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An evaluation of an Advanced Symptom Management System to monitor and manage chemotherapy-related toxicity

Submission date	Recruitment status	[_] Prospectively registered
12/06/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
19/07/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
09/05/2012	Cancer	

Plain English summary of protocol
http://cancerhelp.cancerresearchuk.org/trials/study-looking-at-system-using-mobile-phones-help-people-cope-side-effects-radiotherapy-for-lung-cancer-symptoms-asyms-r

Study website
http://www.cancercare.stir.ac.uk/projects/asyms.htm

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Evaluation of a mobile phone-based, advanced symptom management system (ASyMS©) in the management of chemotherapy-related toxicity

Acronym
The ASyMS study

Study objectives
The hypotheses of the study are:
1. The mobile phone system will provide a more accurate reflection of chemotherapy toxicity at home
2. The mobile phone system will provide a better means of monitoring potentially dangerous toxicity, with rapid access to input from the clinical site

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved by Fife and Forth Valley Research Ethics Committee, reference number 05/S0501/81. Approval was granted in August 2006

Study design
Randomised controlled study design

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

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

Colorectal, breast and lung cancer

Interventions
This study will evaluate the effectiveness of using a mobile phone in the home, monitoring and symptom management of patients receiving chemotherapy for colorectal cancer, lung and breast cancer. Participants in the control group receive standard care and are asked to complete a paper copy of the symptom questionnaire at designated time points throughout the study.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Changes in chemotherapy toxicity as a result of use of the mobile phone system and supporting information technology (IT) infrastructure

Secondary outcome measures
Symptom outcomes that will be used for future statistical power calculations

Overall study start date
01/12/2005

Completion date
01/11/2006

Eligibility

Key inclusion criteria
1. A diagnosis of breast, lung or colorectal cancer
2. Commencing a new course of chemotherapy treatment (defined as those patients commencing a new chemotherapy regime irrespective of stage of disease or line of treatment)
3. Receiving out-patient chemotherapy
4. Aged 18 years or over
5. Written informed consent given
6. Able to read and write English
7. Deemed by members of the clinical team as being physically and psychologically fit to participate in the study

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex

Not Specified

Target number of participants
150

Key exclusion criteria
1. Patients who are unable to meet the above criteria
2. Patients who do not agree to give access to their case notes

Date of first enrolment
01/12/2005

Date of final enrolment
01/11/2006

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Cancer Care Research Centre
Scotland
United Kingdom
FK9 4LA

Sponsor information

Organisation
University of Stirling (UK)

Sponsor details
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+44 (0)1786 473171
research@stir.ac.uk

Sponsor type
University/education

Website
http://www.external.stir.ac.uk/

ROR
https://ror.org/045wgfr59

Funder(s)

Funder type
University/education

Funder Name
Stirling University Research Enterprise

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results:	01/04/2009		Yes	No