

The role of patient treatment preferences in improving trial recruitment: evidence from the ProtecT trial

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Patient treatment preferences

Received wisdom:

- Preferences make it difficult to do RCTs especially when treatments are very different
- Challenging preferences is coercive

Literature:

- Reason for poor recruitment barrier
- Research into them sparse and inconclusive



Reconceptualise preferences from barrier to facilitator of recruitment







ProtecT Randomised Trial

- 3 arm UK trial for localised prostate cancer:
 - Surgery, radiotherapy, active monitoring
- Perceived too difficult to recruit
- Randomised ~1500 men (63%) (1999-2008)
- Research to investigate recruitment process

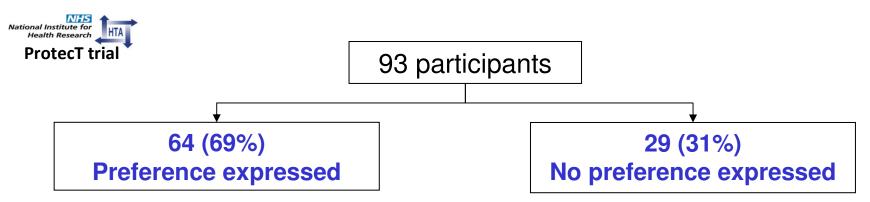


Treatment preferences in ProtecT

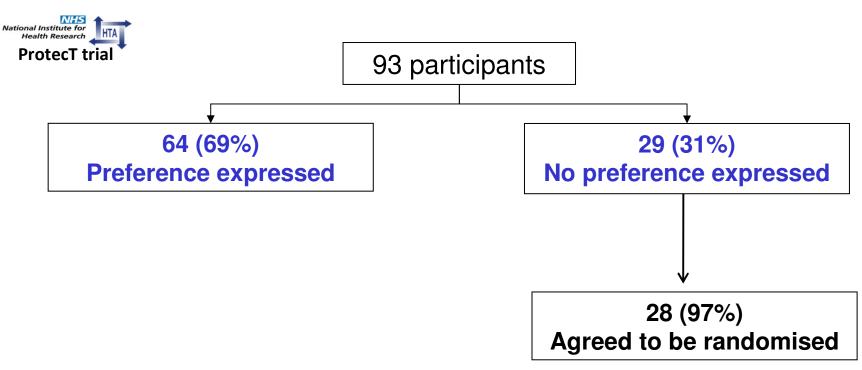
- Consecutive recruitment appts during a 3 month period across all 9 study centres selected
 - 93 appointments
- Recordings analysed Content and thematic analysis
 - When and how preferences were expressed
 - Rationale
 - What happened to them
 - Relationship with treatment received

