Jill Harrison:	00:02	Hi, this is Jill Harrison, Executive Director of the National Institute on Aging 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:	00:29	Hi. It's Susan Mitchell. I'm one of the PIs of the NIA Impact Collaboratory and I'm really pleased to have this podcast with Ellen McCready, Assistant Professor at the Center for Gerontology at Brown, who yesterday presented a terrific Grand Rounds entitled Using a Pilot to Test and Refine Your Measurement Strategy. Hi Ellen. Great to be with you today.
Ellen McCready:	00:56	Hi Susan. Thank you for having me.
Susan Mitchell:	01:00	So I'm looking forward to our chance to chat a little bit more about what you presented yesterday. My first question is The Music and Memory program I know is an established program that's already used in many nursing homes around the country. Can you tell us a bit about its history and then how the fact that it's already somewhat widely used is either advantage or disadvantage in regards to doing this pragmatic trial?
Ellen McCready:	01:30	Yes. The Music and Memory Program, for those of your listeners who are not familiar with it, is where for people who live in nursing homes and have dementia, it's where you find the music that those people enjoyed when they were young adults, we say between the ages of 16 and 26. That tends to be when people are really into music and when you're going out to dances and maybe getting married and hanging out with your friends. We try to find that music that you loved when you were young and we load it onto a personalized music device, so an MP3, iPod, those type of players, and then the nursing home staff are to use the music at early signs of agitation. So the idea is that by eliciting ... and I think that a lot of us that know people with dementia understand that sometimes they don't know what they had for breakfast in the morning, but they remember things about their prom or their wedding or early memories, or their kids when they were young.
Ellen McCready:	02:31	So it's kind of that idea of reminiscent therapies that bring back those memories could be very powerful for someone living with dementia who's in the later stages of dementia and may reduce

agitated behaviors that are common in the disease and may be related to kind of the isolation that people with dementia experience. So that's kind of the idea of the intervention is that you're finding that early music and giving them those memories from an earlier time, and that just giving them those memories may reduce agitation, and the reason that's important is that agitated behaviors can be very difficult for people that are living with people with dementia. So their caregivers and in the nursing home setting, they can be very difficult for staff that work with those residents day in and day out. So this idea that music is powerful is very attractive.

Ellen McCready: 03:23 We don't have to sell people on that, and I think that's why the program, which was started by Dan Cohen, a social worker, became so popular. There are actually thousands of nursing homes throughout the United States who have become certified in the Music and Memory program, and actually there was a documentary called Alive Inside that was on Netflix and just showed the power to bring people who virtually didn't speak anymore were singing their old songs that they loved and telling stories from a different time in their life, and I think it's the power of music in our own lives coupled with this documentary that had made the intervention very widely adopted in US nursing homes. So the advantage of this ... and then I guess coupled with there's a big movement in the country to reduce drugs, anti-psychotic use to manage these agitated behaviors.

Ellen McCready: 04:18 So the idea that we could have this music program to manage behaviors was sort of a win-win. It's attractive to family members and it has an intrinsic appeal and it also appeals to policymakers who want to find alternatives to using drugs to manage behaviors in dementia. So it has a lot of buy in, but there's just not a lot of evidence. So even though it's been widely used, we just don't know if there's actually any evidence that it reduces behaviors.

Susan Mitchell: 04:51 Oh great. Thanks. So have you chosen your own playlist for your Music and Memory iPod?

Ellen McCready: 04:59 I have already started, and I tell people that. The hardest part is finding ... it's really challenging when someone's in institutional care ... like a nursing home is an institution, and sometimes they have a family member, a caregiver who is still quite active in their care, but oftentimes family members live far away or aren't as active in the care of people living in nursing homes that have dementia, and the person may be so far into their

dementia course that they are unable to tell us what music they liked when they were younger. So it becomes this trial and error process of finding the music that someone loved when they were younger, and that's really challenging, especially when you're doing it one off, when you're just trying music and looking for a response in a person that has advanced dementia. So if I could give one piece of advice to listeners, go start your appointments now.

Susan Mitchell: 05:50 Put it with your advanced directive, right?

Ellen McCready: 05:52 Yeah, exactly. Put it as part of your advanced directive. Give it to your kids if you have any or someone that will carry those wishes for you, or just ... well, the technology will change, so don't load an MP3 player now.

