

Title: Exploring the feasibility of using a total diet replacement in women with excess weight affected by stage II to III breast cancer: protocol for a pilot randomized controlled trial

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Background

Breast cancer survivors with overweight and obesity are at increased risk of recurrence and mortality. Low energy liquid Total Diet Replacement (TDR) interventions can support weight loss in chronic disease populations.

Objectives

In the long term, we aim to establish if intentional weight loss, achieved with a low energy TDR program, can improve clinical outcomes among breast cancer survivors with a Body Mass Index (BMI) $\geq 27.0 \text{ kg/m}^2$. This pilot will establish the feasibility of undertaking a phase III trial by estimating key trial parameters, and undertaking a qualitative process evaluation.

Methods

88 women with stage II to III breast cancer and a BMI of $27\text{-}45 \text{ kg/m}^2$ will be randomized (1:1) to receive the TDR program or brief weight loss advice. The TDR program involves a 12 week TDR phase (810kcal/day) and 12 weeks of food reintroduction, followed by a 6 month weight maintenance phase. Behavioral support is delivered remotely by dietitians throughout. Key pilot outcomes include eligibility, recruitment, attrition, adherence to the protocol, and remotely captured weight loss.

Results

The trial commenced in October 2021. Twelve sites are recruiting, 2 participants have been randomized (01 to TDR arm), and 01 has initiated the TDR program.

Conclusion

TDRs are a weight management option for people with overweight and obesity, but the extent to which they affect clinical outcomes in women diagnosed with breast cancer is unknown. This pilot will address

key uncertainties about undertaking a definitive phase III RCT of a TDR program in the breast oncology setting. The trial is funded by Breast Cancer Now and has been prospectively registered: ISRCTN12000313.