IMPACT Grand Rounds 46 – The WHELD Programme

Jill Harrison, PhD:

Hi, this is Jill Harrison, executive director of the National Institute on Aging (NIA) IMPACT Collaboratory at Brown University. Welcome to the IMPACT Collaboratory Grand Rounds podcast. We're here to give you some extra time with our speakers, and ask them the interesting questions that you want to hear most. If you haven't already, we hope you'll watch the full grand rounds webinar recording to learn more. All of the companion grand rounds content can be found at impactcollaboratory.org. Thanks for joining.

Susan Mitchell, MD, MPH:

Good morning, I'm Susan Mitchell. I'm one of the principal investigators at the IMPACT Collaboratory, and I have the pleasure of chatting with Dr. Clive Ballard this morning. I'm going to let you introduce yourself.

Clive Ballard, MD, MPH:

Clive Ballard, I'm a psychiatrist from Exeter in the UK. I've been doing this a lot longer than I'd care to admit, but a big focus of what we've been doing over the years is to try and improve quality of care in care homes and nursing homes in the UK, really based on the sort of early clinical experience of just how terrible the interactions were, and how it just wasn't acceptable. It's a difficult environment to work with, and we've tried hard over the years to develop tools that are straightforward, usable, orientated towards the staff and residents in those environments, and hopefully manage to produce some evidence base around those types of evolved interventions that now do confer some good benefits for people.

Susan Mitchell, MD, MPH:

Thank you. So just to orient everyone, this podcast is following up Dr. Ballard's fabulous IMPACT Grand Rounds a few weeks ago, where he presented a body of work leading up to and including the WHELD program, which is a patient-centered program to help nursing homes manage patients living with dementia in a very patient-centered way and focused on managing behaviors without using antipsychotics, and really, a very holistic approach.

And I have to say, first, a few just comments. What was so remarkable is that so many of the issues, both clinically and scientifically, were so parallel and exactly the same as what we try to deal with here, both clinically, but also conducting pragmatic trials at the IMPACT Collaboratory in this very hard environment to do research in, and reminded me that we should look outward a little bit more at what other folks are doing, so we don't repeat the same mistakes and learn from each other. And again, want to congratulate you on just such an amazing body of work, and I was just struck by its very thoughtful evolution, and its rigor, and its conduct. To that end, I just want to ask you your opinion about... Are you familiar with the NIH stage model for non-pharmacological interventions?

Clive Ballard, MD, MPH:

No. I mean, we have an MRC sort of model in the UK that we followed, but it might be slightly different to the NIH model.

Susan Mitchell, MD, MPH:

Yeah, it probably starts with the developmental work, then stage one is pilot work, and then rigorous efficacy studies, and finally, get to stage 4, and it's pragmatic trials, or effectiveness trials, and finally, dissemination. Although Lisa Onken, who created it, always states that you don't have to be linear, what struck me about your body of work, which is so thoughtful, is it really took a long time, and you've kind of progressed through those stages. I'm wondering what you think about then, actually, to get to this pragmatic, real-world trial of WHELD that you're doing now. Just your thoughts on how long this research takes, and do we really need to have the strong efficacy, and controlled traditional trial before we move into an effectiveness trial, given how long this trajectory of research takes, and how great the need is?

Clive Ballard, MD, MPH:

I mean, I think a lot of the time part of the journey for us was actually evolving the intervention, because we did have evidence of benefits back in the first program we ran in the early 2000s, but I think it was about trying to really make this have an impact for people's quality of life, that then took a little bit of evolution. I think within a five-year period we could have — If we had the intervention there in a relatively evolved way, we could have taken it forward to the point we're at now. It was that journey of really learning how things work in a care home environment, how you tailor it to care staff, and how you sort of augment that intervention to really give the benefits that you want. So I think that was the part that took the journey. I don't think that was so much the kind of process, it was more the learning, and the co-creating to make something that was fit for purpose.

Susan Mitchell, MD, MPH:

What you might find interesting is the backstory about how I kind of, not found you, but got to understand your research more is, at IMPACT, we're all about doing pragmatic trials, and one of the challenges is getting researchers and healthcare systems together at the table at the beginning to design studies, and address things that make sense to both ends. And I got together about half a dozen administrators of nursing home change in the U.S., together at the same table with pragmatic trial researchers and clinicians who work in nursing homes to try to find their area of priority.

