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Evaluation of an e-health intervention for cancer patients support

Submission date
28/10/2011

Recruitment status
No longer recruiting

Registration date
14/11/2011

Overall study status
Completed

Last Edited
13/09/2016

Condition category
Cancer

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Breast and colorectal cancers are two major health problems in developed countries, accounting for nearly 27% of the 3.2 million cancer cases diagnosed in the EU. The majority of people with cancer will receive chemotherapy as part of their treatment and, thus, are likely to suffer chemotherapy-related side effects. Close follow-up and management of such adverse events are of great importance to avoid further and more severe complications in these patients. Thanks to advances in chemotherapy treatment, patients usually stay in their homes while receiving treatment. Side effects are thus dealt with by family caregivers and patients themselves, often with very little support from health professionals. The remote follow-up of chemotherapy-related side effects by means of mobile phones or computers may help these patients reduce the severity of complications by identifying and controlling them earlier and easier. The aim of this study is to find out if the use of a new Web program installed in mobile phones can help cancer patients receiving chemotherapy to better control the side effects of the treatment. The researchers hope to learn more about how this mobile phone-supported system affects the control of side effects, patients' quality of life, number of hospital admissions, and visits to the emergency department. Besides, the researchers hope to find out if patients and health professionals feel comfortable using this new electronic communication system.

Who can participate?
Patients aged 15 or over with breast or colorectal cancer who are about to start a new chemotherapy treatment

What does the study involve?
All participants fill in three short questionnaires at the beginning of the study. It takes around 15 minutes to fill in all the questionnaires. Participants are randomly allocated to either use the phone system or to receive the usual medical care. Participants in the phone group are trained on the use of the phone system. Twice a day they fill in a short questionnaire on side effects using their mobile phone or PC. According to the symptoms they report, text messages or videos are sent back to them. Should the symptoms become serious, a nurse contacts them. They also receive the usual medical care. Additionally, participants may be selected for an interview with a member of the scientific team at the beginning and at the end of the study. Participants also fill in three more questionnaires at specific times during the study.

What are the possible benefits and risks of participating?
Participants in the group using the mobile phone system will be closely monitored for chemotherapy-associated side effects during the study. It is possible that they may benefit from better support and communication with health professionals during chemotherapy, but this cannot be said for certain until this and further studies are completed. It is possible that the results will be used in the future to support other cancer patients during chemotherapy treatment. This study does not involve any additional treatment, so there are no known risks to participants.

Where is the study run from?
Medical Oncology Department, Donostia University Hospital (Spain)

When is the study starting and how long is it expected to run for?
December 2011 to December 2012

Who is funding the study?
Spanish Ministry of Health, Social Policy and Equality (Spain)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Osteba No. 2010/03

Study information

Scientific Title
Evaluation of an e-health intervention for cancer patients support: a randomised pilot study

Acronym
ONCOMED

Study objectives
Cancer patients may benefit from an e-health intervention which could improve the control of chemotherapy-associated toxicity. Such enhanced toxicity control may in turn result in a reduction of hospital admissions and emergency department visits. We postulate that the use of tele-oncology is feasible for the support of cancer patients and may improve the quality of life of these patients in a way that is beneficial for both, patients and health care professionals.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Local Ethics Committee for Scientific Research (CEIC, Donostia Hospital, Gipuzkoa), 20/07/2011

Study design
One-year randomised single-centre pilot study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Breast and colorectal cancer

Interventions
Intervention group: Patients will complete a Web-based chemotherapy-associated toxicity questionnaire twice a day. The questionnaire is based on the Common Terminology Criteria for Adverse Events (CTCAE) version 4.0 and consists of seven questions. The first six questions deal with capecitabine-associated adverse events and their severity. Other symptoms not covered by previous questions can be reported using an additional open-ended question. The questionnaire also includes a free-text question about patients feelings on a particular day, thus allowing patients psychological assessment. Based on the responses to the questionnaire, the e-health system will assess the severity and evolution of symptoms and alerts will be triggered. Amber

alerts will correspond to non-critical conditions. In these cases, the e-health system will generate automatic real-time messages (texts or videos) aiming at advising the patient on how to manage the specific condition. Should the condition be serious, a red alert will be triggered and a nurse will contact the patient through a phone call. Patients in the intervention group will additionally receive the usual care. Patients in the intervention group will receive specific training on the use of the mobile phone or PC versions of the e-health system.

Control group: Patients will be assigned to a medical oncologist who will coordinate and oversee the patients medical care. In the first medical visit, a complete medical history of the patient will be obtained together with the results of complementary tests, which will allow an accurate diagnosis. Should chemotherapy become the therapeutic option, the doctor will then inform the patient about the treatment. The nurse will provide the patient with oral and written information about the medication, possible adverse effects and the care pathway to be followed. Additionally, the patient will be given information on what to do in the case of high body temperature or uncontrolled side effects. Moreover, the patient will be informed of a nurse hotline which may be accessed for any enquiries or concerns from Monday to Friday from 8:00 a.m. to 15:00 p.m. A visit with the medical oncologist will be arranged before each chemotherapy cycle. During the visit, results of control blood tests as well as patients overall health condition will be assessed. Patients management of side effects will also be evaluated.

The follow-up period for each patient included in the study will be of 6 chemotherapy cycles (approximately four and a half months).

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Feasibility and safety of a new e-health system (Oncomed) for the support of cancer patients during chemotherapy treatment

Secondary outcome measures
1. Effect of Oncomed on chemotherapy-associated toxicity control:
1.1. Number of toxicity-associated interventions
1.2. Toxicity evolution in each patient
1.3. Number of treatment withdrawals due to elevate toxicity
2. Quality of life (EORTC QLQ-C30 questionnaire at baseline and after 3 and 6 chemotherapy cycles)
3. Impact of Oncomed on health service use:
3.1. Number and duration of hospital admissions
3.2. Number of emergency department visits
3.3. Number of specialist care visits
3.4. Number of Outpatient Chemotherapy Unit visits
3.5. Number of primary care visits
3.6. Number of telephone calls
4. Cost analysis
5. Patient and professional satisfaction with the tele-oncology system through qualitative analysis (in-depth interviews and discussion groups)

Overall study start date
01/12/2011

Completion date
01/12/2012

Eligibility

Key inclusion criteria
1. Patients with breast or colorectal cancer of any gender
2. Starting a new chemotherapy regime with Capecitabine or CAPOX (Capecitabine plus Oxaliplatin)
3. Willing to use tele-health technologies
4. Capable of communicating and reading in Spanish

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
40 participants in total (20 patients in the intervention group and 20 patients in the control group)

Key exclusion criteria
1. Paediatric patients (younger than14 years of age)
2. Refusal to participate in the study
3. Patients taking part in another clinical trial
4. Those unable to use Information and Communication Technologies (ICTs)
5. Cognitive impairment
6. Physical disabilities preventing participants from using the e-health system
7. Patients with other tumour locations in addition to those specified under the inclusion criteria
8. Patients undergoing radiotherapy treatment
9. Those with life expectancy less than 6 months

Date of first enrolment
01/12/2011

Date of final enrolment
01/12/2012

Locations

Countries of recruitment
Spain

Study participating centre
Olaguibel 38
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Spain
01004

Sponsor information

Organisation
Quality Agency for the Spanish Health System (Spain)

Sponsor details
Spanish Ministry of Health
Social Policy and Equality
Paseo del Prado 18-20
Madrid
Spain
28071

Sponsor type
Government

Funder(s)

Funder type
Government

Funder Name
Spanish Ministry of Health (Spain) - Social Policy and Equality (Ref. Osteba No. 2010/03)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration