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SYSTEMATIC REVIEW OF INTERVENTIONS TO SUPPORT PATIENT DECISION MAKING ABOUT TAKING PART IN HEALTH RESEARCH

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Introduction There is growing interest in applying shared decision making approaches to support informed consent, a vital but challenging aspect of conducting clinical research. We systematically reviewed interventions designed to aid communication and decision making about whether to take part in health research. We aimed to describe intervention characteristics and collate evidence of effectiveness.

Methods Eligible papers were peer-reviewed journal articles reporting any intervention-focused study design. Eligible interventions aimed to improve decision quality among adult patients capable of deciding about their participation in health research, by enabling users to address their own information needs (e.g., question prompt list, QPL) and/or incorporate their values into decision making (e.g., decision aid, DA). We searched 5 databases (1990–2023) and Google Scholar.

Results We included 16 studies, of which 9 were RCTs. In 9 studies, interventions were best described as DAs; the other interventions were QPLs or incorporated QPLs. 8 tools were paper-based; 8 were computer-/web-based, facilitating greater interactivity/tailoring. In 5 papers, resources concerned a specific study; 11 were generic but focused on clinical trials. Cancer was the predominant clinical context (n=14 studies). 4 papers cited theories/models and 7 cited standards/frameworks (e.g., IPDAS). Few papers discussed health literacy or cultural considerations. Studies assessed various outcomes, most often knowledge and choice/intention regarding research participation. Interventions generally increased knowledge, with little effect on participation rates.

Discussion Although the review highlights the potential utility of tools for patients considering health-related research participation, we identified some gaps. Most interventions addressed clinical trials in oncology. Given the need for greater diversity in studies, resources should be tested among diverse populations.

Conclusion Future interventions should address non-cancer settings, study types beyond clinical trials, and key emerging areas like genomics/precision medicine. Digital technology offers opportunities to enhance personalization, customize content for different studies, and maximize accessibility for people of diverse backgrounds.

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COPRODUCING A NOVEL ONLINE INTERVENTION TO SUPPORT SHARED DECISION MAKING ABOUT CANCER GENOMIC TESTING

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Introduction Genomic settings are complex and challenging for informed decision making. Partnering with patients and

professionals, we aimed to coproduce an innovative intervention for cancer patients to improve decision making and CONsent in GENomic Testing (CoGenT).

Methods Developing the CoGenT intervention, incorporating an online Dynamic Consent Platform (DCP) and Question Prompt List (QPL), involved: i) interviews with 34 stakeholders (cancer patients who were/were not taking part in genomic research, carers, study coordinators, clinicians) to elicit information needs (for QPL) and 'think-aloud' feedback on an existing non-cancer DCP; ii) drafting the first QPL about genomic research participation and iii) interviews with 22 stakeholders for feedback, resulting in a prototype DCP to support cancer patients offered genomic testing.

Results Information needs revolved around genomic testing, results/implications, and research participation. Interviews suggested we could enhance QPL utility by providing answers. Views on the DCP highlighted its potential value to inform patients, enable them to indicate preferences, and identify where they need support. Interviews demonstrated the importance of optimizing clarity, accessibility, and engagement in the CoGenT DCP. The QPL includes 29 questions and brief answers on which consent personnel can elaborate if desired. Feedback was positive about the QPL. We refined wording to address participants' suggestions. The prototype DCP is being iteratively reviewed and revised through further stakeholder interviews.

Discussion The CoGenT intervention is valued by patients, clinicians, and research personnel. This work will facilitate equitable access to cancer genomic research by ensuring consent processes meet the needs of key stakeholders.

Conclusion We will pilot the CoGenT intervention to assess effects on decision-quality outcomes compared with usual consent processes in cancer genomic studies. If results are positive, these evidence-based resources will help establish practices to follow when genomic testing enters routine care, with patients and families well-prepared and supported before, during and after testing.

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VALIDATION OF A DECISION-SUPPORT TOOL FOR WOMEN ELIGIBLE FOR ORGANIZED BREAST CANCER SCREENING DEVELOPED ACCORDING TO INTERNATIONAL STANDARDS

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Introduction Women eligible for organized breast cancer screening (OBCS) want to be better informed so that they can play an active part in the decision to participate, or not, in screening. A decision-aid tool (DAT) conforming to international standards, usable by both healthcare professionals and women, had been created.

The aim of the study was to validate an DAT for OBCS, in real-life conditions, with the women and healthcare professionals concerned.

Methods The main objective of the study, on the women's side, was to analyze by comparison before/after reading the DAT: the acceptability of the DAT as well as the level of knowledge, decisional conflict and intention to participate. The women targeted by the OBCS were recruited from the waiting rooms of 4 general practices.