Cyberseminar Transcript

Date: May 16, 2019

Series: Complementary and Integrative Health

Session: Strength and Awareness in Action: A Feasibility Study of Yoga for Post-Acute TBI Headaches

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Dr. Rani Elwy: Thanks to everyone for being on our Cyberseminar today. We’re really excited about this series, which is focused on Complementary and Integrative Health. I am Rani Elwy, I’m at the Bedford VA, and I Co-Direct the Complementary and Integrative Health Evaluation Center, which is funded by both QUERI and the Office of Patient-Centered Care and Cultural Transformation. What I love about this Cyberseminar series, is that we always have a researcher who’s presenting on some very cool Complementary and Integrative Health research that’s taking place either inside or outside the VA. And then we always have a member of the Integrative Health Coordinating Center, within the Office of Patient-Centered Care and Cultural Transformation, who is also joining to provide an overview of how the research that’s been presented works with what is happening currently in the Office of Patient-Centered Care. So today, our presenter is Dr. Lisa Brenner. She is the Director of the VA Rocky Mountain Mental Illness Research Education and Clinical Center, otherwise known as the MIRECC, the Rocky Mountain MIRECC. Who, by the way, are really active Twitter users, both MIRECC and Dr. Brenner, so you should look for them on Twitter. Dr. Brenner is a board-certified Rehabilitation Psychologist, and a Professor of Psychiatry, Neurology, and Physical Medicine and Rehabilitation at the University of Colorado, Anschutz School of Medicine. She is the Director, the Research Director of the Department of PM&R there. She’s also a Fellow of the American Psychological Association, Division 22, which is the Rehabilitation Psychology Division. Her primary area of research is traumatic brain injury, comorbid psychiatric disorders and negative psychiatric outcomes involving suicide. She’s the Research Division Director for the American Association of Suicidology and an Associate Editor of the Journal of Head Trauma Rehabilitation. What I also love about Lisa is that she has been doing a lot of great work in the realm of Complementary Integrative Health within all of these other areas that she works. So that’s what she will be presenting on today. We also have from the Integrative Health Coordinating Center, Dr. Kavitha Reddy, who is an Emergency Medicine and Integrative Medicine Physician at the VA in St. Louis, in Missouri, and she also serves as a Whole Health System Director, in addition to her clinical duties at VA St. Louis. She’s an Assistant Professor in Emergency Medicine at Washington University School of Medicine, and she’s been working closely with VA’s Office of Patient-Centered Care and Cultural Transformation as a Clinical Champion since 2011. And currently is the Lead Clinical Champion for IHCC, the Integrative Health Coordinating Center, within Office of Patient-Centered Care and Cultural Transformation. So we have both Dr. Lisa Brenner, who’s going to be presenting her research, and then Dr. Kavitha Reddy who will be providing an overview of how Lisa’s work fits in with OPCC&CT’s priorities. So I’m going to turn it back over to Dr. Brenner, and thank you again, Lisa, for being on today and sharing this very new research with everyone.

Dr. Lisa Brenner: Well, thanks so much, and it’s such a pleasure to be here. And I should say, before I get started, that like at the end of the slides you’ll see the kind of team it takes to actually do this work. Some very impressive folks, and two of them, Dr. Theresa Hernandez and Dr. Lisa Betthauser are actually here in the room with me, and so I feel like we’re kind of co-presenting, and if I say anything wrong they will certainly help me.

Before I get started I should say, that everything I’m going to say today is me, not the Department of Veterans Affairs. And for all those junior researchers out there, or folks who want to do research in this area, you know we finally did get funding from the TBI Trust Fund from the state of Colorado. I believe this was the sixth grant that we’ve put in, it might have been the seventh; the sixth. So it took six tries to get funding for this project, so don’t give up if you want to do this work, it’s really important work. It’s really important work, and hopefully it’s getting easier and easier to get funding to do this kind of work, and hopefully the results that I’ll show you will show you some of the challenges and, you know, ideas about how we can move the field forward. But I just really want to thank the State of Colorado, and the people who sped in the State of Colorado, for helping us get funding for this project.

So I have several poll questions in here. So here’s the first poll question. Which of the following best describes what you do for work? And so people could just take a minute.

Rob: Dr. Brenner, that poll is up. The question being\_

Dr. Lisa Brenner: Okay.

Rob: \_which of the following best describes what you do for work? And let me just say, to those who downloaded the slides early, I apologize, we had to make a slight change. The original slides had seven answers and I had to concatenate for technical reasons, nevertheless, choices are, mental health clinician, physical medicine and rehabilitation professional, researcher, policymaker or educator, and yoga instructor. And if other is a choice that you would have liked to make you can go ahead and put that answer into the questions pane and I can read that to Dr. Brenner. And Dr. Brenner about 60% of your audience\_

Dr. Lisa Brenner: I am a Psychologist; I like to give a lot of choices.

Rob: Right. About 60% of your audience has voted and things level off right around 75, 80%.

Dr. Lisa Brenner: Okay.

Rob: So we’ll give them a few more moments to make their choices. Things are ramping up. And it looks like they’re leveled off, so I’m going to go ahead and close the poll. And share out the results.

Dr. Lisa Brenner: Okay.

Rob: And I’ll tell you that, 24% of your viewing audience chose number one mental health clinician, \_

Dr. Lisa Brenner: Okay.

Rob: \_ 8% said physical medicine and rehabilitation professional, the largest number 52% say researcher, 12% policymaker, and 4% yoga instructor. And we have a music therapist, we have a music therapist as well.

