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‘Let the computer choose?’: the experience of participants in a randomised preference trial of medical versus surgical termination of pregnancy

Abstract

The TOPS Trial (Newcastle upon Tyne, UK), is the only randomised trial on termination of pregnancy (TOP) methods incorporating a qualitative element that aimed to understand the experiences of women participating in the trial. Based on the results of this qualitative work, this paper aims to provide insights into two strands of understanding; first, women’s experience of participating in research about abortion and second, their experience of participating in a randomised preference trial. Semi-structured interviews were conducted of up to 90 minutes with 30 participants recruited at a single hospital site. Twenty women from the preference arm and ten from the random arm were interviewed. The analysis and discussion of our findings uses reflexive modernisation as a framework for understanding and interpreting some of the actions of social agents i.e. the participants and trial recruiters in the course of a clinical trial as an expert system. We found that the factors that shape women’s experiences and decisions include trust in the expert system and reflexivity and agency on the part of both participants and trial recruiters.

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Background

Clinical research is based on the notion that randomised controlled trials (RCTs) offer the most reliable means of assessing clinical and cost effectiveness of new and existing health care interventions. However, there have been questions raised about the participation of clinical staff, researchers and patients in clinical trials and how their behaviour may affect the validity and reliability of RCTs (Donovan et al., 2002a; Donovan et al., 2002b; Featherstone, 2003; Snowdon et al., 1997; Torgerson & Sibbald, 1998). The introduction of biases in trials may come from treatment preferences of patients and clinicians (Torgerson & Sibbald, 1998), clinician role conflict (Levine, 1992) or issues to do with staff training (Ellis, 2000). Successful participant recruitment is essential for trial success, but informed consent is linked with patients' understandings of the complex notions of 'clinical equipoise' (Chard & Lilford, 1998; Mills et al., 2003) and 'randomisation'(Jenkins et al., 2002; Snowdon et al., 1997). *Clinical equipoise* which 'describes a state of genuine uncertainty regarding the comparative therapeutic merits of the interventions being compared in each arm of the trial' (Daya, 2004) stands as the central plank to the ethical practice of randomisation, but the question arises as to whose 'uncertainty' matters: clinicians or patients (Mills et al., 2003). In one study, randomisation was found to be the main obstacle to trial participation because of participants' wish to have more personal control over their healthcare (Llewellyn-Thomas et al., 1991).

The qualitative study on which this paper is based was undertaken as part of a randomised preference trial of medical versus surgical termination of pregnancy (TOP). Since the 1967 Abortion Act, abortion has been legally available to women in

the UK[1] and the number of abortions in England and Wales has shown an upward trend [8 per 1000 in 1970 to 18 per 1000 in 2008 (National Statistics, 2009)]. Women also now have a choice between surgical and medical procedures. The proportion of medical abortions has more than doubled in the last five years (National Statistics, 2009). Although TOP is one of the most common procedures in the UK, little work has been done that contributes to robust understanding of preferences for the type of procedure. Instead, the objective of much research in the field has been aimed at understanding decision-making on termination in relation to promoting access or reducing delays in referral to clinical services. Kumar et al. (2004) have shown that most women prefer *not* to discuss their decision with health professionals in primary care, but prefer instead to receive information and prompt referral. Unease about discussing personal aspects of termination has also been registered amongst professionals, especially nurses and midwives (this may also explain the paucity of social science research in the field) (Durkin, 2002). Factors affecting the choice of method of termination are already known to be highly complex (Harvey et al., 2001). The problem of decision-making and preferences around termination is therefore quite unlike any other arena of clinical research.

To date, the TOPS Trial is the only randomised trial of TOP methods incorporating a qualitative element that aimed to understand the experiences of women participating in the trial (Robson et al., 2009). It was conducted between 2005 and 2008 in a busy NHS unit in the city of Newcastle upon Tyne in North East England. The primary objective of the trial was to determine the acceptability of medical TOP (MTOP) and surgical TOP (STOP) for pregnancies of less than 14 weeks' gestation, as determined by women's preferred method for a future TOP. Its secondary objectives were to

compare experiences of care, strength of preference, psychological impact and the cost effectiveness of surgical and medical termination. The qualitative component of the study sought to examine women's experiences of decision-making in having a termination, in participating in the clinical trial, and in selecting or not selecting one method of termination over the other.

