TRANSCRIPT
Module 5: Balancing usual MS clinical care and a clinical trial

- Hello and welcome to Module 5 where today we're going to explore balancing your usual MS clinical care with the care that you might receive in a clinical trial. So looking at the outline today, we're going to be tackling some really practical issues, but they're issues that we need to talk about so that they're not unnecessary barriers to your potential clinical trial participation. Although this all may be very new for you, most clinical MS centres have experience with managing the balancing act between clinical MS care and research MS care very well. We're going to look at what to expect moving from clinical to research care and back again. We're going to look at the reasons for clinical trials ending early. We're going to talk about what happens at the end of a clinical trial, and we have two separate video interviews in this module. The first is with two research nurses from a major Sydney hospital and we're going to talk about the teamwork that goes on behind the scenes to ensure that patients receive good clinical care and good research care at the same time, whether they're in the same centre or whether they're sharing between different centres and different neurologists. We're going to look at the importance of that teamwork and the importance of communication. Then we're going to hear about the lived experience from Andrew who lives with MS and who's juggled research with his usual living with MS days in several trials, but he's going to talk specifically about a non-drug clinical trial and how he transitioned those trial benefits to his everyday life after the clinical trial was finished. Firstly, we're going to look at the setup of MS clinics and research centres. So there are usually different investigators and staff in any particular clinical trial at any given time. There's a Chief or Principal investigator who has the overall responsibility of being in charge, and this is usually a senior doctor or professor in a certain field such as medicine, nursing, or allied health. Then we have associate investigators who have different degrees of responsibility in the trial. Plus, there's a clinical trial coordinator or manager and there may also be research nurses, admin staff, and special assessors, for example, to do specific examinations and walking tests in MS trials. If the centre that you're visiting is a small one, the research coordinator may very well wear many of these hats. They may be the person taking your blood, doing the paperwork and making the phone calls. We can have separate or in tandem clinical and research care and what we mean by that is that you have your usual neurologist for your MS care and then you might be at the same or a different centre under the care of a different neurologist or specialist for the particular clinical trial and we would call this separate care. In tandem means it's the same usual care that you're receiving clinically and that site is also doing the research with the same neurologist looking after for both your clinical care and your research care. It matters because communication and keeping everyone updated on what is happening is hugely important. If it's all under the one roof, obviously this is easier, but if it's at different centres, there's just a few extra things to think about to improve communication. However, it's definitely all workable and possible with planning. Thirdly, there's different types of clinical trial centres. We introduced early phase or phase one studies in Module 1, and these centres specialise in this very early human research. We don't have too many of those in Australia. Most of our clinical trial centres are later phase for phase two, three, and four, and they're usually held in a hospital or clinic, but can be in a variety of settings. Does your clinical care change when starting a new clinical trial? It can do. Sometimes drugs or therapies are suspended for the duration of a trial and sometimes they are allowed to continue. What's important here is that everyone knows what is happening

