Women's Cancer Survivorship:

The LYSA (Linking You to Support and Advice) Trial

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Introduction

Background: Improvements in surveillance and treatments for cancer have resulted in increasing numbers of individuals living with and beyond a cancer diagnosis. (1) The National Cancer Strategy 2017 has identified support for this patient cohort as a priority (2). The improved survival rate for many cancers in high income countries demands a coordinated multidisciplinary approach to survivorship care and service provision to ensure optimal patient outcomes and quality of life. This pilot clinic is nurse-led, multidisciplinary and incorporates Patient Reported Outcomes (ePROs) technology for women with early-stage hormone receptor (HR)-positive breast and gynaecologic cancer.

Hypothesis: 1) That the introduction of a cancer survivorship clinic into routine follow-up care will be feasible. 2) That female cancer survivors who participate in the survivorship clinic intervention incorporating ePRO collection and targeted symptom management pathways (intervention arm) are more likely to experience improvements in symptom burden and HRQOL compared to those who do not partake in the intervention (control arm).

Methods

Study Design: Complex interventional study

Specific Aims: To evaluate the feasibility of introducing a Women's Health Initiative (WHI) Cancer Survivorship Clinic in Ireland incorporating symptom management through ePROs collection into routine follow-up care in patients with early-stage HR-positive breast and gynaecologic cancer post-primary therapy.

Sampling Method: Randomized Control Design (Parallel Arms)

Sample Size: 200

Entry Criteria: Women with early-stage breast/gynaecological cancer within 12 months of completion of primary curative therapy:

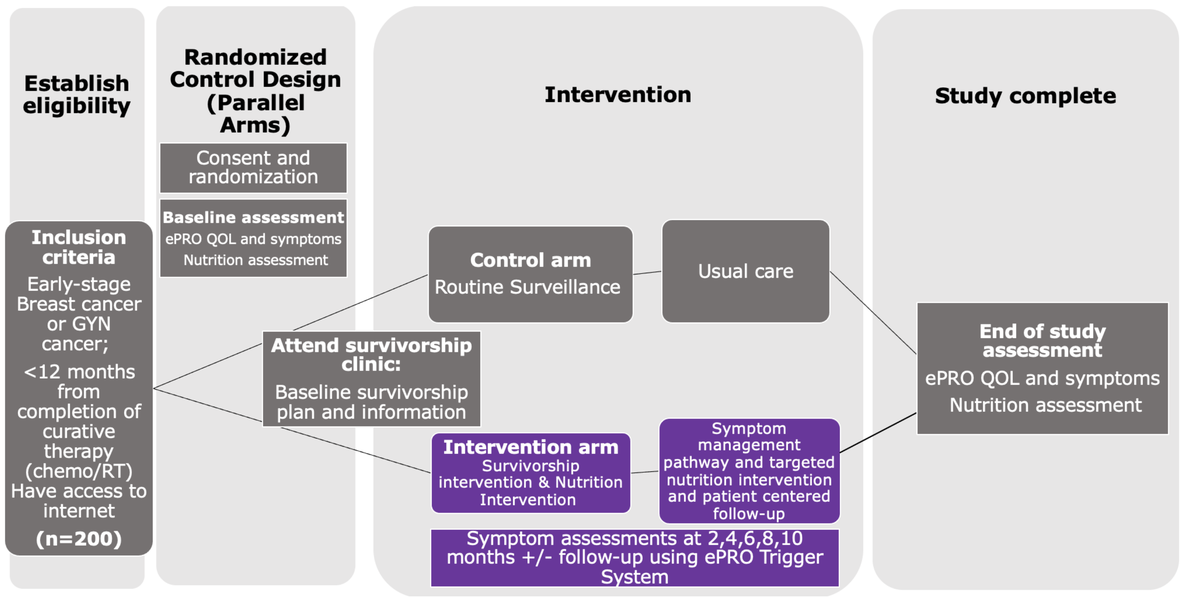
- Breast cancer: Stage I-III hormone receptor-positive (defined as oestrogen receptor and/or progesterone receptor ≥ 1%) and HER2-negative per ASCO-CAP guidelines on or recommended to commence adjuvant endocrine therapy during the study period
- Cervical cancer: Stage I to III treated with curative intent
- Endometrial cancer: treated with curative intent adjuvant radiotherapy +/- chemotherapy

Recruitment Period: March 2021 – September 2022 (+12 follow up)

Site: Cork University Hospital & Galway University Hospital (June 2022)

