eSMART: Randomised controlled trial to evaluate electronic Symptom Management using the Advanced Symptom Management System (ASyMS) Remote Technology for patients with cancers

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WHO: Cancer ‘Tidal Wave’ on Horizon

- 352,197 new cases of cancer diagnosed in people in the UK in 2013
- 162,000 deaths in the UK in 2012 → cause of more than 1 in 4 deaths
- 14.1 million new cases of cancer worldwide in 2012
- 8.2 million worldwide deaths from cancer in 2012
- Incidence worldwide expected to increase by at least 68% by 2030 to 23.6 million new cases per annum

Cancer Research UK
Cancer related symptoms: Negative impact on patient outcomes

- Morbidity
- Mortality
- Quality of Life
- Symptom Burden
- Medicines Compliance
- Anxiety
- Depression
- Physical Functioning
- Supportive Care Needs
- Work Limitations
Shift of care delivery from in-patient towards out-patient care

Evolution of healthcare up until the late twentieth century

Evolution of healthcare since the late twentieth century

Evolution of laboratory medicine up until the late twentieth century

Point-of-care testing for the future

(Price et al., 2010)
Evolution of technology...
....and Healthcare
What are Patient Reported Outcome Measures?

(PROMs)

- A questionnaire that the patient completes
- Gold standard for reporting toxicities

‘..comprise of information from patients about a health condition and its management’ (Lohr & Zebrack, 2009)

‘The distinction between a PRO and an observer – generated report is that the PRO is a self-report made directly by the patient without being made through another party’ (Osoba, 2007)
Project overview

eSMART Model of Care

Personalised & anticipatory care

Real time data transfer

Self-care

Response

Clinical risk algorithm

Amber Alert

Red Alert

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Have you felt sick in the past 24 hours?
(Feeling sick means feeling unwell and nauseated; experiencing nausea)

Είχατε τάση προς έμετο κατά τις τελευταίες 24 ώρες;
(«Τάση προς έμετο» σημαίνει δυσφορία και ανακάτεμα στο στομάχι, ναυτία)
About Chemotherapy

“Adapted from information originally produced by Macmillan Cancer Support”

Chemotherapy is the use of anti-cancer drugs to destroy cancer cells. There are different groups of anti-cancer drugs that can be used. The main group that many people think of as ‘chemotherapy’ is cytotoxic chemotherapy. Cytotoxic means toxic to cells. Chemotherapy drugs are administered either intravenously or orally.

There are over 50 different anti-cancer drugs used in chemotherapy, each with its own, but often two or three different ways of being used.

Greek:

Τι είναι ο καρκίνος;

«Προσαρμογή από κείμενο το οποίο δημιουργήθηκε αρχικά από την οργάνωση υποστήριξης για τον καρκίνο Μακμίλαν»

Τα όργανα και οι ιστοί του σώματος αποτελούνται από μικροσκοπικά δομικά στοιχεία που ονομάζονται κύτταρα. Ο καρκίνος είναι μια ασθένεια των κυττάρων. Ο όρος «καρκίνος» δεν αποδίδεται σε μία και μόνη ασθένεια, με μία και μόνη αιτία και ένα και μόνο είδος θεραπείας. Υπάρχουν πάνω από 200 διαφορετικά είδη καρκίνου και κάθε είδος έχει έξυπνη τον καρκίνο και αντιμετώπιση. Παρ’ όλο που τα κύτταρα στα διάφορα μέρη του σώματος μπορούν να έχουν διαφορετικό ρόλο, είναι σαφέστερο ότι η έλεγχος του καρκίνου είναι ένα από τα πιο πρωτοποριακά στοιχεία που διατηρούνται για την εικόνα του καρκίνου.”
ASyMS device

Clinician handset
ASyMS: Clinician System Access
The eSMART Study

Randomised controlled trial to evaluate electronic Symptom Management using the Advanced Symptom Management System (ASyMS) Remote Technology for patients with cancers: eSMART

Funded by the EU 2014 - 2018 €5,999,991

www.esmartproject.eu  @eSMART_EU

EU funded study testing the ASyMS remote patient monitoring intervention at 11 clinical sites throughout Europe (UK, Ireland, Austria, Norway, Greece)  
10 European and 1 US partner

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- University of Surrey
- University of Dundee
- University of California, San Francisco
- Medical University of Vienna, Austria
- NHS 24
- Kings College London, UK
- University of Athens, Greece
- University of Dublin, Ireland
- Innlandet Hospital Trust, Norway
- The European Cancer Patient Coalition (ECPC)
- Docobo
Objective 1: Examine the effects of ASyMS on patient outcomes for patients with breast, colorectal and haematological cancers during the first 6 cycles of chemotherapy treatment:
- Symptom Burden (primary outcome)
- Quality of Life
- Supportive Care Needs
- Anxiety
- Self-Efficacy
- Work Limitations

Objective 2: Examine the effects of ASyMS on patient outcomes during the survivorship period, one year following chemotherapy treatment.
Objective 3: Assess changes in clinical practice (scalability and implementation) and cost-effectiveness as a result of the ASyMS intervention.

Objective 4: Explore gender- and age-related differences in symptom prevalence and severity, and examine these as influential factors in the implementation of the intervention.

Objective 5: Develop, validate and test predictive risk models (PRMs) to predict the symptoms that people with breast, colorectal and haematological cancers experience during chemotherapy.
The eSMART Study

- Clinical RCT over at least 3 chemotherapy cycles and 1 year follow-up
- Recruitment of >1000 patients
- Patients with breast, colorectal, or haematological cancer diagnosis
- Predictive Risk Model Development
Implementing a European-Wide RCT

• Scoping review
  ➢ Literature & international/national/local guidelines for assessing & managing chemotherapy-related toxicity

• ETHICS
  Multi-site / Multi-country Ethics and R&D approvals

• Translations
  ➢ ASyMS system, PROMS & all supporting study documentation
  ➢ Linguistically validated translation of assessment questionnaires

• Alerts
  ➢ Refined risk algorithms
  ➢ Symptom responses standardised across European sites
• Clinical site provisions
  ➢ Assessment of infrastructure & resource requirements
  ➢ Site trainings (including translated User manual and ‘How To’ video tutorials for ASyMS handsets, ePROMs tablets and web system; establishing a website to log calls for technical support directly with software provider)
  ➢ Feasibility testing and assessment of technological readiness
Use of PRMs in practice – preventative and anticipatory chemotherapy toxicity management

source: http://blog.mymsaa.org/ms-management-of-cognitive-symptoms/
Future possibilities: Connected Health

The number of people using home health technologies will increase from 14.3 million worldwide in 2014 to 78.5 million by 2020.
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