and when it's happening and that there's good communication. We want the usual clinical care team and the clinical trial research team to both be on the same page and both aware of each other's activities and any changes to patient care. If there's a negative finding, meaning that the intervention or the drug doesn't help or is in fact harmful during the progress of the trial, the treatment may be stopped or you may be asked to reconsider continuing in the trial and be asked to sign a new consent form with the updated information in the participant information sheet. Now we're going to talk about clinical trials ending early. There are several reasons why a clinical trial might end early, either for an individual in a particular study or for all the study participants in that research. The study investigators may believe that the treatment is harming or not helping the patient and the doctor or chief investigator may recommend to the patient to stop the trial. There could be expected or unexpected side effects that may be worse than first thought. There might be new side effects or more serious side effects. Study tests on an individual might show a new abnormality or a worsening of condition. If during the study there's an interim study analysis, meaning looking at the data before the end of the study, it may reveal that there are no effects at all or there might be ill effects overall and this may lead to an early stoppage of the trial. Early results may indicate the trial is successful or unsuccessful, but either way, there may be no need to continue with the study. There can be various scenarios from here. Trial participants might be allowed to continue taking the medication or intervention if it has been beneficial and no harm has been seen, or if results aren't so good, it might be stopped like we've previously described and you might be followed up for a period of time by the investigators just to check on how you're going. If there are signs that the intervention in a trial could be unsafe, the research team or the regulators monitoring the trial may stop the trial. Also, if the new intervention is found to be clearly superior or inferior during the trial, the trial may also be stopped to reduce the number of people who receive the less beneficial intervention. What happens at the end of a clinical trial? The research team carefully analyses the information collected during the trial to make decisions about the findings and any need for further testing. Decisions are then made as to whether to progress the study to the next phase. This process can take several months to years depending on the phase of the trial, the number of trial participants and the amount of data collected. The final study report is written after the last person on the trial completes the study. This may be sometime after you finish the trial. Once the final study report is written and released by the study sponsor, your study doctor should receive a final study report from the trial sponsor which may be shared with you upon request. If you do not completely understand the results, you should discuss them with the study doctor. The results are usually presented as a summary of the outcomes of the whole participant group. It's unlikely that you will receive a copy of your individual results, but you can ask for this if it's possible. After your participation has ended, you and the study doctor or research team might discuss ongoing treatment options. What happens to drug therapy when a clinical trial ends? What are the different options available to you as a patient? And these should be stated upfront in the participant information sheet. Sometimes at the end of the trial, the treatment may be continued if it has been effective. Other trials, the treatment cease promptly at the end of the trial. You should be very clear on what the plan is before commencing in the study. Study doctors have an ethical obligation to provide or arrange post-trial care, whether a participant is eligible to continue study treatment or not. This may include referring you back to their own clinic or to another doctor or specialist for follow-up care, referral back to your primary care specialist, or referral to another clinical trial providing access to alternative approved

treatments. And like any major life change, readjusting to life after completion of your trial may take time. You may have grown used to the support of your clinical trial team, the companionship of other participants, and even the demanding time commitment. With all of these things suddenly over, you may find that you have more questions about the future of your health and treatment. Prioritising your health, connecting with other patients, and remembering to do the things you love can help you smoothly transition back to your daily life. And remember that your MS care team is there to answer any questions you may have. Next up, we're going to talk to two research MS nurses, Marinda and Alison, about starting clinical trials and moving between clinics and different or the same neurologists. We're going to talk about what goes on behind the scenes, how we share patients and the teamwork that's involved. We're going to also talk about how communication is absolutely key to a successful outcome for everyone. Hi again and welcome to our discussion for Module 5 where we will be exploring the shared care between clinical MS care and research care and we're going to have some tips for doing this well. So my guests today are from two different sites in Sydney who sometimes share patients or responsibilities. So I have Dr. Marinda Taha to my left and I have Alison Craig to my right. So welcome, ladies. But firstly, could you tell us a little bit about where you work and what your role is?

- Okay, well I work as the MS nurse consultant at a large hospital in Sydney, Concord Hospital, and I've been doing that for several years, having worked in this field for about 18 in total. I guess my main role here is very clinical. I'm sort of the go-to, the resource person to look after predominantly our MS patients, which we have many of. But as an adjunct to that, for many years, I have also done clinical trials in various areas including some at hospitals, so I have sort of have had my foot in both camps.

- Yeah, so I've also got a nursing background and I've been running the clinical trials mainly MS at the University of Sydney Brain and Mind Centre. And we're affiliated with RPA hospital for the last 14 years. And we've got a very nice little group that we work together with. So I'm purely clinical trials.

- So I think sometimes the process of combining normal MS clinical care and then adding or layering research on top of that can seem a bit daunting. So we thought we'd shed some light on what actually can happen in practise. If a patient is with you for clinical care and then wants to take part in a trial or other research at another centre, how do you work together to make that happen?

- Look I'd always be happy to encourage a patient if they wanted to do a clinical trial. And I suppose I would particularly if I knew the site, it's easier, you know, I can contact them and find out, you know, perhaps what they're looking for. I think sometimes patients don't realise there are very specifics, like we have things called inclusion and exclusion criteria and they get the thought of being on a trial, you know, is good 'cause they think something amazing might come out of it, but they may not fit the bill, so to speak. So I would happily try and support them and help them get information and, you know, if once all the right consents and things were down, I'd be happy to share their information just to help the clinical trial coordinator on the other side and the doctors.

