**RUTI STUDY**

I: Okay, thank you very much, I really appreciate that. Could you tell me about your role in the trial again?

P: Remind me which trial?

I: This was –RUTI trial for Chinese herbal medicine in patients with -.

P: Basically recruiting the patients opportunistically, reviewing the ones that we found on searches and then being involved with consenting and prescribing medication; that was my main role.

I: So as a xxx to do what you had to do as a recruiting clinician on this trial?

P: Basically [if you see a patient who gets recurrent UTIs in clinic], so we would invite them in and describe the protocol and whatever and then the other way we recruited patients was to do searches of people who had recurrent UTIs or were prescribed the standard drugs, like trimethoprim and nitrofurantoin often – and so we look at the notes and – we find the patients and then we would check over that before we sent letters out.

I: Okay. And did you find any of these processes difficult? (P: No) No, okay, that’s fine. So it went very smoothly and –

P: And that’s good, yes; the only thing was that there was quite a number of exceptions and – to the study which meant that although it seemed you’d picked up an awful lot of people who, on the searches, were feasible, when you drilled it down to the exclusions, it wasn’t so suitable for many.

I: Okay – and that made it difficult?

P: Yes, that was the main reason why we didn’t recruit very many patients.

I: Okay. So you would say a very strict selection criteria?

P: Yes, because the inclusions – particularly the co-morbidity ones and the renal criteria, meant that most people were out.

I: Okay. Was there anything you enjoyed about this process of the trial?

P: I like doing research generally; I think it’s a good – good potential product, so I was enthusiastic about using the product itself. Patients were very keen to do something non-antibiotic related, so those things. EXPAND!!!!

I: Okay, it’s nice to hear that. And – did you have any thoughts about Chinese herbal medicine before you started this trial or did you have any personal experiences, at all?

P: Only anecdotally. I’ve never done a trial with it and never obviously prescribed it for patients who’ve told me about it. We’ve been involved in other studies for UTIs and so it’s always been something looked into, as part of the research for that in the past. So – yes – not personally had any – not read very much about it, but, yes, good stuff.

I: Could you tell me – was this research – the previous research you did about – for patients with UTIs as well or – is something –?

P: Yes, we’ve been involved with the ATAFUTI Study, so that’s using the same product pretty much but for acute UTIs.

I: Okay, I see. And did you notice any difference between that research you did and this one?

P: Well, yes: this one was for repeat prescriptions – repeat UTI trials – that was for acute episodes, so it was rather easier to recruit to, in fact that we got quite a number of recruits to that one – because the exclusion criteria was rather different.

I: I see – and made that trial more successful because –?

P: I think so, yes.

I: I see, okay. And can you tell me a little bit about – how did you feel about administering herbal medicines during this trial?

P: I didn’t mind herbal medicines in any way really. It was a product study, under test, in the same way as any new product would be, any new drug would be, so it had the same criteria for explaining to patients about potential side-effects etc and it was essentially saying that – it was a more traditional medicine that was under test.

I: Okay, so – so you wouldn’t say there was any change – like in terms of administering, because you knew it’s something else, non- conventional medicine? Did you feel a little bit different, at all?

P: Not at all.

I: Not at all, okay. And – can you tell me a little bit – did you have any concerns during this trial about the medicines or the participants or any other concerns you can tell me about?

P: No, no, not at all. The only thing I would say – the tablets were very large, but that’s not really a major thing.

I: Other than that, any problems with participants, at all? CLOSED Questions

P: No, not at all; I didn’t have anybody who had to be withdrawn and it all went smoothly for the few people we did manage to recruit.

I: How many people did you managed to recruit, at all?

P: I’m not sure, but it was less than five.

I: Less than five? I see. And – tell me a little – what was your impression of the effects of Chinese herbal medicine on the women taking part in the trial; were there any benefits, at all?

P: It’s difficult to draw that conclusion from RUTI because we had a very small number, but ATAFUTI, which is the same product, we had very positive results. The patients did seem to get better from the product. So – you know – I think it’s probably a biologically active substance xxx.

