Rani Elwy: And welcome, everybody to our Complementary and Integrative Health Cyber Seminar. These cyber seminars are part of what we are doing in our Complementary and Integrative Health Evaluation Center which is a QUERI-partnered evaluation initiative with the Office of Patient-Centered Care and Cultural Transformation.

We're really excited to have Dr. Diana Burgess talk to us today about the LAMP Trial. Dr. Burgess is a professor in the Department of Medicine at the University of Minnesota as well as a Core Investigator and Core Director of the VA Advanced Fellowship Program in Health Services Research at the Center for Care Delivery and Outcomes Research at the Minneapolis Veterans Affairs Healthcare System.

Dr. Burgess' research has focused on racial and ethnic disparities in health and healthcare with an emphasis on disparities in pain and pain management; her current research focuses on non-pharmacological treatment for chronic pain with an emphasis on marginalized groups, women and, African Americans; she's also pursuing a new line of research on public health communication about chronic pain.

So, I’m going to turn it over to her in just a second; but first, I’m going to introduce you to a new person to our CIH cyber seminars. For those of you who usually attend, you'll know that we often have Allison Whitehead here from the Office of Patient-Centered Care and Cultural Transformation who gives a nice reflection of the talk that we've just heard as well as provides some information on how people who are listening can scale up these types of interventions at their own VA facilities.

Allison couldn't make it today; but in her place, we have Dr. Janet Clark who is a new person to us. She is now the senior physician lead for Integrative Health Research and Evaluation and Whole Health Education in the Office of Patient-Centered Care and Cultural Transformation. Dr. Clark trained at the University of Iowa College of Medicine for her MD degree and she completed her family medicine residency and chief resident tenure at the University of Utah School of Medicine.

Dr. Clark is certified by the American Board of Family Medicine; her 22 years of clinical practice at community and academic hospitals include the Salt Lake Regional Medical Center; The University of Iowa Hospitals and Clinics; Wasatch County Homeless Health Care; The Iowa City VA Medical Center; and, of course, OPCC. She has additional training in medical acupuncture through the Helms Medical Institute then affiliated with the UCLA School of Medicine.

So, prior to joining OPCC, Dr. Clark was an integrative and functional medicine physician at the Iowa City VA Medical Center; the Clinical Director of Whole Health, and the Medical Director of the Lifestyle Medicine Clinic. So, we're so excited that she can be here to also provide a commentary on Dr. Burgess's research that she presents as well as answer any questions related to Whole Health or VA policy around mindfulness at the end of this talk.

So, now, I’m going to turn it over to Dr. Burgess for her presentation. Thank you.

Diana Burgess: Thank you. Thank you so much, Rani; and thanks for everyone for joining us today. So, I’d first like to acknowledge my great research team, project staff, the Department of Defense that's funded the study, and which, and it's been funded through the Pain Management Collaboratory that I will talk a little about; and I’d like to thank the Pain Management Collaboratory Coordinating Center and investigators who are part of the project who've really provided a lot of great input throughout the project.

Today, I’m going to start by giving you an overview of the LAMP Study which, again, stands for le Learning to Apply Mindfulness to Pain. I then want to really zoom in on the LAMP mindfulness interventions; I’m going to be talking about the underlying frameworks that inform the key intervention components including why we did what we did; I’ll talk a little bit about how we developed it, and I really want to focus on some of the design features of this mindfulness-based intervention that are aimed at enhancing accessibility, engagement, and adherence from the perspective of patients; and then fidelity, sustainability, and scalability. So, really making sure this is something that could reach a large number of veterans and be sustained. And I’m going to leave some time for questions.

So, this is Poll Question 1. I’m going to read it: what is your primary role in VA? Choose one: student; trainee or fellow; clinician; researcher; administration policymaker or manager; or other.

Rani Elwy: And the poll is open and the responses are slowly coming in. And once it slows down, just a little bit I’ll go ahead and close the poll. And it's slowing down; so, I’m going to close that poll and share the results. We have 8 percent that say student trainee or fellow; 26 percent are clinicians; 36 percent are researchers; 10 percent are administrator, manager, or policy makers and 16 percent are other. Back to you, Diana.

Diana Burgess: Great. Thank you. Now, I have a second question: which best describes your experience and familiarity with mindfulness and you can choose all that apply; "I am not familiar with mindfulness," "I am familiar with mindfulness," "I am familiar with the research on mindfulness-based interventions"; "I have conducted mindfulness research," "I have participated in a mindfulness-based intervention such as mindfulness-based stress reduction," and "I practice or have practiced mindfulness meditation on my own."

