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Real-time Electronic Patient Outcome ReporTing of adverse events in UK (REPORT-UK): Phase 3 pilot study

Submission date	Recruitment status	[X] Prospectively registered
18/06/2014	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
02/07/2014	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
26/10/2022	Cancer	

Plain English summary of protocol

Background and study aims

It is very important that any side effects or symptoms people have during clinical trials are reported. Doing this helps researchers to see how safe a treatment is. It also contributes to guidelines on how to prescribe a drug, and to information for patients. In this study, researchers are developing a questionnaire that can be filled out from home using the internet or telephone to report these symptoms and side effects. This means any problems can be recorded straight away, rather than waiting until the next clinic appointment. This project is testing whether an electronic system (using the internet or telephone) is acceptable and used by cancer patients receiving treatment to report any symptoms, side effects and their quality of life on a regular basis during a 3 month period. The research team have already spoken to patients about what types of questions to ask and this stage of the project aims to see how the system will work in practice - for example whether patients use the system and how they find using it.

What does the study involve?

Patients are approached during their routine hospital appointments. The researcher explains the different ways of completing the symptom/quality of life questionnaires from home using the internet and/or telephone. Basic training is given on how to use the systems. Patients are asked to log in to one of the systems from home once a week for three months to answer questions about their symptoms and side effects. Once a month they are also be asked to complete some extra questions about their general quality of life. At the end of the study, patients may also be asked to take part in an interview or complete a feedback form to find out what they thought about the research and the symptom reporting system they used.

What are the possible benefits and risks of participating?

There are no immediate direct benefits to those taking part in this study, but the results will be used to help people with cancer in the future. There are no anticipated risks of taking part in this study - it does not affect the usual care or treatment patients receive in any way. The study is not replacing usual care so all symptoms and side effects should continue to be reported to clinical teams in the usual way (e.g. emergency contacts).

Where is the study run from?
St James's University Hospital, St James's Institute of Oncology (UK)

When is the study starting and how long is it expected to run for?
July 2014 to January 2016

Who is funding the study?
Cancer Research UK

Who is the main contact?
Dr Fiona Kennedy
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https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-developing-questionnaire-people-could-use-home-report-problems-during-cancer-treatment-report-uk-phase-1

Study website
www.report-uk.leeds.ac.uk

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
16823

Study information

Scientific Title
REPORT-UK: Pilot study to assess feasibility and compliance of electronic based system for patients to remotely self-report AEs and other PROMs in UK cancer clinical trials

Acronym
REPORT-UK: Phase 3 pilot study

Study objectives
Reporting of adverse events (AEs) is essential in clinical trials. The current system for reporting AEs, the Common Terminology Criteria for Adverse Events (CTCAE), relies on the clinicians interpretation of patient symptoms. The importance and added value of patient self-reports of AEs and Patient Reported Outcome Measures (PROMs) has been recognised by clinicians, regulatory authorities and health-care commissioners, but robust and cost-effective data collection methods are needed. This project is part of a research programme aiming to develop, introduce and evaluate the feasibility and acceptability of an electronic system for patients to remotely self-report AEs and other PROMs in UK cancer clinical trials (REPORT-UK).

Aims and objectives:
1. To evaluate feasibility and patient compliance with using an internet-based or telephone-based system for collecting patient-reported AEs data and other PROMs (EORTC QLQ-C30)
2. To report the proportion of expected weekly AE reports completed
3. To test the complete IT platform including the patient and research staff interface, and the integration of REPORT-UK data with a standard clinical trial database
4. To explore implementation issues through patient and staff interviews

Ethics approval required
Old ethics approval format

Ethics approval(s)
Yorkshire & The Humber - Leeds East, 18/06/2014, ref: 14/YH/0181

Study design
Validation of investigative therapeutic process

Primary study design
Observational

Secondary study design
Longitudinal study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet

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

Health condition(s) or problem(s) studied
Topic: Cancer; Subtopic: All Cancers/Misc Sites; Disease: All

Interventions
The aim is to recruit a sample of 252 cancer patients from St James's University Hospital, Leeds and University Hospitals Bristol NHS Foundation Trust with either early or metastatic disease receiving chemotherapy, targeted agents, hormonotherapy, radiotherapy or surgery. Participants will be asked to take part in a prospective longitudinal study involving electronic (internet/IVRS) completion of self-reports for up to 3 months during treatment.

Participants will be asked to complete weekly symptom reports (21 common symptom questions) via their chosen method (internet and/or IVRS). Once a month participants will also be asked to complete quality of life (EORTC QLQ-C30). Reports on AEs will be attached to medical notes for clinicians. Interviews with participants and staff will take place at the end of the study.

Follow Up Length: 3 month(s)

Intervention Type
Other

Primary outcome measure
1. Number of patients potentially eligible, number recruited and reasons for non-recruitment; Timepoint(s): End of study

Secondary outcome measures
1. Number of and timing of participant withdrawals from follow-up data collection and reasons for withdrawal; Timepoint(s): End of study
2. Proportion of expected weekly AE reports completed; Timepoint(s): End of study

Overall study start date
20/07/2014

Completion date
07/01/2016

Eligibility

Key inclusion criteria
1. Cancer patients undergoing treatment with curative or palliative intent within the following treatment groups and corresponding cancer sites:
1.1. Chemotherapy: breast, ovarian, bladder, colorectal, leukaemia
1.2. Targeted agents (tyrosine kinase inhibitors, monoclonal antibodies): renal, myeloma, lymphoma, leukaemia, advanced breast cancer
1.3. Hormonotherapy: breast, prostate
1.4. Radiotherapy or chemoradiotherapy: prostate, lung, head and neck, oesophageal, rectal
1.5. Surgery: oesophageal, gastric, pancreas, liver resections, colorectal, lung

2. Patients receiving chemotherapy must be within their first two cycles of treatment
3. Patients receiving radiotherapy must be at the beginning of their treatment
4. Patients scheduled for surgery or within 1 month of discharge postsurgery
5. Able and willing to give informed consent
6. Able to read and understand English
7. Access to a touch tone telephone and/or computer with internet
8. Aged 18 years or over

Target Gender: Male & Female ; Lower Age Limit 18 no age limit or unit specified

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 252; UK Sample Size: 252

Total final enrolment
249

Key exclusion criteria
1. Patients under the age of 18
2. Patients with overt exhibition of psychopathology or serious cognitive dysfunction which would impede study participation
3. Patients taking part in another clinical trial where there is a requirement to complete extensive quality of life questionnaires

Date of first enrolment
20/07/2014

Date of final enrolment
07/10/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

University Hospital Bristol NHS Foundation Trust
St James's Institute of Oncology
Leeds
United Kingdom
LS9 7TF

Sponsor information

Organisation
University of Leeds (UK)

Sponsor details
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governance-ethics@leeds.ac.uk

Sponsor type
University/education

ROR
https://ror.org/024mrxd33

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK; Grant Codes: C7775/A14384

Alternative Name(s)
CR_UK, Cancer Research UK - London, CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location

United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal

Intention to publish date
31/07/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Galina Velikova (G.Velikova@leeds.ac.uk)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		02/03/2017	08/03/2017	No	No
Plain English results			26/10/2022	No	Yes
HRA research summary			28/06/2023	No	No