Susan Mitchell: 06:07 Well, okay, let's move on to the RAPT model. The RAPT model, the readiness for assessment of a pragmatic trial is a framework to help decide whether an intervention is ready for a pragmatic trial, and I'll just run through the nine domains quickly to refresh our audience. Implementation protocol, evidence, risk, feasibility, measurement, cost, acceptability, alignment, and impact. So I know as you presented your Grand Rounds yesterday, you leveraged the pilot phase to try to get your intervention "more ready" for a full pragmatic trial. My question is, do you feel there's certain domains on the RAPT that really have to be in place before even a pilot phase, and others that are really ripe for modifying and improving during the pilot phase?

Ellen McCready: 07:02 Yeah, I think this is a question that's really important, and also ... you're asking me and I'll give you my answer, but I think there's a lot of debate with even in our teams that we're thinking about applying this model. What is the minimum? What's the minimum going into a pilot? What's the minimum going into a full trial? But I'll give you my opinion. So just to back up and clarify, so on the impact, those domains where we scored highly going into our pilot for Music and Memory, because of the factors that I just described, we have high stakeholder alignment with using the music to reduce medication use for managing behaviors. High Acceptability providers are already using it, they already want it. Potential high impact, and we knew it was safe and we thought it was feasible, but where we really lacked a lot of information was on evidence.

Ellen McCready: 07:54 So there really wasn't a good efficacy base for music and memory and there wasn't a strong implementation protocol. So there wasn't a good step-by-step best practice, and what we talked about yesterday was the measurements. So we really didn't know if the behavioral outcomes of interest could be captured in the existing data. Would I say to someone that not having efficacy evidence, you could move right into a pilot or a pragmatic trial? Probably not. I don't think it's the best practice to do what we did in music. I think you really should have some efficacy evidence to even start the pilot phase of a pragmatic trial, but I do think in the nursing home setting that might be more real world efficacy or there's different ways to think about in a complex population that there might be some benefits to at least having real world efficacy evidence before you even start the pilot.

Ellen McCready: 09:01 So this is a bit of a do as we say, not as we did, but I do think that it's definitely important to have buy-in. I don't think that you want to even think about piloting an intervention that doesn't have that level of buy-in. What's the point if it's not aligning with stakeholder interests? And I think you can refine your protocol during your pilot phase and certainly your measurement strategy, I would argue, but you need to know it's safe, and unlike in Music and Memory, I think you should know it's efficacious.

Susan Mitchell: 09:34 Great. Thank you. So let's move on to talk about some outcome measures, and you have quite a few, but first let me ask you about the behavior measures. One is an MDS, minimum data set based behavior measure that's ascertained on the federally mandated MDS quarterly all the time by nursing homes. So it's existing data versus the Cohen-Mansfield Agitation Index, which is a primary data collection tool that you added into your trial. You did this because in the pilot you found that there wasn't great correlation but ... not correlation, but the MDS under reported behavior, whereas when you try to ascertain it using the CMAI you got more prevalence of behavior problems. So I'm sort of wondering what this means for the pragmatic trial and using the MDS. I mean obviously for pragmatic trials it's better to use existing data that's already collected for administrative or clinical reasons, but you found a flaw in that, and I guess I'm wondering what it means for other pragmatic trials based in the nursing home and whether for similar outcomes or other MDS based outcomes, if we feel this type of prior validation is needed, and also I was just wondering, had there ever been some validation before of this behavior measure against the CMAI before you guys did it?

Ellen McCready: 11:16 Right. So those are good questions. So I think what we did find in, as you say, with the MDS measures of behaviors ... so the MDS measures of behaviors, agitated and aggressive behaviors, which we're now calling reactive aggressive behaviors, the three items that are on the MDS actually correspond to the domains in the CMAI. So even though the tools are different and we do suspect under detection in the MDS, the MDS is a derivative of the CMAI. Those items were added to mirror the domains of the gold standard measure, which is the Cohen-Mansfield Agitation Inventory, And the reason that that's important, kind of to your latter point, is that when they were developing the current version of the minimum dataset, the third version, Deb Saliba and her colleagues did compare directly for the same people over the same week, the minimum dataset measures and the CMAI, the gold standard measure, and so to answer your question about whether it has been done before, yes it has.

