

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

<b>Submission date</b> 13/03/2014	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 23/04/2014	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 16/01/2017	<b>Condition category</b> 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?
<a href="#">Results article</a>	results	01/04/2016		Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes