

Uncertainty and patient treatment preferences: preventing or facilitating trial recruitment?

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Outline

- Background
- Barriers to RCT recruitment
 - ❖ Treatment preferences
 - ❖ Uncertainty
- Potential role in RCT recruitment of
 - ❖ Uncertainty
 - ❖ Treatment preferences



Background

- Anthropology
- Trial participant's view of taking part in RCT
 - ❖ CLasP
 - Random
 - Trial
 - Comparison
 - Uncertainty
 - Fate



RCTs

- Highest level of empirical evidence
- Most robust scientific design
- Random allocation eliminates bias
- Best (only?) way to answer important questions
- Funding bodies keen to support them
- GCP

So why are they so difficult to do?



Investigating how RCTs work

- Qualitative research
 - ❖ Interviews with patient participants
 - ❖ Interviews with clinical participants (recruiters)
 - ❖ Observations/recordings of recruitment appointments
 - ❖ Discussion groups with recruiters (training)
- Ethnography - anthropology



Generic lessons from ProtecT for RCTs

- Presentation of information to potential participants is crucial
 - ❖ Order
 - ❖ Uncertainty, balancing treatments, randomisation
- Interpretation of terminology by participants is even more crucial
 - ❖ RCT terms
 - ❖ Treatment descriptions etc.
- Need for training of and feedback to recruiters
- Need to continue to monitor recruitment throughout



Quartet RCTs

1. Different protocols of follow up after primary cancer treatment
2. Laser v. radiotherapy for throat cancer
3. Three combinations of drugs for fever in children in primary care
4. Evaluation of a social policy for people with severe mental health problems
5. Radiotherapy v. surgery for bladder cancer



Findings from six RCTs

- Difficulties
 - ❖ Logistics: recruitment process often complicated
 - ❖ Eligibility: few patients eligible; different definitions
 - ❖ Communication within RCT teams problematic
 - ❖ Some recruiters with poor understanding of RCTs
 - ❖ PIS sometimes did not reflect equipoise
 - ❖ **Patient preferences**
- Initial solutions from qualitative research
 - ❖ New, more balanced PIS
 - ❖ Streamlined recruitment and eligibility process
 - ❖ Training and individual feedback for recruiters about uncertainty, randomisation, terminology, **preferences**



Treatment preferences: received wisdom

- Many patients express preferences for a particular treatment
- Preferences make trial recruitment difficult
- Challenging patient preferences is coercive
- It is impossible to do RCTs when treatments are very different – because of patient preferences
- Literature – very sparse and inconclusive



“If I did have anything done, I would prefer the surgery.. I don't know that much about it but I think if you have surgery probably they could remove something and I would sooner have that then the radiotherapy or the monitoring because this is just my personal view.”

“Active monitoring sounds to me like the right thing to do. That's what I feel at the moment.”

“I think I would like to have it eradicated and go for radiotherapy ... With the monitoring, it's still there. I'd like to get rid of it.”