The research available presents the two options of MTOP and STOP as having *clinical equipoise* meaning that significant ethical dilemmas are not faced by either clinicians or participants. Most studies of women's views about abortion have reported procedure acceptability; typically women have been asked whether they would opt for the same method in the future or recommend the method to a friend (Jensen et al., 2000; Say et al., 2005; Winikoff, 1995); data from randomised trials indicate that acceptability of both methods before 9 weeks' gestation is high (63-92%) with 2-36% of women randomised to STOP preferring a medical procedure in future and 22-37% of women randomised to MTOP preferring a STOP (Ashok et al., 2002; Say et al., 2005). The TOPS trial was conducted because of genuine uncertainty about the benefits or otherwise of medical over surgical TOP.

Qualitative studies linked to clinical trials are increasing but limited in their scope of health care interventions. Studies have tended to focus on older people with chronic disease with recent examples being the ClasP Trial on urinary problems in men, ProtecT Study on prostate cancer (Donovan et al., 2002a; Mills et al., 2003), and the DARTS trial on cardiovascular disease (Heaven et al., 2006b; Murtagh et al., 2007). In these medical interventions, the horizons for treatment are relatively long and decision-making processes are extended. In comparison, the participants in the TOPS

trial were younger women. The intervention that they sought was elective but with time horizons that are (relatively) constrained and limited by law. Additional special considerations apply to research into TOP that may not apply to other health interventions. The women were not 'ill'. Their position as the 'patient' is mediated by the moral context of 'abortion'.

This paper aims to provide insights into two strands of understanding; first, women's experience of participating in research about abortion and second, their experience of participating in a randomised preference trial, thus having implications for the design and conduct of TOP clinical trials. Drawing on ideas about reflexivity as a theoretical framework, we interpret the qualitative data provided by the women participants and trial recruiters as reflexive actors. The qualitative study itself can be seen as an example of institutional reflexivity embedded in a clinical trial as an expert system.

The RCT, the Study Group and the Method

The study design was a partially randomised preference trial and economic evaluation with follow up at 2 weeks and 3 months. Participants were women accepted for termination of pregnancy under clause C of the Human Fertilisation and Embryology Act (1990) amendment of the Abortion Act (1967) with pregnancies less than 14 weeks gestation (based on ultrasound) on the day of abortion. A further group of women attending contraception and sexual health clinics in Newcastle participated in a discrete choice experiment (DCE). The model of preference developed from the DCE was used in the qualitative study to elicit women's perspectives on the results of the conjoint analysis (DCE). The qualitative topic guide was also designed to uncover

how women's attitudes and experiences shaped their decision making and preferences thus contributing not only to determining the cost effectiveness of the two procedures, but also patient satisfaction in TOP services.

Of the 2407 suitable women approached by the research nurse, 530 (22%) declined to take part in the study and 1877 women were enrolled. All women recruited after month ten of the trial were invited to participate in the qualitative sub-study. Prior to discharge from hospital after the TOP, women were given a patient information sheet about the sub-study. At the two week follow-up, research nurses answered questions about the sub-study and ascertained whether women wanted to participate. Seventy-eight per cent declined to be involved. We purposively sought a sample balanced across all four arms of the trial (n=32: composed of 8 women in each of the randomized surgical, randomized medical, preference medical and preference surgical arms). Interested women (n=69,) were then contacted by the researcher 5-18 weeks after the procedure and invited to take part in a single semi-structured interview either at her home or in a private room on hospital or university premises. Of the 69 contacted, 41 initially consented when contacted by the researcher and 30 women from the trial were interviewed; 11 from the Preference Surgical (PS) arm, nine from the Preference Medical (PM) arm, six from the Randomised Surgical (RS) arm and four from the Randomised Medical (RM) arm. Nevertheless, recruitment into the study was often difficult and some potential respondents refused to participate, either by putting the phone down on ML when initial contact was made, or by not responding to messages. Given the sensitivity of the topic, these are expected limitations of the study. Of the 30 women enrolled into the qualitative study, two were asylum-seekers, two were British Asians, and two were economic migrants from

Africa and the EU. Two British white women had partners who were non-white. However, from a comparison with non-respondents, those who were interviewed tended to be older, more educated, in a long term relationship, and more likely to be in paid work.

