This is the authors' final version, post peer-review, of an article published in *Journal of Medical Ethics* 2012;38(12):751-756. The definitive version is available from http://jme.bmj.com/

Supporting positive experiences and sustained participation in clinical trials: looking beyond information provision

Katie Gillies*, PhD, Research Fellow, University of Aberdeen, Health Services Research Unit, Health Sciences Building, Foresterhill, Aberdeen, AB25 2ZD. email: k.gillies@abdn.ac.uk. Tel: +44(0)1224 559698, fax: +44(0)1224554580

Vikki A Entwistle, PhD, Professor of Values in Health Care, University of Dundee, Social Dimensions of Health Institute, Airlie Place, Dundee, DD1 4HJ. email: v.a.entwistle@dundee.ac.uk.

*Corresponding author

Abstract

Recruitment processes for clinical trials are governed by guidelines and regulatory systems intended to ensure participation is informed and voluntary. Although the guidelines and systems provide some protection to potential participants, current recruitment processes often result in limited understanding and experiences of inadequate decision support. Many trials also have high drop-out rates among participants, which are ethically troubling because they can be indicative of poor experiences and they limit the usefulness of the knowledge the trials were designed to generate.

Drawing on recent social-psychological and philosophical-ethical research on trial recruitment and patient participation in treatment decision-making, this paper identifies possibilities for improving communicative support for both initial decisions and ongoing participation in clinical trials. It highlights the potential of a shift in thinking about 'voluntariness', underpinned by relational understandings of autonomy, to encourage more nuanced judgements about the ethics of communication between trial staff and (potential) participants. The paper suggests that the idea of responsively enabling people to consider invitations or requests to participate in particular trials could serve as a general guide to communication. This might help ensure decisions about trial participation are meaningfully informed and voluntary, and that relationships between trial staff and participants contribute to positive experiences of trial participation and ultimately to the generation of the robust knowledge.

(212 words)

Introduction

The norms of research ethics require participation in clinical trials to be 'informed' and 'voluntary'. Strong guidance and regulatory systems for monitoring information provision and consent have been introduced to ensure that standards of informed and voluntary participation are not sacrificed in the pursuit of participant numbers.[1,2] These undoubtedly offer people some protection against being misled or coerced into trials, but they – and associated approaches to trial recruitment - have practical and ethical limitations.[3,4]

This paper draws on recent social-psychological and philosophical-ethical research on trial recruitment and patient involvement in decision making to critique current approaches to ensuring trial participation is informed and voluntary. It identifies possibilities for improving communicative support both for initial decisions for or against participation and for ongoing participation in clinical trials. These possibilities warrant careful consideration because they have potential to promote more meaningfully informed and voluntary consent, and, by enhancing experiences of participation, to reduce participant drop-out and ensure that the resources and effort invested in trials generate robust findings.

Informed consent: current guidance and regulations

Current regulatory guidelines for clinical trials stem from the Declaration of Helsinki.[1] As a set of ethical principles, the Declaration is not legally binding but is endorsed for example by the International Conference on Harmonisation (ICH) guideline for Good Clinical Practice (GCP) and the EU Clinical Trials Directive.[5]

Current guidelines, regulations and practices intended to ensure that consent is 'informed' tend to put more emphasis on the *information provided* to potential trial participants than on the *understanding* these people achieve. They implicitly assume that giving 'competent' people standardised information will suffice. Guidelines suggest information should be provided about (among other things): the fact that the trial involves research; the nature and purpose of the intervention(s) being tested; alternatives; risks and benefits; and the requirement that participation is voluntary. Regulatory regimes usually require that the information be presented in writing and assessed by research ethics committees before use. People who agree to take part must sign consent forms to confirm they have understood the information provided and are participating voluntarily.

Concerns about current approaches

Several concerns have been raised about current guidelines, regulations and associated practices. These relate to: evidence of limited understanding and experiences of inadequate decision support among people invited to participate in trials; the way voluntariness is understood; and the neglect of issues affecting participants' experiences beyond trial entry. We consider these issues primarily in the context of Phase III randomised controlled trials which test interventions that have passed initial safety tests to identify how well they work. Most points also apply to other clinical trials.

