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

Submission date	Recruitment status No longer recruiting	Prospectively registered		
12/06/2006		☐ 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

Contact name

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Contact details

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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

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

Stirling Scotland Scotland United Kingdom FK9 4LA +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