How patient advocates and researchers work together in PRECISION* to identify low-risk ductal carcinoma in situ (DCIS) that may not need aggressive treatment

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Background: Ductal carcinoma in situ (DCIS) now accounts for 15-25% of screen-detected ‘breast cancers’ in over 60,000 women annually worldwide. Most receive invasive breast cancer (IBC) treatments, with questionable benefit and many complications, including financial burdens. Studies show most DCIS never becomes IBC, even if left untreated. PRECISION,* an international consortium, of clinicians, scientists and patient advocates, studies DCIS biology to distinguish low-risk from high-risk DCIS to build confidence in Active Surveillance (AS) as an option for low-risk DCIS. Patient advocates are fully integrated into PRECISION and 3 national clinical trials: LORD(NL), LORIS(UK) and COMET(US) studying whether or not AS is equivalent to surgery for low-risk DCIS. PRECISION uses samples from each trial and other cohorts.

Methods: The Patient Advocate Involvement Panel (PAIP) includes women from NL, UK, and US. PAIP helps:

- Foster teams for better outcomes for women with DCIS.
- Design informational tools for clinicians and patients.
- Share international differences in services, culture, and expectations.
- Measure patient involvement impact.

PAIP participates in Steering Group, Work Packages, and communications, including: conferences, reviews, website and newsletter content, interviews, publications, and social media campaigns.

Results: PAIP has helped: a) develop PRECISION information; b) offer patient-oriented ideas/collaborations; c) resolve international contract barriers; d) identify additional cohorts; e) suggest recruitment improvements; f) give survey feedback; g) co-author publications; h) build relationships with PhD’s/postdocs; and i) engage the public/clinicians on DCIS dilemmas in each country.

Conclusions: We need to better understand DCIS subtypes, stratify associated risks for IBC, harmonize communication, and improve pathology standards within and between countries. PAIP works closely with PRECISION researchers and communicates evidence about risk factors for women who may or may not need treatment for DCIS.

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

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Introduction: Outcomes in early stage breast cancer continue to improve, with increasing numbers of survivors living for many years after diagnosis. Assessment of quality of life has traditionally focused on short-term effects of disease and/or treatment, often in late stage cancer, with less emphasis on issues and challenges facing long-term survivors.

Aims/objectives: The Add-Aspirin trial, an international study assessing use of aspirin for prolonging survival following breast cancer surgery, presents an important opportunity to explore these issues.

Methods: Add-Aspirin is a double-blind, phase III trial recruiting patients with node positive or high risk node negative breast cancer who have undergone curative surgery and appropriate (neo)adjuvant treatment. Participants are randomised to 100mg aspirin, 300mg aspirin or placebo, to be taken daily for 5 years. The trial opened in 2015, with a target recruitment of 3660 participants, of whom 2800 have been randomised to date from 170 centres across the UK, India, and Ireland. Long-term follow-up to 10 years is planned (via routine data collection in the UK). Newly-developed EORTC survivorship questionnaires (both general and breast cancer-specific; QLQ-SURV, QLQ-BR-SURV40) will be completed by participants at 2 and 5 years to address key issues for survivors, including fatigue, mental health, peripheral neuropathy, menopausal symptoms and weight gain. The diversity of the trial cohort and data collection will allow assessment of factors influencing these issues (demographics, lifestyle (including exercise), comorbidities, disease stage and treatment pathway), as well as patterns over time.

Results: Recruitment to the trial is ongoing and will complete in 2020 (primary analysis 2026).

Conclusions: Add-Aspirin presents an important and unique opportunity to explore the issues facing breast cancer survivors in the longer term, to inform future research and interventions in this area. The efficient use of the existing cohort and infrastructure will help to maximise the scientific value of the trial.
PT3

PIONEER - Pre-operative wIndOw study of letrozole plus Progesterone receptor agonist Megestrol Acetate versus letrozole alone in post-menopausal patients with OEstrogen Receptor-positive breast cancer

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Introduction: Pre-clinical studies have identified functional ‘cross-talk’ between the receptors for oestrogen (ER) and progesterone (PR) in breast cancer (Mohammed et al., 2015). Addition of a PR agonist to anti-oestrogen therapy directly modifies ERα chromatin binding and transcription in breast cancer cells, and is anti-proliferative in both in vitro and in vivo models. A semi-synthetic progesterone derivative, Megestrol Acetate (MA) is licensed for use in metastatic ER+ breast cancer, and is also used at a lower dose to ameliorate endocrine therapy-related hot flushes.

Aims/Objectives: PIONEER is evaluating the anti-proliferative effect of combining MA with anti-oestrogen therapy (letrozole – LET) to determine the value of a follow-on adjuvant study.

Trial design: PIONEER is a three-arm, open label, multi-centre, randomised phase II pre-surgical window trial evaluating effects of 15 days of preoperative therapy with LET ± MA in postmenopausal women with newly diagnosed, ER+ HER2- primary breast cancer.

Table: 3-arm randomisation

<table>
<thead>
<tr>
<th>Trial Arm</th>
<th>Treatment schedule</th>
<th>Ratio</th>
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<tbody>
<tr>
<td>Arm A</td>
<td>LET 2.5mg daily</td>
<td>2</td>
</tr>
<tr>
<td>Arm B</td>
<td>LET 2.5mg daily + MA 40mg daily</td>
<td>3</td>
</tr>
<tr>
<td>Arm C</td>
<td>LET 2.5mg daily + MA 160mg daily</td>
<td>3</td>
</tr>
</tbody>
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The primary endpoint is percentage change in proliferation between baseline and day 15 tumour biopsies (measured by Ki67 immunohistochemistry (IHC)). Secondary endpoints include: safety
endpoints and IHC for Aurora Kinase-A, Caspase-3, Androgen receptor/PR and Epithelial-Mesenchymal Transition markers. Exploratory endpoints include transcription factor mapping of ERa and PR (ChIP-seq), on paired fresh-frozen tumour samples. Based on results from previous clinical trials, a mean 66% reduction in Ki67 is anticipated for arm A, and 77.5% reduction for arms B and C, based on preclinical data. A recruitment total of 189 patients is required. Patients are currently being recruited across 10 UK sites; 102 patients have been recruited as of September 2019.
OPTIMA: a prospective randomised trial to validate tumour gene expression test-directed chemotherapy decisions in high-risk hormone-sensitive early breast cancer

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Introduction: Multi-parameter tumour gene expression assays (MPAs) are widely used to estimate individual patient risk and to guide chemotherapy use in hormone-sensitive, HER2-negative early breast cancer. The TAILORx trial supports MPA use in a node-negative population. Evidence in node-positive breast cancer is limited. OPTIMA (Optimal Personalised Treatment of early breast cancer using Multi-parameter Analysis) (ISRCTN42400492) is a prospective international RCT designed to validate MPA's as predictors of chemotherapy sensitivity in mostly node-positive early breast cancer.

Methods: Women and men age 40 or older with resected ER-positive, HER2-negative invasive breast cancer and up to 9 involved axillary lymph nodes are eligible to join OPTIMA. Randomisation is to standard management (chemotherapy and endocrine therapy) or to MPA-directed treatment using the Prosigna test. Those with a Prosigna Score >60 receive standard management whilst those with a low score are treated with endocrine therapy alone. Endocrine therapy for pre-menopausal women includes ovarian suppression. More than 1 tumour may be tested if participants have multi-focal disease. The co-primary outcomes are: (1) Invasive Disease Free Survival (IDFS) and (2) cost-effectiveness. Secondary outcomes include IDFS in patients with low-score tumours and quality of life. Recruitment of 4500 patients over 5 years will permit demonstration of 3% non-inferiority of test-directed treatment, assuming 5-year IDFS of 85% with standard management. An integrated qualitative recruitment study addresses recruitment challenges.
**Results:** The OPTIMA main trial opened in January 2017. Overall recruitment at 1 October 2019 was 1289; 92% had axillary node macro-metastases. Median time from consent to treatment allocation was 12 days (IQR 10-14 days). Prosigna tests have been performed on 709 tumours for 638 participants randomised to MPA-directed treatment; 59% luminal A, 38% luminal B and 3% non-luminal (1% were ineligible on receptor retesting, routine for non-luminal tumours). Of the 65 (10%) participants with >1 tumour tested, 19 (29%) had discordant scores, subtypes or both. 67% of participants randomised to MPA-directed treatment have been allocated to endocrine therapy only.

