

# Talking to teenagers and their parents about randomised trials

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# Difficulties

- Handling uncertainty and other emotions
- Addressing family dynamics
- Discussing randomisation
- Information overload
- Time involved

# Handling Uncertainty

- Difficult in the context of life-threat to help patients feel reassured
- Compounded when doctor's equipoise/ uncertainty extends to choice between 2 treatments or when standard treatment is offered +/- something else
- Difficult to help patients understand that more is not necessarily better

# How to help

- Vital to start with issues that are clear and permit provision of a ‘platform of certainty’
- *“Having looked at all your test results and examined you we know that the best available treatment for you is .....” (standard therapy) and that is what I would normally offer you”*
- *“However we are always trying to improve treatments which is why the best experts have designed a study to test them. Would you like to learn more about this study ?”*

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# Family Dynamics

- Who is the patient ?
- Protectiveness of parents
- Parents with different information needs from each other
- Child/teenager might also have different issues
- Who makes the decision ?
- Chronological age different from intellectual and emotional age

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# Randomisation

- Difficult concept to embrace
- Primary reason for trial refusal
- No 'right' way to describe it
- Descriptions seen as helpful to some are disliked by others (Jenkins and Fallowfield, 2002, 2005)

# Preferences of 600 patients for different descriptions of randomisation

(Jenkins et al, 2005, BJC)

- We reviewed 100 descriptions of randomisation from patient information sheets (PIS) and websites
- 7 descriptions chosen providing a broad range of those in frequent use
- Questionnaires given out by research nurses and clinicians to cancer patients in UK
- 600 questionnaires returned by post

- 1) “...treatment not chosen by yourself or a doctor but by a computer. There is usually a 50-50 chance of receiving either treatment.....” (Royal Marsden Website, 2003)
- 2) “....computer will allocate you randomly (by roll of a dice) ....” (MRC FOCUS PIS)
- 3) “...assigned by chance to investigational group or control group.... ” (NCI Website, 2003)
- 4) “...your specialists will not make the decision themselves, but it will be made by chance...” (BNL Trial PIS)
- 5) “...not chosen by you or your doctor but by a computer like the toss of a coin” (CLL4 Trial PIS)
- 6) “ ...there are at least 2 different groups..and those taking part are put into one group or another... (CancerHelp website, 2003)
- 7) “...a computer will randomly allocate patients ....this is done so each group has a similar mix of patients of different ages, sex, and state of health” (Cancerbackup website, 2003)

# Results

## Clarity of descriptions

No significant differences in choice according to age, sex, previous trial experience or sociodemographic characteristics

## Preferred description

Cancerbackup website most preferred (28%)

## Least preferred

NCI Website (38%) only 3% liked it

(Jenkins et al, BJC, 2005)

## Most disliked statement (NCI)

*“Once you have agreed to enter the trial you will be randomised to a course of treatment. This is a process that assigns participants by chance, rather than by choice, to either the investigational group or the control group.”*

## Cancerbackup's description

*“Once you have agreed to enter a trial, you will be randomised to a course of treatment. This means that a computer will randomly allocate patients to treatment groups in the trial. This is done so that each group has a similar mix of patients of different ages, sex and state of health”*

# EURAMOS 1

*“Randomisation means that you are being put into a group by chance. The group you are put in is done by a computer. Neither you nor your doctor will choose which group you will be put in. You will have an equal chance of being placed in either group”*

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# Information overload

- Most studies show that patients want more information than they are given but this has to be paced and appropriate
- Much emphasis on PIS but many patients do not read them (**Hochhauser 1999, Bjorn,1999**), usefulness correlates with patient education (**Hietanen, 2000**)
- Other research shows that top reason for trial entry is ‘trust in the doctor’ (**Jenkins & Fallowfield, 2000**)
- Implies that verbal communication has greater influence on patients’ decisions than written word

# Information overload

- Amount of information required to elicit truly educated consent undoubtedly a problem
- Information needs may differ depending on personality type of different family members
- Important to signpost, chunk, check and summarise
- When patients are anxious helpful to acknowledge that there is lots to take in and encourage them to ask questions, write things down
- Reminders about PIS and opportunity to speak to research nurse and others again should be given

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- No easy answer
- All clinical trial recruitment is a process rather than one off event
- Explaining standard treatment can be time-consuming and trials an added burden
- A 2 stage procedure is vital

# DVD

- Patient and family are actors
- Jeremy Whelan plays himself !
- Nothing scripted or rehearsed
- Minimal editing done
- Copies of educational materials can be purchased from CRUK Psychosocial Oncology Group website on [www.lifesci.susx.ac.uk/pog/](http://www.lifesci.susx.ac.uk/pog/)