

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

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| Submission date 13/03/2014 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 23/04/2014 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 16/01/2017 | Condition category Cancer | <input type="checkbox"/> 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
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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

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

Study type(s)

Other

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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**

United Kingdom

England

Study participating centre

University of York

York

United Kingdom

LS10 9DD

Sponsor information

Organisation

University of York (UK)

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

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 |