Dr. Lisa Brenner: All right.

Rob: And now we’re back\_

Dr. Lisa Brenner: Awesome.

Rob: \_on your slides.

Dr. Lisa Brenner: Well and I think that, I mean just that the wide range of folks attending this talk, the backgrounds, a lot of people know some of the, I think, both the strengths and the challenges to trying to do this kind of work and how to bring, I think, people from really different backgrounds, you know, yoga instructor, to policy, to researcher, to clinician together to actually do this kind of work, and finding common language is going to be key.

I figured not everybody was going to be a TBI person, so I thought I’d just give a little bit of background on TBI. So a Traumatic Brain Injury really has two key parts. It’s a bolt or jolt to the head, or a penetrating head injury. So you’ve got something that happens to your brain, physiologically speaking. I know we have a lot of things that happen to our brain, but this is a physiological injury event that disrupts function. So, those are the two things you need for brain injury. A part of the challenge is that that includes things that are mild, so a mild TBI, which could be you had your bell rung, or a brief change in your mental status. To severe, which is an extended period of unconsciousness or amnesia. And so those go on a continuum, I’ll say this again in a bit, but the severity of a brain injury is based on the disruption in brain function at the time at the injury, not necessarily on symptoms. So you could have very severe headaches but have a mild TBI. And that’s very confusing to people, I’ll revisit that again in a minute. Generally speaking, functional outcomes are associated with severity, so that if you have a milder injury, which is 80% of all injuries, the odds of returning to baseline functioning in a year is very high. Folks with more severe injuries have more challenges. That being said, many of our Veterans are getting brain injuries or had brain injuries before they joined the military, and that would be a different talk for a different day. We have data to show that really folks are getting injuries from pretty typical civilian things; sports and risk-taking behavior before they join the military, and then once they’re in they sustain injuries in Iraq and Afghanistan. So, mostly our folks don’t have one brain injury, many of them, as you’ll see in a bit, also have comorbid psychiatric conditions or other health-related problems, and so it can become a bit more complicated.

So, to make things more confusing, I always like to show this, because this is any definition that has two ors in it is a problem. So, you have the traumatically induced disruption of brain function that results in a loss of consciousness for less than 30 minutes duration, or an alteration of consciousness manifested by an incomplete memory of the event, or being dazed and confused. If we have PTSD clinicians or researchers on the phone, you know that being traumatically exposed to something, a traumatic psychological exposure can also manifest in incomplete memory and feeling dazed and confused. So you can already start to see the challenges for our Veterans who are in combat situations trying to figure out if it’s TBI or not TBI, but that again is a talk for a different day.

Mild TBI, as I said, is most brain injuries. Certainly, most brain injuries in civilian settings, most brain injuries in combat, and we think of symptoms falling into four clusters. The kind of cognitive cluster, a physical cluster, emotional cluster, and sleep. Headache is right at the top for the physical. Generally, folks talk about having the worst headache of their life that dissipates over time. What we’re going to be talking about today is persistent headaches, so those headaches that go on after we would expect that they would be getting better. I could give you a lecture, and I’m going to show you some more information on post-concussive or post-traumatic headaches. You know, there is lots and lots of challenges associated with this diagnosis. We try to sidestep some of that, and I’ll tell you how in this study. I can say that part of the reason we had challenges getting funding, even from VA sources, were that folks didn’t believe, or folks weren’t resonating with the idea that people who had mild TBI had persistent symptoms. And so we tried to get around that by saying, okay, we want to recruit folks who have a clustering of post-deployment symptoms, and then we were told that that wasn’t a recognized category. So just some of the challenges associated with taking kind of what we see in the real world with OEF/OIF Veterans and turning that into research that can get funded, you know, happy to talk about that too at a different time or some at the end. So as you can see, we focus on headaches, there’s a number of other symptoms.

Headaches are common, if not most common, following a mild TBI. About 30 to 90% of individuals following TBI have headaches, and that’s across severity. A post-traumatic headache is a disorder that starts within seven days after the head trauma. So again, if somebody says, you know, I had a brain injury, I started having headaches five months later, that’s not a post-traumatic headache, it has to be associated with the head trauma. They’re commonly classified as either migraines, tension type or mixed. You can also have cervicogenic headaches, and you know, this does get into kind of some of the questions about, is this actually something that’s happening in the brain, is it muscular, is it, you know, what are the different components that contribute and perpetuate these headaches. Which is again, a whole other discussion. The normal recovery is rapid, as I said, with most headaches resolving within three months. However, some persist, and those are called persistent post-traumatic headaches, which is the area of interest we had.

Here is an article that was published in 2006, which is getting to be some time ago already, highlighting that 18 to 33% of post-traumatic headaches persist beyond a year in OEF/OIF Veterans. Hence not surprising that the clinical practice guidelines for TBI does include recommendations for post-traumatic headaches, and you know, again, medications are not necessarily a first choice. Although, there are a lot of medications being prescribed for these, but really non-pharmacological intervention, such as sleep, hygiene, education, dietary modification, physical therapy, relaxation and modification of the environment are highlighted. You know, on a separate note, if you’re going to take that recommendation and turn it into metrics to see if we are actually meeting that metric in the VA, that becomes very, very hard. Those are very hard to quantify metrics in the medical record, right? So if we were doing work, which is outside what we’re, what I’m talking about today really, but like are we doing guideline-concordant care for Veterans who have post-traumatic headaches, and this was the recommendation we wanted to see. To try to identify all of those things in a medical record would probably, aside from PT, would take natural language processing, because none of those would be identified either by a CPT code and a clinic. So again, some challenges and things we can think about, about how do we code when people are getting alternative interventions in the chart, how do we chart about that, and how can we help ourselves out to try to figure out some of these questions in terms of HSR&D research. So, and obviously, like if, be really hard to do headache education because there’s not a, I can guarantee you that that’s not getting coded frequently in the medical record. So the one thing that we would be able to look at would be pharmacologic intervention, so you certainly could go into the medical records and on a nationwide level look at medications, but that doesn’t help us think about yoga or other physical health interventions we could do.

Okay, so to make things more complicated that, you remember how I talked about the messiness before, so this is more of the messiness. This is a study we did 5,000 years ago now; I can’t believe it’s 10 years ago. So, what we did is we looked at for a person, we looked at post-concussive symptoms in individuals who had a history of TBI, had PTSD or had both. And what you can see here is folks who had PTSD only, almost three times more likely to have headaches. You may not think of headaches as being a post-traumatic stress disorder symptom, but likely it is for many. Here, you can see that folks who had mTBI were four times as likely, and then folks who had both of them were about six times as likely. So this idea that any of these interventions that we are designing would need to be acceptable, probably we’re going to have these come together, and you’ll see, we did have it come together quite a bit in the cohort we recruited, in the OEF/OIF Veterans.

Okay, so poll question number two. So I practice yoga, this isn’t aspirational, this is for real, six or seven times a week, three to five times a week, one to two times per week, a few times a month, a few times per year or I don’t practice. I hate to put those last two together because intention is good. So\_

Rob: That poll is up, and answers are streaming in. You have almost 70%, over 70%\_

Dr. Lisa Brenner: Oh my goodness.

Rob: \_making their choices already.

Dr. Lisa Brenner: People are waking up.

Rob: I guess this one’s easier than the last one. Okay, things have leveled off so I’m going to go ahead and close the poll and share out the results. And Dr. Brenner, 6% say six or seven times per week, 8% three to five, 33% say one to two times per week, 8% say a few times per month, and 44% say a few times per year or I don’t practice yoga at all. Now we’re back on your slides.

Dr. Lisa Brenner: Awesome. Okay, and maybe this could be an opportunity for us all who are interested to say we’re going to do more so next time I’m polled, I am embarrassed to say what my answer would be right now, but I promise next time I give a presentation on this I’ll be able to give a better answer.

So obviously yoga, now onto yoga, yoga has received a good deal of attention in the U.S. Certainly something that was, I think, even 10 years ago more considered to be more fringe, more new-agey, it’s certainly taken hold, particularly with specific populations, and I think we all know kind of what the stereotypical populations who do yoga are. But, you know, it has become an interest, so this is an infographic that I like from the National Center for Complementary and Integrative Health, where they’re talking about yoga as a Complementary Health approach. They actually do have some really nice resources on this page. So yoga is one of the top 10 Complementary Health approaches, 13 million adults practiced yoga in the previous year, and that this is increasing, as you can see, from 5% in 2002 to 6% in 2007. So this is getting kind of old now, I’m guessing it’s more. Why people practice yoga, you know, because their doctor recommended it is 22%, to maintain health and wellbeing 58%, and back pain is the other. And, you know, I think you can see on the other slide, back pain is one of the number one reasons people use Complementary Health practices. As I’ll show you today, back pain is way out ahead on yoga in terms of establishing the evidence for this. And then they’re also talking about, you know, how to minimize your risk of injury, how to adapt, and so again, I know that the National Center for Complementary and Integrative Health does a lot of great work trying to present evidence-based data to individuals, so they can make shared decisions with their providers about when and when not to use yoga. And so far, the evidence is mostly around back pain. So it’s growing in other areas. I’ll just say just in terms of doing these studies here it has been interesting to work with providers here, we’ve had a whole range of responses. Some providers being excited, and really, you know, engaged with us around thinking about it and trying to refer folks. Some providers being concerned that we were giving a religious or spiritual message that wasn’t appropriate for a healthcare system, and probably everything in between. So trying to really help people understand what we’re doing, why we’re doing it and how to help them maybe think differently about yoga than they have in the past. And certainly there is a whole wide range of things out there, in Denver, where we are, but I’m sure everywhere that people call yoga. So, trying to get really specific with individuals, either grant reviewers, providers, ourselves about what yoga is really, really important.

Okay, so this is one of my, a paper that really got me going. And basically the take home, this was actually a MIRECC fellow that did this paper, so a callout to the MIRECC fellowship, but basically what they did is they looked at the use of yoga within specialized inpatient PTSD treatment programs. This paper’s getting older now too. And what they basically found is that lots and lots of the places, you know, the majority of places do have some yoga that is being offered. But certainly, the stringent criteria that we have around evidence-based treatments for PTSD do not apply to yoga. Different things are happening in different places, you know, the idea that it’s a standard treatment or a standard skill set, that yoga, the people that are training or doing yoga are doing common things. The fact that we would know what those things should be, and whether or not the yoga is actually effective, or efficacious or effective is not there. So, again, how do we think about something that we are really systematically doing throughout the VA? We have a sense that it could be good for people, but we don’t have the data to support that. And this does get us into the bigger kind of question and challenges associated with how do you bring the world of yoga and research together?

