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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**Meiser B¹, Quinn VF¹, Kirk J^{2,3}, Tucker KM⁴, Watts KJ¹, Rahman B¹, Peate M^{1,5}, Saunders C⁶, Geelhoed E⁷, Gleeson M⁸, Barlow-Stewart K⁹, Field M¹⁰, Harris M¹¹, Antill YC^{11,12}, Ciciarelli L¹³, Crowe K¹⁴, Bowen MT¹⁵, Mitchell G^{13,16}**¹Prince of Wales Clinical School, Faculty of Medicine, University of New South Wales, Sydney, NSW, 2052, Australia²Familial Cancer Service, Westmead Hospital, Hawkesbury Road, Westmead, NSW, 2145, Australia³Centre for Cancer Research, The Westmead Institute for Medical Research, University of Sydney, Westmead, NSW, 2145, Australia⁴Hereditary Cancer Clinic, Department of Medical Oncology, Prince of Wales Hospital, High Street, Randwick, NSW, 2031, Australia⁵Department of Obstetrics & Gynaecology, Royal Women's Hospital, University of Melbourne, Parkville, VIC, 3052⁶School of Surgery, University of Western Australia, Crawley, WA, 6009, Australia⁷School of Population Health, University of Western Australia, Crawley, WA, 6009, Australia⁸Hunter Family Cancer Service, Waratah, NSW, 2298, Australia⁹Sydney Medical School-Northern, University of Sydney, Sydney NSW 2006¹⁰Royal North Shore Hospital, St Leonards, NSW 2065¹¹Monash Health, Melbourne; ¹²Familial Cancer Centre, Cabrini Health, Melbourne, VIC 3144¹³Familial Cancer Centre, Peter MacCallum Cancer Centre, Melbourne VIC 8006¹⁴Genetic Health Queensland, Nambour General Hospital, QLD 4560¹⁵School of Psychology, University of Sydney¹⁶Sir Peter MacCallum Dept of Oncology, University of Melbourne, VIC, 8006, Australia.

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.

Running title: Genetic testing for women with breast cancer under 50

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

Biography

Bettina Meiser is 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 recognized expert in the area of psychosocial aspects of cancer genetics. She has published over 170 peer-reviewed articles.

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