And across the board, it was how to deal with behavior. And so the next step as we educated them about what a pragmatic trial looks like, this and that, we tried to hone in on what intervention would be testable and feasible in their environment. And so I started looking at the literature, and found the WHELD program, and I introduced it to this group, and they said, "Whoa, that's going to take a lot of time. That's an hour and a half a week, two hours a week, and there's no way. We can't do it. No way." Even though it had all this great evidence, it was "no" from the get-go. And so we landed on something, almost what we consider a nudge, a behavioral nudge, which is a change to the EMR where it would, I don't know, disincentivize anti-psychotic prescription. But can you comment a little bit on this, I know we talked about it a bit at grand rounds, about the intensity of the intervention, I guess.

Clive Ballard, MD, MPH:

Yeah. I think a lot of it isn't... I think it's misleading, because I don't think it's an hour and a half of extra time. I think it's using the time better, because a lot of the focus, for example, is on improving care planning. So people within care home environments are doing care planning anyway. So they're not spending an extra hour and a half, they're spending maybe a small amount of extra time, but going through that process in a way that's more effective and more person-centered. And I think when we're engaging, onboarding care homes, nursing homes into the program, we talk a lot about that, because

initially, there's a lot of pushback around, "We haven't got time to do this. We're all very busy." I think the sell is always, "This won't take you more time, it's just using your time more effectively." You also gain some time if you reduce levels of behavioral disturbance, if you improve interactions with individual residents, then care interventions actually take less time, and they're more pleasant.

So I think what we've usually found is that once care homes buy into the program and do this, they don't really find that it takes them extra time, they're just using the time they have better and more effectively. And a lot of the kind of interventions and planning that we do are things that happen alongside other things, conversations that a member of staff might have with a resident whilst they're helping them with personal care. It's not an additional intervention on top of the care which has to be delivered anyway. So I think it's a little bit of a misunderstanding. We understand the pressures in the environment, and what we're trying to do is to help everybody use the time in a way that's more effective, and creates a more person-centered environment. So it's more effective use of time, not added time.

Susan Mitchell, MD, MPH:

Maybe it would help if you just took a couple of minutes, I know it would be hard, but nursing home X wants to use the WHELD program. So your team comes in, and what does that look like?

Clive Ballard, MD, MPH:

Well, we use a champion model, because I think that's by far the best sort of model of dissemination. Again, the champion program does take a little bit of time. The care homes have to agree as part of the partnership that the person will attend a minimum number of sessions over 12 weeks, so that will probably be a minimum of 12 hours of their time over that period. But that person, they can train up to four champions. They can train one or two if they want, depending what they're able to make available within the care home environment.

And then what we really do is support that champion to then sort of disseminate the training and approaches. So the digital platform is available to all of the staff, but it's the champions within the care home who are kind of support, and oversee, and mentor other staff. And we found that we've tried this direct training models, and we've tried the champion model, and we found the champion model works better, because it's embedded more within the care home, it's more sustained, it's a little bit easier on a colleague-to-colleague basis, rather than us flying in from outside. So that's kind of the approach that we've taken.

Susan Mitchell, MD, MPH:

Is the champion usually the head nurse?

Clive Ballard, MD, MPH:

No, and that's one of the things that we've learned a lot about actually, because when we started doing the program, it often was the head nurse, or the deputy manager, or somebody senior. But actually, what we've learned is that it's better to work out the dynamics within the care home, and understand who's passionate about the program, and who's got the respect of the staff, and that's not always the senior nurse or the manager. They might not have the time, but also they might not have the energy, the enthusiasm. So I think if we are selecting between 1 and 4 champions, we often take a little bit of time with the manager to jointly think about that, and talk to 1 or 2 of the people. And getting the right people, with the right energy, who have got that respect of their peers, is really important.

Susan Mitchell, MD, MPH:

So with the label, I know, there's a buzz phrase here called "train the trainer." Is this a train the trainer?

Clive Ballard, MD, MPH:

Yeah. It is, it's a train the trainer model. Well, actually, we are trying to get away from the word training, because I think what we're really looking to do is more coaching than training. We're trying to help people evolve their own care practice. So I think it's probably coach the coach, rather than train the trainer.

Susan Mitchell, MD, MPH:

Again, at NIA here, they're very... Not quite concerned, cautious about train the trainer models, because they want to be sure that the training can be done with fidelity, and that's been actually shown that that data is there, that when you do this training program, the trainers learn and become fellow trainers.

Clive Ballard, MD, MPH:

Yeah, I think that's really, really important, and I think that's why it's important that we have ongoing supervision sessions with the champions who are coaching within the care homes to help maintain that, and we also have tended to audit one or two things, like some care plans, and some other things to try and keep a good eye on that sort of fidelity. I think the other thing that helps with that is that the digital materials have been very well-validated, they were co-created, they were looked at quite carefully in a pre-study before the trial, to look at specific elements, and how people engaged with them, and what people found the most useful. So the fact that those kinds of individual digital elements are also available to all of the staff I think also helps with the fidelity.

Susan Mitchell, MD, MPH:

And so the evidence showing the fidelity of the training is there?

Clive Ballard, MD, MPH:

Yeah. And I think that is very, very important, because I think that's a big problem with a lot of things. One of my frustrations in this area, and one of the pieces of research we did as part of the previous in-person iWHELD program, was we did a review of all the training that was available in the UK, and there were almost 200 training programs available in the UK, only three of them had any evidence that they were actually giving any benefit to anybody. And what people say is, they're programs that have evidence-based principles, so some of the materials might be things that have come out of research papers. Actually, that's not what makes them work, the devil is always in the detail with these things, and it's how you make them engaging, how you maximize the fidelity, the sort of boring but really important elements that actually make a program work.

Susan Mitchell, MD, MPH:

So you're getting at another area that NIA is always pushing us on is, what's the mechanism? Like a biological agent, we have a mechanism, and it's been shown what the mechanism is, and how it acts on a cellular level. What would you respond if someone says, "Dr. Ballard, very nice, but what is the mechanism of how this works"?

Clive Ballard, MD, MPH:

I think it's all about the quality of the interactions. I think that's what really drives the benefit. So I think there's a lot of elements that go into that, but I think as soon as you're creating positive interactions, you're creating a positive environment. And I think within that, you've got some really key elements, such as... I think what we did find very much is that when we augmented a general approach to person-centered care, with a very specific focus on person-centered activities as part of that, that made an enormous difference.

And I think that's partly because that was giving direct benefit to residents, because they were doing something they were enjoying on a regular basis. But I think it was also something that was easy for care staff to understand. It wasn't over theoretical, it was very practical, they could see exactly what they could do, it was very easy to set a sort of target for how much activity somebody should be doing every day. It's a pragmatic mechanism, rather than a complex psychological mechanism. But I think that's really at the core, better relationships, and a focus on something that's directly giving people enjoyable time.

Susan Mitchell, MD, MPH:

My last question is sort of getting back to methodology. At IMPACT Collaboratory and the NIH in general, we're pretty strict in how we think about pragmatic trials. And I know because I'm Canadian, and I work with Canadians, and I think other places are a little less strict. And I'll tell you what I mean, your outcome, for example, of quality of life, which is ginormously important, can't be gleaned with health administrative data, it has to be done by and large by researchers coming in. And in our sort of definition of pragmatic trial, that wouldn't be a pragmatic trial outcome. I think moving forward, should IMPACT be renewed, one of our biggest challenges is going to be trying to marry the idea of a patient-relevant, or caregiver-relevant outcome, with this idea of making it pragmatic, whether you use natural language processing, or inserting new outcomes in the EMR, et cetera. And so I know you're moving on, or in the middle of doing a more pragmatic type of trial of WHELD, and I wanted to understand how you think about pragmatic trials, and pragmatic trial outcome ascertainment.

Clive Ballard, MD, MPH:

I think with some of these things, some of the things you can very easily measure are things like the number of people taking antipsychotics, and other psychotropic medications. So I think there are some things you can measure very, very pragmatically. I think other things are very hard to measure pragmatically. I mean, quality of life is a difficult thing to measure anyway. It's a particularly difficult thing to measure in somebody with dementia, and somebody with more severe dementia, and I think it's very hard to get away from the research tools that have been carefully evolved to do that. I mean, I think there probably is hybrid ground, and I think the hybrid ground is probably not trying to do that on every resident in every care home. It's to do kind of a little bit of mini sampling, but I think it's very hard to get away from that, to sample at least maybe three residents randomly in a care home.

And similarly, with behavioral disturbances, because I think you can try and capture indirect reports, but they're kind of highly inaccurate. So I think that kind of micro sampling just gives you a little bit of a... It does take a little bit of extra time, but if you're doing that relatively infrequently, it's not adding a lot of burden to anybody. What we have shown as part of the program is that these measures can be done reliably virtually through Teams or Zoom. So I think that means that, you know, lot of the time with doing these types of assessments is somebody having to go out and visit. I think if they can be done virtually, then it saves time for everybody, and a little bit of mini sampling like that should be feasible.

Susan Mitchell, MD, MPH:

Yeah. As you're talking, I'm thinking going through the machinations, and so most of our trials, or many of them, because they're introduced at the level of a nursing home, or whatever, and trying to mimic real world, we have a waiver of individual informed consent for many of them, because it's a programmatic level, trying to do best practices. So even to get a mini sample on folks would require-

Clive Ballard, MD, MPH:

Consenting.

Susan Mitchell, MD, MPH:

... consent. Yeah. And so in our minds, would undermine the pragmatic... I'm not saying it's good or bad, I'm just thinking about-

Clive Ballard, MD, MPH:

For that very reason, the other approach that we have used is dementia care mapping, where you obviously sit down and observe a group of individuals within a care home over six hours, every five minutes, and make a sort of validated judgment on their activity and their well-being. And that's actually quite a good way of looking at positive, enjoyable activities and interactions, and also you get a well-being score over the six hours. One assessor can easily assess 6 or 7 residents in communal area, over a six-hour period. And the advantage of that is that you don't necessarily need the names or any details of the residents, so it's properly anonymous, but it's a good way of assessing it within a care home.

So I think there's swings and roundabouts of that approach. It's a very good and well-validated approach, and we've used that in a number of our studies. Obviously it does require somebody to actually go and visit the care homes, it can't be done remotely. But as you say, the sort of benefit in terms of time and impact is that you don't need to consent to any individuals, it can just be done as part of the audit of the care home's practice. It's probably a much bigger thing in the UK than it is elsewhere, but it's been used very successfully as a sort of practice development tool in the UK, and a lot of staff within care homes are trained to do it.

What we've probably tried to do as part of research programs is either have a researcher do it, or to partner care homes that they swap over to do it, because obviously, there's a bias if they're auditing their own kind of... I mean, it's good for practice development, but if you're trying to get an independent view, we've got to find a way that it's not the staff within that particular home that are doing the assessment. But I think the good thing is, there's quite a good body of people who are trained to do it, so it makes it relatively straightforward.

Susan Mitchell, MD, MPH:

That's very interesting. In our rubric, I would think that maybe... I mean, a lot of our homes are corporately-owned, and so it could be someone from the corporate... Develop a...

Clive Ballard, MD, MPH:

Yeah.

Susan Mitchell, MD, MPH:

Yeah, yeah.

Clive Ballard, MD, MPH:

I mean, it's a four-day training course to learn to do it, it's not too problematic, and let's say it involves really visiting and spending six hours in the care home during daylight hours.

Susan Mitchell, MD, MPH:

Fascinating. Well, I continue to learn from you, and we all do, and I look forward to seeing more great research emanate from your shop. It was wonderful to meet you, and I hope we continue to work together, and think about these things together. So Clive Ballard, thank you so much for today, and for your grand rounds, and for your tremendous work.

Clive Ballard, MD, MPH:

Pleasure. Great to be involved, and great to have the kind of stimulating conversation. I think it's often those conversations that help you think about the ways you can take the work forward. So thank you.

Jill Harrison, PhD:

Thank you for listening to today's IMPACT Collaboratory Grand Rounds podcast. Please be on the lookout for our next grand rounds and podcast next month.