And I’ll talk a little bit more about that in the feasibility slides. So as I said before, who’s way out ahead, who’s like getting an A grade in this, it’s low back pain, this is a fairly recent systematic review. They’ve got 10 randomized control trials with a total of 967 chronic low back pain patients were included. They had eight studies that had low risk and bias, so studies that we can count on. And they found strong evidence for the short-term effectiveness and moderate evidence for long-term effectiveness of yoga for chronic low back pain. And they assert that based on this yoga should be recommended as an additional therapy to chronic low back pain patients. I mean, I think that to me is getting to the gold standard of where we would want to get with other health-related conditions in recommending yoga.

What I’m going to show you is less exciting. So, this is a review that was done on yoga for headaches, again this is not post-concussive headaches, this is headaches on whole, so every kind of headaches. As you can see in the yellow box, one potential trial was identified and included in this review. So already we know we have a problem. One potential trial, and that it had moderate risk of biased. So, and I think these, this, Dr. Kim was generous to say there’s evidence from one RCT that it may be beneficial. Very hard to say from one potential RCT of moderate risk of biased that we could recommend yoga for headaches.

I did want to pull kind of some of the other challenges that we have to think about. As would be expected, based on tradition, research has been done more frequently in other countries, including India, on yoga practices. And so how do we translate those traditions and those practices to the American Healthcare System, or the VA Healthcare System I think is a whole other set of interesting challenges. And so what you can see here, this is 46 out of 60 subjects, so they, this is they did a combination of Ayurveda and yoga therapy. And this is migraine headaches, not necessarily post-concussive headaches, but you can see that they were focused on a Pitta based body constitution. So a hot based body constitution, so you know, if they’re thinking about who should go into their trials they’re thinking that, that is not language we frequently use in the VA to randomize individuals or recommend people to therapies, and I’m not saying that it should or shouldn’t be, it just is not right now. But they were able to show in this study when they found the right cohort these individuals who had headaches, they had significant changes. So how do we translate whatever Pitta might be to yoga Veterans and to Veterans, and then think about yoga specifically, a yoga trial specifically for them? And that is some of what I could use your help with, because I don’t know the answer to that.

So just again, in terms of TBI, even worse, evidence-based, there is some evidence I should say I did not include in here, MBSR or other interventions where yoga is a part of it. I tried to include things where yoga was the primary, and so you can see here we have a piece about functional medicine, a feasibility and results of a case study, a systematic review of yoga and balance. So they’re looking at all across the neuromuscular impairments, so that’s across and not just TBI. They’re having a breathing focused yoga with severe brain injuries, so that’s not the group that we’re mostly focused on in the VA for this pilot trial. That was a brief pilot trial and another pilot study looking at Veterans in military. So again, very limited scientific base to go from.

Okay, so we had spent a lot of time, our team spent a lot of time talking about kind of how to create this intervention. And we wanted to get really specific, particularly in terms of grant writing, about what yoga is. And so we wanted to operationalize it very specifically so that people know, so that grant reviewers knew, and so that we could explain it to clinicians and patients. So for us, in this trial, that yoga meant physical postures, so the physicality, breath awareness, exercises, and mindful meditation. This is a good place to say that we intentionally used words that sounded familiar to our Veterans. We took out words that might deter people, or have kind of, that were more from different cultural backgrounds than maybe U.S. military Veterans. We tried to make this very accessible in that way. We also did not include things that would be spiritual, per se. Mindfulness yes, spirituality not so much. And so really trying to focus on that. Just in terms of kind of some key things that we focused on, in terms of this trial, is acceptability. That really was from the perspective of the participants or the yoga instructors, was it acceptable, was is suitable for them. Adherence, I’m not going to present this data today, but we did want to see if we could get yoga instructors to comply with delivering the key elements. I do want to mention here, we did try to recruit a number of yoga instructors to learn this manualized intervention. This wasn’t something I was expecting to be a feasibility issue, and many of the yoga instructors, as you are going to see very soon, we had a very manualized intervention, because we want to be able to apply most rigorous scientific methods, we want all of our groups to get the same intervention. Either the yoga instructors felt very strongly that the idea of like us making up something that didn’t come from a higher source, in the manual, was not appropriate, or it was really hard for them to think about learning a manual and following a manual. And that the way they taught was different than that, it was more in some cases spontaneous, in some cases maybe less spontaneous but more driven by the season, just many different factors. And so the idea that these folks would have to learn all of these sessions and do them in the same way, and not exactly in the same way, but have the same components every time was a challenge. And thank God, one of our psychologists, Lisa Betthauser who’s here in the room with me, is also a yoga instructor. So she went from not just being a Co-I, but she went from being a Co-I to learning all the sessions and being our second yoga instructor. Of course, she was blind from the outcomes, she didn’t handle the outcome stuff, but if we hadn’t had her it would have been nearly impossible to do this trial. So, one kind of thing to think about is how do we start to have conversations about scientific methods and rigorous design. I truly believe we’re not going to be able to get this kind of intervention, if it is efficacious, into healthcare systems unless we can use most rigorous methods to trial it. And Dr. Hernandez, you’ll see her picture at the end, has done some amazing work in this area with acupressure, and trying to think about how to bring rigorous methods to integrative health, and so you’ll see her picture, but you should definitely look up her work. We also wanted to look at Ecological Momentary Assessment, so could we look at ways of collecting information from patients in real time. Enhanced Treatment, as Usual, I think is something that people are used to hearing about. Certainly, we had a wait, folks wait, but they were in contact with us and so that was enhanced care. And this feasibility is can we actually do this trial, or can we actually do this intervention.

