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Patient's experiences of participation in a clinical trial: MARS 2

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Background

- Malignant pleural mesothelioma
 - Predominantly the lining of the chest wall and lung
 - UK highest incidence in the world
 - Current treatments response variable, high mortality
- Mesothelioma and Radical Surgery 2 (MARS 2) UK Trial
 - compared chemotherapy and surgery to chemotherapy alone
- Nested sub- study: patient's experiences

Methods

- Longitudinal semi-structured patient interviews
- 15 participants
 - Arm A: surgery + chemotherapy (9)
 - Arm B: chemotherapy alone (6)
- Framework analysis (Ritchie & Lewis, 2013)

Participants and interviews

- 41 interviews
- Interview topics
 - **Experiences and views on recruitment and randomisation**
 - **Influences on decisions to participate in the trial**
 - Expectations and experiences of the treatments received and associated care and support needs.

Prior

- Patients approached about the main MARS 2 study
- Informed about the potential of interviews later in the schedule

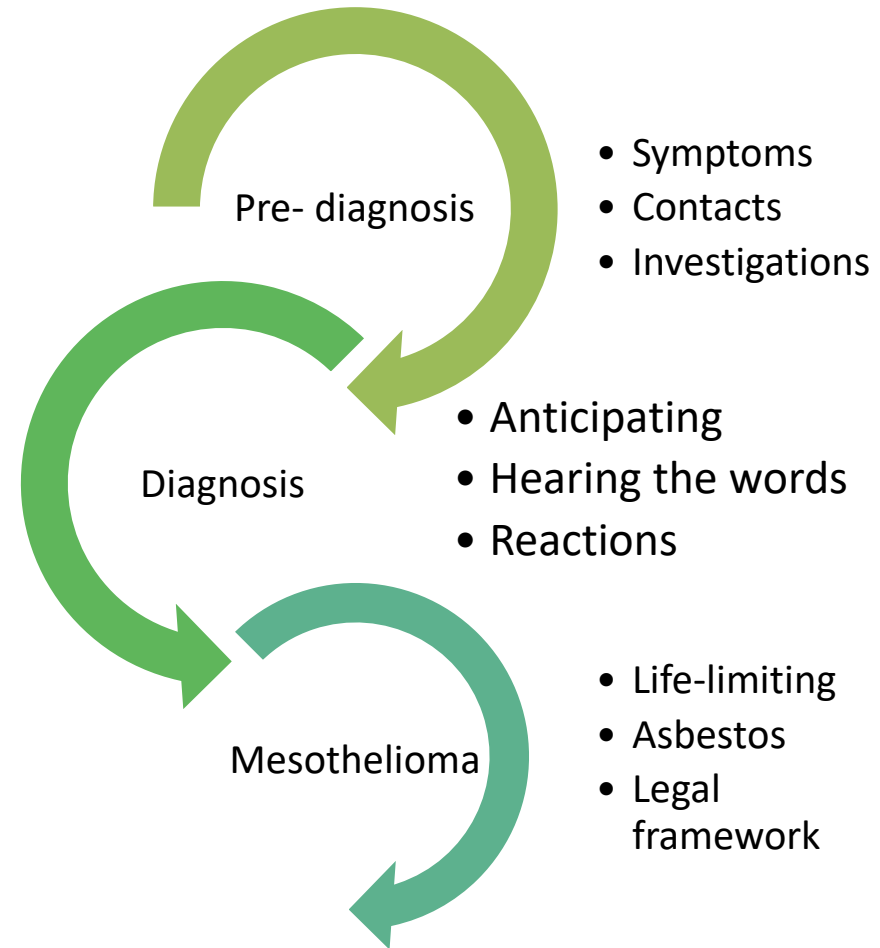
Prior

- Patients meet with surgical team, receive explanation of surgical intervention
- Patients receive 2 cycles of chemotherapy (cisplatin and pemetrexed)

Prior

- CT scan carried out and reviewed by surgeon. A decision on eligibility for surgery is made, patient informed they are going **for randomisation**