Ethical approval for the research was granted by the Local Research Ethics Committee (REC 05/Q0906/38). In addition to this, a set of Ethical Guidelines was written up for the qualitative study using the relevant guidance (British Sociological Association, 2002; UK Parliament, 1998). As a non-clinician, the role of the interviewer was clearly understood as being that of a social scientist who positioned herself as a neutral listener with no overt views on TOP. In the event of any emotional distress, the TOPS Sub-study Participant Information Sheet provided participants with the contact number for the hospital counselling/support service, and the means by which concerns can be channelled through normal NHS complaints mechanisms via the study doctor or senior investigators. However, none of the women used these services. Many of the women who were interviewed seemed to have come to terms with the experience and were able to provide narratives that were reasoned and composed. Interviews produced accounts of a wide range of topics including meanings and attitudes towards TOP. However the main focus of this study was women's experiences of the trial, their choice of TOP procedure, and their responses to the conjoint analysis. To some extent, this procedural focus took the edge off the sensitive and emotive aspects of the research.

Interviews were recorded using a digital recorder, transcribed and anonymised by an experienced medical secretary, and edited for accuracy. The qualitative analysis proceeded through a process of thematic coding, facilitated by QSR NVIVO software. Descriptive and factual themes (or nodes) arose out of the topic guide while referential nodes were drawn from the literature review and analytical questions arising from reading and interrogating the data. The authors held a data clinic to identify and confirm themes which were indexed. Searches for code-able items of speech were undertaken between interviews in the same arm of the trial and across interviews gathered from different arms of the trial. A coding frame of 46 parent and child nodes was created and the nodes were checked for consistency. Each interview was also coded as a case with attributes e.g. age, education and income for base data information. In order to guard against the fragmentation of data through this 'code and retrieve' method of data analysis, fieldwork notes summarising the main points were written after each interview by ML, and individual interviews were examined as whole documents by the qualitative study lead. Thematic headings included 'Decision-making', 'Significant Others' and 'Experiences of Health Care'. This article draws on data from two main nodes, firstly 'Trial participation' with its child nodes or themes of 'benefits from participating', 'feelings about participating', 'information and data collection', 'reasons for taking part', and 'understandings about the research' and secondly 'Thoughts and reflections' in which a total of 105 references were coded.

The experience of trial recruitment

The nurse practitioner-led assessment clinic at the hospital was the women's first direct encounter with the trial where they received the **Patient Information Sheet.** After accepting women for TOP, nurse practitioners explained the two methods of TOP, following which the research nurse would explain the research study and seek to recruit women onto the trial. Only those women who agreed to be followed up after the termination were recruited onto the trial. The dialogue guide for trial recruitment included the following points: the lack of research evidence about which method was best; the value of knowing which method women preferred; that no new drugs or procedures were being tested; and the requirement for follow-up two weeks and three months after the procedure. The explanation given about randomisation was that in order to determine which method was most acceptable, clinicians needed to compare one group of women having a STOP with another having a MTOP. The optimal way to allocate a woman to a group was to have the method chosen by chance. The example given was that of tossing a coin, and in this case, the computer making the choice randomly so that there was a 50 percent chance of having a STOP and 50 per cent chance of having a MTOP. The total number of women recruited onto the preference arm was 1528. The number recruited onto the randomised arm was only 349 (31% of the original target of 1116 women) indicating that women were not as willing to be put in the randomised arm of the trial as had been anticipated from an earlier pilot study.