Rani Elwy: Okay. And those responses are coming in rapidly and they're just beginning to slow down, so I’m going to go ahead and close that poll and share the results. Keep in mind this will not be up to 100 percent because the attendees are able to check all that apply. So, we have 3 percent that say, "I am not familiar with mindfulness"; 75 percent say, "I’m familiar with mindfulness."; 49 percent say, "I am familiar with research on mindfulness-based interventions."; 15 percent, "I have conducted mindfulness research." 33 percent, "I have participated in a mindfulness-based intervention such as mindfulness-based stress reduction."; and 61 percent say, "I practice or have practiced mindfulness meditation on my own."

Okay. Back to you.

Diana Burgess: Great. Well, thank you. So, there is a lot of familiarity with mindfulness and practice of mindfulness in this crowd; that's excellent. So, I just want to give you a brief overview to contextualize the project. So, as I’m sure you all know, we have what have been called these dual public health crises of chronic pain and opioids; and in response, lots of professional organizations have focused on the need to shift from what's been called opioid-centric pain management to multimodal models of chronic pain management that use evidence-based non-pharmacological treatments, which I’m going to call NPTs, including complementary and integrative health approaches. So, this includes the CDC recommendations, the guidelines from the American College of Physicians about treatment for chronic low back pain; this recommendation came forth in the National Pain Strategy and the report from the Institute of Medicine; it also characterizes the VA and DoD clinical practice guidelines for opioid therapy for chronic pain.

However, although the use of NPTs are up, they remain underutilized including in the VHA; although it really is the case that the VHA has been leaders in promoting and providing resources for NPTs including CIH, complementary and integrative health approaches, and other approaches--and I think that Dr. Clark will be able to speak to that. But nonetheless, the goal of this project and the PMC and the PMC is to really promote the use of NPTs for chronic pain.

And as many of you know, veterans are disproportionately affected by chronic pain and opioids; so, up to 50 percent of male veterans and 78 percent of female veterans report pain; chronic pain coexists with mental and physical health conditions that affect veterans; this includes PTSD, substance abuse, and depression. NDA patients are, again, disproportionately affected by the harms of opioids. So, for example, in one study, they were almost twice as likely to have accidental fatal poisonings with analgesics and opioids or with drugs and opioid analgesics were the drug class most commonly involved. So, this has been noted as a big issue for veterans.

In response the NIH-DoD-VA Pain Management Collaboratory, or the PMC Initiative, was developed to study the effectiveness of non-drug approaches to chronic pain management in military and veteran healthcare delivery systems. So, the PMC, from these three--NIH, DoD, and VA--have provided about $81 million in grants over 60 years and this money funds a coordinating center and 11 pragmatic trials of NPTs including the LAMP Trial.

So, now, we're going to focus a little bit on the LAMP Trial. The objective of the trial is to test the effectiveness of two mindfulness-based interventions, which I’m going to call LAMP MBIs for improving veterans’ chronic pain and mental health comorbidities; and as part of this, we're going to oversample women veterans because women are just disproportionately affected by chronic pain compared to male veterans, as well as being more likely to experience the mental health comorbidities that come with pain. The LAMP MBIs are grounded in behavioral change strategies; and as I mentioned earlier, are designed to optimize engagement and adherence, fidelity and sustainability, and reach large numbers of veterans.

So, for those of you who are researchers, you might be aware of what we call the UG3 and UH3 grants; where you have a development phase which is the UG phase, and then if you meet certain criteria, you get to go to the UH3 phase, and that's really a great luxury because we really get to spend time developing our intervention materials and making sure that we're ready to hit the ground running.

We had three goals in this development phase: the first was to develop and implement an engagement plan to involve veterans and stakeholders as partners; the second was to use iterative user-centered design methods to adapt two MBIs for veterans with chronic pain; the third goal was to conduct a three-arm pilot randomized controlled trial; and we also ended up using this time to translate our intervention to virtual delivery due to COVID-19-- and I will say a little bit more about this: this was originally an in-person intervention; we had to make a quick decision: do we want to transfer or could we just...? This was back in April 2020--or maybe everything would blow over in a couple of months and we could just go back to in-person? Well, I’m very glad we decided to translate this to virtual delivery. Below, you see a couple of pictures of our veteran engagement group; this isn't our whole group, but they've been fabulous, we've been working with them in-person, then later virtually, in these intensive meetings and they've really contributed to really every step along the way of the project.

This phase right now is called the trial phase or the UH3 phase. We are conducting a three-arm pragmatic randomized control trial of VA patients with chronic pain at four VA facilities--Minneapolis, Durham, Los Angeles, and Indianapolis--and our goal is to enroll 750 patients. And we chose these different sites because we wanted to get gender diversity and racial and ethnic diversity.

The three conditions which I’m going to talk more about are the Mobile+Group LAMP, the Mobile LAMP, and the usual tier control group. Now, we are now running these virtually, so they're all running, they're all being conducted with facilitators out of Minneapolis, but patients are from all four sites. Patients are being recruited through the electronic health record; they're sent a letter and a postcard, and that's followed by a screener via the internet where they log in with the password, they answer questions; and if they continue to qualify, then there's a chart review to rule out certain things that would make it inadvisable for our participants to take part in this, for patients to take part.

