	DA	Web-based + video	Cognitive-social health information-processing theory; ODSF; IPDAS	VCE: barriers questionnaire; content tailored to barriers; personal summary of preferences presented
Morgan 2022 [23]	DA	Web-based	Technology acceptance model	VCE: barriers questionnaire; content tailored to barriers; personal report re compatibility with study participation
Okada 2021 [24]	DA + QPL	Computer -based (tablet)	IPDAS	Quizzes to check understanding of content; QPL with responses displayed to research coordinator or doctor
An 2024 [27]	DA + QPL	Web-based + video	ODSF	QPL; interactive techniques such as hover effect, sliders, quiz, optional chatbot

(*continued on next page*)

Table 2 (*continued*)

Study ID	Type	Format	Theory/model and standards/ framework	Interactive aspects/features
Ellis 2002 [33]	Info + QPL	Printed booklet		QPL
Eggly 2023 [19]	Info + QPL	Printed booklet	Common ingroup identity model	QPL
Kass 2009 [34]	Info + QPL	Computer -based + video		QPL
Dear 2012 [20]	Info + QPLs	Website (database)		QPLs; consumer-friendly database of registered trials by phase, recruitment status, entry criteria, treatment etc
Fleisher 2020 [28]	Info + QPL	Web-based + video	Illness self-regulation theory, information-communication theory	QPL
Tattersall 2017 [21]	QPL	Printed		QPL
Haas 2024 [25]	Dynamic consent platform	Web-based + video		Multi-step consent 'wizard' allows granular choices; can later change preferences, alerting researchers

Note. DA = decision aid. QPL = question prompt list. IPDAS = International Patient Decision Aid Standards. MRC = Medical Research Council. ODSF = Ottawa Decision Support Framework. VCE = values clarification exercise. *Study included 2 separate but similar DAs.

lacking diversity, and short follow-up of outcomes post-intervention.

3.3. Effects of interventions

As well as describing interventions, another goal of this review was to collate evidence regarding efficacy. Table 3 shows intervention effects on key outcomes (more detail in Supplementary table 5) in the 11 studies that compared the intervention with a control condition using inferential statistics. Among ten studies comparing knowledge post-intervention versus control, seven found improvement in the intervention group, of which six were statistically significant (Table 3). Among six studies comparing decisional conflict post-intervention versus control, four found a favourable intervention effect (i.e., lower conflict), of which two were statistically significant. Among five studies reporting attitudes to research participation, two found more positive attitudes post-intervention compared with control, both statistically significant. Among five studies reporting satisfaction, two found higher satisfaction post-intervention compared with control, of which one showed significantly higher satisfaction with the intervention. Of nine studies comparing participation rates post-intervention versus control, the majority (n = 8) found no significant difference (Table 3).

We also examined study findings considering interventions by type (i.e., decision aids versus question prompt lists). The clearest evidence of a favourable intervention effect was improved knowledge due to decision aids, observed in four randomised trials [17,18,31,32]. Decision aid and question prompt list studies also suggested research participation rates were largely unchanged after using either type of intervention. It was difficult to draw conclusions regarding intervention effects on decisional conflict, satisfaction, and attitudes – and effects of question prompt lists more broadly – due to limited data and mixed findings (Table 3).

4. Discussion

4.1. Discussion

This systematic review included 18 studies, with over 3200 participants, focusing on interventions to support patients with communication and/or decision making about taking part in any type of health-related research. Interventions targeted people who either were actively considering whether to take part in a specific study at the time, or who might plausibly do so in the near future. Apart from two exceptions, interventions focused on participation in clinical trials. In all but three studies, participants had a diagnosis of cancer or were at elevated risk of developing cancer. Across the included studies, interventions consisted of a mixture of printed and digital materials. Based on controlled studies reporting effects of the intervention, interventions generally increased knowledge about research participation and had little effect on actual, intended, or hypothetical participation rates.

Table 3
Overview of effects of interventions on key outcomes, compared with control.