Encounters with the information-provision and decision-making described were generally felt to be adequate and appropriate. A small number of women stated that there was too much emphasis on explaining the research and getting a decision from them about randomisation and which procedure to choose, rather than explaining in

depth what one would expect from each procedure. It has to be acknowledged that it is difficult in assessment and recruitment to get the balance exactly right in providing information about the procedure itself as well as information about the research. There are also limits to the amount of information women in an emotional state can take in at various points in the consenting process. However, most women were positive about their experience, as a 26 year old mother recounted:

It was it was excellent, em the day that I first went for my bloods and I was given a sheet which had the procedure for... medical and the procedure in plain English, simple terms for surgical? So you were able to sit and read that in the reception and sort of have a little idea of what it all entailed before you went in…..
Yeah it was just the right amount it wasn't too much 'cos you, you're not really in the frame of mind to sit and read loads of paragraphs and everything it's just enough – Susan (PS)

The role of the nurse practitioners and research nurses in helping the women through the process was also important:

Very good, they provided everything I needed to know and answered every question that I asked and em.. were very supportive along with it well gentle with us they were kind of you know, I was terrified obviously – Tina (PM, aged 25)

However, the initial assessment could be a very busy encounter:

It was, it was a lot to take in on one day and when I went home I just you just feel so drained because you've had to answer so many questions and give out so many details and it, it was really hard going, but at the end of the day it's for your benefit so so I had to do it – Kayleigh (RS, aged 19)

Susie (RM, aged 20): ....by the time I got there and they were asking me questions I didn't really care, because I just wanted it to be done so I wasn't
Interviewer: So was it the case of whichever was quicker?
Susie: Yeah, just what, I just wanted anything I didn't mind at the time which one it was, because I didn't know if I said surgical it might take some more days or not, so I just said 'Yeah let's go for it', whatever

Her experience as a participant in the randomised medical arm was less than ideal:

Susie: ....they didn't really say a lot ....which was quite bad because I remember em, when, when you go to the toilet and it when it came out em I didn't expect anything .... because they hadn't said, this is what this is what .... Yeah, will happen or anything like that so it was a real shock

The quotes above illustrate the relational nature of information giving and receiving which was especially important considering the emotional states that the women were in. It demonstrates the importance of personal relationships of trust highlighted by Giddens (1990), which works to supplement the abstract system of the clinical trial. In some cases, there was time for women to think and reflect on the information they received but there were also cases where decision-making was rather more of a reflex

action. Scott Lash (2003) describes non-linear reflexivity in decision-making as having more to do with the reflex than reflection i.e. immediate, indeterminate and quick. He argues that in the present age of reflexive modernity, 'we may wish to be reflective but we have neither the time nor space to reflect … in an atmosphere of risk in which knowledge and life-chances are precarious' (p51-52). In the time-pressured clinical encounter, this experience is heightened when treatment options are considered. For women in the trial, this reflexive decision-making in some cases was made on the basis of 'unawareness' or incomplete knowledge [cf. Beck (1999)] of exactly what would happen to them with either method of termination.

The collection of outcome data

Women consented to whichever method of follow-up contact suited their own personal circumstances. At two weeks after the procedure their choices for method of contact included: return to a follow up clinic either in the hospital or at a community clinic; postal questionnaire; telephone contact by the research nurse limited to 3 attempts to contact; access to a password protected web-based questionnaire; and/or an automated sms text message which contained one question related to future termination method requesting a yes/no reply. At three months data collection, methods included postal questionnaire and web-based questionnaire only. A text reminder was sent for those opting for a web-based questionnaire and text contact.

Women's encounters with the data collecting instrument i.e. the questionnaire, elicited a variety of interesting responses that are worthy of comment, not only from a theoretical but practical healthcare perspective. Generally speaking all the women

were linked by the emotional consequences of having a termination. One young woman wanted to get on with her work at university and did not appreciate having to be reminded by the questionnaire of the abortion. Another reflected:

And I thought I was alright and when I had to fill the question in, the questionnaire in I remember being upset when I went home… because L. had come with us for that one, and he said 'Well what's wrong?' I said 'Well it's all just come back' – Judith (RS, aged 29)

The following is an example of a negative response to the inflexibility of closed items in the questionnaire. The preference for a person to relate to rather than an inanimate research tool is also expressed, and her description of the chat with the nurse suggests that personal relationships of trust are important for her:

So I was kind of, I got quite frustrated at some of the questions and the questionnaire I was quite like, this is like the most vaguest way you could pick, I don't even know what you're asking me kind of thing em but I think with someone explaining them when I was chatting to like to the nurse about all that kind of stuff, someone explaining the questions is a lot easier I think than trying to understand that questionnaire – Maya (RM, aged 24 years)

Some women on the other hand found answering the questions therapeutic because of the time and opportunity to engage in self-reflexivity:

Michaela (PS, 27 year old mother of two): Some of them [questions] were like, you had to ponder over for a while you know, didn't know what to put but I think it's a good way of helping us to get over it.