The primary outcome is the Brief Pain Inventory Interference score repeated at ten weeks, six months, and 12 months. And, of course, everybody is serving at baseline. If you're not familiar, the Brief Pain Inventory Interference score really assesses function, like how much does pain interfere with your daily life? Work, doing activities you enjoy. Secondary outcomes include key comorbidities such as post-traumatic stress disorder, depression, anxiety; and we are also going to examine the results by gender, and we're going to conduct an implementation analysis guided by the VA framework.

If you want details, we published a piece in Pain Medicine that can give you all the details of the trial.

So, the good news is enrollment is going well; we started this fairly late in the game because we had to regroup; we've run three cohorts meaning people that participate in one of the three conditions; and as of May 13th, we closed enrollment for Cohort 3; and so far, if you look on the first kind of light blue line, 479 were eligible based on the screener: 356 men and 123 women; and we actually waitlist 120 men to Cohort 4. This was unusual because we decided to switch to email recruitment, which we had no idea would be so successful; it was very successful. And for the researchers out there, I don't know if everybody knows that there are emails in the medical record and you can actually recruit veterans by email. So, we expect to enroll the next line 243 in Cohort 3; we already have enrolled 144 in Cohorts 1 and 2, so, we expect to have about 387 enrolled total and we're going to start our next group of people this summer.

And what's exciting about this is that we're basically cold-calling people; we identify people with chronic pain and the medical record and we invite them to take part in this; and in our last cohort, we just sent them an email with the materials and there's a lot of demand, people really want to participate in this which is exciting.

So, now, I’m going to switch to unpacking the key components of the LAMP mindfulness-based intervention for chronic pain. So, chronic pain is being recognized as a complex biopsychosocial phenomenon; and we're grounding this intervention in what's called the dynamic biopsychosocial model in which their pain is a complex interplay of biological processes, psychological processes, and social processes.

There is a growing recognition in the biopsychosocial model, that pain requires management versus cure; cure would be a more biomedical approach where, basically, you find something organic and you do something to fix that, like a medicine or some kind of procedure; and we know that chronic pain really is best addressed through this biopsychosocial approach. In this study, we really emphasize adaptive resilient pain behaviors; and we're focusing on more self-management, less use of substances, more physical activity, more social interaction, and more emotional regulation.

So, mindfulness-based interventions, or MBIs, focus on mindfulness as the driver; and we're defining "mindfulness" as self-regulation of attention on present moment experience and it's characterized by curiosity, openness, and acceptance. So, I noticed that there were a lot of mindfulness practitioners on the call, a lot of people are aware of it; so that the idea is that you're not just paying attention, but you're paying attention with a particular attitude; you're curious, you're open not just cognitively but in your body; and basically, you're trying not to fight what's happening, you're just trying to explore it with this open attitude with a certain degree of acceptance.

In MBIs, we teach mindfulness and we give opportunities for participants to practice mindfulness; and we really want to teach skills like attention regulation, body awareness, emotional regulation, and shifts in self-perception; and we talk about mindfulness as a practice, so it's not just something that you learn, it's something that you really need to practice because it's a whole mind-body experience and practice.

So, as I think many of you know, mindfulness-based stress reduction was developed by Jon Kabat-Zinn and it really is the predominant MBI in research and in practice. And Jon Kabat-Zinn was a pioneer in figuring out how you can take these mindfulness practices and package it in a way that could be scientifically studied; and it really brought mindfulness into clinical practice, and it sparked an entire huge research literature.

So, mindfulness-based interventions are considered evidence-based non-pharmacological treatment for pain or NPTs; there's been a number of systematic reviews on mindfulness-based interventions for pain and more general reviews, and they showed that MBIs improve pain and comorbid conditions like depression, anxiety, sleep difficulties, PTSD. In a recent systematic review on MBIs for a number of conditions, the authors concluded the evidence of benefits of MBIs on pain is abundant among different populations.

However, despite the promise of MBIs, effect size is rough and small and vary across studies; I should say that's true for pretty much all of the treatments for chronic pain--non-pharmacological and pharmacological--and there's often low engagement and adherence. There can be issues with fidelity and reproducibility; fidelity is often not addressed and that's an issue because we want to make sure our interventions are delivered the same way each time in research and in practice. A recent review by Marchand et al concluded that there are just big gaps in the literature regarding the use of MBIs for veterans; and really and really MBIs are a complex intervention with a multitude of potentially active elements; and in this early research, there's been a little bit of a black box where people are just starting to really unpack these different elements and think about how the different elements might really focus on particular conditions.