Mills N et al. Journal of Clinical Epidemiology 2011; 64: 1127-36

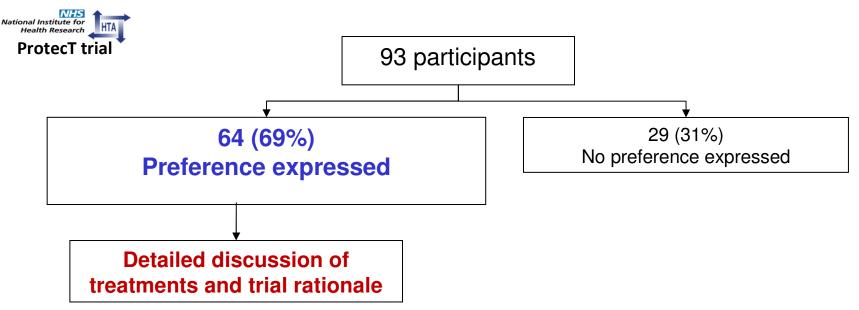




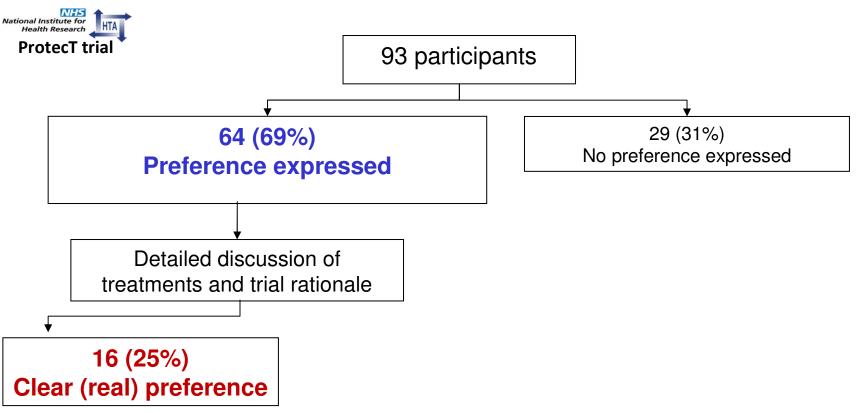




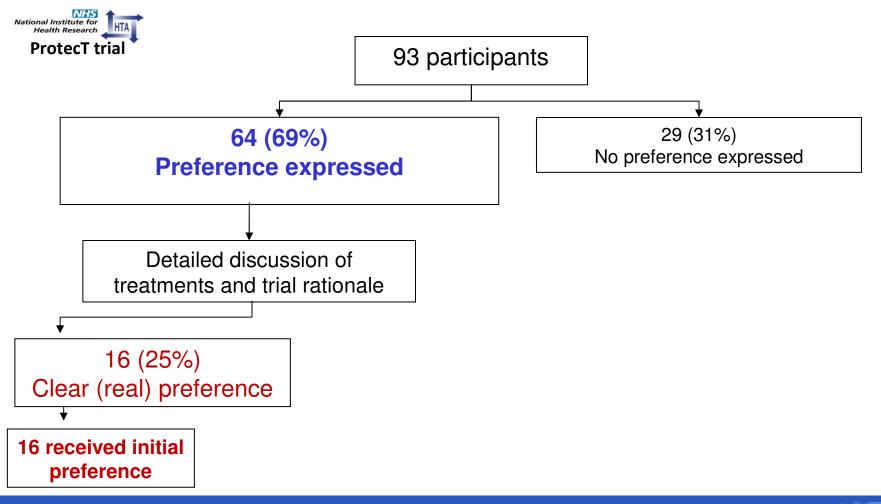




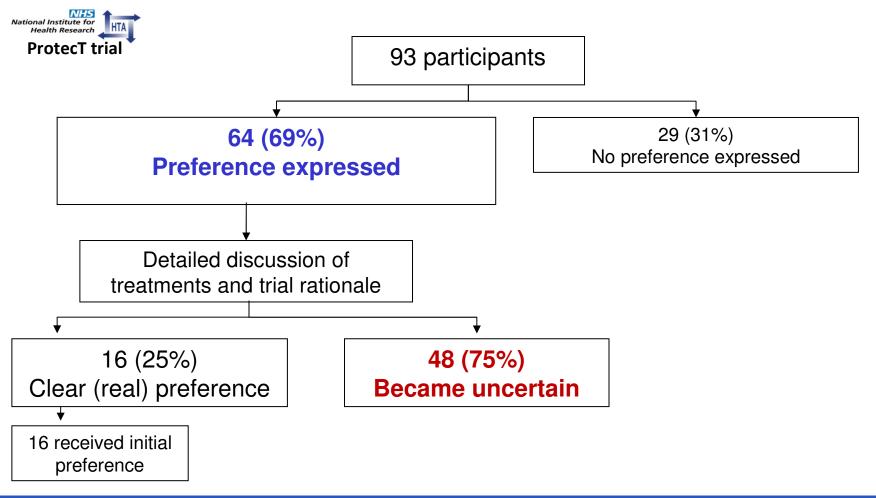




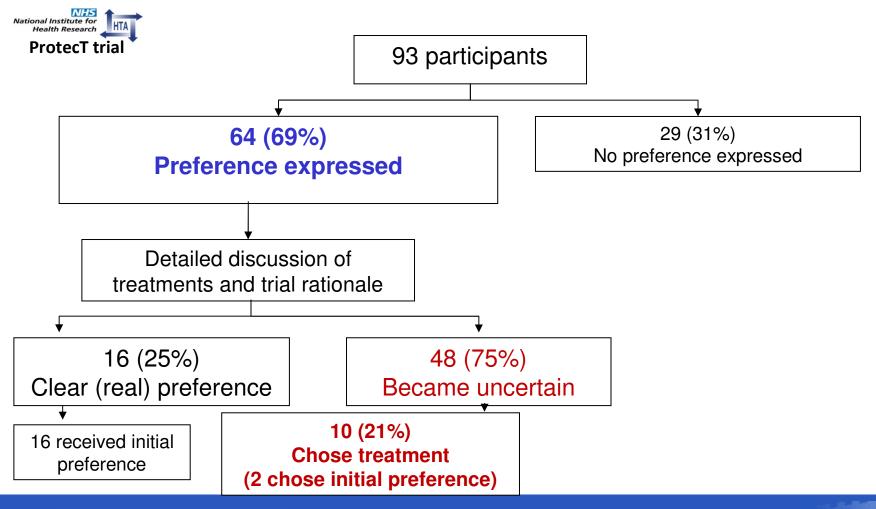




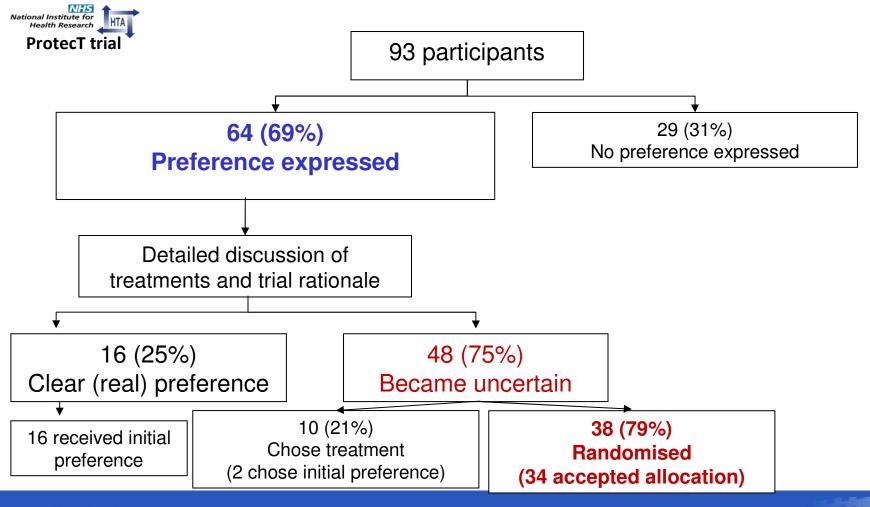








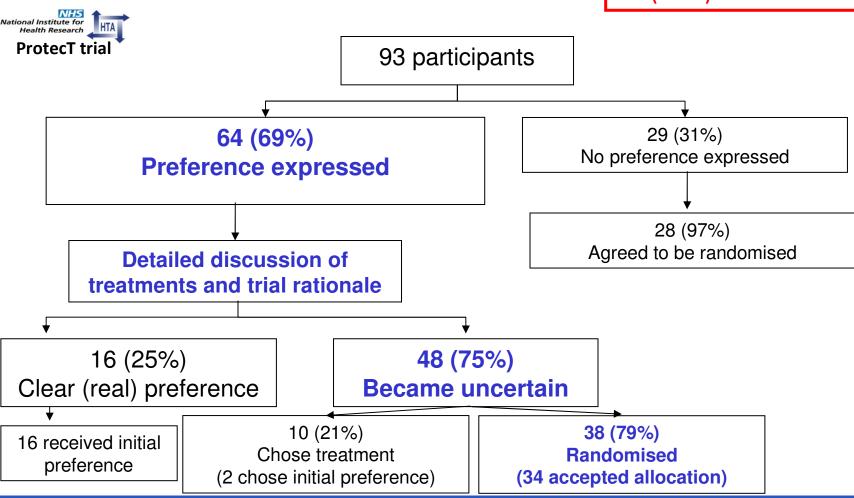






Preferences

24 (26%) chose treatment; 69 (74%) were randomised





1. Explore views on treatments early on "What are your thoughts on the treatments?"



- Explore views on treatments early on
- 2. Acknowledge preference



- 1. Explore views on treatments early on
- 2. Acknowledge preference
- 3. Ascertain rationale
 Reasons usually multi-layered & complex



- 1. Explore views on treatments early on
- 2. Acknowledge preference
- 3. Ascertain rationale
- 4. Counterbalanced information

Position of clinical equipoise

Uncertainty of the prognosis

Putting concerns into perspective

Pros/cons of desired and less desired treatment



Example: techniques in action

Man (In ProtecT): If I went in for the operation.... then you've got the recovery, then you've got this that and the other (side effects) and then I think I'm better to leave it (have active monitoring)

Recruiter: The guarantee with that I would say is that they would get rid of the prostate cancer you get that reassurance

(Continue discussion about all treatments and trial)

Wife: Oh as he walked through the door he was definitely (opting for) monitoring....

Recruiter: How do you feel (now)?

Man: I don't know, when does the decision actually have to be made?

(Discussion about the trial/randomisation)

