PanDA
Pancreatic cancer Dietary Assessment study

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PanDA? What is PanDA?

- **PanDA**: Pancreatic cancer Dietary Assessment

- **Prospective observational** study of prevalence, assessment and treatment of **pancreatic exocrine insufficiency** in **patients with inoperable pancreatic malignancies**
Pancreatic Exocrine Insufficiency (PEI)

Abdominal pain
Weight loss
Steatorrhea

Symptoms + Faecal elastase

PERT: Pancreatic Exocrine Replacement Therapy
Why is it important to diagnose and treat PEI?

Cancer

Diagnosis of cancer (advanced stage) + Assessment of fitness for treatment (chemo) → Treatment (aim of improving patient’s outcome)
Why is it important to diagnose and treat PEI?

Diagnosis of cancer (advanced stage)

Assessment of fitness for treatment (chemo)

Treatment (aim of improving patient’s outcome)

PDAC

• PEI can impact negatively on patient’s quality of life and fitness, affecting treatment delivery and even response to treatment

• By securing an adequate nutrition, patients may tolerate and benefit more from treatment.
PanDA: Why do we need to involve dietitians?

Audit of our previous clinical practice (2014)

- 183 patients; PDAC/panNETs
- PEI is very frequent in patients diagnosed with pancreatic cancer: 63% of patients had symptoms in keeping with PEI
- Diagnosis based on symptoms; no specific diagnostic technique was used
- Not everyone with symptoms was treated with PERT
- Importance of dietitian input for ALL patients
• Prospective observational study (150 patients)
• Patients diagnosed with PDAC and panNETs

• **Demographic cohort**: How frequent is PEI?

• **Diagnostic cohort**: Breath test. FE1. Which is the best way to diagnose PEI? Can we design a diagnostic panel?

• **Follow-up cohort**: Validation of diagnostic panel. QoL. Patients outcomes

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**The demographic cohort**
N=50 evaluable patients
Assessed at baseline for symptoms of pancreatic enzyme insufficiency (PEI) and nutritional status using data from a standard of care panel of blood tests.

**The diagnosis cohort**
N=50 evaluable patients
Assessed at baseline for symptoms of PEI and nutritional status using data from a standard of care panel of blood tests and a faecal elastase measurement. A breath test will test for PEI.

**The follow-up cohort**
N=50 evaluable patients
Pancreatic enzyme replacement therapy (PERT) prescribed (as req)
PEI diagnostic panel from Step 1 (Diagnostic Cohort) will be validated

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Dietitian input for **ALL patients**
## PanDA: Schedule of events

<table>
<thead>
<tr>
<th>Demographic cohort</th>
<th>Diagnosis cohort</th>
<th>Follow-up cohort</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>First (and only) appointment</strong></td>
<td><strong>First appointment as per demographic cohort</strong></td>
<td><strong>First appointment</strong></td>
</tr>
<tr>
<td>• Symptoms, concomitant meds, PS, comorbidities</td>
<td>1-2 weeks after baseline appointment</td>
<td>• Baseline assessment (symptoms, concomitant meds, PS, comorbidities)</td>
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<td></td>
<td></td>
<td>• Use of designed diagnosis panel for PEI</td>
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<tr>
<td>Collect data from standard of care blood tests for;</td>
<td>• Every activity detailed in the Demographic cohort</td>
<td>• Dietitian assessment (including weight, BMI, MUAC, handgrip strength, SC-test and FAACT–A/CS (with VAS)) and intervention (PERT treatment if required)</td>
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<tr>
<td>• Haemoglobin</td>
<td>• $^{13}$C Breath test</td>
<td>• QoL questionnaires (QLQ-C30 and QLQ-PAN26 +/- QLQ-GLNET21)</td>
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<tr>
<td>• Mean corpuscular volume</td>
<td>• Collect data from standard of care Faecal elastase-1 test</td>
<td>• Test acceptance questionnaire</td>
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<tr>
<td>• INR (international normalized ratio)</td>
<td>• Test acceptance evaluation</td>
<td>• Feedback questionnaire (4-6 weeks later by post)</td>
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<tr>
<td>• Serum total protein concentration</td>
<td>• Cancer treatment follow-up (rate of starting treatment &amp; dose intensity)</td>
<td>• Cancer treatment follow-up (rate of starting treatment and dose intensity)</td>
</tr>
<tr>
<td>• Albumin</td>
<td>• Survival follow-up</td>
<td>• Survival follow-up</td>
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<tr>
<td>• Pre-albumin</td>
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<tr>
<td>• Retinol binding protein</td>
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<tr>
<td>• Cholesterol; inc Total, LDL &amp; HDL</td>
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<td></td>
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<tr>
<td>• Triglycerides</td>
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<tr>
<td>• Amylase</td>
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<td></td>
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<tr>
<td>• Vitamins A, D &amp; E</td>
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<tr>
<td>• HbA1C</td>
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<tr>
<td>• Transferrin</td>
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<tr>
<td>• Ferritin</td>
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<tr>
<td>• Magnesium</td>
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</table>

• Dietitian assessment (including weight, BMI, MUAC, handgrip strength, SC-test and FAACT–A/CS (with VAS)) + (PERT treatment if req)

• Cancer treatment follow-up (rate of starting treatment & dose intensity)

• Survival follow-up

Follow-up appointments

• Dietitian review (including weight, BMI, MUAC, handgrip strength SC-test and FAACT–A/CS (with VAS))

• Symptom monitoring (diary and clinic review)

• PERT treatment & toxicity monitoring (compliance diary and clinic review)

• QoL questionnaires (QLQ-C30 and QLQ-PAN26 +/- QLQ-GLNET21)

• Test acceptance questionnaire

• Feedback questionnaire (4-6 weeks later by post)

• Cancer treatment follow-up (rate of starting treatment and dose intensity)

• Survival follow-up
Charity (PCUK) input for study design / PIS / ICF
  - Type of award: 2015 Clinical Pioneer Award

Sponsor (The Christie NHS FT) approval
Protocol fully developed (with support from dietitian)
Approved by REC (November 2017)

Plan to start recruitment Q2 2018
Full-time dietitian to be appointed (March 2018)
Due preliminary results (demographic and diagnostic cohort by June 2019)

PanDA represents one of the first step towards the development of future leaders on dietetics research in pancreatic cancer.
On behalf of The Christie HPB/NET Team and Dietetics Service…

Thank You!!