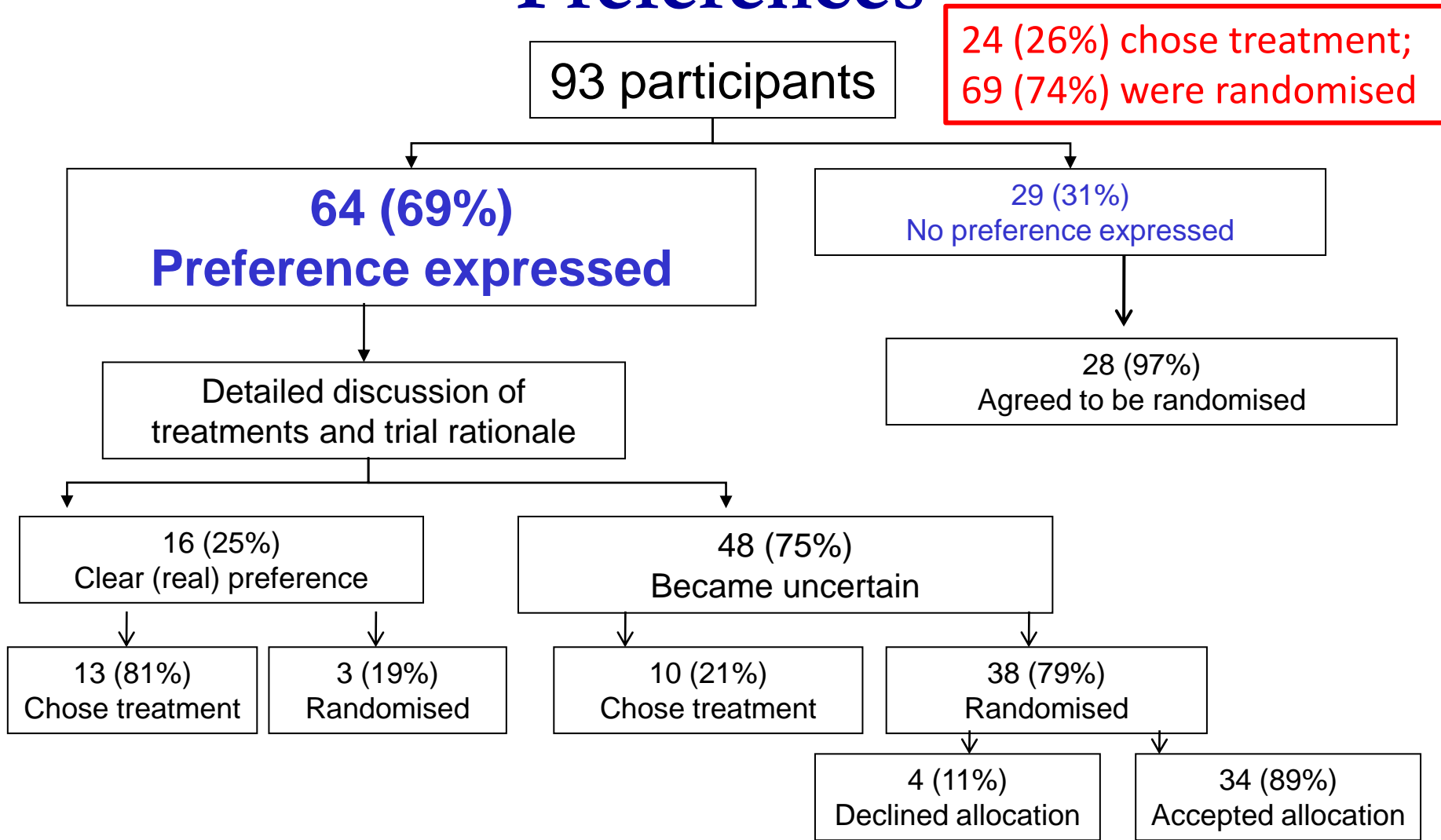
Treatment preferences in ProtecT

- ❖ All recruitment appointments in ProtecT study routinely audio-recorded
- ❖ Consecutive recruitment appointments during a three month period across nine study centres selected
 - 93 appointments
- ❖ Recordings analysed
 - Content and thematic analysis
 - When were preferences expressed, how were they expressed, what happened to them

Mills N et al. *Journal of Clinical Epidemiology* 2011, 64 (2011) 1127-1136



Preferences



Summary: ProtecT treatment preferences

- ❖ Majority of participants – 69% expressed initial treatment preferences during recruitment appointment
- ❖ Discussion with recruiters led to
 - 16 (25%) firming up views and obtaining preference
 - 48 (75%) becoming more uncertain and open to randomisation
 - 38 (79%) agreed to be randomised (more than half to a different treatment from original 'preference')
- ❖ Overall – out of original 93
 - 24 (26%) chose treatment; 69 (74%) were randomised



What exactly are treatment preferences?

- ❖ Range along a continuum from hesitant opinions to well-formed intentions
- ❖ Can be clear or not
 - “Surgery rids the prostate and therefore rids the cancer. I would be worried about it spreading if I had active monitoring.”
 - “Radiotherapy makes all your hair fall out.”
- ❖ Process of recruitment can help to distinguish stronger from weaker preferences

Mills N et al Exploring treatment preferences facilitated recruitment to randomized controlled trials. *Journal of Clinical Epidemiology* 64 (2011) 1127-1136



ID 52: “When I came in I thought I’ll get surgery and have done with it ... but I am listening to you and now I’ve swung towards the radiotherapy ... [Discussion about AM] ...

The monitoring would be nice, but I just need something to be done ... [Discussion about treatments]

I’m not happy to go through an operation which, if the radiotherapy works, I wouldn’t have had to have had ...

[Discussion about randomisation and RCT]

Well you’ve given me another alternative to how I was thinking.”

RECRUITER: “So you’re feeling more open to the radiotherapy?”

ID 52: “Yes yes.”

RECRUITER: “And a little bit open to the active monitoring?”

ID 52: “Yes . well it’s reassured me ...”

RECRUITER: “And a bit open to the surgery ...”

ID 52: “That’s right.”

(Randomised to radiotherapy; accepted allocation in appointment)



Conclusions

- Treatment preferences and uncertainty need to be more critically evaluated and may provide opportunities for RCT recruitment
- Qualitative research can contribute to improving recruitment to RCTs

