



STAR-TREC

The Randomisation Interview: how to approach patient recruitment?

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Mandate: Public Prioritisation



Rank	Question
1	What is the best way to treat early cancers in the back passage?
2	How can we reduce the chances of leakage from a join in the bowel?
3	Which polyps predict risk of developing bowel cancer?
4	How can we improve care for patients with severe infection related to their bowels?
5	What is the best way to check that cancers of the back passage do not come back?
6	What is the best way to look after patients with Crohn's disease with fistulas around their bottoms?
7	How do we personalise treatment for cancer of the back passage using genetics?
8	How do we improve screening for bowel cancer?
9	Why do some patients develop spread from bowel cancer?
10	What is the best way to close the "hole" when the anus is removed?

Recruiting to RCTs can be difficult...

Contrasting arms No treatment comparators • Watchful waiting

Optimising recruitment: Understanding pathway Plan to pre-empt difficulties

Recruitment Pathway

Complex process

Not an event

Key Components of the Recruitment Appointment

What patients need to hear to enable them to make a fully informed choice about trial participation

Rationale for the RCT:

Uncertainty and equipoise



What to say? You need a simple plan.

- They have cancer that is bad
- The cancer is small this is good
- <u>As the cancer is small there may be more than one</u> way to treat it
- This choice can seem a little stressful (but really it's a good thing)
- We will help them understand their choices

Balance of Treatments



Balancing Treatments 1

- Standard treatment is surgery to remove rectum
- Existing evidence
 - Lots of people treated 'routine'
 - Cure very likely





Balancing Treatments 2

- As the cancer is small could try and treat it using radiotherapy without a big operation
- Existing evidence
 - We know that some small cancers disappear after radiotherapy
- Lack of evidence
 - Not many people treated (*experimental*)
- Potential Benefits
 - treatment might be easier in short term for some
 - might have less side effects
- Potential Harms
 - treatment might not work <u>still need the big operation</u>
 - We have not treated enough people to know if this approach is as good at curing cancer as standard surgery?





Randomisation: <u>Process and Purpose</u> "In your own words"



Randomisation

<u>Process:</u>

Method for achieving groups that are as equivalent as possible (the only difference will be the treatment)

<u>P</u>urpose:

Enables fair comparison at the end of the study (so that any difference between groups is due to the different treatments rather than the characteristics of the patients treated)

Neither the staff nor patients can choose the treatment



Patient choices:

- 1. Pick standard treatment
- 2. Enter a study comparing standard treatment versus the new experimental treatment

If they enter the study then treatment is <u>decided by chance</u>/ they do not get to choose!

WE WILL ASK THEM TO RANDOMISE

Explore Preferences

Incomplete information

Simulations

Practice makes perfect

Final thoughts

- Personal choice
- We must explain pros and cons clearly
- Up to the patient to decide what is right for them

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