Limited understanding and experiences of inadequate decision support

It is increasingly recognised that standardised information provision does not lead to uniform understanding (or even uniformly adequate understandings),[6] and that the self-reports of understanding that people provide in conversations with trial staff and on consent forms may be misleading.[7] Several studies, including qualitative investigations in which people have discussed their experiences of trials they have been invited to join, have shown that, even after receiving information that complies with regulatory guidance, consenting participants sometimes misunderstand key features of trials in which they are enrolled.[6]

Knowledge of the key features of a trial and recognition that participation is optional may not suffice to ensure people make 'good' (informed and personally appropriate) decisions about their participation. Their understanding needs to include an appreciation of the potential implications of trial participation in their own situation and for what matters to them personally.

Although measures have been developed to assess people's understanding or 'decisional capacity' in clinical research contexts, these operationalise understanding in limited ways. Some check people's ability to repeat or recall information without considering their comprehension, and some focus on knowledge of the trial in a general sense without considering their appreciation of the trial's implications for them personally. Their validity is sometimes unclear.[8]

Shortfalls in (potential) participants' understanding can often be linked to problems with both formal trial information resources (participant information sheets etc) and/or conversations involving trial staff.

Formal trial information resources are often quite lengthy. This may be more appropriate for some trial situations and potential participants than others. People who satisfy basic competence criteria have: diverse but often limited literacy skills; varied understandings of their health issues, potential

interventions and clinical trials; and different experiences, attitudes and capabilities relating to decision-making about their healthcare and participation in social activities. Those who are less able to process, appraise and use written information for themselves are more prone to make poor decisions about whether or not to take part.

Current guidance acknowledges that individuals may have *'specific information needs'* and require customized methods of information delivery, but it says little about what forms of customization are acceptable.[2] In practice, trial teams usually default to providing more rather than less information to pass regulatory requirements.[9] Too much information, however, can overburden people, discourage engagement and/or impair decision making.[3,9] Attempts to re-order or condense information presented in formal trial resources may be helpful, but limitations in the assessment of understanding render their overall effects unclear.[6]

The relative inflexibility of formal information resources might be compensated by opportunities for more flexible communication in conversations between potential participants and trial staff (including clinicians involved in recruitment). However, the less readily regulated information provision that occurs in these conversations may itself be problematic. Trial staff might, for example, be more pressured and concerned to recruit participants than to ensure potential participants have a good understanding of key issues. Some staff lack the knowledge and communication skills to facilitate the development of understanding, and various biases may arise in trial staff's presentation of options. An analysis of early consultations about a trial comparing treatments for prostate cancer found that trial staff spent more time discussing some treatments than others, leading potential participants to develop preferences.[10] Corrective action resulted in improved presentations in the later stages of this trial,[10] but in many trials the quality of conversational information provision is unknown. Intensive training to improve communication during trial recruitment consultations can improve staff skills in a number of domains,[11] but such intensive training is not universally given.

Overall, questions about the adequacy of information provision and broader forms of supportive communication for the deeper, personalised understanding and decisional confidence needed for 'good' decision-making seem somewhat neglected in current guidance and practice. This may in part reflect prevailing ways of thinking about 'voluntariness', which tend to limit the forms of support that are recognised as appropriate.[12] We consider this issue next.

Thinking about voluntariness

The requirement for voluntariness is intended to ensure that potential trial participants are not subject to coercion or other unethical influences. This is an appropriate goal, but some ways of thinking about voluntariness reflect an outdated view of the ethical principle of respect for patient autonomy and might impair practical attempts to promote it.[13]

In healthcare contexts, the principle of respect for autonomy is usually understood in terms of respect for autonomous choices, which are defined as choices made intentionally and with sufficient understanding and voluntariness, or freedom from controlling influences.[14] This definition is often understood and used in quite limited ways that at least implicitly rely on the unrealistic assumption that people are rational and isolated individual decision-makers.[12,13,15,16] These understandings and uses seem to neglect key issues in terms of how people consider and consult with others in decision-making.[16] They support a tendency to equate 'voluntary' choice with 'independent' choice, and to think that health professionals should not help in ways that might 'direct' or 'interfere' with individual patients' preferences.[12,13,17]

