



Partial prostate Ablation versus Radical prosTatectomy

Interview schedule: recruiters

1) Background

- How long have you recruited patients to RCTs?
- How did you become a recruiter?
- **Have you recruited to other RCTs, before this one?**
- **How did you come to be working on this RCT?**
- **Have you received any training (a) as a recruiter; (b) for this RCT?**
- **When you start recruiting to this trial?**
- **Please describe how recruitment has been for you in this RCT.**

2) Recruitment pathway

- How are patients recruited into this RCT? Is there a “recruitment” appointment?
- Who undertakes the assessment of patient eligibility for this RCT? Are you involved in eligibility assessment?
- How do you find out which patients to approach about the RCT?

3) Introducing/explaining the trial

- How do you introduce/explain the trial to patients?
- Why do you think this RCT is needed?
- What is involved in taking part in this RCT; and in each arm?
- What happens to patients if they agree to take part?

4) Randomisation

- How do you explain to patients how the decision is made in the trial about which treatment they will receive?
- How easy do you think the concept of randomisation is for patients to understand?

Note: If this seems threatening, acknowledge that this is a difficult and confusing concept for

everybody and then explore again.

- Does randomisation seem sensible and reasonable to you?

5) Uncertainty

- How do patients react to the idea that the specialist doctor does not know what the best treatment is?

- How do you describe the uncertainty?

- How do you feel about explaining uncertainty?

- Do you ever have a feeling during an appointment that a patient should really have one treatment rather than another? Probe: Why? What do you do about that?

6) Informed consent

- How easy do you think it is to obtain fully informed consent for patients participating in this RCT?

(Probe: what is informed consent; how do you know when you have reached it?)

- Are you ever concerned about the possibility of coercing patients into taking part in the trial?

7) Treatment preferences of patients

- Do patients express preferences for particular treatments?

(Probe – what are their preferences; do you know why they express preferences?)

- What do you do when a patient expresses a preference?

(Probe – do you accept it – what happens next? Or do you ever explore or challenge their preference?)

- What other reasons (not preferences) have patients given for not taking part in this RCT?

- What do you do when a patient gives a reason for not wanting to take part?

8) Difficulties during recruitment

- What would you say are the main difficulties you face as a recruiter?

- Can you describe specific examples of ‘good’ and ‘bad’ recruitment experiences

- Is recruitment organised well? Do other people explain the RCT to patients?

- Are there difficulties with any particular arm?

- Do patients have strong preferences?

- Do you think this RCT is the right thing for these patients?

9) Personal views

- Do you think your work as a recruiter is similar or different from your usual work/practice?

Probe: In what ways it is (a) similar, (b) different?

- Do you think your work as a recruiter has changed the way you practice outside research?

- How do you feel about being a recruiter? Probe: Do you see yourself as a doctor/nurse/clinician, scientist, or researcher (if nurse also add 'patient advocate'); or all of these? Are there benefits or problems that arise from these different roles?

- Do you know (or have a hunch) about what the outcome of the RCT will be?

- If you were a patient in this position today, would you agree to be recruited to the RCT and be randomised? Or would you choose a treatment? Which one?

10) Finally - improving recruitment

- What might, in your opinion, improve the recruitment appointments?

- Do you think you (or others) need more support or training?



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Interview schedule: recruiting TMG members

11) Background

- How long have you recruited patients to RCTs?
- How did you become a recruiter?
- Have you received any training as a recruiter or for RCTs in general?
- When did you first get involved in this RCT?
- What is your role in this RCT? Probe for details.
- Would you describe yourself as a scientist, clinician, doctor/nurse, trialist, researcher, or..?
Or do you have more than one role? [If more than one role – are these roles complementary or are there conflicts?]
- Why do you think this RCT is needed?
- What is involved in taking part in this RCT; and in each arm?
- When did recruitment start?
- How well is recruitment going? Probe for details.

12) Protocol

- Could you describe the key aspects of the protocol?
- What is the evidence base for this trial? Probe for details of systematic reviews.
- Are the eligibility criteria for the RCT clear? Do you think PIs agree with them (and comply with them)?
- Are there reasons why recruitment is/would be difficult in this RCT?
- Would you say that you are ‘in equipoise’? What does ‘equipoise’ mean to you?
- Do you think your colleagues (PIs and recruiters) are “in equipoise”? Probe for details.
- How easy is it for you to accept uncertainty in relation to evidence? How easy is it for PIs/recruiters?

13) Recruitment pathway

- How are patients recruited into this RCT? Is there a “recruitment” appointment?
- Who undertakes the assessment of patient eligibility for this RCT? Are you involved in eligibility assessment?
- How do you find out which patients to approach about the RCT?

14) Introducing/explaining the trial

- How do you introduce/explain the trial to patients?
- Why do you think this RCT is needed?
- What is involved in taking part in this RCT; and in each arm?
- What happens to patients if they agree to take part?

15) Randomisation

- How do you explain to patients how the decision is made in the trial about which treatment they will receive?

- How easy do you think the concept of randomisation is for patients to understand?

Note: If this seems threatening, acknowledge that this is a difficult and confusing concept for everybody

and then explore again.

- Does randomisation seem sensible and reasonable to you?

16) Uncertainty

- How do patients react to the idea that the specialist doctor does not know what the best treatment is?
- How do you describe the uncertainty?
- How do you feel about explaining uncertainty?
- Do you ever have a feeling during an appointment that a patient should really have one treatment rather than another? Probe: Why? What do you do about that?

17) Informed consent

- How easy do you think it is to obtain fully informed consent for patients participating in this RCT?

(Probe: what is informed consent; how do you know when you have reached it?)

