

eRAPID cognitive interview study

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

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>

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

10522

Study information

Scientific Title

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

Acronym

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

Primary study design

Observational

Study design

Observational interventional pilot feasibility study

Study type(s)

Other

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. Wording 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(s)

A bank of adverse event items

Key secondary outcome(s)

No secondary outcome measures

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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

United Kingdom

England

Study participating centre

St James Institute of Oncology

Leeds

United Kingdom

LS9 7TF

Sponsor information

Organisation

University of Leeds (UK)

ROR

<https://ror.org/024mrxd33>

Funder(s)

Funder type

Research organisation

Funder Name

NIHR - Programme Development Grants (UK)

Results and Publications

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Plain English results			25/10/2022	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes