

Title: Supporting endocrine therapy adherence in women with breast cancer: the development of a complex behavioural intervention using Intervention Mapping guided by the Multiphase Optimisation Strategy

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Background: Adjuvant endocrine therapy (AET) reduces mortality in women with breast cancer, but adherence is suboptimal. Most existing interventions to support AET adherence have been unsuccessful, are atheoretical, and have not focused on the most salient barriers to adherence.

Objectives: We aimed to provide an exemplar of the process for developing an intervention package to support adherence to AET, using Intervention Mapping (IM) and the Multiphase Optimisation Strategy (MOST).

Methods: Iterative development followed the six stage IM framework: 1) literature review of barriers to adherence and existing interventions; 2) selection of intervention component objectives; 3) identification of theories and practical strategies to support adherence; 4) development of intervention components; 5) implementation considerations; 6) evaluation plans.

Results: The final intervention package comprised four intervention components: SMS reminders to encourage habitual behaviours; information leaflet targeting erroneous beliefs; Acceptance and Commitment Therapy based guided self-help to address psychological distress; side-effect self-management website (stages 1 to 4). The MOST framework guided our decision to use an optimisation criteria of effectiveness capped at a maximum per person cost (stage 5). The intervention components will be evaluated for feasibility in a 2^{4-1} fractional factorial pilot, prior to an optimisation trial using a 2^4 full factorial design (stage 6).

Conclusion: We used IM guided by MOST to develop theoretically informed intervention components to support AET adherence in women with breast cancer. Evaluation will involve a pilot and optimisation trial to build an effective and low cost intervention package.