Robin Masheb: Good morning, everyone, and welcome to today's cyber seminar. This is Dr. Robin Masheb Director of Education at the PRIME Center of Innovation at VA Connecticut and I will be hosting our monthly pain call entitled Spotlight on Pain Management. Spotlight on Pain Management is a Collaboration of the PRIME Center; the VA National Program for Pain Management; the NIH-VA-DoD Pain Management Collaboratory; and the HSR&D Center for Information Dissemination and Education Resources.

Today's session is Yoga for Chronic Low Back and Neck Pain.

I would like to introduce our presenter for today, Dr. Erik Groessl. Dr. Groessl, is Principal Investigator and Health Services Researcher at the VA San Diego Medical Center; and also, Professor at the Herbert Wertheim School of Public Health at the University of California San Diego; and Center Director of the UCSD Health Services Research Center.

Our presenter will be speaking for approximately 45 minutes and will be taking your questions at the end of the talk. Feel free to send them in using the question panel on your screen; if anyone is interested in downloading the slides from today, go to the reminder email you received this morning and you will be able to find the link to the presentation. Immediately following today's session, you will receive a very brief feedback form. We appreciate you taking the time to complete this as it's critically important for us to provide you with great programming.

Also joining us on the call today is Dr. Friedhelm Sandbrink, he's a neurologist, the VA National Program Director for Pain Management, and Director of Pain Management in the Department of Neurology at the Washington DC VA Medical Center. He will be happy to take questions related to policy at the end of our session.

And with that, I'm going to turn it over to our presenter.

Erik Groessl: Great. Thank you, Robin. Good morning everyone and thank you for attending. Today, I didn't have results from one specific new study to present so I'm going to review a couple studies that I've completed in the past, one large VA study completed and presented in 2017, and then I'm going to talk about a couple newer studies that are ongoing.

I want to start by acknowledging all the great staff and people who have made this research possible. VA Rehab Research R&D funded a couple of these trials; also NCCIH, and VA Cooperative Studies. I probably can't mention all the people involved in all of the studies

So, a quick overview. First I'll start with a background of chronic pain, chronic back pain and neck pain mainly; and then I'll talk a little bit about the VA RCT, I just mentioned yoga for veterans with chronic low back pain, and this has been published and presented before. I'll also talk a little bit about an NCCIH R-34 study where we compare two types of yoga from military personnel with chronic low back and neck pain; and then I'll touch on a VA Cooperative Studies Program, the SCEPTER Trial briefly that's ongoing; and also touch on a SPIRE, a pilot of SPIRE – Pilot Yoga + Mantram for chronic pain in vets with PTSD.

So, I won't spend too much time on the background slides. We know that chronic low back and neck pain are highly prevalent conditions, they result in not just pain but also functional impairment, psychological symptoms, lower quality of life, and certainly enormous cost burdens for our health care systems. Veterans experience higher rates of chronic pain; this graph shows the number of veterans reporting different kinds of pain and we see back pain at 58 percent in our population; neck pain is about fourth at 19 percent. But we also know that pain medication, which was in the past a primary treatment for many in the VA, yet was often ineffective and had very serious side effects which we're still combating and dealing with in the opioid epidemic.

So, let me shift and talk a little bit about yoga. This is traditional--a diagram of what traditional yoga was meant to be--and there's eight different limbs. So, the first two limbs are these restraints and observances; these are a little bit philosophical, they're not always present in yoga today, but Limbs 3 and 4, certainly the poses and the breathing, that's what we mostly think of as yoga today with also parts of maybe Limbs 5, 6, and 7, some meditation and concentration is usually part of yoga today. These were all designed to bring a person towards, a goal, a state of oneness and samadhi.

So, modern yoga is different; it's been transformed, it's more exercise-oriented like the people in this gym shown in the picture; there's a greater emphasis on the physical postures and movement, less of a spiritual emphasis. And yoga has also evolved to be more of a therapy or treatment. So, yoga therapists receive additional training--an additional thousand hours of training to be better able to apply yoga to people with different health conditions.

So, when we talk about yoga, what we really think of mostly are the postures, the breathwork, and some directed attention, which I mean that could cover focusing on one's breath, that could cover meditation, could also just be focusing on one's alignment and doing a pose properly. Movement, I had in parentheses here, it's usually part of what we think of as yoga but there are types of yoga--one of which I'll talk about later

on--restorative yoga--which involves very little movement; it's more relaxation and meditation.

