

A process evaluation trial of a telehealth service intervention to support uptake of breast cancer prevention medications.

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Background: Breast cancer prevention medications (BCPrevMeds), such as tamoxifen and anastrozole, halve breast cancer (BC) risk. Our prior research has shown that only 2% of Australian women who know they are at increased risk of BC have ever used BCPrevMeds, and that this evidence-implementation gap is driven by lack of awareness of BCPrevMeds by patients and their primary care physicians (PCPs). In addition, few PCPs report feeling confident to discuss BCPrevMeds, most would not initiate prescribing, but 98% would provide ongoing prescriptions if initiated by a specialist. The Preventing Cancer with Medications (PCMed) Specialist Telehealth Service intervention was developed, based on the Knowledge to Action Implementation Framework, to respond to these findings. The PCMed intervention delivers personalised information to patients to facilitate their informed decision-making, initiates BCPrevMeds prescriptions, and supports PCPs to manage patients during their treatment course. **Methods:** A mixed methods process evaluation trial is evaluating the effectiveness, adoption, acceptability, feasibility, fidelity, and cost of the PCMed intervention. Women aged 20–70 years with no history of invasive BC or DCIS are eligible if they have a remaining lifetime BC risk > 20% or 10-year risk of > 5%. The intervention includes 1 to 2 telehealth sessions with a medical oncologist or nurse practitioner in which patients receive tailored education about the BCPrevMeds relevant to them, a personalised discussion of the absolute risk reduction they could achieve with BCPrevMeds and tailored discussion of other benefits and side-effects of BCPrevMeds applicable to them. Those who desire BCPrevMeds receive a prescription and are reviewed in 8 to 10 weeks to manage any side-effects. Care is then transferred to the PCP who receives educational information and detailed instructions to continue management. A telephone hotline is available for clinicians and patients to address any concerns relating to side effects during the treatment course. Effectiveness of the PCMed Service intervention will be determined by comparing uptake of BCPrevMeds before and after the intervention, using a chi-square, Fisher's exact test, and/or mixed effects regression (as appropriate based on the number of uptake events). Secondary outcomes include adoption of the intervention (the proportion of eligible women who attend the PCMed Service), acceptability for patients and referring clinicians (survey and semi-structured interviews based on the Theoretical Framework of Acceptability), feasibility and fidelity (adherence to the planned intervention processes), and cost (using a micro-costing approach). Currently 33 of a planned 63 participants have been recruited – sample size is based on 80% power to detect a change in uptake from 2% to 20%. Clinical Trial Information: ISRCTN15718519. Clinical trial information: 15718519. Research Sponsor: Tour de Cure; RSP-307-2024; National Health and Medical Research Council (Australia); 1195294.