I want to highlight that this trial, in particular, which focused on this feasibility of the design elements. That’s different in some ways than the feasibility of yoga as an intervention. We wanted to see if we could actually do this trial as we had it designed. Were there components of it that would work, or not? We had an exercise run-in, and I’ll talk about in a minute. Would our recruitment strategy work, could we retain participants, and would the Ecological Momentary Assessment, the EMA work? And then we were interested in acceptability, and we have really, really struggled here too with this idea of proximal and distal outcomes. We did a different trial that was funded by the MIRECC before this, where we had participants who on qualitative interviews said that being in the yoga was awesome, they loved it, it was great, and then the outcome measures that we are used to changed barely at all. So how do you translate what we’re seeing on these qualitative interviews into more traditional outcome measures is I think still a lot of work needs to be done in that area.

So who were we focused on? Those with a history of mild TBI. We used a structured clinical interview, we wanted post-concussive headache pain that was persistent. We wanted people to come in with a significant amount of headache pain to start with, and we also did not want to have a mess with our, anybody getting hurt, so everybody had to get medical clearance. We didn’t want the first yoga trial that was funded here to result in people getting hurt. We also focused on those that were between 18 and 50.

Okay, so a little bit about the intervention. We, as I already highlighted, we had originally started with thinking about this as a psychological distract intervention, and using trauma-informed yoga approach, and then we modified that to focus on post-concussive headaches, specifically focusing on stretching and parts of the body, thinking about muscular skeletal functions that does contribute to headaches, and switching things up to actually focus on that during the intervention. It was 8 weeks, 16 sessions, so twice a week. We had one theme per week, but different flows each week, and post-concussive headache and mindfulness language was woven throughout the sessions. And so this, I can hear Ann Bortz, the yoga instructor, saying this, yoga can teach us that sensations and feelings are constantly shifting and changing. That whatever is felt is time limited. So if you are, we have some cognitive behavioral therapists on this phone call, certainly that idea that like, you know, feelings and thoughts are always shifting, and we have the ability to monitor them but not buy into them, certainly, those kinds of thinking was brought forward to this.

It was a manualized intervention, so you can see here are the 16 sessions, and you can see the theme for each week. And each week both sessions are focused on the same theme, but that we do move through different poses each week and try to build each week. And so there is a building within the practice each week, there is a building across the whole yoga, all the yoga sessions, and then you can see that there’s certain things and certain things that we wanted the instructors to cue on around the skills that we were teaching that week. So I gave an example of a cueing to the mindfulness skill, and then I gave an example of some of the poses. So, certainly you can see this is a list for yoga instructors to learn, you know, and we tried to help have cue cards. We also did fidelity checks to makes sure that in fact individuals were adhering to the yoga practice, and I feel like I could give a whole session with Lisa and Ann about how we put this together, how they put it together, how to teach it, how to do a manualized intervention, but I won’t go much further into it, but I just wanted to tell people that this itself was a lot of work in trying to get this down.

Okay, so here was the study design. So we did baseline, we did an exercise run-in, and I’ll talk about the exercise run-in on the next slide. We did another follow-up on the exercise run-in, individuals were randomized to either, you know, Enhanced Treatment As Usual, or the yoga intervention, we did a follow-up, and then crossed over, and then so for some groups we have a maintenance for and some we don’t. So everybody got a chance to do yoga in the end. Again, we were really interested, could we maintain people in the trial long enough, could we get people on the waitlist to stay long enough, could we get people to come to two yoga sessions, all those things were part of it.

Now, this was my big idea. I’ll say this big idea I don’t think panned out. But this was from our previous trial, we had several individuals come and they just thought it was too hard. It was just the physicality of it was too much. We had a more open group then; I think that having younger Veterans made this more obsolete. But I thought well, hey what if we had a session to start with, the exercise run-in, where if we just show them the poses and what it’s going to be like physically people could opt in or out right after the yoga session. So we gave people a time, where it says right before randomized post-run-in time 1b, we gave them the choice to keep going or drop out. Based on now knowing what the physicality of it was I would say, I’ll show you data but I don’t, what, we have more, yes, yeah, yeah, I don’t have the data here, but I don’t think this is, I would not recommend this. So if you are writing a yoga trial and you somehow heard that our team did the yoga exercise run-in, and you think it’s a great idea, it was not a great idea. It was a Lisa Brenner bad idea. So don’t do that.

Okay, because we had only one person drop out after that, so I guess we had a lot of bigger problems than that. That was not our biggest problem.

We also wanted to see how this worked. We gave people lots of different options about how to collect this data. We ended up using REDCap mostly, most of our participant's used university REDCap. You can see the kinds of emails that people got, and so we were able to collect real-time information from folks every day about how their headaches were, I can’t even begin to tell you how much data we have for this. So this was a massive culling of data for us just for this talk today.

And then you can see, I don’t know if everybody is familiar with REDCap, it’s an amazing resource, and so using REDCap to see kind of how our folks were doing. As we started going through, I actually went to a talk in the middle of this trial, and thank goodness it was a feasibility trial so we could try new things, but I heard Dan Taub[phonetic] talk about CI Therapy, and the transfer package, which they do in terms of doing homework, and how he started saying like, you know, he’s very behavioral and like saying if you’re not checking up on people and providing them feedback without doing their homework, about doing their homework they’re not going to do it. And I was like, oh my God, I can’t believe, I’m a Psychologist and we’re not checking in with people and telling them to do their homework, other than these emails. So then we started calling people. And you’ll see some of that data. I think it actually did end up helping in time for people to at least remembered that they could do their homework, and their homework was yoga practice.