So, when we wrote this grant, we argued that the MBSR poses particular implementation issues for the VA; and in talking to Dr. [Fligler] and Dr. Serpa, who are very involved in mindfulness and Whole Health, we recognize that now VA has moved away and Whole Health has moved away from MBSR--and I’m hoping Dr. Clark, at the end, can talk a little bit to this--but when we wrote the grant, we really saw some issues with MBSR for VA and outside the VA.

So, in VA, we have over 9 million patients, many who have chronic pain; and, in general, the demand for complementary and integrative health exceed supply; there is an excellent article by Fletcher et al documenting this, that there's just a lack of time, space, funding, and staff training to provide CIH for everyone who wants it, even though, again, Whole Health and VA are just way ahead of other systems.

This is also true for MBSR. MBSR is very resource-intensive; it requires certified instructors and it's a very intense and expensive certification process. MBSR consists of eight two-and-a-half-hour-long sessions, conducting groups, and a daylight retreat, so there's issues of how to scale it; there's issues of engagement and adherence; and then there's access barriers due to the in-person format. So, I think, as many of you know, patients often live far away from the VA; there are always parking issues; in Minneapolis and other parts of the country, there are weather issues, so this could easily take up a lot of your day if you have to do this all in-person.

There's also been some excellent research conducted in VA showing qualitative research on veterans' experiences. And one finding that emerged is that women veterans may feel uncomfortable with the group format; so, women veterans, as many of you know, many experience military sexual trauma or other types of sexual trauma--and they often report just feeling uncomfortable in a group, closing their eyes with men, so that was on something else we wanted to address.

So, the LAMP interventions, I’m going to describe them briefly and then go into them in more depth. So, the Mobile+Group LAMP consists of pre-recorded modules presented by a mindfulness instructor that are viewed in an online group setting, and interspersed with discussions led by a trained facilitator who does not have to be an expert in mindfulness; and this was built on a project led by our co-investigator, funded by the NIH that we call the YMCA Study, which is basically using this format to deliver mindfulness to get older adults to move more; and that really was kind of the core of this that we built ours on. Mobile LAMP is the same pre-recorded modules, but it doesn't include a group component. And we added three facilitator calls to increase engagement.

So, in the pilot study, in the UG3, we didn't have a person; we just sent people their workbook which is a part of this, instructions for getting into their app, and we found out that people just weren't engaged to that. So, now, we have the same facilitators called the beginning, the middle, and the end to orient people to the program, provide some motivation, answer their questions and really just kind of help them do the program; both of these have eight mindfulness lessons; and the Mobile+Group LAMP now has a Session 0 to help people kind of navigate the online components.

So, LAMP uses behavioral change strategies to optimize MBIs to meet adaptive pain behavior goals. So, it was informed by the Behavioral Change Wheel Model, which is a model by Michie et al, that synthesizes 19 behavior change frameworks; and if you look on the left, you see this model--don't worry about the whole model, but I want you to focus on that green circle in the middle that has three components: capability, opportunity, and motivation, so we call it the COMBI; and if you look in the middle, you could see that we're developing capabilities, motivations, and opportunities to change behavior using frameworks and techniques from many empirical studies.

What we want to change is we want to increase adaptive pain behaviors and decrease maladaptive behaviors; we want more self-management, more emotional regulation, less use of substances, more physical activity, and more social interaction. So, we're really trying to kind of open the black box and be very specific about why mindfulness will help people with their pain; and that is really key and we're being open about this with our participants as well, which I’ll talk a little more about.

So, intervention design. And this was all led by Dr. Evans who was just amazing, he was so rigorous. And I’m going to go into this in a little bit of depth because I think it's very helpful for those of us working in this area where things haven't necessarily been developed at all with the same rigor that Rani brought to this.

So, we really focused on the following questions: what are the target behaviors; what do pain sufferers need in terms of capabilities, opportunities, and motivations; what are the appropriate intervention strategies; what content and behavior change techniques should be included; and what modes of delivery should be used? And for our yardstick, we really wanted it to be affordable, practical, effective, acceptable, safe and equitable.

So, to do this, we used an MBI refinement process led by Dr. Evans; we did an entire intervention mapping technique--I’ve talked about this elsewhere, we're working on a paper on this--but the two key pieces were a needs assessment and the use of behavioral change therapy or behavioral change theory. Our needs assessment involved input from our Veteran Engagement Panel, our Stakeholder Advisory Panel, which included our partners in the Office of Pain Management and the Office of Patient-Centered Care and Cultural Transformation; as well as experts in mindfulness and experts in developing mindfulness acts--and we talked to Judd Brewer, he's developed some very successful mindfulness apps that he's rigorously tested.