Thinking in this vein can discourage the provision of some potentially supportive forms of communication. For example, while prevailing ideas about respect for autonomous choices can readily be used to justify clinicians challenging the beliefs a patient exhibits if those beliefs are demonstrably false,[14] it is less clear whether and how they can justify helping a person who understands the key facts but is unsure of their preferences or lacks confidence to choose.[18] It is likely that clinicians' concerns not to interfere lie behind the many anecdotes of patients feeling 'abandoned' when forced to make their own treatment choices. There is some evidence of similar troubling experiences among people who are given information then left alone to decide about trial participation.[19]

Experiences of participation beyond trial entry

Current guidance and most work on communication and experiences of trial participation pays little attention to what happens after people enter trials – at least until trial results are available. However, trials often have problems with participants refusing to accept their treatment allocation after randomisation, not completing data collection, and otherwise 'dropping out'.[20] Some of these problems might be rooted in inadequate support for decision-making about trial entry. There is some evidence that participants who withdraw from trial have difficulties with the trial information.[20] And people who enter a trial with a strong preference for one intervention may suffer from resentful demoralisation and not persist if they are allocated to another intervention.

There are also various reasons why participants' situations, beliefs and expectations may change during the course of the trial. Such changes generate needs for clarification and supportive communication that are not always met.[21]

The drop out of trial participants due to preventable poor experiences and inadequate communicative support from trial staff is ethically troubling for several reasons. Apart from direct concerns about how human volunteers are treated, reduced participant numbers can seriously affect the robustness of the knowledge that the trial was designed to generate.

Thinking ahead: ideas for improvement

The concerns outlined above have prompted several innovative developments by trialists. Insights from recent work on patient involvement in treatment decision-making also suggest possibilities for improvement in trial contexts. We review their potential in this section.

Patient led consultations

A recent study of trial recruitment conversations led to a distinction being made between consultations involving 'recruiter-led' rehearsals of standard lists of topics prioritised by informed consent guidance, and more flexible consultations driven by questions potential participants wanted to discuss after reading participant information sheets.[22] 'Patient led' consultations were associated with higher rates of acceptance of treatment allocation after randomisation.[22] However, this promising strategy might not suit all potential participants: some are likely to struggle to identify and get their agendas addressed in consultations even if recruiters seek to facilitate this.

Decision-support

A range of decision support interventions (DeSIs), or decision aids, have been developed in recent decades to help people facing diverse choices about healthcare options. DeSIs have been evaluated in several treatment and screening contexts and found to have positive effects on knowledge and several other outcomes associated with decision quality. [23] Interest is now turning to the question of whether potential trial participants might benefit from the use of DeSIs within or alongside formal trial information resources. Several authors have hypothesised that DeSIs might: help people to see the structure of the choice(s); facilitate direct comparisons of options (including options to participate or not) by presenting equivalent information about each; and encourage people to think about what matters most to them.[24,25]There have, however, been few empirical tests of their

hypotheses to date. In one study, a decision aid was tested among women who had already agreed to take part in a trial comparing two drugs for Ductal Carcinoma In Situ: these women found it helpful and thought it increased their understanding beyond what they had learned from the trial's approved participation sheet.[26] In another study, an explicit values clarification task of the kind associated with decision aids was tested among healthy women who were asked to consider a hypothetical decision about trial participation. Those who were given the explicit values clarification task evaluated more information in the light of their personal values and expressed lower ambivalence and decisional uncertainty than those who were not.[27]

