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Review article

Systematic review of the empirical investigation of resources to support decision-making regarding *BRCA1* and *BRCA2* genetic testing in women with breast cancer

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ABSTRACT

Objective: Identify existing resources developed and/or evaluated empirically in the published literature designed to support women with breast cancer making decisions regarding genetic testing for *BRCA1/2* mutations.
Methods: Systematic review of seven electronic databases. Studies were included if they described or evaluated resources that were designed to support women with breast cancer in making a decision to have genetic counselling or testing for familial breast cancer. Outcome and process evaluations, using any type of study design, as well as articles reporting the development of decision aids, were eligible for inclusion.
Results: Total of 9 publications, describing 6 resources were identified. Resources were effective at increasing knowledge or understanding of hereditary breast cancer. Satisfaction with resources was high. There was no evidence that any resource increased distress, worry or decisional conflict. Few resources included active functionalities for example, values-based exercises, to support decision-making.
Conclusion: Tailored resources supporting decision-making may be helpful and valued by patients and increase knowledge of hereditary breast cancer, without causing additional distress.
Practice implications: Clinicians should provide supportive written information to patients where it is available. However, there is a need for robustly developed decision tools to support decision-making around genetic testing in women with breast cancer.

Contents

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1. Introduction

Traditionally, genetic testing for women diagnosed with breast cancer has been offered within specialist services. The focus of provision has been on those with a family history and usually after completion of active treatment. Several factors are influencing the increasing number and nature of referrals for genetic testing. Technological advances mean testing is becoming cheaper and faster. It is also recognised that a substantial proportion of women with no family history of breast cancer, but who have other increased-risk features (including younger age at breast cancer diagnosis, certain ethnicities, tumour characteristics) may carry a *BRCA1* or *BRCA2* (hereafter *BRCA1/2*) mutation. This has resulted in changes to the threshold for referral to genetic services [1]. Additionally, while considerable international variation exists, testing for germline mutations at the time of cancer diagnosis to inform treatment decisions (treatment-focused genetic testing – TFGT) is becoming more common. Knowledge of *BRCA* mutation status is increasingly used or requested to support decision-making between breast conserving surgery versus mastectomy and/or contralateral mastectomy. The advantages and disadvantages of combining treatment of the primary cancer with that of future risk of the developing a second new primary can then be considered [1].

There is also evidence of increased public awareness of inherited predisposition to breast cancer and more referrals for genetic counselling following wide media coverage of preventative surgeries of actress Angelina Jolie (*BRCA1* positive and with a family history of breast and ovarian cancer) [2,3]. Finally, the advent of targeted drug therapies [4] means more breast cancer specialists are recommending genetic testing to their patients to inform the choice of chemotherapy regimens and inclusion in clinical trials.

The result is a trend towards 'mainstreaming' of genetic testing; with the ambition of offering testing for *BRCA1/2* as part of routine patient care for young women diagnosed with breast cancer. It is therefore imperative that women are supported to make an informed choice about genetic testing given the likely short timeframes following diagnosis [5]. Women diagnosed at a younger age ($\leq$50 years) represent a group for whom treatment decisions can be particularly complex; for example, they may consider risk-reducing surgery in the context of concerns about adverse impacts on fertility, sexual functioning, body image and self-esteem [6]. In a busy oncology clinic, the time and knowledge base to adequately inform women about the pros and cons of genetic testing is often limited.

Empirically evaluated decision support interventions (or decision aids) have been found to increase knowledge and result in patients feeling better informed and clearer about what matters most to them when making medical treatment and screening choices [7]. Decision aids aim to supplement clinical consultations and help patients make considered choices. They clearly state the decision to be made and the options available with associated benefits and harms. They also include components that allow patients to recognise their values associated with the decision being made [8]. This is different to educational materials that describe the health condition and options but do not attempt to support patient contributions to the decision-making process [7]. Similar resources have been developed for women with breast cancer choosing between breast conserving surgery and mastectomy [9] and women at high-risk of developing breast and/or ovarian cancer making decisions about genetic testing [10]. Decision support tools could be particularly valuable in the context of decision-making for TFGT, where there is increased pressure to compress specialist genetic counselling into the timeframe required for the treatment of the primary cancer.

This systematic review therefore aimed to identify existing resources developed and/or evaluated empirically in the published literature designed to support women's decision-making regarding genetic testing for *BRCA1/2* mutations. This was the first phase of a study, which set out to develop such a decision support tool for young women recently diagnosed with breast cancer. This is in line with the Medical Research Council guidelines for developing and evaluating complex interventions, which recommends identification of the relevant existing evidence base, ideally by way of a systematic review as a first stage of intervention development [11]. The objectives of the review are threefold: to characterise published resources, assess their acceptability and evaluate their impact. As well as informing intervention development, this evidence synthesis will serve to generate new research questions in line with clinical priorities and make practice recommendations on the basis of current evidence.

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