So, in this diagram, these components of yoga listed on the left in purple go on to affect different physiological and psychological processes which we're still studying and learning more about, and they go on to, in general, produce benefits in mental and physical health.

So, a quick reminder: yoga is not just one thing, there are many different types of yoga. I think many of us have one impression of yoga, if you've tried yoga; and I think there is a common form, that form is the type that--I typically study hatha yoga, but there are many different types of yoga. So, it's important to describe and think about what is in an intervention.

As far as research on yoga for chronic low back pain and chronic neck pain, there were two big studies published in a 2011 study by Karen Sherman in a study by Dr. Tilbrook out of the UK; both had two to three hundred subjects so they were large samples, and they both found yoga was better than self-care for reducing disability. The Sherman study also found reductions in pain and reductions in medication use; but in that study--in the Sherman Study--there was a stretching arm to the study and yoga was not superior or better than stretching.

Tilbrook was conducted, as I said, in the UK; this was done at nine different clinical sites and community clinics and they did not find improvements in actual pain; they found improvements in disability so that was kind of interesting.

And then as far as neck pain, there haven't been any real large randomized trials; there are two trials here 2013 and 2016, about 50 subjects. And Holger Kramer's study found less neck pain, reduced disability, better quality of life compared to exercise, so he was comparing the yoga to an exercise active intervention, so that was an impressive result. It hasn't been followed up yet, though, with a larger study.

Also, Dunleavy in 2016 where they found lower neck pain disability scores for yoga and pilates compared to control.

So, overall, these studies are high-quality studies conducted in community HMO settings; they enroll about two-thirds of the participants as women--and this just makes it hard to generalize this the results to military populations and veterans; their higher socioeconomic status and we know many of our VA patients have fewer resources and other comorbid conditions.

So, back in 2010-2011, I was trying to get a study funded to look at yoga for veterans--it was actually before the Sherman and Tilbrook study was published--and we were funded in 2012 after--it took about five or six admissions--and we enrolled 150 VA patients with chronic low back pain here in San Diego to either yoga or a delayed treatment group receiving usual care and so they could continue with anti-inflammatory medications, physical therapy, whatever usual care that was ongoing--in fact, both groups continue receiving usual care if they desired and the delayed treatment group received yoga--and was offered yoga, I should say--after six months.

So, this was hatha yoga designed to be easily modifiable: so poses, deep breathing, some meditation; it was done at a slow to moderate pace and we wanted to certainly accommodate veterans of all abilities. So, we had amputees, we had people 79 years old, we had people 21 years old all enrolled.

So, the intervention was yoga was done twice weekly for 60 minutes; we also strongly encouraged regular home practice and we conducted assessments at baseline, six weeks, 12 weeks and 6 months. Here's a quick picture showing some of our veterans doing yoga; they had chairs available to make it safe while doing certain balancing poses; we did have to kind of use a patient education classroom, there was not a nice facility here ready for yoga at that time.

So, I'm going to jump to the results. Again, you see at the bottom, these results were published back in 2017, there was a second study looking at other secondary outcomes that came out in 2020. One main finding: no serious adverse events. There were maybe two out of 75 people who did yoga, two non-serious adverse events. We found that the yoga group had larger--significantly larger--decreases in disability and significant and significantly greater improvements on other outcomes such as pain, fatigue, and quality of life.

So, the decreases in pain and disability were, I guess, small to moderate in size; if you look at effect sizes almost all of the non-pharmacological and pharmacological interventions for chronic low back pain produce at best, moderate effect sizes. So, we found these effects despite lower than optimal attendance, a more impaired population than in previous studies; and decreased use of opiates and other pain treatments. So, the decreases in opiates were and other pain treatments, there was no differences by group, but everybody in the cohort decreased their opiate use--and I'll show you more detail on that in a minute.

So, this slide just shows the change in our primary outcome which was the Roland Morris Disability Questionnaire Score. And we see that the yoga group in the dotted line, disability continued to decrease after the

intervention ended at Week 12; in fact, the difference between the groups was not significant until six months. So, we're thinking there was definitely benefit of 12 weeks, twice a week, and a strong emphasis on home practice to try and sustain this practice. And from what we asked participants at six months, the practice was sustained for many of our veterans producing this effect. Now, we did find changes in many other outcomes right at 6 weeks and 12 weeks such as pain itself.