Intervention type	Study ID	Knowledge	Attitudes	Decisional conflict	Satisfaction with decision / consultation / intervention	Participation– actual / intended / hypothetical
Randomised controlled trials						
DA	Juraskova 2014 [17]	▲	▽	▽	△	△
	Politi 2016 [18]	▲	_	▲		_
	Meropol 2016 [32]	▲	▲	_	▲	_
	Sundaresan 2017 [31]	▲	_	▲	_	△
Information + QPL	Ellis 2002 [33]	△			_	▽
	Kass 2009 [34]	▲				△
	Dear 2012 [20]	▼		△		▽
QPL only	Tattersall 2017 [21]	▽			_	
Quasi-experimental studies						
DA + QPL	Okada 2021 [24]	▲		△		
DA	Sorenson 2004 [22]					▽
	Morgan 2022 [23]	▽	▲			▲

Note. ▲ significantly more favourable outcome in intervention group ($p < .05$). ▼significantly less favourable outcome in intervention group ($p < .05$).
△ non-significantly more favourable outcome in intervention group. ▽non-significantly less favourable outcome in intervention group.
— study only reported 'no significant differences', data not shown.

Most interventions contained generic information applicable to clinical trials in general. Interestingly, although our search terms did not include any cancer-related words, the vast majority of studies we found were in oncology. This likely reflects the broader prevalence of communication research within oncology, recognising the psychosocial impacts associated with the diagnosis and its management. However, even resources developed or evaluated in a cancer setting may be feasible to use or adapt for other settings (some papers were unclear as to whether intervention content was actually cancer-specific). Generic interventions may have the advantage of informing patients about key aspects of clinical research, laying the foundations for considering a particular study. Often, these interventions included a list of questions to help patients obtain information about specific studies and/or details that are personally relevant – that is, to gain information tailored to their needs. However, this may necessitate additional resources or further conversations to ensure important study details are addressed. A comprehensive approach was exemplified by a Japanese quasi-experimental study involving a decision aid that included a section addressing a specific trial, a general section suitable for other trials, and a question prompt list [24]. Should this intervention be proven effective in a randomised trial and translated into English and/or other widely spoken languages, it could provide a useful template that clinical researchers internationally could customise to be applicable for their specific studies.

Among 18 included papers, over three quarters were published from 2014 onwards. Overall, we observed a near-even split between printed versus digital tools. Interventions in studies published up to 2015 were more often printed and those published from 2016 on were more often digital, but there were multiple exceptions to this. Both formats enabled interactive elements. Question prompt lists (print or digital) intrinsically aimed to proactively engage patients in choosing questions to bring up for discussion during clinical encounters. Decision aids (print or digital) often utilised values clarification exercises encouraging users to consider the perceived importance of pros and cons to study participation. With computers and the internet increasingly ubiquitous, digital tools may prove more scalable and customisable than print materials [36]. Computerised decision aids tailoring the content presented to each user, based on individual characteristics, will likely become more sophisticated over time. These 'personalisation' features represent a potentially fruitful area for further development [37]. Similarly, given existing evidence that interactive environments enhance learning and satisfaction [38,39], digital interventions can take advantage of opportunities to incorporate interactive features (e.g., quizzes, Q&A, chatbots) [23,24,27,30]. However, as digital health technologies continue their expansion it is critical to consider and address the potential equity implications for vulnerable populations including those in poor health [40].

The evidence we reviewed came exclusively from high-income countries; only three studies took place outside the USA and Australia. Some papers said the interventions utilised plain language or allowed users to look up unfamiliar terms in a glossary. However, few studies explicitly addressed the needs of people with lower health literacy during intervention development and evaluation. A handful of studies – all from the USA – attended to the needs of patients from a racial/ethnic minority population by incorporating diverse patients' views in intervention design decisions and by ensuring visual depictions of patients were inclusive. All included interventions were in the country's dominant language (one Japanese, one Dutch, all others English). One intervention has a Spanish version, but evaluation appears to have taken place only in English [18]. Software developments increasingly facilitate translation, but it is important to note that automated translation cannot address nuances of potentially relevant cultural differences [41]. The evidence base could be broadened in applicability by adding studies conducted among underserved populations and settings, such as people with lower literacy, linguistic and cultural minorities, and low- and middle-income countries (subject to the availability of health research to consider joining). There is also a need to develop resources for Indigenous populations, reflecting pertinent cultural and historical considerations. Indigenous and other cultural minority populations may experience mistrust of medical institutions and research, rooted in longstanding health disparities and discrimination, requiring targeted strategies to address [42]. These steps are especially important given the need for clinical research to become more accessible to more diverse participants.

