



The University of
Nottingham

Division of Social Research in Medicines and Health



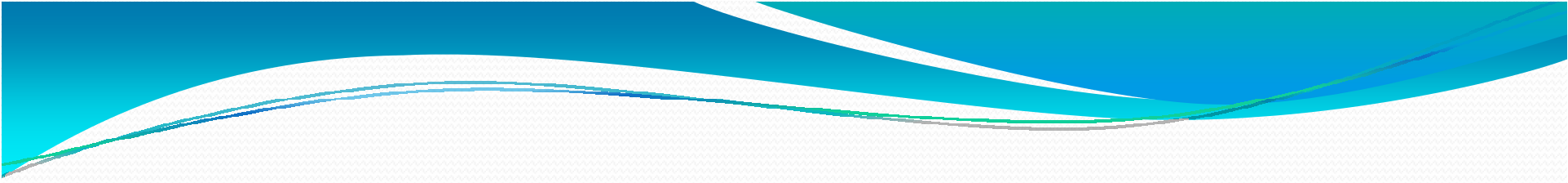
Empowering the patient

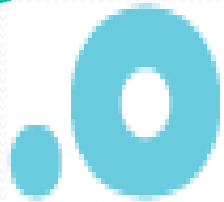
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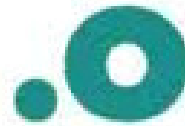
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- We rely on patient's willingness to volunteer
 - Reaching recruitment targets can be a challenge.
 - Patients who volunteer do not always have a clear understanding of trial process or design, despite the best efforts of ethics committees and researchers




healthtalkonline.org
youthhealthtalk.org

- <http://www.healthtalkonline.org/myflv.swf?myFlv=introductionVideos/Clinical%20trials%20ofinal.flv>

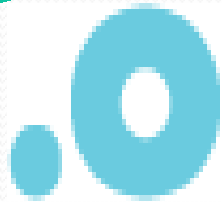
See and hear
people's real-life
experiences of
Clinical Trials



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- Patients should never feel coerced into taking part
 - They should understand the uncertainty and potential risks involved in testing new interventions.
 - Avoid therapeutic misconception
 - ‘It is important not to exaggerate the possible benefits’ and suggests the wording

“We cannot promise the study will help you but the information we get from this study will help improve the treatment of people with [name of condition]”

National Research Ethics Service. Information Sheets & Consent Forms Guidance for Researchers & Reviewers. Version 3.5 May 2009.



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Public awareness and involvement - clinical trials, clinical trials, trials, research, trial design, patient and public involvement, public awareness, research priorities, consent, informed consent : Healthtalkonline

What does personal benefit mean?

- Patient's reasons for taking part are multi-faceted and many people cite benefits which have little to do with direct clinical improvement
 - More relaxed and more frequent appointments
 - Care in a specialist team with expert staff
 - Active engagement in their health monitoring or care,
 - More frequent or intensive monitoring
 - Information about the latest research into their condition
 - Moral or altruistic concerns

What does personal benefit mean?

- Patients weigh up the **physical** and **emotional** benefits they expect from a trial against the **risks** and **time commitment** involved
- People who decided not to take part were also mainly concerned about the balance of personal risk and benefit.
- Yet such benefits are rarely addressed in information given to patients.

Locock L, Smith L Personal benefit, or benefiting others? Deciding whether to take part in clinical trials *Clin Trials February 2011 vol. 8 no. 1 85-93*

What can we change?

- Information sheets are usually very long
- Complex language
- Whilst most were satisfied with information received, some felt it was too complex.
- Gaps in understanding were evident, especially around randomisation.
- Trust in trial staff was high.
- Desire for feedback of trial results was common



Involve patients in design

Public awareness and involvement - clinical trials, clinical trials, trials, research, trial design, patient and public involvement, public awareness, research priorities, consent, informed consent : Healthtalkonline



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Parents of children taking part in trials

- Sometimes the doctors and nurses are almost too apologetic when approaching parents causing some parents to feel a little uncertain about what is being asked of them
- When approaching parents at a critical time, the best way to approach them and inform them will vary from parent to parent.
- Trust and the quality of the relationship with the doctor or nurse plays a huge part when parents are making the decision about enrolling their children.
- Importance of having enough information and not feeling too rushed.



Parents of children taking part in trials

- Suggestions to improve information
 - using fewer acronyms for trial names
 - information that is easy to read with the use of simple explanations,
 - more explanation about the purpose of the trial
 - having time to read information



Parents of children taking part in trials

- information at the child's level, including how procedures are explained
 - e.g. “just a teaspoon” was used to explain how much blood was going to be taken in a blood sample
- Inform parents of trial results
- Being able to communicate with other parents whose children were in the trial
- Use patient representative groups to inform trials





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