**Conclusion:** OPTIMA is one of two large scale prospective trials validating the use of test-guided chemotherapy decisions in node-positive early breast cancer. It is expected to have a global impact on breast cancer treatment.

**Funding:** OPTIMA is funded by the UK NIHR HTA Programme (10/34/501). Views expressed are those of the authors and not those of the HTA Programme, NIHR, NHS or the Department of Health.

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Correlations between and molecular drivers of Oncotype DX, Prosigna, EndoPredict and Breast Cancer Index: a TransATAC study

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Introduction: Oncotype DX Recurrence Score (RS), Prosigna PAM50 ROR score, the EndoPredict score (EP/EPclin) and the Breast Cancer Index (BCI) all provide substantial molecular prognostic information however there is incomplete information on the concordance between them and their molecular drivers.

Aims: To assess (i) the correlation between all four scores in TransATAC and (ii) the degree to which each of the scores is driven by proliferation, oestrogen signalling, HER2 signalling and invasive properties insomuch as these are reflected by each component module of the RS.

Methods: Data was available for all four molecular scores from 785 patients with ER+/HER2- primary breast cancer treated with 5 years’ tamoxifen or anastrozole in TransATAC. The clinical features included in the final scores of EP and ROR were omitted in this study. Scores were measured by the respective manufacturers. Spearman rank correlation was used.

Results: Correlations were moderate to strong for RS vs EP (r=0.63), ROR vs EP (r=0.68), ROR vs BCI (r=0.74) and EP vs BCI (r=0.67) but weak for RS vs ROR (r=0.32) and RS vs BCI (r=0.35). Correlation between each score with individual RS modules are in the Table. ROR, EP and BCI correlated most strongly with the proliferation module but RS with the oestrogen module.

<table>
<thead>
<tr>
<th>Molecular score</th>
<th>RS module</th>
<th>RS</th>
<th>ROR EP</th>
<th>BCI</th>
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</thead>
<tbody>
<tr>
<td>Proliferation</td>
<td>0.36</td>
<td>0.86</td>
<td>0.71</td>
<td>0.74</td>
</tr>
<tr>
<td>Oestrogen</td>
<td>-0.79</td>
<td>0.00</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HER2</td>
<td>-0.04</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Invasion</td>
<td>0.26</td>
<td></td>
<td>0.14</td>
<td>0.15</td>
</tr>
</tbody>
</table>

Conclusions: In contrast to common thinking, RS is driven only weakly by proliferative features and more by those related to ER/PR pathways. The EP, BCI and particularly ROR are dominated by proliferative features. These relationships contribute to differences in the prognostic performance of these tests.
Resource to Prepare patients for deep Inspiration breath hold: The RESPIRE project

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Introduction: Incidental irradiation of the heart during radiotherapy can have long-term consequences. Deep Inspiration Breath Hold (DIBH) is used for patients receiving radiotherapy for breast cancer to reduce heart doses. Using DIBH, mean heart dose can be reduced by between 29-67% compared with free breathing; differences in dose reduction may be due to patient anatomy or variability in chest expansion achieved at an individual level. A recent survey identified patient compliance, ability to hold their breath for the required time, and reproducibility of breath hold as major challenges to implementing DIBH. Between 12-21% of patients are reported to find the technique challenging. While coaching has been shown to reduce maximum heart dose compared with non-coached patients, formal coaching is not typical in most radiotherapy centres and no standard patient resource is available to support practice prior to radiotherapy planning.

Study Aim: To develop a series of instructional videos to enhance the number of patients that can achieve breath hold, improve patient self-efficacy and patient satisfaction with care.

Method: A co-design methodology involving patient representatives and health practitioners (HCP) was used to develop a series of instructional videos and podcasts. Co-design workshops were audio recorded and transcribed verbatim. Video scripts were based upon themes identified through framework analysis. Patient representatives participated in video scripting and appeared in the videos.

Results: Key themes from the PPI workshop included: information needs; positioning during radiotherapy; and pre-treatment readiness. Additional themes from the HCP workshop included current DIBH service challenges and teaching the DIBH technique. Five videos and two podcasts were developed.

Conclusion: Participatory co-design facilitated video development to support a more effective DIBH experience. Based on initial feedback from patient representatives and HCPs the videos are both suitable and usable. An evaluation will follow to assess the resources’ effectiveness in supporting breath hold capability.
Effects of tumour-specific cyclase-associated protein-1 expression and body constitution on clinical outcomes in patients with early breast cancer

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Introduction: Obesity induces molecular changes that may favour breast cancer progression, including metastatic spread, and consequently lead to impaired survival outcomes in breast cancer patients. Expression of Cyclase-Associated Protein-1 (CAP1), an actin regulatory protein and functional receptor for the obesity-associated adipokine resistin, has been associated with poorer cancer prognosis.

Aims: The primary objective is to investigate the interplay between body composition and CAP1 tumour expression regarding breast cancer outcome through long-term survival analyses.

Methods: Tumour-specific CAP1 levels were evaluated by immunohistochemistry among 718 women with primary invasive breast cancer within the population-based prospective Malmö Diet and Cancer Study. Kaplan-Meier and multivariable Cox proportional hazards models were used to assess survival differences in breast cancer-specific survival (BCSS) and overall survival (OS) according to body composition and CAP1 expression.

Results: Study participants were followed for up to 25 years (median 10.9 years), during which 239 deaths were observed. Patients with low CAP1 tumour expression displayed anthropometric measurements indicating an unhealthier physique (wider waist and hip, higher body mass index and body fat percentage). Low CAP1 expression was associated with unfavourable tumour characteristics (higher histologic grade, high Ki67, and oestrogen receptor negativity). Overall, patients with low tumour-specific CAP1 expression had impaired BCSS (adjusted HR (HRadj)=0.52, 95% CI 0.31-0.88) and OS (HRadj=0.64, 95% CI 0.44-0.92) compared to patients with strong expression.

Conclusions: Low CAP1 tumour expression was associated with higher body fatness and worse survival outcomes in breast cancer patients, demonstrating a possibility of CAP1 as a biomarker for breast cancer prognosis.
Improving outcomes for Women diagnosed with early breast cancer through adherence to adjuvant Endocrine Therapy (SWEET)

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Introduction: Five years of adjuvant endocrine therapy (AET) substantially reduces risks of recurrence and mortality in estrogen-receptor (ER) positive early breast cancer. However, adherence is suboptimal: 20% of women show poor adherence at two years and 50% at five years. No effective interventions to support women with AET adherence currently exist.

Aim: To develop and evaluate an intervention to reduce poor adherence to AET, improve cancer-specific health-related quality-of-life (HRQoL) and reduce long-term recurrence in women with ER-positive breast cancer.

Methods: Workstream (WS)1 will iteratively develop a person-centred, evidence-based, theoretically-informed intervention to support AET adherence. This will include: a tailored, face-to-face consultation with a trained health professional soon after AET prescription; an app/website including a symptom monitoring tool and other support mechanisms; a three-month follow-up telephone consultation to address any emerging concerns; and regular email/text contact. WS2 will assess the feasibility and acceptability of the intervention. WS3 will deliver a RCT with an internal pilot and process evaluation. 1018 eligible women at medium/high risk of recurrence will be randomised to usual care or intervention+usual care. Adherence, cancer specific HRQoL, and potential mediators, will be measured at 6, 12 and 18-months post-randomisation. WS4 will assess cost-effectiveness of the intervention. WS5 will use theory, qualitative research and stakeholder involvement to develop a pathway to impact and inform potential for scale-up within the NHS. WS6 will assess effectiveness in reducing recurrence at five years. PPI will be integral throughout.

Results: This project will start February 2020.