Then we used several tools. We did mind-mapping; we used an intervention spreadsheet that I’m going to go into in-depth and we just kept developing learnings; what did we learn through all of these different processes? We then had a process diagram--which I’m going to show you--we started out by using all the information we gathered to decide on the structure and format; we then came up with our eight themes and topics, one per session; from this, we developed key messages that each module address we wrote scripts for each module which we vetted particularly with Dr. Greg Serpa, who is a consultant and he's sort of the VA mindfulness expert extraordinaire; we developed our keynote slide deck and workbook, and the slide deck forms the basis of the facilitator-delivered group sessions, and there's a workbook versus facilitators and also a workbook for participants. We then filmed the videos. We did post-production and then we created facilitator training modules. So, this was pretty intensive.

The intervention spreadsheet really briefly had columns for each weekly session; so eight topics; and then each week had seven activities; each activity had five columns that had the learning objective, what COM intervention functions, so what capability, opportunity, motivation will be targeting; what would be the format; how much time; what behavior change techniques we would use, and then we had rows which are our assets. So, we linked to scripts, presentations, videos and the workbook.

Here is just an example: don't have to read the whole thing, but again, this was done for every activity for every week--and there are seven, so it was intense. So, for this one, for example, it was Week 1 Mindfulness and Pain, and this was just talking about the educational video. So, we had a bunch of learning objectives for the video, we talked about what it would address, the format. And then if you look on the very right, it talks about how we're really using the techniques of education and persuasion, and then we talk about kind of what's there under these different components.

And the goal of this was to make sure that everything was integrated; we wanted to make sure that the scripts, the videos, the presentation, the workbook all fit together in terms of the message, in terms of the language; and we all went through this a lot because it's easy to be inconsistent. So, we really wanted to drum home these messages.

Our veteran and stakeholder partners were just really invaluable. So, as I mentioned, our Veteran Engagement Panel is a racially-diverse mixed-gender group of veterans with chronic pain and they really helped us; in addition to helping us with the entire study design. they helped us with the intervention a lot, particularly how do you really engage people in this; how do you help people adhere; how do you make it veteran-centric?

And we had them actually do some of the exercises, we talked to them and some of the things--they were very honest. I mean the big question, in the beginning, is, "How is mindfulness going to help my pain?", which I think lots of people have; and interestingly, in a lot of mindfulness-type things it's not always explicitly addressed--or even if it is addressed, participants who were interviewed don't really still understand why it's going to help them; and especially when you think those people are used to a biomedical model of pain where pain is something that you cure, it's a physical thing, kind of realize we really need to get into the mind-body connection. There are also some things they really didn't like, so we made a lot of changes.

And they've been great also when we had to adapt to COVID-19 and switch to virtual care.

Our Stakeholder advisory panel includes VA leaders in Whole Health and pain management, leaders who dealt with women veterans, non-VA experts, really helped us a lot with engagement and adherence, sustainability and scalability, and Dr. Fletcher and Dr. Sandra [00:33:37] in particular, have really been kind of helping us understand what new innovations and new programs are happening in Whole Health and the Office of Pain Management that we need to know in terms of thinking about if this isn't effective, where will it live?

With that, we worked with them when we were shifting to virtual care and we realized there were a lot of issues: a lot of them were not familiar with Zoom, it was stressful for them. So, we ended up developing an entire Session Zero, and training materials, and extra support to help them navigate doing this online. So, that was huge and just essential.

So, now, this is very busy, so we're going to go from left to right; but in a nutshell, or in a single slide, it explains how we designed our study to fit this COMBI model. So, on the left, we see opportunities; that's in green. On the left is our intervention, which I’m going to talk about the group intervention, and then I’ll explain how it was pared back for the mobile app. But the group now has nine 90-minute structured sessions; the first is Session Zero which is all about technology and about sort of group processes. It's nine weeks, it's led by VA facilitators who are not experts in mindfulness; we hired these for the project, but the idea is this could be done by Whole Health coaches.

During the sessions, there are workbook reflections, there are group discussions and then there are mindfulness videos that are conducted by a trained mindfulness expert, Alex Haley, who just has a lot of experience and would also be the type of person to do an MBSR intervention, who's been trained in that. Then there's home practice using the app and using the workbook.

The core elements of our intervention are education, skills training, enablement--enabling people to do it to do everything--and persuasion. And again, our yardstick was it should be affordable, practical, effective, acceptable, safe, and equitable. And the equitable part was interesting because this is something done online, so you do have to have access to an app to do it; but yet, there are trade-offs because on the other hand, in-person sessions also have access barriers because it's hard for rural veterans, it's hard with people with disability, and when we were trying to decide whether to switch this to a virtual; we thought, "Okay, to make it equitable and safe, we really don't want to put veterans at risk to enter the VA and enter these spaces where there's a risk of COVID." And now, that seems very obvious, but thinking back to like April 2020 when we had to make this decision, we had lots of discussions like, "Maybe we'll probably go back to life as normal." So, anyway, that all kind of came into our decision in developing this intervention.

