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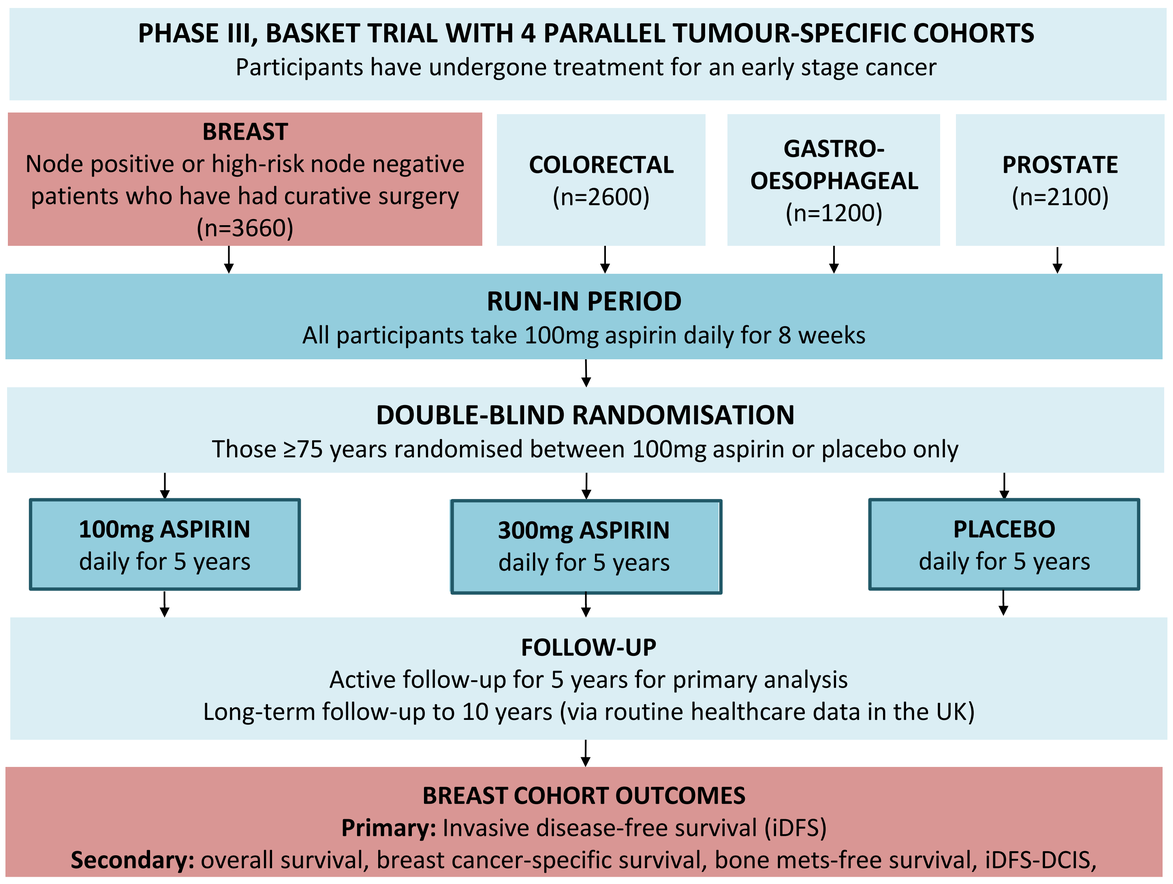
Embedding a survivorship study in an ongoing trial: Adding value to Add-Aspirin

Introduction

- Outcomes in early stage breast cancer continue to improve and increasing numbers of people live for many years after diagnosis
- Assessment of health-related quality of life (HRQOL) has traditionally focused on short-term effects of disease and/or treatment, often in late-stage cancer
- Little is known about the issues and challenges facing long-term survivors
- The ongoing Add-Aspirin trial presents an important and unique opportunity to explore these issues

The Add-Aspirin trial



- Add-Aspirin is a double-blind, international, phase III basket trial
- It is assessing use of daily aspirin for preventing recurrence and improving survival following treatment for early stage cancer
- Breast cancer participants have had curative surgery +/- (neo-) adjuvant therapy for node positive or high risk node negative disease
- The trial opened in 2015 and is recruiting across 170 centres across the UK, India and Ireland
- 3000 of target 3660 breast cancer patients have been randomised
- Recruitment to the breast cohort will complete in 2020 with the primary analysis in 2026
- Participants will be followed up for at least 10 years

Lay summary

Early detection and improvements in treatments mean that people with cancer often live for many years after a diagnosis. Little is known about the impact of diagnosis and treatment on their long-term quality of life.

The Add-Aspirin trial is looking at whether taking daily aspirin can stop cancers from returning. It will involve 3660 people who have had breast cancer surgery. Information about their health will be collected over 10 years.

The trial provides an important opportunity to study the issues facing people who have had cancer. People taking part will complete questionnaires about their mental and physical health. Results will help doctors to inform patients about long-term impacts of treatment, identify those at greatest risk, and provide better support.

Survivorship study

Aims

- To describe both global quality of life and tumour-specific survivorship issues over time, and explore factors affecting these
- In the breast cohort, areas of focus will include peripheral neuropathy, menopausal symptoms, weight gain and fatigue, as well as sexual and psychological concerns
- Inform further research and the development of interventions to improve HRQOL for survivors

Questionnaires

- EORTC QLQ-SURV core and tumour-specific modules will be used
- Designed to capture the range of physical, mental and social HRQOL issues relevant to survivors ≥ 1 year after diagnosis
- Developed through international consensus and extensive validation (See van Leeuwen M *et al*. Health and quality of life outcomes. 2018;16(1):114).

Implementation

- HRQOL will be assessed at 2- and 5- years after randomisation in the breast cohort (and at relevant time points in the other cohorts)
- The questionnaires will be self-administered, with the aim to have both online and paper-based options available to maximise response rates
- Tumour-specific analyses will assess factors influencing outcomes (including demographics, lifestyle (e.g. exercise), comorbidities, disease stage and treatment pathway), as well as patterns over time

Conclusions

Add-Aspirin presents an important and unique opportunity to explore the issues facing breast cancer survivors in the longer term.

This work may inform future research and interventions to improve quality of life for survivors.

Efficient use of the existing cohort and infrastructure will maximise the scientific value of the trial.

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