Interviewer: Was it? Do you think it helped you to get over it?

Michaela: I, in a way it did, yeah, because I haven't really spoke about it to people

Nobody asked me if I was sad, nobody asked me if I cried, but this, the leaflets you sent the form you sent me. It talked about, it asked, there was a question that asked me how did I feel. But nobody except for my husband and only once he asked me how do you feel…Yes I had to talk about it and I was very happy to put it on paper and send it..in. – Asmaa (RS, 32 year old mother of two)

I thought well.. other people must have these emotions if they are using it as an example if they ask how I feel I felt all of them, and it helped me to feel I am not on my own, you know – Susan (PS, 26 year old mother)

These experiences of women seem to indicate that the expert system of the clinical trial provided them with opportunities to reflect on their experiences and for some of them to realise that they were not acting on their own, or were alone in their pain. It could thus be argued that this is an example of the expert system facilitating self-reflexivity and providing a safe space for women to voice their feelings regarding a taboo subject that is avoided even by their loved ones. Disclosure of these feelings depends on a complex of factors that our data is unable to throw definitive light on. According to an Irish study (Fletcher, 1995), these include protection from repercussions, concern for others, the ambivalence of their feelings and the lack of

space to voice them. What we can conclude is that many women in a research setting appreciate these spaces to make their feelings known. Outwith a research setting however, the situation may be altogether different.

In terms of lessons to be learnt, it is important to acknowledge the emotional context of the trial in the collection of data from trial participants. The volume and balance of information that the women were receiving, and when they were receiving it needs sensitive handling. Women were clearly appreciative of the one-to-one contact with nurses, their kindness and non-judgemental care. A number of women felt that participation in the trial was therapeutic with having an opportunity to provide feedback and feeling that one is not alone in the pain of her experiences. For many vulnerable women in these situations, having a choice and a voice in their treatment can be an affirming and empowering experience.

The randomization experience

The experience that the women had of being placed in different arms of the trial also uncovered aspects that could be interpreted as demonstrating reflexivity within the expert system of a clinical trial. Once women had decided to participate in the trial they were asked if they would be willing to have their method of termination chosen/determined by chance i.e. letting the computer choose. Those women not willing to have their method chosen by chance were allocated their preferred method. Women were not asked directly why they did not want to be randomised. From the economic evaluation conducted as part of the trial, women's strength of preference for future TOP method was clear. Women were allocated to the preference arm by the

strength of preference for their method, that is, they wanted a guarantee and exercised agency so that they would get their chosen method. There was no difference in strength of preference for those that would chose MTOP compared to those that would choose STOP (Robson et al 2009). Women who had no preference for either method and/or were ambivalent may have preferred to 'let the computer choose' as a resolution for their ambivalence.

While the concept of *equipoise* is usually framed within the clinical community where a consensus is reached about the comparative efficacy of the different interventions, from the patients' perspective, the situation of *equipoise* can act to enable a participant to agree to join the randomised arm of a trial:

About each em each method and what it involves and I just thought there was so many pros and cons of each one that I really couldn't decide which one would be better for me and then when I was told about the, the research that you were doing I just thought it would be better seeing as I couldn't personally decide anyway 'cos I just thought each method had good and bad points, I just thought it would be better to do the research – Laura (RM, 18 year old student)

In the following quote, the two options were equally weighted on the basis of past experience and lay consultation:

Interviewer: .. you were given an option to either have a preference or not have a preference, how did you decide to, you know let the computer choose?
Linda (RS, aged 27): Because I couldn't make me own decision ...[laughter] em

basically I've ..been through the surgical procedure before in the past ...And I know people who have had the medical procedure who haven't said that it was fantastic but, .. then they didn't have the surgical procedure so they couldn't tell ... So I thought well I'm undecided I'll just let the machine decide for me

In this process, there is no indication that the women were under any kind of pressure to choose a method even though the choice was given. So in spite of being given this autonomy, their position of *equipoise* did not allow them to act on it.

