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eRAPID cognitive interview study

Submission date 28/07/2011	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 02/12/2011	**Overall study status** Completed	
Last Edited 25/10/2022	**Condition category** Cancer	

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-looking-developing-new-questionnaire-about-side-effects-treatment-eRAPID

Study website
http://erapid.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
10522

Study information

Scientific Title
Reviewing the validity of items for patients to self report adverse events: A patient cognitive interview study

Acronym
eRAPID

Study objectives
To review selected items for self-reporting of adverse events (AE) for acceptability, comprehension and clinical meaningfulness in a sample of breast, lung, renal, gynaecological and colorectal and cancer patients undergoing treatment at the Bexley Wing at St James University Hospital. The study will result in a bank of appropriate items reviewed for face and content validity, cultural relevance and comprehensively reflect local patient experience for remote self-report in the eRAPID project.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Leeds East Research Ethics Committee, 10/06/2011, ref: 11/YH/0159

Study design
Observational interventional pilot feasibility study

Primary study design
Observational

Secondary study design
Non randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
http://erapid.leeds.ac.uk/index.php/project-1/c-review-the-acceptability-and-applicability-of-items-via-cognitive-interviews-with-patients/iscrn-cogntive-interview-patient-information-sheet/

Health condition(s) or problem(s) studied
Colorectal Cancer, breast cancer, gynaecological cancer, renal cancer, lung cancer

Interventions
We plan to approach 60 gynaecological, renal, breast, lung and colorectal cancer patients attending St James University Hospital Bexley Wing as an inpatient outpatient or day case who are receiving biological and chemotherapy. We will adopt a purposive sampling strategy

balanced by age, gender and tumour group recruiting similar numbers until data saturation is achieved.

Participants will be invited to take part in a cognitive interview, it is anticipated that this will take approximately 1 hour. The cognitive interview will involve two stages:
1. Completion of a questionnaire featuring items questions about the most commonly occurring AE for patients undergoing biological and chemotherapy treatment appropriate to the cancer site
2. Verbal probing which aims to reveal the cognitive processes relevant to answering survey questions and is an ideal way to pre-test questions in participants. The audio recorded verbal probing will apply to questions where patients have had difficulty answering a question and if they have experienced that symptom, to check for false negatives the researcher will probe a random selection of questions where patients have not indicated difficulty or symptomatology. Verbal probes will explore:
2.1. General views about completion of the questionnaire
2.2. Wwording of questions (particularly for cultural literacy)
2.3. Interpretation and comprehension of questions
2.4. Comprehensibility of the response scale,iv) difficulty

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
A bank of adverse event items

Secondary outcome measures
No secondary outcome measures

Overall study start date
18/07/2011

Completion date
05/12/2011

Eligibility

Key inclusion criteria
1. Undergoing chemotherapy and biological treatment with curative or palliative intent
2. Able and willing to give informed consent
3. Have gynaecological, breast, lung, renal and colorectal cancer
4. Male or female
5. Lower Age Limit 18 years

Participant type(s)
Patient

Age group

Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
UK Sample Size: 60

Total final enrolment
60

Key exclusion criteria
1. If taking part in other studies run by the group
2. If not able to read and understand English
3. If exhibiting overt psychopathology or serious cognitive dysfunction which would impede their being able to take part in the study

Date of first enrolment
18/07/2011

Date of final enrolment
05/12/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
St James Institute of Oncology
Leeds
United Kingdom
LS9 7TF

Sponsor information

Organisation
University of Leeds (UK)

Sponsor details

Woodhouse Lane
Leeds
England
United Kingdom
LS9 7TF

Sponsor type
University/education

Website
http://www.leeds.ac.uk/

ROR
https://ror.org/024mrxd33

Funder(s)

Funder type
Research organisation

Funder Name
NIHR - Programme Development Grants (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

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	01/09/2016		Yes	No
Plain English results			25/10/2022	No	Yes