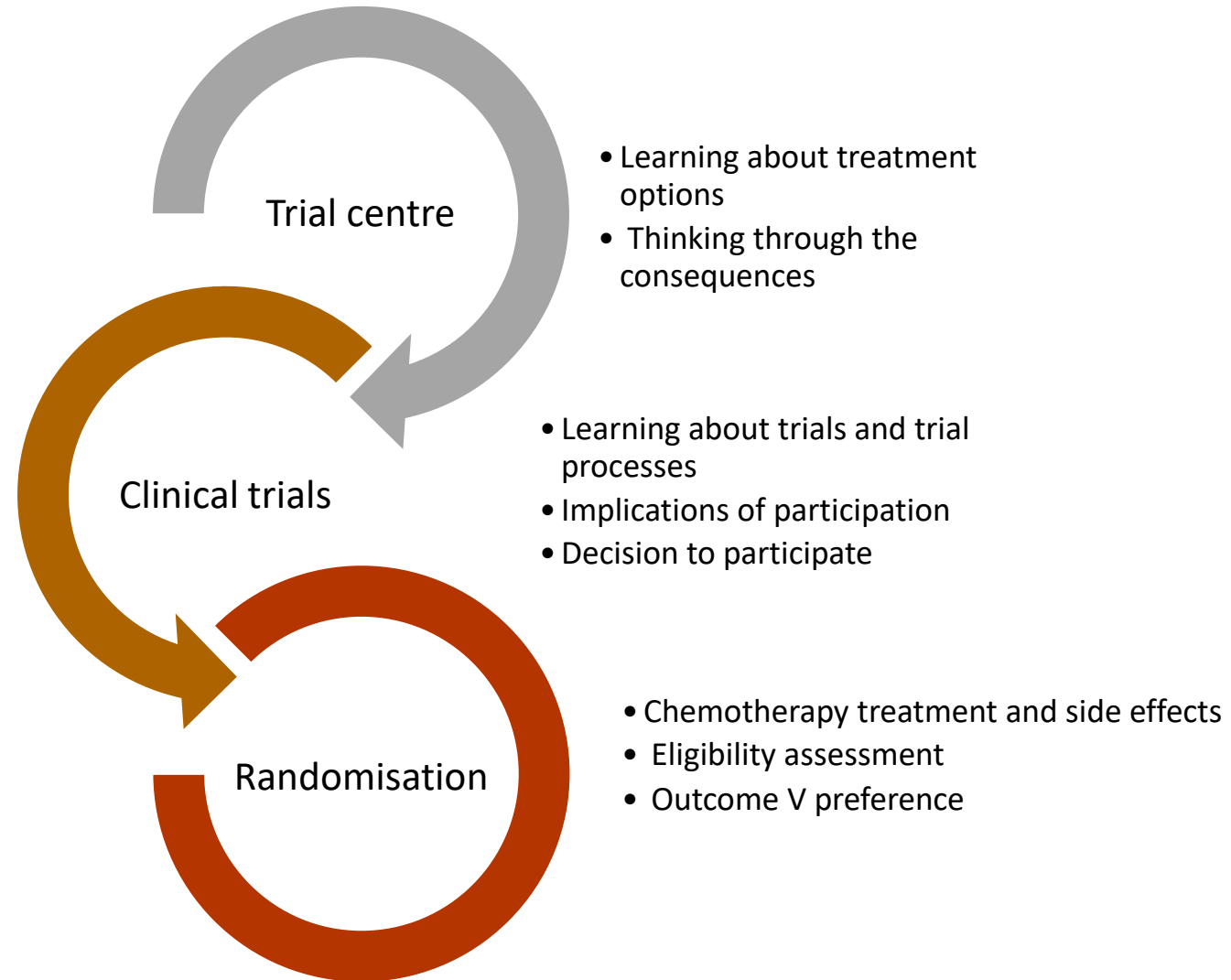
Theme one: getting to the trial



Mesothelioma insights

- *“I worked in the factory, but also there’s tips of it everywhere round where I live..... loads of lads at work had died and even a neighbour two doors up, and she had never worked there.....because of things how it is over there I did expect something, sometime maybe”*