Now, to the right is the primary targets of the intervention; the first two gray boxes focus on capabilities and these are knowledge and skills. So, the specific knowledge elements that we want people to acquire are the following: what mindfulness is and how does it help with pain? Which, again, that's what makes us different from a lot of MBIs; it's very pain-focused. Key mindfulness concepts: what they are and why they matter for pain.

So, what are the consequences? We focus on the mind-body connection, on thoughts and feelings, kindness to self and others, and we focus on perspective. One interesting thing is when we started this, we really thought we would make this much more veteran-like and military-like; and then in working with our stakeholders and our veterans, we realized, "No, that's not working." Especially for a lot of women, they didn't necessarily want all this military language, so we really thought about this a lot--and another thing I should say in terms of adapting this for women veterans, we made sure that we recorded all of the meditations in the male and female voice, we have women in here; we really tried to do a lot. We had the recommendation that we do separate groups; we didn't do that, but we actually do have questions to see whether that would be a thing. But right now, since it's delivered virtually, it also seems that that might be making women feel more safe, so we're going to kind of dig into that a little bit more.

Skills. Mindfulness practices to develop mindfulness skills; attentional focus on the breath, feedback from the body, noticing when the mind moves away from the body, and reconnecting back to the body. So, I'm in the middle gray box. We want our participants to notice when judgment arises and then to start again with compassion; so, compassion is really woven through this. We want them to learn how to pay attention to habitual negative perspectives, considering alternative perspectives, shifting perspectives, so those are the skill.

And then the motivations, we really are focusing on beliefs and optimism. So, there are things that one can do to make pain more manageable. Mindfulness is one way to do this; mindfulness is a skill that can be developed with practice. We're really trying to instill capability, "You can do this; you can do things even if you have pain." And every week pretty much, we meet with our interventionist Roni, and Alex Haley, who's our mindfulness expert, and our two facilitators, Mallory and Kim, and we talk about how the sessions are going and how their conversations with people in the app group are doing.

And it really feels like people are getting it; I mean the conversations that we have, the group discussions, are really meaningful; and these are not necessarily people who are your stereotypic mindfulness people. We started in Minneapolis, which kind of skews white, male and older. So, you wouldn't necessarily think that these are people that show up when you go to like the local mindfulness center and really people are getting into it, people have reported using this in their regular life because a big component of this is what we're calling mindful moments, how can you use mindfulness in your everyday life?

So, whereas MBSR, I believe, really focused on just 45 minutes of practice a day, we're focusing much more on using mindfulness kind of throughout your day many times and people have talked, for example, like one veteran talked about finding out he had to get an MRI and then using all of these skills while he was waiting, while he was doing it, so that has been really rewarding. We're in the middle of data collection, but right now, our facilitators feel really good about how it's going.

So, here's an example of how it all comes together. This is Section 6. On the left, in black, we just talk about the different components: the facilitator presentation, workbook reflections, they have their workbook in the class, group discussions, and mindfulness videos. The behavior change techniques in Section 6 are going to be information, reviewing goals, social support, social reward, problem-solving, instruction, and practice and rehearsal, and verbal persuasion. So, if you can see on the right, this is something that's in our facilitator handbook and they go through this and they check it off while they go; and the goal is to stay on time and to really--this is manualized, so we talked about wanting to make sure that we had high fidelity; the idea is that it will be done the same way every time so we know that the intervention is being delivered the way it was intended, and we massage this a lot in our pilot phase and through a lot of practice.

So, in this particular session, if you go on the top white line, therefore in the first three minutes, there's a facilitator presentation--we always start like that--and then the next 20 minutes are allotted for reflection and group discussion. So, in that, they do a workbook reflection on their own and then there's a group discussion, and this is all accompanied by these slides that go up on the screen to keep everybody oriented. Then the next 13 minutes, there's a video--an educational video--Finding the Positive; then there's another video, an eight-minute video on mindful movement, and they're doing this along with it. So, as part of the orientation, we tell people you need to have a private or private-ish space, you need to be able to be doing this in the course, don't do it in your car, we really set expectations that this is like a class you're actually doing it.

Then there's a 10-minute break; then there's another video, this is a guided meditation on experiencing openness; then there is a 20-minute reflection and group discussion, so they do another workbook reflection, a group discussion. Then in the next four minutes, around the third to the bottom line, there's a facilitator presentation and then they review the session for the week, the Session 2, this is going to be the session that's upcoming. And then there's kind of an ending with reminders and questions. So, that's about 90 minutes.

But I should say we actually modified this even further that we now open the Zoom room in advance--I think about 20 minutes--and that's kind of like kind of a chit chat, a get-to-know-you thing where people kind of bond and then the facilitators are involved afterwards. We actually have a primary facilitator and a secondary facilitator with the cell phones who helps people out; we also have a couple of people on call who are trained as facilitators, they could jump in as needed; they can provide tech support. So, there's a lot going on because, as you might imagine, for those of you who've worked as veterans with different ages, technology is not always easy; even when it works well, it doesn't always work so. But luckily, we've run through, we're almost done with cohort two and things are going really well which is very exciting.