According to standard practice, nurses recruited women who did not have a strong preference for a method but were willing to be randomised for the sake of making a contribution to the research. Those who had a definite preference for a method were discouraged from joining the randomised arm:

Jacqui (PM, aged 24): I asked the researcher I said 'Well you know, can I do the random thing, and then if it comes up as a surgical can I change my mind?' and she went 'No, if you've got a preference that's the one you've got to have'.

Three women found it difficult to decide whether or not to enter the random arm, as they were uncertain of the strength of their preference for the surgical method. For two of these women, their decision to be randomised was facilitated by research nurses in the following ways:

Kayleigh (RS, aged 19): I did say, I did prefer the surgical way but then I just said oh well, it's up to you if you want to you can, it wasn't really a big deal for me so…….

Interviewer: what about the option to choose was it useful to be able to choose between medical and surgical

Kayleigh: Yeah definitely yeah definitely.

Interviewer: Even though you didn't actually choose

Kayleigh: Yeah even though I talked to her first and I said well I would prefer the surgical and then she said well you know, she explained the study and I was like oh well go on then!

Judith (RS, aged 29): And when I was sitting in the waiting room they'd given me the survey information I was reading it, about the two choices of abortions because at first I thought if I get a choice I want the pill one where ..And then after I was reading it I was thinking 'No I don't really want that any more' [laughter] so and then they said to me yeah if you take part in the survey we will let the computer choose, I'm going 'Oh right fine', she said 'If you're not happy with it you can change your mind and I was like 'Mm ok just, j-just press the button' and she went like 'You're asleep' I thought even better I don't even have to know what's going on, it's just gonna, I'll go to sleep and I'll wake up and it'll all be fixed

These two examples demonstrated how nurses attempted to increase participation rates in the randomized arm of the trial, the first by explaining the research in more detail, and the second by offering the option of a change of method if the computer chose a procedure that was unacceptable to the women. These examples may also be interpreted as nurses having the reflexivity and agency to exercise their own initiative in adjusting the application of the protocol (i.e. the formal process) in order to expedite an increase in numbers in the randomized arm required for the clinical trial.

'Cross-overs' – women who changed their minds

As part of trial set up research nurses underwent a period of training to try and ensure consistency of information provision to women. In order to try and increase recruitment to the randomised arm of the trial, the Patient Information Sheet and the research nurse dialogue was amended after nine months of the trial following recommendations by the Trial Steering Committee. This standardised dialogue was reinforced by specific phrases introduced by the nurse practitioners prior to women meeting the research nurses:

1) From the sheet you will have gathered that there is a lack of research evidence about whether medical or surgical termination is best.
2) We are doing some research to find out which method women prefer to help improve services and we need your help.
3) The best way to find this out is if you have your method of termination chosen by chance

The last of these key phrases was explained more fully by the research nurses.

During 2007 the trial coordinator became concerned that the occurrence of women who changed their method of TOP after randomisation was increasing; suggesting that the delivery of the standard recruitment dialogue may have changed from that originally agreed. An informal exploratory discussion was initiated between the trial coordinator and research nurses and the previously agreed recruitment dialogue was

reinforced. The trial coordinator continued to monitor the number of women changing methods after randomisation and recruitment caused no further concern.