Man: Doesn't it say in that you could be cracking a walnut with a sledgehammer and you might be-

Recruiter: Could be but we don't know that you see...this is the thing we might need a sledgehammer we just don't know, that's the problem



(Continue discussion about treatments and the trial/randomisation)

Recruiter: And that (allocated treatment) will be right for that man (Man: Yeah) because none of us know any different......

Man: That's just like opened another- it's given another argument so to speak which up until this point here...I didn't know the implications, therapies...because to be honest I just put that on the back burner.... this has been very informative....I am happy with this because now I know in the end it's going to work for me.....

Recruiter: So how do you feel then, what are we going to do? **Man:** I'm, I'm happy with all three so to me it would seem a crying shame not to take part in this work today...well, well they've all got their pluses, they've all got their minuses...I haven't got a preference as such you know they're all equal. (Told allocation) To be honest I would have been ok with any.

Outcome: Randomised to AM; accepted allocation in appointment



Conclusions: Patient tx Preferences

- Common at recruitment
- Range on a continuum:
 Strong-vague, informed-not
- Dynamic
- Essential part of process of recruitment:
 Acknowledge, understand basis, tailor information
- Can facilitate rather than hinder recruitment



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Further information:

Mills N et al. Exploring treatment preferences facilitated recruitment to randomized controlled trials. JCE 2011; 64: 1127-36