Apart from the lack of diversity among participants – a key limitation, as discussed above – sample size in the included studies was in many cases limited, and some authors acknowledged their studies were underpowered. Another common limitation was relatively short follow-up and/or substantial attrition among participants, including differential drop-out in a few cases. Some papers cited theories or models of communication, knowledge, or decision making that influenced the development of their interventions, and several referred to standards or frameworks such as the International Patient Decision Aid Standards [35]. However, a few studies did not report utilising these sources of theoretical and/or practical guidance. There is also increasing recognition of the value of co-design approaches to intervention development, to ensure a focus on concerns and aspects of the decision that matter to the target population [43,44].

Qualitative research on the needs of patients when making trial enrolment decisions has suggested that interventions should try to support people to learn about the research in their preferred way and in view of their own circumstances, as well as giving patients space to deliberate about the best course for them [3]. This review suggests that the types of interventions we identified may be useful to support better communication, informed decision making and consent for patients considering research participation. Among the intervention evaluation studies we identified, knowledge and actual or intended research participation were the most frequently reported outcomes, which is in line with the broader informed consent and shared decision making literature [13,45,46]. A knowledge gain associated with the intervention was observed in most studies that assessed this. Studies that assessed decisional conflict also tended to show positive intervention effects, though sometimes these were relatively subtle changes. A smaller number of studies reported positive effects on attitudes and satisfaction. Our tabulation and synthesis of study findings focused on key outcomes that were relevant to our research question and reported frequently across studies. Individual studies did not always measure many of these, and some showed positive effects on different ones, but it was beyond the scope of our review to cover all outcomes.

Until recently, there was little guidance regarding which outcomes are appropriate for studies evaluating whether interventions to improve trial participation decisions are 'effective', due to a lack of evidence as to which outcomes are meaningful for users [47]. To consider one example of tensions around this, results of a Delphi survey and discussions at a subsequent consensus meeting as part of the ELICIT Study [45] showed that views differ regarding whether someone's choice to either take part in a study or decline is an appropriate measure for evaluating interventions whose aim is ostensibly to provide balanced information and support informed decisions, rather than influence decisions one way or another. Diversity of opinion among both researchers and patients led to recruitment rate being omitted from the core outcome set developed by the ELICIT Study – a minimum set of important outcomes for evaluating clinical trial consent interventions [45]. Adoption of this core outcome set could facilitate synthesis of future studies. Despite its omission from the outcome set, however, for purposes of research planning there is practical utility in understanding the potential impact of consent resources on recruitment. The findings we identified suggest that, for interventions evaluated in these studies (aiming – per our eligibility criteria – to help patients make well-informed decisions to take part or not), any impact on recruitment rates is likely to be minimal. This is consistent with evidence that even strategies designed explicitly to increase recruitment (e.g., bespoke development and user testing of information materials) make little or no difference [48].

This review was broader in scope, overall, than previous reviews [1, 46] and therefore included more studies. Unlike the Cochrane review which was restricted to RCTs of clinical trial decision aids [1], we included other study designs and did not assess interventions according to a standardised assessment tool. This is because we wanted to include a wider range of interventions than those strictly qualifying as decision aids, acknowledging that rigid application of the technical definition of a decision aid may sometimes produce an intervention that is lengthy and complex without necessarily reflecting truly patient-centred care [23]. Our characterisation of interventions was based primarily on descriptions in the included papers but also drew on some additional information in other papers detailing intervention development. A review of literature from 2009–2019 on interventions to support decision making about cancer clinical trial participation [46] had narrower eligibility criteria than ours, being limited to 10 years and only involving patients with cancer. On the other hand, it also included interventions for providers (e.g., research nurses) and materials that could be characterised simply as education. We were interested in interventions with an interactive element to help patients consider their values or situation – hence, we excluded purely didactic interventions that inform patients in a more passive way. We believe the nature of the interaction between user and tool is a key characteristic with the potential to continue evolving with advancing technology. Although our review focuses on materials for patients, we note that families also contribute to study participation decisions, either by supporting or influencing patient choices or as proxy decision makers, and they have their own communication and decision support needs that future research should address [49].

