HORIZONS: a cohort study to explore recovery of health and well-being in adults diagnosed with cancer

Welcome

Macmillan Survivorship Research Group
Faculty of Health Sciences
University of Southampton
Programme Management Group

Strategic Advisory Board

Tumour Specific Expert Panels
Data Monitoring Committee
User Reference Group
Scientific Advisors (including international)
Your team

Introduce yourself

Which cohort(s) do you work on

Are there any questions you would like answered today?
Introduction

The aim of HORIZONS is to understand how cancer and its treatment impacts on peoples lives.

It will adopt a longitudinal cohort approach.

Data will be collected from:

- Patient Report Outcome Measures (PROMs)
- Case Report Forms (CRFs)
- Nested Qualitative Work
Introduction

Our research questions

• What impact does cancer and its treatment have on people diagnosed with cancer in the short, medium and long term?

• What are the health outcomes, experiences and self-management activities over the life-course across different cancer types and what influences these?

• How do people connect with and mobilise resources which enable them to self-manage consequences of cancer and its treatment?
HORIZONS Cohort Study

• 3 years of recruitment (from Autumn 2016)

• Aim to recruit over 3,000 patients

• 6 pilot sites (Phase 1)

• Phase 2 sites opened early 2017

• Your sites represent “Phase 3” and all will be open by the end of 2017

• Over 50 sites in total
Our initial cohorts

- **Breast cancer**
  - Women <50 years old

- **non-Hodgkin lymphoma (NHL)**
  - Diffuse Large B Cell NHL (including rare subtypes)

- **Gynaecological cancers**
  - Ovarian cancer (including Primary Peritoneal & Fallopian Tube)
  - Endometrial cancer
  - Cervical cancer

- Total sample – all eligible patients on screening log and approached

- Ideally patients will be approached before the start of primary treatment but there are some exceptions
Other studies

• Participation in other research studies is not an exclusion criterion for this study.

• Site staff should give information to all eligible participants to allow them to choose if they want to participate in the study.

• If the patient is participating in, or considering participation in another study, HORIZONS should still be offered to the patient, unless it is an exclusion criteria of another study to which the participant is already consented.
Importance of patients in HORIZONS study design

- Input to the study processes
- NCRI user forum
- Knowledge Cafés
- User Reference Group
- Tumour Specific Expert Panels
- Strategic advisory board
- Questionnaire review
- New members?
## Regulatory authority progress

<table>
<thead>
<tr>
<th>REC</th>
<th>HRA</th>
<th>Portfolio</th>
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</table>
| • Favourable opinion from proportionate review June 2016  
• 16/NW/0425 | • HRA approval January 2017 for Phase 3 sites (all of you!)  
• IRAS 202342 | • Adopted August 2016  
• Portfolio CPMS ID 31610 |
Recruitment Timeline & Milestones

- September 2016: First 3 pilot sites opened
- November 2016: 3 further pilot sites opened
- Early 2017: Roll out of Phase 2 sites
- Throughout 2017: Roll out of Phase 3
- 2019: Completion of recruitment of 3,000 patients

2016

2017

2019
**Recruitment**

**Screening**
- Screen for all potentially eligible patients, all eligible patients entered on to Screening Log and given research number

**Prior to pre-treatment appointment**
- Send potential participants PIS and PIL in advance of their appt.
- Approach potential participants to discuss HORIZONS and give patient a PIS to consider before next appt.
- If potential participant is found to be ineligible (i.e. already started treatment) or missed (i.e. because of resource limitations) record on Screening Log

**Pre-treatment**
- Discuss the study with the patient and whether they want to participate
- Introduce the study and discuss the patient’s potential participation - give them the PIS
Decline: Patient does not wish to take part

Site research team completes anonymous decliners’ log (age and ECOG status)

Member of the site research team sends completed decliners log to the Coordinating Centre periodically

Consent: Patient would like to take part in HORIZONS completing questionnaires and giving researchers access to their medical records. Participant is given baseline questionnaire and pre-paid envelope

Site research team takes informed consent from participant and completes contact details form with participant

Member of the site research team sends completed Screening Log, contact details forms consent forms decliners log to the Coordinating Centre.

Participant completes baseline questionnaire and returns it to the Coordinating Centre

Site research team completes CRF of medical details from the medical records and returns to HORIZONS Coordinating Centre

Site research team completes CRF of medical details from the medical records and returns to HORIZONS Coordinating Centre

Patient requires more time to consider participation. Local site research team provides contact details form, consent form, baseline questionnaire and pre-paid envelope for patient to take home. If patient then decides to take part they return the completed contact details form, consent form baseline questionnaire directly to the Coordinating Centre in the pre-paid envelope. The consent form will be forwarded to the site research team to be countersigned and filed
**HORIZONS - Breast Cancer Cohort - Screening Log**

<table>
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<tr>
<th>Study short title</th>
<th>HORIZONS study: Understanding the impact of cancer diagnosis and treatment on everyday life</th>
<th>Ethics No.</th>
<th>16/NW/0425</th>
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<tr>
<td>Sponsor</td>
<td>University Hospital Southampton NHS Foundation Trust</td>
<td>Principal Investigator</td>
<td>Prof Claire Foster</td>
</tr>
<tr>
<td>Site</td>
<td>Chief Investigator</td>
<td>Agreed day for faxing</td>
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**FAX COMPLETED LOG SHEET TO HORIZONS – WEEKLY: 023 8059 7967 or 7951**

**Log Sheet No:**

<table>
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<tr>
<th>NHS &amp; Hospital Number</th>
<th>CONCEAL prior to faxing</th>
<th>Screening Date dd/mm/yy</th>
<th>Study ID: Pt initials, site ID, cohort-B. Consecutive study number BS01B001, LC01B002 etc.</th>
<th>Outcome:</th>
<th>Proposed treatment start date</th>
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<tr>
<td></td>
<td></td>
<td></td>
<td>1. Full consent / 2. Reduced consent / 4. Documents taken home: Study ID include initials eg: BS01B001 etc.</td>
<td></td>
<td>Proposed Tx start / / /</td>
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<tr>
<td></td>
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<td>3. Declined / 5. Missed Approach / 6. Ineligible following screening: XX instead of initials eg: XX01B001 etc.</td>
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- **Full consent**: 1. Fax Contact Details Form and Consent Form
- **Reduced consent only**: 2. Fax Reduced Consent Form and completed Reduced Demographic form
- **Declined any participation**: 3. Reason declined and fax completed Declined Demographic form.
- **Documents taken home**: 4. Proposed Tx start / / / 
- **Missed approaching (eligible)**: 5. Reason not approached.
- **Ineligible following screening**: 6. Reason Ineligible following screening.

# Add study ID to Questionnaire or Demographic form

# Complete basic demographics, with patient's permission

3 Minimum criteria for screening: diagnosis of primary breast cancer, clinical stages I – III and awaiting primary treatment with curative intent

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**Macmillan Survivorship Research Group**

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**WE ARE MACMILLAN CANCER SUPPORT**
Full sample cohort - Reviewing activity

- Total eligible screened
- Approach those eligible
- Approached consented
Introduce study to patients

**Participant Pack** – review with participant & discuss study (HORIZONS Coordinating Centre will send out packs to sites)

- Letter of Invitation
- HORIZONS Flyer
- Patient Information Sheet
- Consent Form
- Contact Details Form
- Questionnaire
- Freepost return envelope to the HORIZONS Coordinating Centre
Full cohort demographics

Representativeness of results

Fundamental to research question

Full cohort study

Applicability of findings

Traits in those that decline
Baseline Questionnaires – before treatment

- Participant completes Baseline Questionnaire and seals it in pre-paid reply envelope
- Participant or site staff member posts pre-paid envelope containing baseline questionnaire to HORIZONS Coordinating Centre
Follow Up Questionnaires

- New time points! Protocol version 3
  - 3m, 12m, 18m, 24m annual to 5 years
- Sent centrally by HORIZONS coordinating centre
- Paper or online
• Site resource; recorded SIV’s, documents
• Participant online completion of follow-up questionnaires; 3m, 12m, 18m, 24m, annual

www.HORIZONS-hub.org.uk

Welcome to the HORIZONS Programme website

HORIZONS is a large study of people across the UK who have had a diagnosis of cancer. We are interested in how a diagnosis of cancer and its treatment affects a person’s life over time. The aim is to understand what is important to people with cancer during their treatment and in the months and years afterwards which will help to inform support services in the future.

Please use the buttons below to navigate our site.
Case Report Forms

- For each full and reduced consent participant, CRFs will be completed by site staff

- **BASELINE CRF** (at recruitment / consent)
  - Diagnosis

- **6 MONTH CRF**
  - Primary treatment

- **12 MONTH & ANNUAL CRF**
  - Longer term health
Pilot sites

- University Hospital Southampton NHS Foundation Trust
- Hampshire Hospitals NHS Foundation Trust (Winchester and Basingstoke)
- Norfolk and Norwich University NHS Foundation Trust
- Ipswich Hospital NHS Trust
- Surrey and Sussex Healthcare NHS Trust
- Tameside and Glossop Integrated Care NHS Foundation Trust
Phase two sites

Northern Ireland
- Antrim Hospital (Northern Health and Social Care Trust)

Wales
- Betsi Cadwaladr University Health Board

Scotland
- University Hospital Crosshouse and University Hospital Ayr (NHS Ayrshire and Arran)
- Beatson West of Scotland Cancer Centre (NHS Greater Glasgow and Clyde)
- Borders General Hospital (NHS Borders)

England North West
- The Royal Preston Hospital (Lancashire Teaching Hospitals NHS Foundation Trust)
- Macclesfield Hospital (East Cheshire NHS Trust)

England North East
- Queen Elizabeth Hospital (Gateshead Health NHS Foundation Trust)

England Midlands
- St James' Institute of Oncology (Leeds Teaching Hospitals NHS Trust)

England South West
- Derriford Hospital (Plymouth Hospitals NHS Trust)

England South East
- East Kent Hospital NHS Foundation Trust
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Consented (n=255, mean= 62%, median= 75%)
B=90 88% / G=100, 67% / N=65, 85%)

Approached (n=354, 86%,
B=123 85% / G=154, 92% / N=77, 77%)

Missed (n=58, B=22 / G=13 / N=23)

Docs taken home (n=37, B=11 / G=25 / N=1)

Declined (n=62, B=22 / G=29 / N=11)

Consented (n=255, mean= 62%, median= 75%)
B=90 88% / G=100, 67% / N=65, 85%)

Full consent (n=233, B=83 / G=91 / N=59)

Reduced consent (n=22)

Eligible (n=412, B=145 / G=167 / N=100)

1 = Percentage of eligible patients
Consented (n=255)

- Full consent (n=233)
- Reduced consent (n=22)

Still eligible (n=222)

- Excluded (lost to follow up before T1) (n=6)
- Deceased (n=4)
- Withdrawn (n=1) - Option 2

Sent T1 questionnaire (n=120, 54%)²

Completed T1 questionnaire (n=76, 63%)³

² = Percentage of eligible patients
³ = Percentage of eligible patients sent a T1 questionnaire
What have we learnt so far?

Each cohort has different windows of approach, some of which are very small.

Lessons learnt

- If you ask people to participate they are receptive to the study.
- Involvement of the wider team (CNS, breast care nurse) can be really beneficial.
Keeping in touch

- SIV
- Meetings
- Other Networking opportunities
- Newsletter
- Regular cohort specific teleconferences
Prof Claire Foster
Chief Investigator

Dr Lynn Calman
Senior Research Fellow

Dr Becky Foster
Research Fellow
Eligibility and CRF queries

Dr Josh Turner
Research Fellow
Eligibility and questionnaire queries

Faye Doyle
Programme Manager
Strategic advice

Becci Petch
Trial Coordinator
Study Set up and day to day queries

Amber Cole
Senior Trial Administrator
Day to day queries, 2 week status update checks

Bjoern Schukowsky
Trial Administrator
Screening logs, status updates CRF reminders

HORIZONS@soton.ac.uk
Any questions