So, this table looks at opioid pain medication use and other pain treatments. So, I want to focus on the 20 percent here; this was the usage of narcotic pain medication at baseline across both groups, 19 and 21 percent, and that dropped to 11 at 12 weeks and 8 percent at 6 months, so we saw a significant decrease in both groups. Also, other pain medical treatments for pain, we saw the total sample decreased from 51 percent to 38 percent, a significant decrease, also a decrease in self-help pain treatments.

So, it seemed that there weren't differences by group as I keep saying, but people entering the study seemed to want something different and to want to reduce opioid usage. This was back in 2013 as well, so kind of early in the awareness of the opioid crisis.

So, this slide compares the characteristics of our sample to the other main studies of yoga for chronic low back pain and what we see is a pattern just showing that our VA patients; they were a little bit older; they were three-quarters men; they were more diverse--51 percent non-white; they had a little bit lower education; there were higher numbers of those that were unemployed or disabled. We had one in five almost, had been homeless in the past five years is the way we asked the question--these other studies didn't even think to ask about homelessness or something like that--the back pain duration was 15 years so almost 50 percent longer than the other studies; the disability index was was higher certainly than the Tilbrook study, a little bit higher than the Sherman study; narcotic medication usage 20 percent versus 7 percent in Sherman study and was not even mentioned in the Tilbrook study. So, although Sherman reported reduction in pain medication, they started out with only 7 percent using opioids.

And finally, attendance was lower in our study. So, why is that? Well, when we asked our participants why they were having trouble attending, there were many reasons relating to having to work, work and school conflicts, transportation issues was number one so many of our VA patients ride the bus or ride public transportation, and coming to the VA, although they know how to get to the main medical center, they've been here many times, they still are not able to easily come up here twice a week in a fairly large metropolitan area.

So, this slide looks at the percent of participants in three studies that achieve this clinical improvement in disability; it's defined in the literature as a 30 percent decrease in the RMDQ score and what's very interesting, it really reflects kind of the resistant chronic low back pain in our participants.

So, in the Sherman study, they compared yoga and stretching to self-care and this was really just self-care information, so they were not receiving much of an intervention. Yet, 55 percent of those subjects had a clinical improvement at six months; they also got 66 percent and 72 percent in the treatment groups. In the Cherkin study on chronic low back pain, they were looking at MBSR and CBT, but their usual care group, 44 percent had a clinical improvement without really any intervention at six months.

In our VA patients, my usual care group, 24 percent had a clinical improvement. So, we're seeing 24 versus 44 or 55 percent; I think this really speaks to it--and I should mention 57 percent had a clinical improvement in our yoga group--but looking at the 24 percent, it really speaks to the fact that our VA patients experience chronic low back pain that is likely more severe, more chronic, and possibly more resistant to treatment, and therefore, our results were pretty positive--or very positive, I think.

So, I'm going to shift a little bit. We did some follow-up analyses for this study and we looked at cost-effectiveness--and I don't want to spend too much time on this, I'll try and run through it and explain it as best I can, but if you're not familiar with cost-effectiveness, some of it may not fully make sense here.

So, our measures of effectiveness were the percent improved on Roland-Morris, I just described; also QALYs--quality-adjusted life-year--derived from the EQ5D, we had a 12-month time horizon, we looked at costs and benefits from the health care system perspective; we tracked actual intervention costs, and we also got actual health healthcare costs from VA medical records.

We also conducted sensitivity analyses, kind of testing a few assumptions we had to make, how they might vary and affect our results; and I also created a scenario comparing ongoing yoga to existing physical therapy services in the VA. And this graph shows the healthcare costs--I apologize it's not very clear, but what it really shows is in the blue line, it's the usual care group--the red line is yoga--there were no significant differences. These are total health care costs, so they were affected by other conditions and they're quite variable.

We did have four six-month lead-in time points and then two follow-up time points, so we're looking at costs mainly in the one year after the intervention started. Costs go up a little bit in the yoga group and then go back down; they are on a downward trend, so we do plan to look at those further out still but haven't completed that yet.

So, we mainly focused on the cost of the intervention and the benefits--the effectiveness; in our study, we paid a little bit more to bring a very experienced yoga instructor down who had worked with veterans with chronic low back pain before. So, the net cost of our 24-session yoga program was about $465 per person, but this resulted in 25 more clinically improved participants as far as disability, and also 0.04 QALYs that's projected over the first year. So, this produces an incremental cost-effectiveness ratio of about $1400 per clinically improved participant and 11,600 per QALY.

So, while there's not really a good metric for that first number, the $11000 per QALY is well below the $50,000 per QALY cutoff, indicating yoga is a highly cost-effective intervention.

So, I was looking at a paper by Rob Saber, he compared yoga for chronic low back pain with physical therapy in that study, and found that yoga was equivalent to physical therapy. And in that study, yoga participants received 12 yoga sessions and physical therapy participants received about eight up to eight physical therapy sessions. So, the big difference in cost comes from the fact that I estimated that ten people could attend each yoga class whereas physical therapy is delivered one-on-one.

Also, physical therapists appear to make, based on--this is US labor statistics--about twice as much as a typical yoga instructor. So, given ten people can be treated, a few more classes at about half the hourly wage, if yoga could be delivered in the VA on an ongoing basis likely by employees of the VA, so somebody who's delivering yoga on a regular basis, possibly somebody who has another role or another job in the VA and is trained to deliver yoga, it could be delivered much more efficiently and at a lower cost of about $100 per participant; whereas in this estimate--this is just a hypothetical scenario--physical therapy--a course of physical therapy would cost about $600 or 6x as much.

So, I guess before I move on, kind of the summary point theory is yoga seems very cost effective and it really seems it should be considered as one--there are other non-pharmacological and mind-body interventions that seem to be effective for chronic low back pain, but it really seems yoga provides a great option for the back pain in particular.

Now, I'm going to shift and talk a little bit about the Optum study and this was conducted with active-duty military personnel, but it relates to

the VA in a number of ways--I mean certainly, these military personnel become veterans many of them at some point--but it also looks at yoga for chronic low back pain and neck pain. So, here, we're trying to treat two different types of chronic pain. Before this study, I don't know of any yoga studies that really looked at different kinds of chronic pain. Most of the literature focuses on osteoarthritis, chronic neck pain, chronic back pain, only one condition at a time.

Another important aspect of this study is we compared two different types of yoga, so we're trying to get at which type of yoga might be more effective in this population. This is a feasibility study funded by NCCIH, so we're looking at just we are able to do this randomized trial among active-duty personnel? It's a pilot study, we don't have a large enough sample size to conduct statistical significance testing, that's the word I'm looking for.

So, as far as the study design, we randomized 50 active-duty personnel with chronic low back and or chronic neck pain to either Hatha yoga or restorative yoga, and these were 60-minute classes. They were offered three times a week, we asked participants to come one to two times. So, two times if they wanted to come twice, but at least once a week; and then we strongly encouraged home practice on a daily basis, we give them a manual; it describes maybe five basic poses they can accomplish in 15 minutes each morning; and our goal is to examine feasibility through measures of recruitment, retention, and attendance, also safety and satisfaction ratings; and we conducted outcome assessments, baseline 12 weeks and 6 months.

So, the hatha yoga was very similar to what we did in the VA; it's based on iyengar and vini yoga, these are types of yoga that are very adaptable; people of all abilities can do this yoga. The poses were always demonstrated by the instructor; the movement between poses is conducted at a slow to moderate pace in conjunction with slow deep breaths, and there's brief meditation at the beginning and sometimes at the end.

So, the restorative yoga, this is the one that has very little or no movement; it emphasizes relaxation; sessions typically include five poses over 60 minutes. So, they're in a pose for ten to 12 minutes at a time. So, as you see in the picture, restorative yoga is done mostly lying down, often eyes closed, and the instructor provides dialogue on breathing techniques or guided imagery.

So, our results real quickly. The IRB with the US Navy took about 11 months, that was quite an accomplishment; we thought it was going to take three months, it did not; recruitment went well, it took a little bit longer in first cohort recruiting at the Naval Medical Center in San

Diego. Retention was good for the study, 86 percent and 80 percent at six months were retained for assessments; attendance, we had some problems, it was less than optimal; but 12 of the 49 subjects stopped doing yoga at some point and at least five attended fewer than three classes. We also found no serious adverse events. So, the yoga we're doing appears to be safe.

So, as far as participant satisfaction, we did find high satisfaction on most aspects of the yoga; satisfaction was a little bit lower with class availability and this was a little surprising because we offered classes in the mornings at the Naval Medical Center, also in the evenings and on weekends at a community studio nearby. So, we tried to accommodate three different times during the week that they could do yoga--this was in-person yoga certainly before COVID. But they were active-duty folks, they were all working and very busy; they were younger than our veteran population, so an average age of about 33; and they were married, had kids, things like that.

And I do want to draw attention to the tan or sand-colored highlighted area here. We did find higher satisfaction in the restorative yoga group, so we're kind of thinking that people with busy lives and stress in their lives and chronic pain, they didn't really like doing a more strenuous form of yoga even though it's not highly strenuous they really appreciated the more relaxing form of yoga.

As far as our health outcomes, again, we didn't have a sample size to conduct significance testing and make firm conclusions about whether yoga worked; we saw some indications of improvement in health, improvement in disability; we have effect sizes--and the two groups on the far right here are the hatha yoga group and the restorative group and these are Cohen's D pre-post, so not real strong effects but improvement in disability 0.4; 0.5 on the pain severity index; 0.4 on the PROMIS pain index.

The other group not as much; there was some improvement on the BPI pain severity, the PROMIS, and SF-12 physical health. We did get some strange effects on SF-12 mental health where they reported slightly worse--very slightly worse-- scores there.

So, I wanted to look deeper at some of these scores, and I separated participants who had follow-up--complete follow-up--into two groups; those who had back pain only and those who had any type of neck pain. So, neck pain by itself or neck pain and back pain; and this gave us 21 participants in each group. And the yellow is kind of a cross--it's a back pain-specific measure in the neck pain group and vice versa, so we are ignoring the yellow. But what we see is the back pain participants responded quite a bit better, despite attending slightly fewer sessions. So,

a mean effect size of 0.41; people with neck pain--or neck pain and back pain--despite attending more, had very little effect, so I wanted to explore that further.

So, I broke the neck pain group down into those attending hatha yoga and restorative yoga, the two different types. And these are very small sample sizes, we can't make any firm conclusions; but we see the mean effect size in the hatha yoga group for people with neck pain is almost non-existent. In fact, when looking deeper, four to five people in this group, their neck pain and neck pain-associated disability got significantly worse. So, something in that intervention was aggravating their neck pain in this group.

The restorative group, there were some decent effects on certain variables, but again, they had higher attendance.

So, in conclusion for this feasibility study, we established we could do the research, it was feasible. We can't make firm conclusions based on the small samples; we do think, though, that neck pain may respond differently than chronic low back pain to some types of yoga and we need to work on the interventions before we expand to a larger study. I certainly plan to talk to Holger Kramer from Germany who got some good results in his study about how we can adapt the interventions to address neck pain better.

Restorative yoga may be more appealing to people with stressful and busy lives, that's another tentative conclusion from this study; and we hope to make some adjustments and conduct a multi-site trial in the future.

So, now, I'm going to shift gears again and just talk very briefly about the SCEPTER Trial; this is a study I'm involved with that it will also include yoga for chronic low back pain; this is a VA Cooperative Studies Program; the PIs are Dave Clark and Matt Bair; Matt Bair did present this study in 2019, and I can tell you although the study has been delayed because of COVID, it is getting back on track and is on target to launch later this year.

So, this is a large study conducted at 20 different VA medical centers with plans to enroll 2500 veterans with moderate to severe chronic low back pain, and the study will be conducted over the next six years. And just a little bit about the study design: it's a smart design study, so there's two phases at which participants can be randomized. In Phase 1, participants are randomized--all 2500 are randomized to either internet-based self-management, enhanced physical therapy, or usual pain care which might be anti-inflammatory medication, basic physical therapy, self-care information.

Then in Phase 2, any participants that don't respond after 12 weeks or three months are re-randomized to either CBT spinal manipulation, or chiropractic, or yoga. And then outcomes are measured at three-month time points up to a full year of follow-up.

So, some of the key impacts of this study. This is a trial of guideline concordant therapy, especially in Phase 1; it's kind of step care, it really tries to model ongoing or typical VA care in Phase 1; there's comparative effectiveness data especially in Phase 2, comparing three non-pharmacological treatments. There are outcomes--quite a few outcomes being measured beyond pain and function--a lot of chronic low back pain studies do not include some of these extra measures--and the large sample size enables us to look at predictors of responsiveness, so pain phenotypes and characteristics of people who respond or don't respond.

This also incorporates treatment preferences. So, at both phases, participants can cross off one of the treatment options and only be randomized to one of their two favorite options, so that's an interesting feature of this study. Data is also being collected on implementation and cost effectiveness. So, yeah, it'll be a while before study results are in, but that's a good study--a very interesting study to watch going forward.