4.2. Conclusions and practice implications

This review highlights the potential utility of resources such as decision aids and question prompt lists for patients considering participation in health research. Despite an increased focus broadly on improving consent to research, the eligible peer-reviewed literature we found was relatively small. Most interventions targeted clinical trials, and most studies were in oncology. We found few examples for other health conditions or study designs other than clinical trials. Future interventions should address these gaps, as various clinical contexts will raise different aspects for interventions to accommodate [47]. Box 1 presents some key principles, features, and additional points extracted from the studies included in this review, as examples of aspects that developers of future interventions might consider alongside drawing on relevant theory or guiding frameworks. Emerging areas like complex trial designs, genomics and precision medicine are increasingly coming to the fore, in addition to important contemporary issues such as the sharing of research data. Developing evidence-based resources with generic content as well as components that can be customised for a given study/setting may represent a promising avenue for future work. Digital technology offers new opportunities to enhance interactivity, tailor and personalise content, with potential to contribute to maximising accessibility and optimising support for people from diverse communities.

Box 1
Suggestions for future interventions, drawn from studies included in this review.

Some key principles to apply:

- Co-design intervention through formative research with members of the target population, ensure it is culturally sensitive, and focus on concerns and aspects of the decision that actually matter to patients and families
- Design intervention using a simple, clean layout, and aim for it to be engaging
- Avoid monotonous text; instead break information into short sections in logical sequence, aiming for simple, conversational language using familiar words and active voice
- Explain any jargon and incorporate supporting visuals and diagrams to facilitate understanding, including among people with lower health literacy
- Test intervention among members of diverse population groups to improve accessibility

- For digital interventions, ensure participants with different levels of computer literacy can have a high-quality experience and gain benefit from the intervention
  - o To help achieve this, draw on relevant expertise (e.g. web designers) and aim to minimise complexity and facilitate flexible navigation that is easy to follow

Some specific features to consider including:

- Enable participants to self-tailor their experience of intervention, for example by selecting which components to view and/or the order of presentation, if appropriate
- Encourage participants to check accuracy of their understanding of key material, for example via a quiz on preceding content before progressing to subsequent section
- Provide a ‘participant summary’ enabling healthcare providers and/or research staff to learn from a patient’s input, responses, or selections, and address their needs accordingly
- Facilitate repeated review of intervention content ‘as needed’ over time, and enable participants to return and modify their responses where feasible
- For digital interventions, take advantage of technology to utilise features such as:
  - o instructional voiceovers and/or animations to convey key messages
  - o ‘pop ups’ to display definitions when users click on or hover over medical terms

Other considerations for future work:

- Communication and decisions about research participation may be better viewed as a process occurring over time, requiring a staged approach allowing time for deliberation
- Attend to the social context of a patient’s decision about research participation – consider roles of and relationships with healthcare professionals, family and community

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CRediT authorship contribution statement

Jolyn Hersch: Conceptualization, Data curation, Funding acquisition, Formal analysis, Investigation, Methodology, Project administration, Resources, Supervision, Visualization, Validation, Writing – review & editing, Writing – original draft. **Lauren O'Hara:** Data curation, Formal analysis, Investigation, Methodology, Project administration, Visualization, Writing – review & editing, Writing – original draft. **Ilona Juraskova:** Conceptualization, Funding acquisition, Methodology, Resources, Supervision, Writing – review & editing. **Rebekah Laidsaar-Powell:** Writing – review & editing. **Nicci Bartley:** Writing – review & editing. **Katie Gillies:** Methodology, Writing – review & editing. **Mandy Ballinger:** Writing – review & editing. **Wei Wang:** Data curation, Writing – review & editing. **Phyllis Butow:** Conceptualization, Data curation, Funding acquisition, Methodology, Supervision, Writing – review & editing.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Appendix A. Supporting information

Supplementary data associated with this article can be found in the online version at doi:10.1016/j.pec.2025.109339.

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