



## Recruitment and informed consent: Guidance

January 2016

Please try to approach all patients about the PART study if they have intermediate risk localised prostate cancer.

This document includes suggestions that may help with recruitment and informed consent to PART. You may wish to consider using some of these suggestions alongside your own individual style.

### Starting the consultation

- Try to reassure the patient that prostate cancer is a very common disease in men, and that there are several treatment options available. The consultation is about finding the right option for the patient
- Introduce the PART study, and ask patients to ‘keep an open mind’ until you have given them all the information they need
- o Reassure them that they have plenty of time to consider the treatment options

### Introducing the PART study

- It is very important to establish uncertainty (*‘We don’t know which one is best’*)
  - o Be mindful to convey equipoise throughout
- Mention the study early on (*‘Because we don’t know which is best, we’re taking part in a study called PART’*)
- Avoid the term ‘trial’ and use ‘study’ instead
- It can be helpful to explain that the team involved in the patient’s care have already discussed their specific case, and agreed that it would be appropriate to offer them the opportunity to take part in the PART study
- You can explain the benefits of study participation - for example, the close follow-up and monitoring, and that the aim of PART is to produce evidence so that future patients will not have to face current treatment uncertainties

- It is also good to mention that PART is a study funded by the NIHR Health Technology Assessment Programme (the NHS funding body) and is being carried out in five centres around the UK
- Present the study in an enthusiastic and straight-forward manner, without apologising

### Outlining the treatment options

- Patients can be overwhelmed by the options that are available to them. It may help to provide an overview of the treatment options:
  - o Active surveillance
  - o Radical treatment/treating the whole gland
  - o Partial treatment
- You could put the discussion in the context of ‘partial versus whole gland treatment’. For instance, it might help to explain:
  - o *‘The prostate is the only gland in the body where we tend to treat the whole gland. There are a number of different ways of treating only part of the prostate where the cancer is, but there is the most data on HIFU. HIFU has got advantages in terms of side effects and in terms of preserving part of the prostate, although less is known about the long term outcomes. NICE Guidance states that HIFU is not recommended other than in the context of controlled clinical trials comparing their use with established interventions (such as surgery). This is what the PART study aims to do.’*
- It’s important to present balanced information about both HIFU and surgery
  - o Avoid loaded terminology (i.e. ‘gold standard’, ‘experimental’)
  - o Balance the benefits and drawbacks of each (*see Table 1*)
- It can be common for patients to arrive at a consultation with a preference for a particular treatment. Gently find out the reasons why a patient prefers one option over the other, and see if they understand both operations so that you can ensure that they are not misunderstood or have been misinformed

*Table 1: Advantages and disadvantages of the PART treatments*

Surgery (whole gland treatment)	HIFU (partial ablation)
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**Possible  
advantages**

- Surgery will aim to remove all of the cancer
- Surgery has shown good oncological outcomes
- Patients can have radiotherapy if re-treatment is needed
- There is less follow up for this procedure

- There is less impact on sexual functioning and continence compared to radical treatments
- Shorter stay in hospital (typically less than 24 hours)
- Quicker recovery (normal activity can be resumed within a few days)
- Patients can have radical treatment if re-treatment is needed

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**Possible  
disadvantages**

- As with any major operation, there are risks in having surgery
- There is a longer stay in hospital (this may be for one to seven days)
- There are side effects to the procedure, including urinary problems and erectile dysfunction
- Patients won't be able to have children naturally after surgery

- There is a still small risk of side effects, including urinary problems and erectile dysfunction
  - Less is known about the oncological outcomes for this procedure
  - There is more follow up for this procedure (this can be both a positive and a negative)
  - There is a higher chance of needing retreatment
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### Explaining randomisation

- It is helpful to avoid using terms such as ‘toss of a coin ‘or ‘decided by a computer’ to explain randomisation
- Instead explain that if the patient were to join the study, they would have an equal chance of having HIFU or surgery
- Explain the rationale for randomisation (to avoid bias). One way to explain this is to say:  
*‘Sometimes we don’t know which way of treating patients is best. To compare the two, we need similar groups of patients to have either HIFU or surgery. The only way to make sure that the groups of patients are as similar as possible is to have the allocation decided by chance: a process called randomisation. If patients or doctors decided who went in each group then we might start with one group having younger fitter patients to start and therefore doing better because of this not the treatment. Putting people into groups by chance means that all of this variation is simply cancelled out. If you agree to take part in the main study, you will have an equal chance of having HIFU or surgery. Whichever treatment you are allocated to, you will be treated with the best possible care and the doctor treating you will be experienced in the technique.’*
- Randomisation can be a solution to uncertainty

### Closing the appointment

- It is really important to directly ask the patient they wish to join the study
  - If they do, check they would accept either treatment and then arrange randomisation
- If they are hesitant about taking part, reassure them that they can take some time to consider whether they want to take part, give them the main PART information sheet and advise them that can contact the research nurse (or whoever appropriate) if they have further questions

### The QRI team is here to help

Please aim to record all discussions with patients, providing they are happy for you to do so. This gives us an insight into what works so we can help you and others to recruit.

For further questions and support, contact [daisy.townsend@bristol.ac.uk](mailto:daisy.townsend@bristol.ac.uk)