Another part of the infrastructure that we set up is we had every session is taped, and so that the Veterans had access to this at all the time. They could go do this, and you’ll see it near the end of the trial, we tried something a little different in terms of the dosing, and how to get at dosing with this. You know, the idea of dosing, how many yoga sessions do you need to make a difference, there aren’t a lot of great manuals out there about how to dose yoga for an interventional trial. And so we kind of thought well maybe if we can get people to do it twice a week in class that will help with behavior change. I think what you’ll see is we can’t get people to come to class twice a week. So that, we need to think differently about that.

Okay, so feasibility this was the big idea. We’re going to recruit all of these folks. We’re going to make sure there’s enough women. We’re going to do the exercise run-in. We’re going to randomize and get people to sessions.

And what you’ll see we assessed 473 individuals for being eligible. I’m not going to go through everything but I’m just going to tell you that in the end, we got 23 people really, plus, through yoga.

So it took 473 to get to 23. And I think we got smarter over time about how to pick those people and how to run this. But if this was run, if we hadn’t done a feasibility acceptability trial and we just run this as an RCT, it would not be good. Because we would not have been able to recruit or learn enough about what we need to do to make it work.

So I do want to tell you a little bit about the cohort, it’s not going to be particularly surprising that the sample characteristic, it was mostly men, which is great if you think about yoga being something that mostly women do, age 38, about a third have a college education. Slightly less than half were married. Half were working full time, and about 30% were students. I do want to say that it is really, really hard to schedule things for this cohort to come to. And I’ll say this again as we get to the end, I’m not convinced that in-person teaching is the best way to go. And I think we need to think about different alternatives, different opportunities, ways to provide this for people in times that they can do. People had childcare issues, they had class issues, they had work issues. We did offer yoga in the evening, we offered yoga during the day. We tried to switch it up in every way, and I wouldn’t say that that made a big difference. And really people finding time, meeting people where they are when they have the time seems to be the best. Now how to do that in a single site trial, I need Rani and people who are way smarter than me to help think about how to do that.

So our folks had a meeting of three TBIs, mild TBIs, 65% had a lifetime history of a major depressive disorder, 14% currently had it, 6% had a lifetime history of bipolar disorder, a significant amount of substance abuse, 63% had lifetime alcohol abuse, and 76% of the sample had lifetime history of PTSD. So again, this idea that we need to develop interventions that would be good for post-concussive headaches, but that would be okay for folks who have [unintelligible 41:01] mental health problems, also important, important to know that folks did have significant headaches at the time they entered the trial.

We did experiment with a lot of measures. You’ll see where one thing we did was use this beliefs about yoga scale. And really trying to get a sense of like who, how does this help drive who would want to be in this study, or how we might recruit, is this analogous with Pitta. Maybe, or something that we can use to help drive a recruitment and identify those who would be expected to follow through. Because we knew there would be a lot of drop out, as there has been in the past for us. And so what we really found is the folks who wanted to be in the study, not surprisingly, indicated that they are very likely to believe that yoga would benefit them. That it would improve their overall health, that it would increase their self-awareness, and help with focus. So, this idea that, you know, we need to find that group of people, and maybe those are the folks this could be a screener then for folks who would get in. Then you could say Lisa, well that’s the biggest placebo, you’re taking folks who think it’s going to work and you’re giving it to them. Well, I would say that’s true for all therapies, right? There’s tons of psychotherapy trials that show if people believe the therapy is going to work they’re going to do better, and if people don’t believe it’s going to work they don’t think it’s, there’s good expectancy and credibility it won’t work. We have expectancy and credibility data too, that I’m not going to show you today, but something to think about is a way to screen.

So here you can see 23 of 28 attended at least one yoga session. Among those attending, at least one, that we have the mean and median here of, so people were able to attend about eight sessions on average. So one a week. So already telling me that our dosing is messed up, right? That two times a week is not going to be what we need, and the challenge then is that if that’s the right dose, if two times a week is the right dose, we can only get them in one time a week, what are we going to do?

So, this is a lot of data. What I basically want to show you here is it didn’t really matter if we made people wait. There wasn’t a big difference in people waiting if they wanted to do yoga, they came in. If they were not interested, they did not. And so, you know, this in terms of feasibility, the wait now, wait or now, making people wait I’m not concerned about that.

So, as we started to see this kind of big drop out, I thought okay, thank God again this is a feasibility trial. Do both yoga sessions need to be in-person, or could we have one session a week and then could we then say the second session we want you to do at home for homework and we’re going to be calling to make sure that you do it? Okay?

And so we did this with wave six, and that had seven sessions, and then we had a wave seven. And so I wanted to get one more wave in. This is just an interesting thing, for wave seven we just said everybody in right now, we didn’t have to like mess around with waiting, making people wait, we had people call, we assigned them to the group right away, there were none of them were randomized, and you can see that eight out of eight of those made it to the first session. So there is something about kind of that whole front-end period of trying to fill enough to randomize that does facilitate us losing people on the front end. But back to the wave, so wave six was still a wave group. So if you think about in this, they had eight possible sessions to attend in-person, the group the way the yoga now attended on average about five, and the wait attended about six.