Given current regulatory requirements, formal evaluations of DeSIs may be difficult to mount in 'live' trial contexts, particularly if they seek to compare DeSIs with current standard approaches.[24] And the design of both DeSIs and evaluation studies will require careful thought and research. If used as stand-alone resources, DeSIs may be too complex for some people unless they are highly sophisticated and interactive, but the development of sophisticated and interactive DeSIs may be too costly to seem warranted in small to medium scale trials. DeSIs may not suffice to avoid or to check for the problems that can arise with people's understandings and preferences relating to trials and the interventions they evaluate. They are also unlikely to substitute for the valued forms of support that people can derive from good interpersonal relationships with healthcare or trial staff, especially in high stakes situations.[28]

Conversational explorations by trial staff of potential participants' treatment preferences might also be helpful. In a recent study, these were shown to promote more informed decisions about participation in a prostate cancer treatment trial.[29] As noted above, however, some ways of thinking about voluntariness tend to discourage this kind of intervention.

Rethinking voluntariness: justifying broader forms of support

Broader forms of supportive communication can in principle be justified as respectful of person autonomy using relational understandings of autonomy which de-emphasise ideas of isolated 'independence' in choice.[15,17] Relational understandings have emerged as philosophers have grappled with the question of what personal autonomy can mean if we take seriously the profound ways in which our social and cultural environments and networks of relationships influence how people can and want to shape their individual lives.[30,31] Relational understandings recognise that our capabilities for autonomy (including skills for self-discovery, self-definition and self-direction) are

socially influenced and can be situationally modified.[30,31] They draw critical attention to the different ways in which our social relationships and interactions – including with family members and clinicians - can support or undermine the development and exercise of autonomy capability,[15,32] and they discourage a simple equation of voluntariness with either selfish or independent or isolated action.[16,17]

Relational understandings highlight the potential value of some professional intervention as supportive of the development and exercise of autonomy by individual patients.[13,15,32] They do not sanction an 'anything goes' approach to communication about trial participation, but can encourage nuanced and context sensitive explorations of the appropriateness of various forms of communication. However, as work on their application in the context of treatment decision-making has highlighted, they are likely to require high communication skill levels and flexible virtuous practice by trial staff to ensure their engagement with each individual is in effect autonomy supportive.[12] This raises questions about whether and how staff should be encouraged to use broader forms of support in practice, and how their practice (as well, perhaps, as the influence of family members) should be monitored.[12,17]

Although it is difficult to monitor the adequacy or appropriateness of trial-related communications in context sensitive ways that give credit to appropriate flexibility, modifications to consent forms might help to some extent. Participants are currently asked to affirm on consent forms that their participation is voluntary. Although their understandings of voluntariness are likely to vary, their responses are generally assumed to be valid. With a little methodological development, questions to both participants and non-participants might serve to monitor how people are invited to join trials. Checks could be made not just on knowledge/understanding but also on experiences of staff support, decisional certainty/uncertainty, decisional confidence/regret, congruence of attitudes and action, and decisional ownership. Potential participants' qualitative comments about the ways trial staff and others communicated with and influenced them could also generate useful insight.

A guiding ethos or approach

Ideas about various text based and conversational information and decision support interventions could perhaps be usefully be integrated within a broader (and more broadly applicable) ethos or approach to communication that could serve to guide the provision of robust but flexible support to people who are invited to take part in trials. One option that has been introduced for communication about screening is the 'consider an offer' approach.[33] Although screening programs

have different objectives than clinical trials, some similar issues arise, and a modified version of the approach might be a useful starting point for thinking about communication in clinical trial settings.

The 'consider an offer' approach for communicating about screening was developed because two prevailing approaches - labelled 'be screened' and 'analyse and choose' – both had significant limitations.[33] The 'be screened' approach aims to persuade people to have screening. It is characterised by: encouragement to be screened; information provision that emphasises the potential benefits of screening and de-emphasises the potential harms; and a lack of recognition that some people might reasonably prefer not to be screened. This approach fails to reflect the benefit-harm profile of screening tests and limits scope for informed choice.[33] Current regulations relating to clinical trials clearly preclude a parallel 'participate' approach for similar ethical reasons. The contrasting 'analyse and choose' approach aims to ensure that individuals make informed choices about screening. It is characterised by the provision of comparative data about the various outcomes of being screened or not. This approach can be criticised for potentially: imposing an unnecessary burden of detailed decision analysis; leading to poor decision making (because too much information and pressure to make the best choice can be unhelpful); and deterring uptake of effective and appropriate screening.[33] These concerns clearly parallel those mentioned above in relation to increasing information provision for potential trial participants, thus leaving them alone to work out whether or not to participate.