I: Okay. Could you expand a little bit – like – what benefits did you see in the patients; terms in of symptoms, how did they describe it differently; what was it exactly?

P: They got better.

I: They got better? Okay. And did they notice any side-effects, at all?

P: Not that I can recall being told.

I: Okay. And – a few more questions, we’re finishing soon. Having been involved in this trial, can you tell me any ways your thoughts about Chinese medicine have been now changed?

P: I feel more positive that – if they are trying to get some real evidence base behind using them, that would mean them moving into the mainstream medical use, really.

I: I see. So you mentioned you had some involvement of previous – previously of a Chinese herbal medicine, would you say because of your previous involvement, you are more interested to find out about these medicines?

P: Yes, I would, yes.

I: Okay, I see. And would you say specifically for recurrent UTIs, your thoughts about Chinese medicine have been changed, or in general?

P: In general.

I: Okay. And – can you tell me – how do you think about Chinese herbal medicine differs from conventional medicine? You know you mentioned that a little bit, but could you expand that a little bit for me? GOOD!

P: Well at the moment it’s something that isn’t licensed in the same way and there really isn’t the evidence-base behind it. So I think any [avenues] that push it towards having to have the proof behind it, would mean it’s much more reliable and believable.

I: Okay, so the main concerns that most of the GPs have at the moment, is mainly the – evidence, there is no like scientific evidence for the proof; do you agree with that?

P: Yes, yes. That was actually what I just said, basically, yes.

I: Okay, I see. But what do you think about the fact that some of the medications we are taking – there is some conventional medication, like there is no scientific evidence for the proof for them either; what do you think about that?

P: I think that – we need to be moving towards evidence-based medicine generally and, yes, there are traditional things that haven’t actually had those studies done, but it then becomes quite difficult if things have been established for a long time – to get the ethical approvals to remove them. But, yes, I think – as a principal, we should try and get the evidence-base behind everything we do.

I: Yes, I agree with that, we should be, yes; we need to get evidence for everything, yes. So – would you consider using Chinese herbal medicine as part of your treatment in the primary care for recurrent UTIs in the future, once we have scientific evidence?

P: Very much so, yes.

I: Okay. So what would you need to be in place to enable this to occur?

P: Studies like the one we’ve just been doing basically; if it proves it works and proves the safety, then I think it will move very much into the mainstream.

I: Yes indeed and how do you feel about using herbal medicines for other infections, for example, for respiratory tracts infections?

P: I think it’s an interesting one. I feel a little nervous – unless we’ve got some evidence behind it. UTIs don’t tend to be quite so potentially serious as lower respiratory tract infections; most of them are self limiting anyway and, you know, looking at NICE Guidance, we’re meant to be leaving them alone until they’ve been going for a while anyway. I think we’re trying to look at the same with lower respiratory tract infections and should we wade in with antibiotics? So I guess it is very much the same, but just anecdotally I felt slightly more nervous and that’s probably not rational, but – you asked how I felt about it.

I: Yes, I see what you mean. And so you would say – exactly – would you think we need more studies for other infections as well?

P: Yes I do, yes.

I: And in terms of this trial we did – do you have any suggestions as to how we could improve this trial for a larger study in the future? I understand you mentioned about the restriction of the selection criteria, we could change that.

P: Yes, I think that is the main thing really; it really cut out – we had loads on our first searches and then slowly but surely everybody got wheedled out.

I: Okay, so apart from that, was there anything else you can think of we could change?

P: No, I think that was a good thing.

I: Other than that, so everything went smoothly and there was no problem at all?

P: Yes, everything did, yes.

I: Okay. And is there anything else you would like to tell me today about your experience, anything –?

P: No, no, it was a good study; it was just tricky to recruit to.

I: Okay, thank you very much, this is the end of the interview.

P: Okay, xxx, bye.

I: Thank you, bye.