Ellen McCready: 12:34 It was done during the validation of the minimum dataset by the Rand researchers, and basically what they found ... so their validation population was 418 long stay nursing home residents, but it wasn't specific to people with advanced dementia. So the percentages are a little bit lower of what we would see if we really focused on the population of interest in our study, but it gives you an idea. What they found was only about ... in using the MDS data, 5% of long stay residents had any physically agitated behaviors in the past week, compared to 6% on the gold standard measure had any physically aggressive behaviors in the past week. So those numbers are very close, but where they found the difference was when they looked at verbal behaviors directed towards others, they found about 7% had any of those types of behaviors on the minimum dataset compared to 12% on the gold standard measure, and when they looked at other types of behaviors that weren't really directed at anyone, like tapping, pacing, other types of internally agitated behaviors, they found 6% had any types of those behaviors on the MDS compared to 14% on the gold standard measure.

Ellen McCready: 13:54 So what this tells us is that these two measures have been compared and what we know is that particularly for non-severe "behaviors," so verbal behaviors directed towards others and other types of agitated behaviors, the MDS suffers from under detection. So the behaviors are not recorded in the MDS, by about half.

Susan Mitchell: 14:20 So a little bit of a different question. I know you said yesterday you spent a fair bit of time yourself in the pilot facilities doing

some of this work, and I know you're a PhD or non-clinician, and I wonder what it was like for you to actually go into the nursing home and see these residents and where you're actually applying this research from a non-clinician standpoint, and if that experience shaped your way either you're looking at this trial or the type of research we're trying to do in the collaboratory.

Ellen McCready: 14:59 So going into the sites was great for me. I mean it was a really great experience. I probably ... I was in nursing homes because I was part of the evaluation team for the [inaudible 00:15:09] demonstration project in Minnesota, but this was another ... I think that everybody who's doing an implementation study should have to go into the nursing homes and at least be there for a couple of days. It was very eyeopening to me, not just to understand what the barriers to doing the intervention were. For example, I went at baseline and then I went back four to six months later, and there was one site where the equipment was still in the box, or I went out and they told me they couldn't download any music for the entire four months because they don't have internet, and there's all these things that you learn when you have to actually go on site and be there that you don't get sitting in an office.

Ellen McCready: 15:58 So it was a very humbling and good experience to me. The other piece that I learned firsthand was what we are really asking in the data collection. So these staff interviews where you have to take frontline nursing staff off the floor are really a burden. They're time consuming, they're hard, the staff isn't really trained to ... the CNA staff were nervous about completing the surveys. It raised their anxiety to have to sit with a researcher and answer questions. So I think deciding how many people we really needed to have staff interviews for, how much time that was really going to take staff off the floor for was really part of what went into doing our power calculations.

Ellen McCready: 16:45 I would have said to do more if I hadn't actually been there and saw what it took to get to ... kind of what a hardship it was to take stuff off the floor to do those interviews, and I think just from the effect of the intervention perspective, I was able to see during the pilot some of the stories that you see in the documentary, some of the really exciting success stories, but I also saw residents for whom it didn't work or who they forgot that they had put the iPod on and they kind of left him with it and I saw that they didn't have the verbal capacity to tell them to take it off, but they started like patting the headphones off.

Ellen McCready:	17:29	So a lot of the ways we designed our implementation best practice protocol is to really be aware of our approach to how you put the music on people, holding the headphones, making sure you only keep it on for 30 minutes, check back with the person. So a lot of these best practices actually came from seeing some mistakes in the pilot that were made by our pilot sites. So I would encourage, if you're doing any kind of study to in the pilot go to the sites if you can and visit them, see how they're both doing with how hard your measurement strategy is really to implement, how they're really doing with implementation, and get some first hand knowledge of what the impacts going to be of the intervention.
Susan Mitchell:	18:09	Great. Well thank you. Well I think that's all the questions I have. Thank you very, very much for your insights, Ellen, and we look forward to seeing the results from Music and Memory and wish you a luck as you're in the implementation phase, and I hope it all goes well for you, but thank you so much for sharing your experience.
Ellen McCready:	18:31	Thank you so much for giving me the opportunity and I hope we have some good news to share with you about Music and Memory, but either way we will learn a lot, I know, through this process that we can share and to other folks that want to look at these non-drug interventions. Hopefully we can share our experiences in using the different measures so that they can plan their trials.
Susan Mitchell:	18:51	Great. Thanks so much.
Jill Harrison:	18:54	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.