The 'consider an offer' approach aims to avoid the pitfalls of 'be screened' and 'analyse and choose' approaches to communicating about screening. It seeks to support personal autonomy without overburdening people with unwanted information and decision-making tasks, and without deterring uptake of effective and personally appropriate screening.[33] The approach involves explaining an offer or recommendation of screening and enabling people to consider that by: providing responsive information and discussion support to facilitate personal assessments of the offer; being clear that even recommended offers might reasonably be declined; and ensuring people feel safe getting the support they need to make a decision that is right for them.[12] Some basic features suggested by the 'consider an offer' approach are given in the box. A similar ethos or guiding approach for communicating about clinical trials might be labelled, 'consider an invitation/request'.

Adoption of the 'consider an invitation/request' ethos or approach would not necessitate any particular communication interventions. It might, for example, be delivered with or without the use of DeSIs or patient led-consultations. It might encourage provision of shorter information resources

and more emphasis on opportunities for responsive communicative support to help people consider their potential participation, but would not dictate that one particular format or combination was right for all trial contexts. The approach is characterised primarily by its grounding in relational understandings of people and their responsibilities and capabilities (especially for autonomy) and by its orientation to ensure that information provision and communication with potential participants (a) enable development of the kinds of understanding required for personally appropriate decision-making and (b) reflect a commitment to promote the kinds of voluntariness in decision-making that can emerge from within personally supportive relationships.

The 'consider an invitation/request' approach requires flexibility to ensure appropriate responsiveness to diverse individuals and situations. This will make it difficult to monitor and evaluate, especially according to the methods usually privileged in considerations of evidence of effectiveness. However, its potential to encourage attention to the overall tone and implication of communication, and to enable diverse people to engage more effectively and confidently in decisions about trial participation warrants careful investigation in practice.

Looking beyond trial entry

The supportive intent of a 'consider an invitation/request' approach could readily be continued beyond the point of trial entry. The ethos, or guiding approach, could be extended into the development and use of communication opportunities at key points in trial participation, for example after delivery of a major intervention or at meaningful chronological intervals during follow up. These communication opportunities could serve multiple overlapping purposes, for example to: remind participants of the aim and key features of the trial; encourage and support contribution to all data collection points; express appreciation for participants' ongoing contributions; and listen to participants' experiences to inform future trial communications. Recurring communication points could allow trial staff to recognise and relate to participants as individuals, and several studies suggest this is valuable. For example, the importance of good organisation and ongoing communication was highlighted in a trial of nutritional interventions for older people,[34] and empathic engagement during the delivery of an intervention contributed to people feeling valued and continuing as participantsin a trial of acupuncture.[35]

Conclusion

There is significant scope to improve on current communication relating to trial participation. Recent social-psychological and philosophical-ethical research suggests a number of possibilities for

development. These include extending communicative support beyond standardised information provision and beyond initial decisions about participation, and adopting an overall ethos or approach to communication that is oriented to enable people to understand and respond in personally appropriate ways to invitations/requests to participate in trials.

There are, of course, resource implications associated with these possibilities. It costs, for example, to develop decision aids, to promote trial staff's familiarity with relational understandings of autonomy, to train them in advanced communication techniques, and to build responsive relationships with participants over a series of interactions. There are also some ethical risks: in unscrupulous hands, encouragement to intervene supportively might undermine patients' autonomy. However, investments in good communication may generate cost savings elsewhere, and there are various ethical and epistemological advantages to be claimed if the efforts result in fewer people feeling they are inadequately supported to respond to an invitation to join a trial, declining participation because they are poorly informed, participating on the basis of poorly grounded preferences, or dropping out because of poor experiences of participation. Given their potential to promote meaningfully informed and voluntary participation in clinical trials, broader forms of supportive communication warrant further consideration.