So, just to sort of go through the key things on the app. The app has educational videos, meditation videos, mindful movement videos, and they can do their home practice; they also have the workbook and then they have these three facilitator calls.

So, just to sum up our program versus other programs--and again, we don't know what all the other programs are out there. I believe we wrote this grant in 2017 and so we really based this on trying to make improvements over the state of the field at the time; but basically--and we've been kind of reviewing the literature--but, in general, we really stuck to the general principles and core concepts of MBSR and other programs that generally are modeled on MBSR; and the content is presented by mindfulness experts.

We have a lot of differences to enhance accessibility, engagement, adherence, fidelity, sustainability, and scalability, so it's much shorter. The group sessions are 90 minutes and the practices are really designed to be very short like 10 minutes mindful; we have all of these different practices called sort of mindful movement, mindful moments, and we're encouraging you to integrate this throughout your life. We're integrating specific behavior change techniques; I think, implicitly, in a lot of mindfulness-based interventions, there's the idea that--I mean there are behavior change techniques, especially the support one gets from a group, but we try to be very explicit, we use less jargon, so we record our sessions by an expert instructor facilitated by non-experts, and I think this could really help our scalability; our sessions are very structured, so it's manualized, we have a very specific training program for facilitators, slides manual, training manual, we have very structured fidelity checks, we have a very structured process of reviewing and providing feedback, and meeting every week.

It is specific to pain; it's customized for veterans; and the mobile version is going to be very interesting. At one level, it doesn't have that group component that people find very helpful; but on the other hand, there are veterans who don't want to be in group classes, so we'll see; we're also going to try to do some analyses to see if certain types of people might prefer certain types of interventions.

And I didn't put this down here, but the video piece really makes it accessible, and we know now that the VA and Whole Health is really moving to doing a lot more stuff virtually and I think that is really going to make it more accessible; we had a lot less trouble recruiting people for sessions than we did in the pilot, I think because it doesn't take this giant chunk out of your day, you can fit it in a little bit.

Looking at the top. So, yeah, engagement adherence. Right now, we feel like our adherence is pretty good, we still don't--we're looking at it people are getting to a lot of the sessions, we still have some veterans that are missing sessions, we're really trying to work on that; people seem quite engaged; and, again, we feel like it will be very sustainable and scalable.

So, I am going to stop now for questions and comments, but I really appreciate you guys taking the time today to be a part of this. Thanks.

Rani Elwy: Diana, this is Rani. Thank you so much for that very wonderfully-detailed and really terrific presentation. I’m now going to pass it over to Dr. Janet Clark so that she can provide a couple minutes of reflections or thoughts about your presentation. Thank you, Dr. Clark.

Janet Clark: Thank you. Hello to all. So, I’ve been sitting on the edge of my seat and just so excited to learn about this work; and as somebody from the Office of Patient-Centered Care who's very much, very passionate about the continuing work of providing complementary and integrative modalities for patients for management of all chronic medical issues, even though we know we're where we think so much about moving toward these conversations about well-being, what's been so amazing and gratifying to watch is that with many chronic medical issues that require ongoing management--and, of course, chronic pain is very much included in that--watching the benefits that patients get from developing agency, and feeling like they get power back, and being surprised about things that they could do.

And so, when you were talking about your COMBI--your capability, opportunity, and motivation--rubric for that conversation, that was really thrilling. It's wonderful to me to hear conversations about the biopsychosocial approach to pain; and for myself, one of the wonderful things about it is we learn more, and as we have things like the study that are going to really improve our understanding of how patients respond and what is the best mechanism especially for marginalized groups, what is the best mechanism for us to reach them with these modalities, we're really in this place that we're having to backpedal so much because we've really taught our patients to think of their pain as being an anatomic issue; we've really taught our patients that their pain is a biomedical issue, and so we have so much education to do around this.

And Diana, as you were alluding to the fact, patients don't always understand why mindfulness and meditation would be helpful for their pain; that's one of the great opportunities we have is to teach them about their nervous system because we have a lot of unteaching to do; patients have been taught that their MRI explains their pain; patients have been taught that pain will be improved by passive mechanisms like surgery, and injections, and medication; and while some of those things may be helpful for some to some degree, we know that the self-care and self-management aspect of it is so incredibly important, so it's just really exciting to learn about this work and it will be exciting to watch it continue.

Rani Elwy: Thank you so much, Dr. Clark, for that commentary and reflection and I really--I love the pathway that this whole presentation on mindfulness and Diana's project is going; and we have so many people who've provided you comments, Dr. Burgess. So, I’m not going to be able to get to all of them but I’m going to try to take a selection of them to ask you.