Within the clinical trial, there were 40 women who changed their method of termination. Thirteen (1.6%) of the women in the PM group changed their mind and requested STOP while 4 (0.56%) of the PS group requested a medical procedure. Eleven women (6.8%) of the RM group subsequently requested STOP, while 12 (6.4%) of the RS group requested a MTOP. This suggests that women were more likely to change their mind about termination method if they initially agreed to be randomised. In this group of 40 women who 'crossed over', more than half (55% compared to 49% in the trial) had pregnancies of under nine weeks. Their ambivalence may be explained by their perception that either method on balance with their associated side effects would be effective and safe for pregnancies below nine weeks. When asked about satisfaction with care, 43 per cent of women who 'crossed-over' (compared to 37.4% in the trial) gave no response. Thus women who were ambivalent about the two methods were also more likely to be ambivalent about the treatment that they received in the TOPS service. The behaviour of these women may also be interpreted as exhibiting individual agency but whether there was a generalised distrust in the expert system of the clinical trial is less clear.[2] The reflexivity on the part of the trial coordinator on the other hand demonstrates the importance of her role in the clinical trial.

As an example of a 'crossover' case, Cath was randomised to the medical arm but opted to have a surgical procedure.

I know what it's like to get research done but since it's a sensitive issue it was a little bit like that seemed to take over the appointment a little bit and I felt that they were very keen .. to say 'It doesn't matter which method you have, it'll be fine that's why it's ok to have a random trial' because the medical's like this and the surgical's like this and really there's no difference between the two but however I always kind of felt myself there is a difference between the two sort of obviously physically and secondly psychologically I think it does have an impact em and so I didn't mind talking to the Research Nurse but then I felt very rushed because I was the last person, and she was kind of like 'Well do you want to do it or not? ' and I'm like 'Well yeah I'll do it but then when it came up on the computer medical and I wasn't keen, if it came up surgical I would have just carried on in the route – Cath (PS, aged 26)

According to this account, the nurses presented the choices as being in a situation of 'clinical equipoise' in terms of bio-medical outcomes but the interviewee, who was thinking instead about the psychological impact, did not accept this. In her rational evaluation of the two methods, she alludes to inadequate 'knowing' and competing bodies of knowledge as the unintended consequences of reflexive modernity (Beck, 1999). Under pressure of time to oblige, she agreed to randomisation, but in contrast to other women and possibly because of her own professional experience and training, she eventually asserted her right to choose the surgical over the medical procedure. Thus those parts of the clinical trial experience where decisions have to be made within a set time i.e. at trial recruitment, contrasts with those experiences of women during data collection, with reflexivity operating in different ways.

Reflexivity and research

Clinical trials are large scale mechanisms for institutional reflexivity (Webster, 2004) that rely on complex organizational structures (Heaven et al., 2006a) and expert systems (Dixon-Woods et al., 2007). RCTs are perceived as the 'gold standard' of clinical research, with evidence from trials being increasingly demanded by policy-makers and fund-holders and quoted in the media. This growing dependence on 'expert systems' is characteristic of the age of reflexive modernity. However, the validity and reliability of trial outcome data depend on the selection and recruitment of trial participants, participants' emotional and psychological needs and how their values and experiences affect the outcomes of the trial. From our findings, insights into experiences of trial participation have led us to ask the following questions: do difficulties in recruitment reflect public distrust in 'expert systems' i.e. 'structural reflexivity' and/or 'self-reflexivity'? Are there opportunities for reflexivity in the life of the clinical trial that take into consideration participants' social and emotional needs?

In our present discussion, reflexivity is taken as a condition of modernity and refers to the continuous operation of mechanisms for collective and individual monitoring of social practices. Reflexive modernization theorists (Beck, 1992; Beck et al., 1994; Giddens, 1990) have argued that rather than rely on traditional sources of authority, people increasingly make reflexive choices based on informed decisions. Something like this seems to underpin attempts to construct evidence-based policy (Niessen et al., 2000) and the application of evidence based practice in clinical settings (May et al., 2006). These 'informed' decisions must themselves be constructed on the basis of the beliefs and actions of others—the TOPS trial was one such episode of institutional

reflexivity. Its funding agency (the National Institute of Health Research, Health Technology Assessment Programme) wanted both quantitative data about the effectiveness of two different means of TOP, and qualitative data about the 'perceptions' of women in the trial, to provide building blocks for rational policy decisions about service delivery.