Box: Key features of 'Consider an invitation/request' approach

Based on the 'consider and offer' approach to communication, which was originally developed for decisions about screening[30] communication about clinical trials within the 'consider an invitation/request' approach aims to support personal autonomy but *without* overburdening people with unwanted informational details or decisional tasks and *without* deterring personally appropriate trial participation. The approach seeks to help people to consider invitations/requests to participate in particular trials, for example by:

1. providing accessible initial presentations of the invitation/request (e.g. short summary sheet, video or brief introductory discussion) and;
2. ensuring initial presentations are accompanied or followed by opportunities to access flexible forms of decision support (including more detailed information and 'no pressure' discussions) to help people as required to:
    - Assess the rationale behind the trial and the invitation/request to participate
    - Consider the relevance and implications of their own participation or non-participation (this may involve thinking through potential benefits and harms to others as well as to themselves)
    - Assess the interests and trustworthiness of trial organisers and staff
    - 'Sound out' their initial ideas about whether or not they want to participate and why, and perhaps to hear how and why other people have decided for and against participation, before they 'commit' to a decision

3. Reassuring people that decisions for and against participation can be reasonable and will be respected (not *just* that decisions against participation will not affect the quality of their healthcare).

Within the overall approach, particular communications should be tailored for specific trials and potential participants.

References

1. World Medical Association: Available from [http://www.wma.net/en/30publications/10policies/b3/index.html] *Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects*. 2008.
2. National Research Ethics Service. Information Sheet sand Consent Forms: Guidance for Researchers & Reviewers. National Patient Safety Agency, National Health Service. May 2009.
3. Manson NC, O'Neill O. Rethinking Informed Consent in Bioethics. Cambridge University Press. 2007.
4. Corrigan O. Empty ethics: the problem with informed consent. Sociol Health Illn. 2003 Nov;25(7):768-92.
5. ICH Harmonised Tripartite Guideline for Good Clinical Practice E6(R1). *Step 4* Version. June 1996.
6. Flory J, Emanuel E. Interventions to improve research participants' understanding in informed consent for research: a systematic review. JAMA. 2004.6;292(13):1593-601
7. Joffe S, Cook EF, Cleary PD, et al. Quality of informed consent in cancer clinical trials: a cross sectional survey. Lancet. 2001.358(9295):1772-7.
8. Dunn LB, Nowrangi MA, Palmer BW, et al. Assessing decisional capacity for clinical research or treatment: a review of instruments. Am J Psychiatry. 2006. 163(8):1323-34.
9. Epstein RM, Korones DN, Quill TE. Withholding information from patients--when less is more. N Engl J Med. 2010.4;362(5):380-1.
10. Donovan J, Mills N, Smith M, et al. Quality improvement report: Improving design and conduct of randomised trials by embedding them in qualitative research: ProtecT (prostate testing for cancer and treatment) study. Commentary: presenting unbiased information to patients can be difficult. BMJ. 2002. 5;325(7367):766-70.
11. Jenkins V, Fallowfield L, Solis-Trapala I,et al. Discussing randomised clinical trials of cancer therapy: evaluation of a Cancer Research UK training programme. BMJ. 2005. 19;330(7488):400.
12. Cribb A & Entwistle VA. Shared decision making: trade-offs between narrower and broader conceptions. Health Expect. 2011.14(2):210-9.
13. Ells C, Hunt MR, Chambers-Evans J. Relational autonomy as an essential component of patient-centered care. International Journal of Feminist Approaches to Bioethics. 2011.4(2):79-101.
14. Beauchamp TL & Childress JF. Principles of Biomedical Ethics. Oxford University Press. 1994.
15. Entwistle VA, Carter SM, Cribb A, et al. Supporting patient autonomy: the importance of clinician-patient relationships. J Gen Intern Med. 2010.25(7):741-5.
16. Hallowell N. Consent to genetic testing: a family affair? In: Corrigan O, McMillan J, Liddell K, Richards M, Weijer C. (Eds) The limits of consent: a socio-ethical approach to human subjects research in medicine. Oxford University Press, 2008. Pp185-198.
17. Entwistle VA, Cribb A, Watt IS. Shared decision making: appraising broader conceptions that enhance clinical relevance. J Roy Soc Med, 2012;
18. Walker RL. Medical ethics needs a new view of autonomy. J Med Phil. 2009; 33; 594-608
19. http://www.healthtalkonline.org/medical_research/clinical_trials/Topic/3638/
20. Eborall HC, Stewart MC, Cunningham-Burley S, et al. Accrual and drop out in a primary prevention randomised controlled trial: qualitative study. Trials. 2011.11;12:7.
21. Stone DA, Kerr CE, Jacobson E, et al. Patient expectations in placebo-controlled randomized clinical trials. J Eval Clin Pract. 2005. 11(1):77-84.
22. Mills N, Donovan JL, Wade J, et al. Exploring treatment preferences facilitated recruitment to randomised controlled trials. J Clin Epidemiol. 2011. 64(10): 1127-365.
23. O'Connor AM, Bennett CL, Stacey D, et al Decision aids for people facing health treatment or screening decisions. Cochrane Database Syst Rev. 2009. 8;(3):CD001431. Review.
24. Entwistle V. Supporting participation in clinical research: decision aids for trial recruitment? Health Expect. 2008.11(3): 205-7.
25. Brehaut JC, Lott A, Fergusson DA, et al Can patient decision aids help people make good decisions about participating in clinical trials? A study protocol. Implement Sci. 2008.23;3:38.