And then 13 out of 15 of those folks, so 87% of them at least used the homework videos at least once, and 6 out of 15 used them weekly. Okay, so I mean I think this by the end you can say, oh my God I cannot believe all of this work to get this. But, you know, I think trying to figure out how to give maybe one in-person session, one at home session, whether that’s tele, or with videos, or some other way, would be the way to get to the dosing that we’re thinking about.

Now, did those, did the people who came like it? Yeah, they really liked it. We used a client satisfaction questionnaire and people were mostly satisfied with the intervention. We used an acceptability [unintelligible 45:39] point of greater than 24, and we had 20 out of 23 that were above that. So, if you are willing to come to yoga and participate you find it acceptable. So that was less of an issue than the feasibility of the trial.

I wanted to show you all the different measures that we gave, really focusing on the tentative outcomes here. So trying to think about all different kinds of outcomes, from really traditional more promise measure, quality of life measures, to headaches measures, to headaches impact, to heart rate variability, to the EMA, to pedometry, we wanted to see like does this increase function. So we have data on all this. I’m not going to show you this today.

I also near the end of the trial read an article about looking at more objective measures like cortisol. And so for the last participants, we did collect cortisol sampling from individuals, and we did it both before they did the yoga sessions and after. And really looked at, so here is the baseline just to show you that folks who were doing yoga are happy to give you cortisol. What we found in this is that we did have a good diagonal profile, so that was that it was higher in the morning and lower in the evening for individuals, and that just the core concentration levels for our yoga participants were about twice as high as general population. So as you would expect, individuals who have a history of TBI, a history of psychiatric conditions, a history of probably other health-related problems, which we have data on, are going to be starting out with higher cortisol levels. So this will be something that we can share in the future too.

And just a whole gazillion of questions. So is the study design feasible? Maybe. For whom is the question. Could we use this whole host of data that we’ve collected to identify those who are most likely to participate? Could we facilitate participation across sites? Somehow so that we could have a larger pool of individuals to pull from, and that we could recruit and get people into studies more quickly, because I should also, should have done a poll question to ask you how much you think we got funding for this. But if we hadn’t had the MIRECC to back into, in terms of some of the budge and effort, this was, I mean this we did get a grant, I’m really grateful for, but the amount of work this took was way outstripped what we would have been able to do if this was a single investigator at one site trying to make this happen. Was the intervention acceptable and for whom? What are the right candidate outcomes and what the next steps?

So this is like the team, all these folks played an important role, whether that was, you know, running the study, doing the yoga, helping with the stats, doing the follow-up, doing the cortisol. And so thanks to everybody on this, there you see Dr. Hernandez and Dr. Betthauser, who are here with me.

And also wanted to highlight to people that we do have a yoga website that we did create for participants that you’re welcome to look at, love feedback on it. And this is where we host all the yoga. So we actually couldn’t have done this study without our University partners and the University partnership, and without MindSource, and as was said at the beginning we’re on Twitter. So I put my Twitter feed and University Twitter feed and our MIRECC Twitter feed. And so I think that’s, that’s it. So that’s what I have for you today.

Rob: Before Kavitha makes her comments I’d just like to announce to audience members if you have questions please do submit them using that questions pane in the GoToWebinar dashboard. Kavitha, Rani?

Dr. Rani Elwy: Hi, yes, it’s Rani Elwy and I just wanted to say to everyone, first of all, thank you very much, Dr. Brenner, for your presentation and for people to be thinking about some questions that they’d like to ask to Dr. Brenner and her team. But right now, while you’re thinking about them, I’m going to turn it over to Dr. Reddy so that she can provide some commentary from the Office of Patient-Centered Care perspective. Thank you, Dr. Reddy.

