Title: Refining and Optimizing a behavioural intervention to Support Endocrine Therapy Adherence: Protocol for the ROSETA Pilot Trial

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Background: Non-adherence to adjuvant endocrine therapy (AET) increases mortality in women with breast cancer. Guided by the Multiphase Optimisation Strategy (MOST) we developed four intervention components targeting medication adherence barriers: SMS reminders (target: memory); information leaflet (target: beliefs); acceptance and commitment therapy (ACT)-based guided self-help (target: distress); website (target: side-effects).

Objectives: To answer uncertainties about the feasibility of conducting an optimization trial, this pilot aims to establish: i) eligibility, recruitment, retention and follow-up rates; ii) intervention component adherence; iii) availability and feasibility of collecting outcome and process data; iv) estimates of variability in outcome measures; v) estimates of intervention component costs.

Methods:
In this multi-site pilot trial, we will randomize 80 women with early stage (I-IIIa) breast cancer using AET to one of 8 conditions within a 2^{4-1} fractional factorial design with a nested process evaluation. Women will receive usual care, plus a combination of the four components. Medication adherence will be assessed using routinely collected pharmacy data. Progression to the optimization phase will consider consent rates, component adherence, and availability of data.

Results: The trial received ethical approval (21/WA/0322) on 10.26.2021 and will begin recruitment in 2022.

Conclusion: The ROSETA pilot will establish the feasibility of undertaking an optimisation trial of four intervention components aiming to support medication adherence in women with breast cancer. The trial is funded by the National Institute of Health Research (NIHR300588) and was prospectively registered (ISRCTN: 10487576).