- What happens, yeah, if a patient asks about a trial or if one of our neurologists identify a patient, you know, for a trial, they will then call me down immediately to come and talk to the patient. The University is really very strict on coercion and especially if the neurologist is an investigator on the trial as well.

- I can see how it's real teamwork there just to get the best outcomes for the patient, isn't it? So you said that you're trying to avoid coercion at all times, which must be really hard when a patient is being treated by their neurologist and then asked to be in a trial. Sometimes they feel like they need to say yes. But the process that you've just described really looks after the patient's interest, doesn't it?

- Yeah, even if I go down and give them the patient information sheet and answer the questions at that time, we send them home with the patient information sheet.

- I think some patients are too frightened to say no to their doctors. And I would always say, "You can always say no, that's your choice.

- Yeah, so it's good that you're doing that second check as well. You know, you're just supervising to see that everything's okay. So if patients hear about clinical trials from sources outside of their normal clinic, they might feel apprehensive about how they mention that to their treating neurologist. Firstly, is it important for them to do so? And secondly, how could they go about that?

- I would always want a patient to talk to us about a trial. I think it's really important everything's out in the open. There's no point trying to go off and do something that we don't know about 'cause we may not know how it affects the treatment that they're on. And you know, whilst we would encourage them if they wanted to do it, I just think it would be way more advantageous for them to talk to us. And if they were uncomfortable talking to the neurologist, I would be happy to do that on their behalf as well. I absolutely do that.

- So I think what you've mentioned both of you is just how important communication is when you're dealing with clinical care and research and clinical trials. So how do you maintain that communication when you're working with people that might be at different sites?

- I guess just by talking to each other really. I mean, we certainly, you know, any excuse for a catch up and there's been occasions where there might've been, you know, patients that have been seeing our doctors for their clinical visits, but for one reason or another, they might've been on the trial here. And so we would have their information or there was another case recently where a patient was on a trial of Marinda's and there was an issue with, you know, development of new lesions. And so they were in contact with us and, you know, the decision was made that she actually came off the trial and, you know, we took her on with different treatment. So I think it's really critical and we're pretty good at being in touch with each other. Well, we just want the best for the patient. You want to maintain their wellbeing and safety above all else whilst, you know, keeping them well.

- And it sounds like that communication link is just so strong and that's what leads to the success, doesn't it? And for the best outcomes for the patients.

- And I think that's important for all sites. You know, whether I've got a patient of Newcastle or Royal North Shore, wherever, you know, I keep in contact with the MS nurses there. They're crucial for me.

- I just wanted to say thank you to both of you for giving up your time to help us explore this today. I think it will be very reassuring for people to know what goes on the other side to make this happen logistically and practically and how flexibility and good communication can really enhance the trial experience not just for the patients, but for the staff as well with that back and forth and looking up to people.

- Thanks, Therese.

- Now we're going to talk to Andrew who lives with MS. Now, Andrew participated in a non-drug clinical trial and he's going talk to us about how he balanced being in that trial with his normal life living with MS. Andrew's also going talk to us about how he was able to reap the benefits of being involved in that clinical trial after the clinical trial was finished. Hi again and welcome to Module 5. So to help me with this today, I have Andrew Potter. Welcome, Andrew. Some of you will already know Andrew in his role as a National Advocates Coordinator at MS Australia. First up, what sort of clinical trial did you participate in?

- The one I'm going talk about with you this afternoon was the mindfulness trial that I did through one of the Universities on the Eastern Seaboard of the nation. It was a couple of years ago and it was a very interesting trial to undertake.

- Right, and did it happen close to home or was it remote?

- No, it was online. I live and work remotely in regional Tasmania, so I can be anywhere, anytime online. This was through a University in New South Wales and it was a trial in relation to people with MS and the inherent, potentially the inherent benefits of actively and positively practising healthy mindfulness. And I thought, hmm, I'll give that a go as a trial. I've got no idea what I'm in for. And I was a little sceptical when I started, just being a bloke from the bush a bit. But that soon, yeah, I, I left that scepticism behind and thoroughly enjoyed it. It was for six months and it was every day for an hour, which was a huge commitment. And I got better at it as I went through the trial, which was, I didn't know at the time, but that was anticipated and expected, so I was very much a stereotypical guinea pig in the trial and I loved it.