26. Juraskova I, Butow P, Lopez A, et al. Improving informed consent: a pilot of a decision aid for women invited to participate in a breast cancer prevention trial (IBIS-II DCIS). Health Expect. 2008.11(3):252-62.
27. Abhyankar P, Bekker HL, Summers BA, et al. Why values elicitation techniques enable people to make informed decisions about cancer trial participation. Health Expect. 2011.14 Suppl 1:20-32
28. Entwistle V, Prior M, Skea ZC,et al. Involvement in treatment decision-making: its meaning to people with diabetes and implications for conceptualisation. Soc Sci Med. 2008.66(2):362-75.
29. Wade J, Donovan JL, Lane JA,et al. It's not just what you say, it's also how you say it: opening the 'black box' of informed consent appointments in randomised controlled trials. Soc Sci Med. 2009.68(11):2018-28.
30. Mackenzie C, Stoljar N (Eds). Relational autnomy: feminist perspectives on autonomy, agency and the social self. New York: Oxford University Press, 2000.
31. Meyers DT. Self, society and personal choice. New York: Columbia University Press, 1989.
32. Sherwin S, Winsby M. A relational perspective on autonomy for older adults residing in nursing homes. Health Expect. 2011.14(2):182-190
33. Entwistle VA, Carter SM, Trevena L, et al. Communicating about screening.BMJ. 2008.22;337:a1591
34. Fearn P, Avenell A, McCann S, et al. Factors influencing the participation of older people in clinical trials – data analysis from the MAVIS trial. J Nutr Health Aging. 2010.14(1):51-6.
35. Scott C, Walker J, White P, et al. Forging convictions: the effects of active participation in a clinical trial. Soc Sci Med. 2011.72(12):2041-8.

Contributors and sources: Both authors developed the original idea for the article, KG wrote the initial manuscript and both authors contributed to revisions of drafts of the manuscript, including the final version. KG is guarantor

Competing interests: All authors have completed the Unified Competing Interest form at http://www.icmje.org/coi_disclosure.pdf (available on request from the corresponding author) and declare: xx is supported by a personal fellowship award from the from the Chief Scientist Office (CSO) of the Scottish Governments Health Directorate (PDF/09/01), and xx's post is part-funded by the Chief Scientist Office of the Scottish Government Health Department, NHS Education Scotland and the Scottish Funding Council (via the Alliance for Self-Care Research). The authors have authors

have prepared this manuscript independently of the funders. The authors have no other relationships or activities that could appear to have influenced the submitted work.

Provenance and peer review: Not commissioned; externally peer reviewed.