At one level, then, the conduct and results of this trial reflect patterns of *structural* reflexivity about social conditions of existence. At another, and particularly in the investigation of choices, decisions and beliefs, it represents a mechanism that interrogates participants' self-reflexivity using techniques for investigating patterns of self-perception and self-monitoring. The problem of reflexivity also exposes the temporal tensions of the trial. In the time-pressured clinical encounter, experiences of self-monitoring of decisions, choices, and preferences are heightened when treatment options are considered. In a randomised preference trial, there is the added dimension of understanding; the conditions in which participation in the different arms of the trial is constructed—the mechanisms by which randomization is carried out—and conceptualising its implications. Meanings and implications become critical of course, as we follow Giddens' (1992) shift from expert system to emotional authority (May & Cooper, 1995). Here, as the statistical abstractions of trials remove from real life interactions, then the one-to-one relationships based on personalised trust and expressed through the qualitative sub-study have become increasingly necessary—at an *institutional* level—to give these abstractions meaning.

Conclusion

Qualitative sub-studies within trials tend to be used either as initial (reconnaissance) studies to assist in decision-making about instrument design, study organisation and recruitment; or as formative process evaluations of ongoing work. In this unique study, we aimed to better understand the factors that shape women's experiences of the health service contexts in which clinical trials are undertaken and to identify those factors that promote and inhibit women's involvement in clinical trials on TOP. Because of the study design, women who were recruited were not put off participation due to randomisation as in other studies (Llewellyn-Thomas et al., 1991) because they could express a preference and be allocated to the preference arm. Bias due to treatment preferences (Torgerson & Sibbald, 1998) was minimal because of the clinical equipoise expressed by most (though not all) patients, and the training and monitoring by the trial coordinator overcame many staff issues highlighted in other trials.

With the significant percentage (88%) of women who were enrolled on the trial from those who were approached, and the expressed willingness of participants in the qualitative study to be 'helpful', it appears there is no lack of trust in the 'expert system' of a clinical trial as Gidden's thesis would suggest (1990). Perhaps this was because trial participation was facilitated by the one-to-one encounters with health care practitioners that engendered trust. Trust in persons supplements trust in abstract systems according to Giddens (1990). At the same time, the appreciation of the opportunity for 'self-reflexivity' is found in the interview data and the expert system can be seen as facilitating such self-reflexivity. However, the low numbers recruited onto the randomised arm and occurrence of 'cross-overs' suggests the desire of some women for individual control, a finding supported by research elsewhere (Ellis, 2000;

Llewellyn-Thomas et al., 1991). Whether there is a distrust of systems and structures that Beck describes is less clear. As established by other studies (Jenkins et al., 2002; Snowdon et al., 1997), the idea of randomisation may be difficult to accept but women who were interviewed were not averse to the method of 'letting the computer choose'. As for information about the two methods of termination, women appeared for the most part to be satisfied.

In the clinical encounter, trial recruiters may exercise individual 'agency' to facilitate recruitment into the randomised arm. This included their emphasis on clinical equipoise, but also by offering participants autonomy in making the final choice of TOP method even though they agreed to be in the random arm, 'letting the computer choose' initially. The agency exercised by them demonstrates a degree of structural reflexivity in their non-compliance of the formal systems of the trial. At another level, the reflexive monitoring by the trial coordinator in charge of the trial nurses is another example of the reflexivity that occurs within the expert system. As a result of her supervision, the proportion of 'cross-overs' i.e. women changing their initial method was low. So there is structural reflexivity occurring at the patient-practitioner encounter and self-reflexivity during data collection, as well as reflexive monitoring at the level of trial management to maintain the validity and reliability of the trial. That all these processes are going on illuminates the capacity of actors within social organisations at the meso-level which will in turn mediate social structure and action at the macro-level. As qualitative researchers studying the experiences of participants in a clinical trial, we see ourselves engaged in a collective appraisal of these social processes and part of the reflexivity of modern social life, in which 'social practices

are constantly examined and performed in the light of incoming information about those very practices, thus constitutively altering their character' (Giddens, 1990:38).

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Footnotes

[1]This act does not apply to Northern Ireland where abortion is only allowed in cases where the medical well-being of the mother is threatened.

[2] It is not clear how many women changed their minds on the day of randomisation or changed nearer the time or on the day of the procedure, and thus to what extent they were influenced by significant others.