Ethics Approval reference (CREC): ECM 4 (y) 20/10/2020

Green light: 12 March 2021

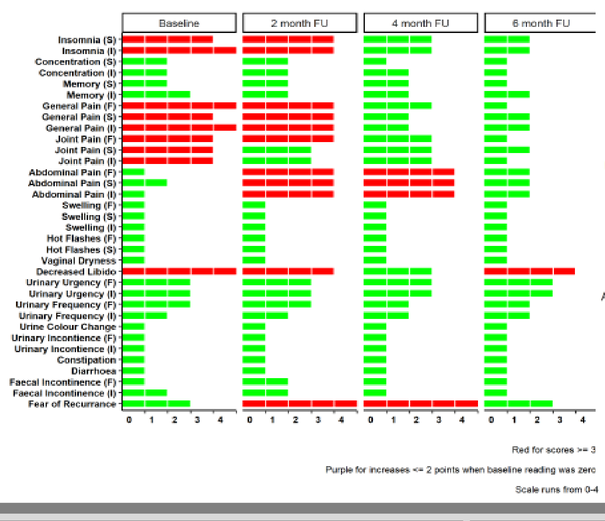


Figures below: Example of a Trigger List Report that the Research Nurse and Research Dietitian review 2 monthly for participant's follow-up, based on their on ePROs.

Completed surveys

Patient ID	Survey package	Survey number	Completion date
TEST-002	Baseline Survey - Breast Cancer	1	24-09-2021 13:38:37
TEST-002	Follow-up Survey	2	24-09-2021 13:39:27
TEST-002	Follow-up Survey	3	24-09-2021 13:39:44
TEST-002	Follow-up Survey	4	24-09-2021 13:40:03

PRO-CTCAE Symptoms



Additional Triggers and Scores

Study schedule and instruments/measurements

	Intervention arm	Control arm
Baseline	**WHI Survivorship Clinic Visit** • Nurse Visit • Symptom management education • Anthropometry & Body Composition Assessments • Dietary Intake Assessments ❖**ePROs** • Baseline QOL survey • PRO-CTCAE & PROMIS Symptoms* and Malnutrition screening tool	**WHI Survivorship Clinic Visit** • Nurse Visit • Anthropometry & Body Composition Assessments • Dietary Intake Assessments ❖**ePROs** • Baseline QOL survey • PRO-CTCAE & PROMIS Symptoms and Malnutrition screening tool
Ongoing monitoring (months 2,4,6,8,10)	**Follow-up as clinical/trigger symptom requirement** or at 6th month ❖**ePROs** • PRO-CTCAE & PROMIS Symptoms and Malnutrition screening tool	**No follow-up** ❖**ePROs** - None
End of the study (12th month)	**WHI Survivorship Clinic Visit** • Nurse Visit • Anthropometry & Body Composition Assessments • Dietary Intake Assessments • Diet Education ❖**ePROs** • End of the study QOL survey • PRO-CTCAE & PROMIS Symptoms and Malnutrition screening tool • Feasibility survey & Interview/focus groups • Onward referral to community dietitians if further support required	**WHI Survivorship Clinic Visit** • Nurse Visit • Anthropometry & Body Composition Assessments • Dietary Intake Assessments ❖**ePROs** • End of the study QOL survey • PRO-CTCAE & PROMIS Symptoms and Malnutrition screening tool • Feasibility survey & Interview/focus group • Onward referral to community dietitians if required

***Symptoms assessed using PRO-CTCAE & PROMIS items:** A core list of symptoms/adverse events that are identified including gastrointestinal, attention/memory, pain, fatigue and insomnia, mood-emotional distress/depression, anxiety, fear of cancer recurrence, gynaecological, urinary, sexual issues and hot flashes.

Summary / Conclusion

Overcoming recruitment challenges:

Informed Consent performed virtual or face-to-face (considering participant's preferences)

Recruitment extension: Extension of study recruitment period from 12 to 18 months

Amendments to eligibility criteria:

1) Chemotherapy no longer a requirement as part of curative intent treatment
2) Extension of completion of primary curative treatment period from 6 to 12 months

Addition of 2 satellite centres (SIVUH & UHK) as a referral base for potential candidates.

Addition of UHG as 2nd Recruitment site.

Current study status:

Castor Platform – Ongoing use of Castor Electronic Data Capture to ensure highest standard of data collection and analysis.

Recruitment: 200/200

Data analysis: October- November 2023

More information:

clinicaltrials.gov registry

Video Trial description

Principal Investigator contact information

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Study Sponsor: UCC

Study Funders: Irish Cancer Society & Breakthrough Cancer Research

References:

1. National Cancer Registry (NCRI). Cancer Factsheet Overview and most common cancers. 2017
2. Government of Ireland. National Cancer Strategy 2017-2026. Dublin; 2017