Theme 2: Learning about the trial



Theme two: learning about the trial

- Lots of positives
- Challenges
 - *we tend to get bombarded with paperwork and booklets, and I've tried to read them all and some of it makes sense and some of it's way over my head.....sometimes understanding the expressions that they use and the descriptions of various things..... sometimes it does seem an awful lot of stuff to take in...some bits, I know, don't apply to me but ..It's sometimes a bit confusing sorting out the exact very important bits (Int 4).*

Achieving equipoise

- *“He explained to me that.....given the current state of medical knowledge and techniques available.....if it was him personally that had mesothelioma, if surgery was available as well as chemotherapy he would probably go down that, if he had the ability to affect the outcome he would hope for it and probably would want it and equally if it was his family” (Int 13)*
- *“It has been explained to me in words of one syllable – in a very compassionate way I might add...that there is no evidence that adding radical surgery will make a massive difference.....To be fair to them they said we just do not know and that is the reason why we are conducting the trial” (Int 13)*

Equipoise

- *“He said at the moment, he said looking at your screen, he said you are right on the borderline for me to do this procedure of stripping all around your lung. He said, I wouldn't be doing this operation if I didn't think it was going to give you a better time of life - he didn't say what length of life, he said better time of life”. (Int 6)*

Reasons for trial participation

- To get surgery (if this was their preferred treatment option).
 - To support a “positive” approach to coping
 - To get enhanced support and care that might be available to trial patients
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- Altruism through being involved in research

- *“What I wanted from MARS was that...it has given me some hope, because in the beginning they were.. a little bit, oh you've only got so long and all the rest of it, you know what I mean? And I was thinking, oh...bugger this for a game of soldiers! That...apart from giving other people a chance, that it would also give me a chance, if you understand”. (Int 10)*
- *“I just thought, I'll do that, you know. If it doesn't work for me, you're like a guinea pig really aren't you, it will work for somebody else, won't it. Experimenting with things isn't it, so that's the way I look at it”. (Int 2)*

Understanding randomisation

- *“They explained it well. There would be 50 people on the trial, 25 would go one way and 25 would go the other way and it would be entirely randomised”. (Int 10)*
- *“They put all the results of the two, what happens on the chemotherapy side of it...and put it into a computer and then the computer spits out a name.....I don’t want her, I don’t want her, yes we’ll have him....presumably there’s a criteria that it has to meet and obviously, because I had responded to the treatment and that’s why I got picked for the surgery”. (Int 11).*

Preferences for randomisation outcomes

- *“As a lay person, I felt that if I can use this term the full loaf if you like, the whole loaf was really, really a process of receiving both aspects chemotherapy and the radical surgery”. (Int 13)*
- *“Because I’m a mechanic, maintenance, I see it as a hands-on thing so I was going for the surgery. That’s what I would’ve gone for because I can see it plain in my mind; they cut it out, get rid of it”. (Int 4)*
- *“I still consider myself quite fit and I thought to myself maybe if I had that op it could flatten me like and put me out for months and months. So, I wasn’t too upset, put it that way..... If it had been offered to me I would have taken it but secretly I was glad that it wasn’t”. (Int 5)*

Not getting your preferred treatment

- *“I sort of got my hopes built up, you know. I had a scan.....blood tests and then the breathing tests and everything and the surgeon.....said that I would be an ideal candidate for it. So, I was sort upbeat for that, if you understand what I mean..... and then it came up with the chemo.....then, to be perfectly honest with you, I was a little bit, oh. You know what I mean? It was like someone putting a pin in a balloon. Not with it going bang, but deflated”. (Int 10).*
- “[I] sort of wished I hadn’t got to go through it but you take what is given and offered”. (Int 11)

Key points

- Managing the volume and complexity of trial information
- Understanding trial processes – randomisation
- Achieving equipoise

Summary

- By exploring patient's perspective this nested study provides insights into the challenges patients face when deciding to participate in a clinical trial.
- It highlights the benefits of incorporating these approaches into trial programmes
- The findings can be used to develop strategies to support understanding and decision making that reflects patient's priorities and concerns.

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