- Are you ever concerned about the possibility of coercing patients into taking part in the trial?

18) Patients

- How do you think patients feel about taking part in RCTs in general?
- How do you think these patients feel about taking part in this RCT?

- Do patients express preferences for particular treatments?
(Probe – what are their preferences; do you know why they express preferences?)
- What do you do when a patient expresses a preference?
(Probe – do you accept it – what happens next? Or do you ever explore or challenge their preference?)
- What other reasons (not preferences) have patients given for not taking part in this RCT?
- What do you do when a patient gives a reason for not wanting to take part?

19) Difficulties during recruitment

- What would you say are the main difficulties you face as a recruiter?
- Can you describe specific examples of ‘good’ and ‘bad’ recruitment experiences
- Is recruitment organised well? Do other people explain the RCT to patients?
- Are there difficulties with any particular arm?
- Do patients have strong preferences?
- Do you think this RCT is the right thing for these patients?

20) Personal views

- Do you think your work as a recruiter is similar or different from your usual work/practice?
Probe: In what ways it is (a) similar, (b) different?
- Do you think your work as a recruiter has changed the way you practice outside research?
- How do you feel about being a recruiter? Probe: Do you see yourself as a doctor/nurse/clinician, scientist, or researcher (if nurse also add ‘patient advocate’); or all of these? Are there benefits or problems that arise from these different roles?
- Do you think this RCT will be successful? Probe all the reasons for answer.
- Do you know (or have a hunch) about what the outcome of the RCT will be?
- If you were a patient in this position today, would you agree to be recruited to the RCT and be randomised? Or would you choose a treatment? Which one?

21) Finally - improving recruitment

- What might, in your opinion, improve the recruitment appointments?
- Do you think you (or others) need more support or training?



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Interview schedule: Patients

1. Perhaps if we could start off with your diagnosis of prostate cancer. Could you tell me a little bit about when you were first diagnosed and what, if anything, have you done about it?
(*previous treatments, experiences, etc*)

2. Overview of information consultation

I think you had an appointment with (*name*) recently? Could you talk me through what happened?

(*Probe to get at who said what and how he/she felt about the events?*)

Probes:

- When did you first hear about PART? (*also from where/whom?*)
- How was the study of treatments explained to you?
- Did it make sense to you why it was being done?
- What was said about the treatment options & side effects? (*explore understanding and evaluation of different treatments, pros/cons of each treatment, process, recovery, other*)
- How did you feel initially when you were told about the possibility of receiving one of the treatments?
- At this point did you have an opinion as to what treatment you might prefer?
- Were there any aspects of the study that you were uncertain about?
- Were you happy with the way the appointment went? Was it as you expected? (*Probe: why or why not*)

3. Did you decide to take part in the (name of study) or not?

a. For ALL:

Probes:

- How did you come to your decision? (*reasons for taking part/not taking part*)
- What information was important in reaching your decision? (*probe for type/source/content*)
- How easy it was to make the decision?
- What were the key factors in reaching this decision? (*explore patients' evaluations of different treatment outcomes and their perspectives on what is an important difference between outcomes*)
- What would have happened if you couldn't decide?
- What was your nurse/doctor's reaction about your decision?

b. If YES:

i. Understanding randomisation

- How was it decided what treatment you will get? Why was it decided like this? (*Probe – What is this study trying to find out? Why do you think they ask people to take part in medical trials? Purpose of trials? Do you think one treatment is better than another?*) (*equipoise*)
- Did you think you were more likely to get one particular treatment rather than another? Why? (*chance*) (*If hint at chance – why was it down to chance?*) (*comparison with audio-recording*)
- What did the nurse/doctor say would happen? What did you think would happen? Were you in the room when the decision was made? What happened? (*comparison with audio-recording*)
- Did you think anyone knew what the decision about treatment allocation was before you were told? (*concealed allocation*)
- How did you feel about this way of deciding what treatment you should have? Is there a better way?
- Did you feel the nurse/doctor had views about the most suitable treatment for you? Would you like them to have recommended one of the treatments?
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ii. Views on allocated treatment

- *If randomised:* How did you feel about the treatment that you were allocated? Did you accept it? (*if yes or no, are you still happy about this?*)
- Was it the treatment you wanted? What would you have done if you had been allocated (*name the other treatment*)?

c. If NO:

- *If chose treatment:* Why chose this particular treatment? How did you decide? (*Concerned about the other treatments? Concerned about being involved in a study? Had you heard anything about the treatment before?*)
- What do you think the treatment will involve? (*process of treatment, the time it would take to recover*) What is good about this treatment? Did they tell you about any risks or complications with this treatment?
- What did you hope would be outcome/end result of your chosen treatment (*symptom relief, cosmetic, other*)

4. Provision of information in consultation

- Do you think you had enough information or not about the different sorts of treatment available? Was it given to you at the best time?
- Do you think you had enough information or not about how the treatment was to be decided (*i.e. about randomisation*)? Was it given to you at the best time?
- Was there anything that you didn't understand in the consultation with the nurse/doctor (*re treatment options and randomisation*)? Did you feel able to ask them questions?
- What were your thoughts on the written information you were provided about the (name of study)?
- Other than the written information we gave you and what the doctors have told you, was there any other information that you were given / told / sought for yourself? Have you spoken to others (*experts/family/friends*) or looked for any information on (the condition) and its treatments through the library, media, internet etc? (*explore types and why they sought extra info; any conflicting information - and how they resolved this*).
- Are there ways that the information you received could be improved?

1. Concluding the interview

Anything else you want to say about taking part in the study so far or about this interview?

- Reiterate confidentiality / thanks