- Andrew, you mentioned that there are a lot of extra visits and extra time each day required to be in the trial. So how did you balance that with your normal life living with MS? Was it hard to add them in?

- It was. To start with, I did change the time. At one stage, I delegated that I'd do this... At this time, I finished work at 3 o'clock in the afternoon. I thought, well I'll do it at 3:30, not a good time. So I learned that pretty well straight away. So I flicked it around and did it at 9

o'clock every day and started work later. And for me, given I'm better in the morning and my brain was clearer first thing in the morning and I was more motivated in the mornings too, I had a much better outcome. And then I transitioned after a couple of months into 8 o'clock in the morning so that I could have my breakfast, do my routine of the morning, have my breakfast, and then get into the mindfulness to set my day up psychologically. And it took a little while, but after a week, I loved it. I loved the fact that I was doing it at 8 o'clock in the morning, which is weird for me, but 8 o'clock in the morning was the best time and it gave me a boost for the rest of the day. And then I started to look forward to 8 o'clock tomorrow, each day. I took a couple of weeks to find that place and I was supported by the facilitator of the trial through that process too. They were great. Led me hand by hand all the way through it, so it was great.

- Well, it shows two things, firstly, that there are trials in flexibility, so the trial support team and the trial staff tried to help you along that way to find solutions. But the second thing I really like about what you've just said, Andrew, is that you made it work for you within what could be done and what could be flexible to make it fit in with your life and for people living with MS, I think when you just said then doing it at the end of your workday, there probably was a collective sigh of ugh, that would be so difficult, but you made it work for you in a way that still fit the trial, so that's fantastic. But when you were participating in the trial, was there any change to your clinical care or that just went along in the background like clockwork and the trial was sort of laid on top of that?

- The intention was to stay precisely as it was. So not have any alternate changes in any of the meds that I'd taken, any of my routines so that it was gauged, the intention was for my life to be very stable and pattern orientated so that we could then measure the inherent benefit if there was any benefit or not of mindfulness. So same med, same exercise regime with exercise phys that I do every morning a couple of times a week. Same walking routine, same exercise bike routine I do. It was all very, with military precision, I stayed living my regular life and that was difficult for me to then think, oh, I'm going to change from 3 o'clock in the afternoon to 9 o'clock and then 8 o'clock, but with support, they led me by the hand through the process. But then once I got it together and I was comfortable with the 8 o'clock and I knew in fact what I was supposed to be doing 'cause I was very green in relation to mindfulness when I first started. Once I got into the groove, it just started to flow and it's, yeah, yeah, yeah, it was a good outcome.

- So did the trial staff, I'm assuming that you let your treating neurologist and MS care team know about what you were doing in the trial. Were they supportive of you participating as well?

- Oh yes, absolutely. They said anything that's going to benefit you, that's non-intrusive, and this isn't, go for it. And if you need to talk or if you need any support, sing out. A couple of times I spoke to my MS nurse about different things as you do. And he was great in relation to supports that he provided at the time, but it was a really easy trial to undertake. The biggest challenge for me was my time management with being at work and the physical challenges I had with my MS of the morning and then later during the day. That was the biggest component of the jigsaw to put smoothly together to be honest. Actually doing the trial was the relatively easy part once I got into the groove.

- Yeah, okay, so benefits after the trial was completed, Andrew, did you continue to see benefits?

- I let it go for two days and I missed it. And I still do it every day and it's about four years later, four or five years later and I'm still doing it every day and it's part of my absolute routine. Just things I do and there's a particular, it's corny, but there's a particular song I play, a little piece or whatever, and that's my reminder on my alarm to go and get in position to do my stuff. And yeah, I look forward to it everyday. It's great.

- Well, thank you for sharing that with us, Andrew, today. I think it's been great because you've shown us that trials can be flexible. You can work it into your normal way of life. You can also be considerate of your particular MS symptoms and you've also shown that great communication between you, your normal MS care team, and the research team can have great results. So thank you for sharing all that with us.

- My pleasure. Thank you.

- [Therese] Thank you for completing this module. A list of resources and references is also available if you would like to explore these concepts in more detail. I encourage you to please take the quiz to check your level of understanding before moving on to Module 6 where we will be focusing on accessing clinical trials and different ways that you can do that. We'll see you again in Module 6. Thank you.