Conclusion: More than 11,500 women die from breast cancer annually in the UK. This programme offers real potential to reduce breast cancer recurrences and deaths thereby benefiting patients, the NHS and society. Wider potential can be envisaged in relation to supporting adherence to other anti-cancer oral therapies and informing studies looking at new approaches to cancer follow-up.
ATNEC - Axillary management in T1-3N1M0 breast cancer patients with needle biopsy proven nodal metastases at presentation after neoadjuvant chemotherapy ClinicalTrials.gov NCT04109079

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Introduction: The presence of cancer in the axillary lymph nodes on needle biopsy in patients with early stage breast cancer before neoadjuvant chemotherapy (NACT) has been the determinant of the need for axillary treatment (in the form of axillary lymph node dissection (ALND) or axillary radiotherapy (ART)) after completion of NACT. Axillary treatment damages lymphatic drainage from the arm and patients can develop lymphoedema, restricted shoulder movement, pain, numbness, and other sensory problems. NACT results in complete eradication of cancer in the axilla in around 40 to 70% of patients, extensive axillary treatment might no longer be necessary in patients with no evidence of residual nodal disease.

Aim: To assess whether omitting further axillary treatment (ALND and ART) for patients with early stage breast cancer and axillary nodal metastases on needle biopsy, who after NACT have no residual nodal disease is non-inferior to axillary treatment.

Methods: ATNEC is a pragmatic, phase 3, open, randomised, multicentre trial in which participants will be randomised to the standard arm of axillary treatment or the experimental arm of no further axillary treatment. The co-primary outcomes are disease free survival (DFS) and self-reported lymphoedema. Secondary outcomes include arm function, quality of life, axillary recurrence free interval, overall survival and cost-effectiveness. Recruiting 1900 patients will allow demonstration of 3.5% non-inferiority for DFS with 5% 1-sided significance, 85% power, allowing for 7% dropouts and assuming 90% 5-year DFS rate on standard arm. It would allow the detection of 5% differences in proportion of patients with lymphoedema with 90% power, a 5% 2-sided significance and allowing for 25% dropouts.

Results: ATNEC is in set-up and due to open to recruitment summer 2020.

Conclusion: ATNEC offers the potential of reducing unnecessary axillary treatment, its associated side effects and improving patients’ quality of life in the future.
Let’s talk about Sex: Comparing clinician and patient perspectives in the management of sexual difficulties in UK women after breast cancer treatment

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NCRI Breast CSG Patients members identified limited research into the management of symptoms after breast cancer treatment. Up to 70% of breast cancer patients experience sexual difficulties. Normally effective treatment for vulvo-vaginal atrophy and associated sexual arousal and pain difficulties, with Oestrogen replacement, is usually contraindicated in women with oestrogen-dependent breast cancer.

We surveyed 345 breast cancer patients and 126 health care professionals (HCPs). 91% of patients reported having a partner, but only 48% remained sexually active after treatment. 44% of the non-sexually active participants stated breast cancer treatment as the main reason for this. 87% of patient participants experienced sexual difficulties, yet fewer than 14% of HCPs thought that sexual difficulties were that frequent. 38% didn't know that their patients had any sexual problems. Most patients had no discussions with HCPs about the impact of breast cancer treatment on their sexual lives either prior to (85%) or following (82%) treatment. This concurs with HCP survey; only 22% of HCPs reported routinely asking women about sexual concerns. 44% of women were offered no help with sexual concerns. 61% felt a discussion with their specialist nurse about sexual consequences of treatment would have been helpful. HCPs stated the main reasons for lack of discussion of sexual concerns were lack of clinic time, no local referral route, other clinical priorities and lack of knowledge.

Six themes emerged from qualitative analysis of free text:

- Impact on relationships and partner;
- Neglected area especially by HCP;
- Staying alive vs quality of life;
- Needing or wanting more information and or support;
- Unable or difficult to have sex post cancer – due to physical or psychological issues;
- Changes to body image and self-confidence

Results highlight significant unmet needs in women after breast cancer regarding HCP’s provision of information and management support for treatment-associated sexual consequences.