The eSMART RCT: Comparing electronic Symptom Management using the Advanced Symptom Management System (ASyMS) with standard care for patients during adjuvant chemotherapy

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Chemotherapy-related symptoms

- Sore mouth/throat
- Flu like symptoms/infection
- Diarrhoea
- Constipation
- Sore hands and/or feet
- Nausea/vomiting
- Pain
- Fatigue
- Paraesthesia

Incidence

Severity
(mild, moderate, severe)*

Bother
(Not at all, a little, quite a bit, very much)

*NCI CTCAE Common Terminology Criteria for Adverse Events

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The Advanced Symptom Management System (ASyMS)

- Mobile phone-based
- Utilises an electronic Patient-Reported Outcomes (ePRO) measure, so ePRO system

Patient completes ePRO symptom questionnaire on mobile phone on a daily basis and whenever he/she feels unwell.

Data transferred to server and subject to clinical risk algorithm.

Amber alert (moderate symptoms)

Red alert (severe or life-threatening symptoms)

Real-time

Alerts transmitted to clinician’s handset.

Clinician logs onto website to review alert and contacts patient.

Automated message prompts patient to check self-care advice.
Project overview

- Repeated-measures, parallel-group, stratified RCT
- Over ≥3 cycles of first-line chemotherapy (CTx) plus up to 1-year follow-up (f/u)

1108 patients with breast cancer, colorectal cancer or lymphoma

Random allocation, stratified by clinical site and cancer type

Intervention group
Uses the Advanced Symptom Management System (ASyMS) during chemotherapy to enable remote, real-time symptom monitoring

Control group
 Receives care as per the clinical site’s standards

Primary end-point:
↓ Symptom burden during CTx

Secondary end-points:
↓ Symptom burden during f/u
↑ HR-QoL (CTx and/or f/u)
↓ Needs for supportive care (CTx and/or f/u)
↑ Self-efficacy (CTx and/or f/u)
↓ Anxiety (CTx and/or f/u)
↓ Work absenteeism (CTx and/or f/u)
↓ Health service access costs
+ Effects on processes of care delivery and clinical practice

Predictive Risk Modelling (PRM)
Outcome measures

- Memorial Symptom Assessment Scale (MSAS)
- Functional Assessment of Cancer Therapy – General (FACT-G)
- Supportive Care Needs Survey SCNS-SF34
- State-Trait Anxiety Inventory – Revised (STAI-Y)
- Communication & Attitudinal Self-Efficacy Scale for Cancer (CASE-Cancer)
- EuroQol (EQ-5D)
- Work limitations Questionnaire (WLQ)
- Client Services Receipt Inventory (CSRI)

Qualitative evaluation

Baseline, Pre each cycle of chemotherapy

Case note reviews

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Recruitment

Overall (1108)

Centres
Austria 1
Greece 3
Ireland 3
Norway 1
UK 4

Breast
Colorectal
Lymphoma
Challenges – at MVCC

Screened 90 patients since May 2016

Not Approached (27)
- 11 - Clinical reasons
- 6 – Non-clinical reason
- 10 – Not eligible (chemo regimen)

- Change in standard care chemotherapy regimens since study conception affects eligibility
  - FOLFOX replaced with XELOX (Colorectal) - 4
  - Weekly paclitaxel replacing FEC-T (Breast) - 6
Challenges – at MVCC

Approached BUT Declined (30 patients)
• 11 – not comfortable with technology
• 2 – wanted control over AOS contact
• 6 – questionnaire burden
• 8 – too much going on
• 3 – not interested

RANDOMISED 32 PATIENT
1 subsequently withdrew
Challenges - MVCC

- Significant Information Governance concerns by NHS Trust during trial set-up

- Recent Cyberattack
  - Trust had no access to internet and thus web portal for 7 days

- Patients reverted to standard care and telephoned AOS
Patient Feedback – MVCC

- Reassuring. I’ll miss it. Nice to have the nurse phone me. Everyone should have a phone like this.

- Easier than phoning up. Reassuring that someone had information on how I feel today.

- It was reassuring to know that my symptoms were being recorded and stored somewhere. I triggered two alerts and received phone calls back with helpful/reassuring advice.

- It made me take my temperature every day, and it was reassuring to know that it was normal.
Thank you

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