So, one person has asked about the behavior change techniques, "What are your lessons learned about which techniques are more effective?" and this person asks if you could please comment on motivational interviewing versus education and versus persuasion.

Diana Burgess: Oh, that's a really good question. So, we are in the very early stages. I think a lot of what we talk about right now, because we have meetings with our facilitators every week, is the group and the sort of influences of the group, and the social support, and people are really sharing your stories. So, I do agree that it's not--there are these 20 and they do--so, it's very active as Dr. Clark talked about, it's not even passive in the way that they're being talked at. There are the facilitated conversations and people want to participate, and then there are the workbook exercises which really ask people to sort of get curious and reflect on how the week's exercises went, and what they noticed.

So, I feel like we are really--it's not MI--motivational interviewing--and it's not being done by a single person, but it has that spirit of self-investigation that is really kind of key to mindfulness and kind of key to our intervention.

Rani Elwy: Thank you for that. So, I’m going to try to get to as many questions as possible. One person asked, "What were the big do-not-dos that you learned from participants?"

Diana Burgess: Oh, that's interesting as things you shouldn't do? Luckily, we based this on something that had already been developed by Dr. Evans; but in the pilot, when we worked with our veteran engagement panel, we realized we needed to provide, just like Dr. Clark said, there was just a lot of skepticism like why? So, we were recruiting people basically, kind of cold calling, like we're recruiting them because they have pain in their electronic health records.

So, we worked really hard with our veteran advisory panel to come up with promotional materials to kind of explain, "Why would this help me with my pain?" Because I think that basic thing is just not intuitive. And we also have some examples from MBSR and some of our really kind of test videos and scripts that they really didn't like; like I think there was one about hitting your thumb with a hammer from, I think, that might have been from MBSR; and they just said, "No, this is chronic pain; this is big in my life; this is not just like acute pain that happens."

So, we really--and the other thing that we didn't realize so much is we thought--we had our MDSR instructors and our and we thought, "We need to make this more military-like,” but we realized that the self-compassion was important and getting people to engage in curiosity; and I think allowing some type of skepticism, our facilitators are really good because we want we really want to cultivate certain attitudes--the right openness--and it remains to be seen how people do in their practice; I mean that's something that--I guess the big lesson that we did learn from our pilot study was that it's very hard to just give somebody an app and a workbook and expect that they're going to do it, that that human connection and support, and back-and-forth interactive question and answering is going to be important. And I did talk to I’m Dr. [Kliger] about this, that we're going to need to have staff; we probably don't think that you just hand this out to people and it will work.

Rani Elwy: Thank you. So, there are many questions--which I apologize to people in advance we're not going to be able to get to them; if we don't get to them before the top of the hour, please send your question to Dr. Burgess at her email here, so that you can get that answered. So, Diana, there's a point that this week's HEEL investigator, "Dr. Collins, who everyone should know is the Director of the NIH, named compassion as a core principle for addressing pain and opioid use disorder. Can you elaborate on this as a core principle within your mindfulness-based intervention?"

Diana Burgess: Yeah, being kind on yourself to yourself is really important; and in some of our preliminary work, our veterans talk to us about how they came from a culture which was the military culture, which was very physical and you suck it up, you embrace the sock, you really don't--and you also don't reach out to other people. So, I think it's being compassionate to yourself and your pain, and not this idea of not judging yourself and also not judging your judging and mindfulness practice; we find that people often feel like, "I can't do it right."

So, we really have a begin-again attitude, this attitude of being kind to yourself; and then this piece of reaching out because I think for everybody with pain, pain is very isolating, so we're trying to talk about this as sort of part of the human condition, and it's a universal experience. So, I don't know if people are familiar with \_\_\_\_\_ [00:57:54] work; it's mindfulness and it's also, "You're not alone; this is universal and you can take care of yourself." So, I agree, I think it's just critical for pain sufferers in general and veterans, in particular.

Rani Elwy: And the last question that we're going to be able to get to today is could you say more about how the biopsychosocial concept of pain, the unteaching of a biomedical concept is integrated into the LAMP MBI curriculum?

Diana Burgess: Yeah, we've really tried to come up with ways to talk about the mind-body connection; because one thing that comes up is when you're talking about biopsychosocial, people say, "Well, it's not just in my head; my pain is real," and that's always something you have to address when you move there. So, we have our mindfulness actually have chronic pain and really talks about it in ways that people can understand about how the mind and the body work together as opposed to that, "It's either this or that." And I do think that is really critical because we don't want to make people feel like they had to justify their pain, that we're discounting it; we're trying to be bigger while affirming that, "Yes, your pain is real."

Rani Elwy: So, Dr. Burgess, thank you once again for your presentation. It's one o'clock and so we need to close this session. I’m going to turn it over to Maria for that closing statement; but thank you to Dr. Burgess, thank you to Dr. Clark, and to everyone for being here.

We'll see you again in July.