And finally, I'm going to wrap up and just talk a little bit about a smaller pilot study I'm conducting currently. This is Yoga + Mantram Repetition for Chronic Pain and PTSD. So, veterans with PTSD, we know are more likely to report the presence of chronic pain; the pain they report is more severe; and the disability they report is also more severe, and are also at increased risk for substance use disorders.

So, we know that mind-body interventions like MBSR, Mantram meditation, and yoga have been shown to be effective to it for addressing different kinds of chronic pain and PTSD symptoms. The Mantram Repetition, for those of you who are not familiar with it, this is an evidence-based intervention developed here in the VA mostly in San Diego by Dr. Jill Bormann; and in this intervention, participants choose a spiritual or meaningful phrase. It's personal to them, they don't have to tell anyone and they repeat this phrase regularly, usually silently, they can repeat it out loud, they can write it if they want, but it's a type of meditation and it brings--Jill studied this with PTSD participants, also people with HIV; a number of different intervention groups, it's been delivered to employees here in San Diego; and it really helps to alleviate anxiety and provides quite a few health benefits.

So, the main idea behind this pilot study was to add Mantram Repetition to yoga because it provides a portable tool. So, yoga is hard to do in some settings--it's hard to do on a bus, for example, it's hard to do in a grocery store--I mean it's not that hard to do, it's just that people don't

want to do it. So, a Mantram can easily easily be practiced anywhere because it can be done silently; and even the deep breathing aspects of yoga are uncomfortable for some people to practice; if they're waiting in line at a grocery store they may not want to be taking big deep breaths to calm themselves down, so Mantram helps accomplish that.

So, this is a VA R&D study, looks at feasibility we're enrolling 32 participants they'll be randomized to either yoga + Mantram Repetition or to Veteran.Calm, which is a relaxation control intervention; and we'll have 12-week interventions with assessments at the end of 12 weeks baseline, 12 weeks, and then 18 weeks.

And so, this study is ongoing, I just wanted to provide a little update and tell people about it; we had some significant delays, but we're back actively recruiting. Our first cohort of 16 is being enrolled as we speak later today, and we hope to start the interventions within about two to three weeks. So, there will be more to come from this study.

And finally, I just want to try and summarize--I know I've talked about a lot of different studies and a couple are ongoing, we won't know more for a few years on those, but non-pharmacological options for chronic pain are now recommended as first-line treatments. So, there's a paper from 2017 recommending these treatments be used first instead of medications. We know that research supports yoga as an effective and cost-effective option for veterans with chronic pain; but it may not work for everyone; we saw that response to yoga may vary by different types of chronic pain and by types of yoga.

So, a final question is how can the benefits of yoga best be shared with our veterans with chronic pain? So, that is kind of an ongoing question; yoga is offered in over 100 VAs nationally; it's widely offered through the Whole Health Program, but that targets more general wellness and people with chronic back pain can attend those classes. But we could also consider offering classes--yoga classes-- specifically for people with chronic pain as well--I'm not sure we have enough yoga classes to offer it to everybody; there's an interesting study Stephanie Taylor's conducting, a demonstration study that looks at some of these issues; but I think that the data certainly warrants a wider usage and encouraging our veterans to consider these other options going forward.

So, I'm going to stop there and open it up for questions. Thank you.

Robin Masheb: Thank you, Dr. Groessl. It's good to have you back at Spotlight on Pain management and to see how your work and how this work in general about yoga has advanced and gotten more complex, it's really very exciting. So, congratulations to you and your colleagues on this.

We have a lot of questions rolling in I see a number of people have asked about getting the slides. The slides will be available on the HSR&D website for cyber seminars; you can use the scroll down window to get the spotlight on pain management, and you can find this talk--I'm not sure if it'll be up right now, it takes a day or so to get onto the website; but all of our past presentations, you can also find there.

Let me see if I can get into some of these questions. Can you talk a little bit about--there's some concern from people about whether more specific postures might be contraindicated for chronic neck pain or chronic low back pain, kind of at a more granular level than the type of yoga?

Erik Groessl: Sure. Definitely. And this ties in with a question here I see from Allison Whitehead. So, this yoga intervention was developed back starting in 2003 by Dr. Sunita Baxi here at the VA San Diego in conjunction with physicians and expert yoga instructors. And so, they carefully considered which poses to use and include in this study.

