

Streamlined Genetic Education Is Effective In Preparing Women Newly Diagnosed With Breast Cancer for Decision-Making About Treatment-Focused Genetic Testing: A Randomized Controlled Non-Inferiority Trial

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Abstract

Purpose: Increasingly, women newly diagnosed with breast cancer are being offered treatment-focused genetic testing ('TFGT'). As the demand for TFGT increases, streamlined methods of genetic education are needed.

Patients and Methods: In this non-inferiority trial, women aged <50 with either a strong family history (FH+) or other features suggestive of a germline mutation (FH-) were randomized before definitive breast cancer surgery to receive TFGT education either: as brief written materials (intervention group, IG) or during a genetic counseling session at a familial cancer clinic (FCC, usual care group, UCG). Women completed self-report questionnaires at four time points over 12 months.

Results: 135 women were included in the analysis, all of whom opted for TFGT. Decisional conflict about TFGT choice (primary outcome) was not inferior in the IG compared to the UCG (non-inferiority margin of -10, Mean difference=2.45, 95%CI[-2.87,7.76], p=.36). Costs per woman counseled in the IG were significantly lower (A\$89), compared to the UCG (A\$173; t(115)=6.02, p<0.001).

Conclusions: A streamlined model of educating women newly diagnosed with breast cancer about TFGT appears to be a cost-effective way of delivering education, while ensuring that women feel informed and supported in their decision-making, thus freeing resources for other women to access TFGT.

Key words: Rapid testing, BRCA1, BRCA2, breast cancer, family history, psychological adjustment, genetic counseling, intervention

Biography: Bettina Meiser is and a Professor and Head of the Psychosocial Research Group, Prince of Wales Clinical School, University of New South Wales, Sydney, Australia. She is an internationally recognised expert in the area of psychosocial aspects of cancer genetics. She has published over 170 peer-reviewed articles. Her research program focuses on the psychological impact of cancer genetic counselling and testing, and the design and evaluation of interventions in this setting. She has undertaken research on the psychological impact of genetic testing a range of conditions including, amongst others, hereditary breast and/or ovarian cancer (HBOC), Lynch Syndrome, Familial Adenomatous Polyposis (FAP), and hereditary melanoma. She has also conducted

innovative research on the psychosocial implications of new gene testing technologies, including the impact of treatment-focused genetic testing following a diagnosis of breast and/or ovarian cancer and the impact of testing for low-risk gene variants related to breast cancer. Bettina Meiser has been involved in the development and evaluation of a range of psycho-educational materials, including decision aids, for use in different settings in the cancer genetic counselling setting and oncology. All of the decision aids she has developed for people at increased genetic risk for hereditary disorders are being widely disseminated to familial cancer services around Australia. She is also undertaking extensive research on cultural aspects of cancer genetics.