Dr. Kavitha Reddy: Thank you, Rani, very much and Dr. Brenner that was an amazingly awesome presentation. It’s nice to see the application of TIH with our patient population, so, and I do have some thoughts, and we’ll kind of go over those as it relates to your presentation. So I was thinking as you were talking, the diverse symptoms of traumatic brain injury, you know, as you mentioned, you were looking at population and the symptom of headaches, but there’s actually quite a few other symptoms people experience with traumatic brain injuries. And when you look at that list of symptoms it does correlate very nicely with the whole health components of health and wellbeing. So this is the idea that really caring for these patients from a multifaceted approach is incredibly important. You know, looking at sleep, looking at their nutrition, looking at their surroundings, looking at their movement. Yeah, exactly, every one of these areas correlates to a different area on the components of health and wellbeing, if many of you have seen that circle. And so, thinking about a whole health approach for these patients is incredibly important. And it comes up again later in your presentation thinking about people attending some of these classes. And what we know is if we take a full health approach we really focus on the activation and motivation for the patient before, and just telling them all the different resources we have. And obviously, we see that at many sites we have these great offerings, and even have them at weekends and nights, and at you know, at convenient times. But if the Veteran themselves is not activated yet around that goal, it sometimes becomes very hard for them to make that behavior change. And so again, just thinking about how to bring in the whole health perspective. And then there’s something that you mentioned that I think is so true is the limitation of coding and tracking mechanisms. Within VA we spend a lot of time working on novel infrastructure for coding. We do have four-character codes for yoga that can be applied to different clinics, if that’s what is being delivered. We have health factors for yoga that can be used to delineate that that approach is being delivered. And just recently we approached AMA for a new CPT for yoga, and although that will likely be a long road getting that it is a first step towards trying to get some more specificity in coding. So we do have some mechanisms for capturing that data, although a little bit difficult. Some other things I just wanted to mention is, you know, I really liked your poll, asking folks their experience with yoga, and I just want to reemphasize how important in our day to day work self-care is. And obviously given the evidence, we see some supporting evidence for depression as well, yoga can be a wonderful addition, and can even be done in your office. The breathwork piece can be done in your office as well. So, I wanted to just underline that. In addition, a few other comments, we do have minimum standards for yoga instructors and yoga therapists that our office has created, as well as position descriptions for yoga instructors. So that can support a lot of the work you’re doing in the field. And we’ve developed some standard episodes of care if you choose to do yoga in the community, in contract with somebody, try to outline the number of sessions that you might want to improve. But I will point out that it’s very interesting, Lisa, when you were talking about the number of sessions and what’s applied in each session, because I think to date, we’ve all had a difficulty understanding the dose. What is the dose of yoga that would actually get an individual to developing a competency in yoga or improving functionality? And obviously that’s very individualized, but I like that you’ve mapped out these 16 sessions, and what was the competency or the goal that would be achieved at each session. So really nice to see if that is the right dose over time. I wanted to also mention Telehealth, you were mentioning trying to outreach to people virtually, and our office has developed a Tele-Whole Health supplement where it maps out some of the logistical needs to be able to deliver yoga via Telehealth, and now with VA video connect, might be another opportunity to be able to televise those classes. And so, you know, I really also think the evaluation outcomes that you shared is important for this group, and for the providers in the field. We’re really trying to assess the effectiveness of yoga, and so you gave several great examples of what we could be looking at for the quality of care. So I think, Rani, those are my comments, unless there’s something specific you want me to comment on other than that.

Dr. Rani Elwy: No, I think that’s fantastic. Thank you so much Dr. Reddy, I would ask you to stay on in case there are comments from the audience members that might be better directed to you. So I’m just going to turn it over to Rob so that he can bring up some of those questions. Thank you, Rob.

Rob: Thanks Rani, we do have a couple of questions queued, up and not much time so, what do you think of using a telephone app for practice at home?

Dr. Lisa Brenner: I think a telephone app would be great. I think we had it on video. You know, I think we’re just struggling with like are there things that really being in-person, being part of a group, and then also getting some feedback and adaptations to help people in real time, can that be paired, you know. And I think these are, a lot of these things are the same questions we’re having with psychotherapy, right? So if you think about like SHUTi for insomnia, giving SHUTi, SHUTi we have a trial right now on SHUTi for Veterans, if people aren’t familiar it’s a CBTI, so Cognitive Behavioral Therapy for Insomnia. You know, CBTI you can do completely on the computer. Do some cohorts need to have a care manager? So do some cohorts need to have a psychologist, or a mental health provider with them? How do you think about kind of how do you need to augment apps or other strategies to make things work? You know, we’re certainly thinking about that in terms of psychotherapy, but I think, you know, in terms of alternative interventions also. And I should say that I use a phone app all the time to do yoga, but I’ve taking a bazillion yoga classes. So, you know, there’s a certain point where you’re reminding yourselves what you already know, versus you need someone helping you.

[Inaudible 56:44]

Dr. Lisa Brenner: Yes, and I would say that, you know, there’s a, I mean some of the Veterans that came, Lisa, please say, I mean say\_

Dr. Lisa Betthauser: Yeah, I would say like a lot of our Veterans actually did not have fair experience with yoga or had very minimal experience with yoga. And physicality wise they actually, you know, in the first like about three weeks struggled through some of the poses, and it was like after that point then they really improved in their ability to listen to the cueing, the verbal cueing, we did not provide any physical modifications by touching, it was all verbally done. And then you could, it was at that point that they were comfortable enough with it, understanding the language we were using, even though it was plain English, and being able to adapt their body into the poses that we wanted them to correctly get for kind of the correct benefit and the correct posture.

Dr. Lisa Brenner: Thank you.

Rob: Thank you. The final question we have at this time is, what biofluid did you use to measure cortisol?

Dr. Lisa Brenner: Spit.

Rob: Was it spit?

Dr. Lisa Brenner: Saliva.

Rob: Saliva?

Dr. Lisa Brenner: Yes, saliva. Saliva, yeah.

Rob: Well, that’s all the questions\_

Dr. Lisa Brenner: But we did\_

Rob: \_that we have at this time. Oh, I’m sorry. Go ahead.

Dr. Lisa Brenner: All right. No, no, I was going to say we, you know, certainly there are challenges around saliva for cortisol, but we certainly didn’t think that taking people’s blood after they did yoga or before they did yoga would be the way to go.

Rob: Thank you. That was the final question we had at\_

Dr. Lisa Brenner: Great.

Rob: \_this time. There was one person who asked to have the website pasted in, and I did paste the website to your study on the MIRECC\_

Dr. Lisa Brenner: Great.

Rob: \_at UC Denver, and I just shared that to all in the questions, if audience members if you’re\_

Dr. Lisa Brenner: Super.

Rob: \_interested. Does\_

Dr. Lisa Brenner: Thanks, everybody.

Rob: \_anybody have closing comments? If there are no closing comments then I’ll just go ahead and I’ll say thank you very much Dr. Brenner, and all, for preparing and presenting today, comments and hosting and everything else.

[ END OF AUDIO ]