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Are people's perceived risks of medicine side effects affected by the words we use to describe them?

Submission date
13/03/2014

Recruitment status
No longer recruiting

Registration date
23/04/2014

Overall study status
Completed

Last Edited
16/01/2017

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Within the European Union (EU), pharmaceutical licence holders have to make public information on potential adverse effects associated with medicines. EU guidance is that this information should include estimated frequencies of any effects; however, there is uncertainty about the most effective way to do this. In the UK two influential organisations, the MHRA and NICE, have advocated using risk expressions that combine a numerical estimator and a verbal term: e.g. "this side effect is common (it may affect more than 1 in 100 people)". However, there is no apparent evidence to support this recommendation and a concern is that the use of the verbal terms (very common, common, uncommon, rare, very rare) may lead to increased risk estimates. There is also a lack of evidence about the risk qualifier terms. In this case, the recommendation is to use the term 'may', although 'will' would seem more accurate.

Who can participate?
Adults accessing the study via two pages (http://www.cancerresearchuk.org/cancer-help/about-cancer/treatment/cancer-drugs/paclitaxel AND http://www.cancerresearchuk.org/cancer-help/about-cancer/treatment/cancer-drugs/) on the Cancer Help UK website.

What does the study involve?
Participants are randomly allocated to receive information on five side effects of Taxol using either a numerical term only or a combined numerical and verbal term, and using either the word 'will' or the word 'may'. Participants read the information and then estimate the frequency of the 5 side effects and of any side effect occurring. They also give estimates of the severity and 'harmfulness' of the side effects, using 5 Likert scales. Finally participants complete 8 questions intended to measure their numeracy skills.

What are the possible benefits and risks of participating?
Potential benefits of participating are to have a clearer understanding of the risks associated with the medicine, Taxol. There are no risks associated with taking part - just the time given to completing the questionnaire.

Where is the study run from?
The study is the result of a collaboration between researchers at the Universities of York and Leeds, and the website Cancer Help UK (owned by the charity Cancer Research UK). The data are held on a database at the University of Leeds. The PI, Dr Peter Knapp, is based at the University of York, UK.

When is the study starting and how long is it expected to run for?
January 2013 to April 2014

Who is funding the study?
1. University of Leeds (UK)
2. University of York (UK)

Who is the main contact?
Dr Peter Knapp
peter.knapp@york.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Peter Knapp

Contact details
Department of Health Sciences
University of York
York
United Kingdom
LS10 9DD
+44 (0)1904 321675
peter.knapp@york.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
York-Leeds CRUK9

Study information

Scientific Title
What is the effect of two framing variables on perceived risks associated with the medicine Taxol?

Acronym
CRUK9

Study objectives
That participants' risk perceptions will not be influenced by two potential framing influences: first, providing frequency information using numbers alone or a combination of number and words; second, using different verbal qualifiers to convey risk.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Leeds, Institute of Psychological Sciences research Ethics Committee, 22/06/2012, ref: 12-0127

Study design
Factorial trial (2x2) with concealed random allocation of individual participants

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Other

Participant information sheet
There is no PIS - that was approved by the REC. There is brief information on the website before people agree to take part. By agreeing to take part, people are confirming that they have received sufficient information about the study.

Health condition(s) or problem(s) studied
Cancer

Interventions
Information. (Risk frequency information presented in one of four ways).

There are four arms to the trial. Participants read the information about the medicines and then answer some questions about it. That is, 'follow-up' is immediate.
In all four arms of the trial participants receive information about 10 potential side effects of Taxol - the way that that risk is expressed varies across the four trial conditions.

The side effects:

1. May affect more than 1 in 10 people.
2. Very common: may affect more than 1 in 10 people

3. Will affect more than 1 in 10 people.
4. Very common: will affect more than 1 in 10 people.

(The incident rate bands vary according to the SE being portrayed).

The trial is evaluating the effect of adding verbal risk terms to the numerical information. Also, the use of the terms 'may' and 'will' to convey risk.

Intervention Type
Other

Primary outcome measure
1. Estimated frequency of any side effect occurring
2. Estimates frequency of 5 individual side effects

Secondary outcome measures
1. Estimated severity and degree of harm from the side effects
2. Participants' numeracy

Overall study start date
01/01/2013

Completion date
01/04/2014

Eligibility

Key inclusion criteria
Adults (aged 16 or over) accessing the study via two pages (http://www.cancerresearchuk.org/cancer-help/about-cancer/treatment/cancer-drugs/paclitaxel AND http://www.cancerresearchuk.org/cancer-help/about-cancer/treatment/cancer-drugs/) on the Cancer Help UK website.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
318

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/01/2013

Date of final enrolment
01/04/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of York
York
United Kingdom
LS10 9DD

Sponsor information

Organisation
University of York (UK)

Sponsor details
Department of Health Sciences
York
England
United Kingdom
LS10 9DD

Sponsor type
University/education

ROR
https://ror.org/04m01e293

Funder(s)

Funder type
University/education

Funder Name
University of Leeds (UK)

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Funder Name
University of York

Alternative Name(s)
The University of York, York, Ebor, Universitas Eboracensis

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

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	01/04/2016		Yes	No