Also, the fact that the styles of yoga like iyengar, they're really designed to be modifiable and to use blocks, and straps, and blankets, and whatever is needed to help approximate a post. So, the instructors are not trying to get people with functional limitations to do the perfect yoga pose and stressing, "Yeah, you've got to have good alignment." In general, they're trying to and be encouraging, and any movement, and stretching, and approximation of a pose is encouraged and verbally rewarded, I should say.

So, yeah, there is concern over certain poses like up dog, forward bend--and there's effort to correctly teach people how to do these, but to very gently urge them towards these postures. And again, we've had no serious adverse events--the Karen Sherman study, they had one ruptured disc out of about 300 participants--but I think about 90 did yoga.

So, in general, across the all the studies of yoga for low back pain when it's done carefully with an instructor, there's very few adverse events that are being found by these poses.

Let me just say a little bit more. We do have a manual--a specific manual and protocol that's followed; we don't require instructors to do every single pose in the exact same order every session, we want to mix it up; but in general, yes, they are asked to stick to the protocol and the instruction manual.

Robin Masheb: Great. I'm going to roll a couple of questions up into one. You did such a great job and your colleagues looking at all different outcomes beyond pain and also the cost-effectiveness analyses are so interesting. Can you tell us a little bit about what's going on in terms of looking at outcomes

and reduction of pain medications and how you might be factoring in things like VA disability status into your analyses because of concern that getting better might harm somebody's disability status?

Erik Groessl: Yeah, we haven't really looked at service-connected percent--that's something we should probably look at, I'm not remembering that we looked at that. But we certainly didn't find a lot of people--there are people that enroll in these studies and never come, there's always a couple; they're not coming to yoga. We certainly have no observations from the instructors that people came to the yoga and then didn't want to do it or didn't seem to be trying. So, if they were going try and come to yoga twice a week, and do home practice, and come to assessments, I mean they're getting maybe $40 or something for doing these assessments; that's not a lot of money.

I think we found they were very interested; overall, our participants went from 20 percent on opioids to 8 percent and they were already interested in that on their own; they mentioned that in qualitative--I did have some qualitative data that I didn't present. But yeah, I'm not sure if that answers that.

Robin Masheb: And let me move on to a couple of other questions. People were curious about are you still enrolling sites for the SCEPTER and how you can get patients I guess either to the study or just referred for yoga in general?

Erik Groessl: Well, I mean the SCEPTER study actually started about a year and a half ago--and then was delayed for a year. So, they have identified the 20 sites and they put out a call probably over a year ago, and I believe they have identified backup sites and they chose those based on geographic disbursement--and they tend to be larger VA medical centers that can recruit 120 people fairly quickly as opposed to smaller clinics.

So, I don't think that's an option, but somebody--your site may already be part of the study and someone doesn't know about it or they're on the waiting list in case a study somehow couldn't accomplish the study goals.

As far as referral to yoga, Stephanie Taylor and Melissa Farmer just announced a paper coming out... I don't have it in front of me... that describes the use of complementary and alternative or integrative medicine in the VA system. So, that's one resource that may be able to help people find out what's offered at their medical center; there's also Connected Warriors which is a nonprofit that provides free yoga to veterans and their families and to active-duty military in the community--and Connected Warriors has gotten tied in with the VA system and provides some classes for some VA programs as well. Also, the Whole Health Program, Office of Patient-Centered Care and Cultural Transformation, there's resources there through Whole Health.

Robin Masheb: Yeah, lots of people are asking for resources on being able to get your manual. So, is doing that through Whole Health, would that be the best way?

Erik Groessl: No, as far as my manuals people can email me at my VA email and I am happy to distribute both the instructor manual and the take-home manual--the home practice manual; and I think when I presented in 2017, I sent it out to about 60 different people after that talk. So, happy to do so.

Robin Masheb: Great. We have so many questions to this talk which is amazing; it shows how interested people are and I know we just have a couple of minutes. So, I think I'll get one out to you which, I think, hits a lot of concerns and questions that people have which is about the training of the yoga teachers and what maybe you did to kind of make sure that they were well trained, that they were adherent to following the manual, and maybe just some of your thoughts about that, about training and also making sure that the yoga that they're teaching is safe. I mean, obviously, we want everybody to honor their bodies but I think also teaching the teacher how to make sure that they keep emphasizing those messages is very important.

Erik Groessl: Yes, yes, it is very important. And we, in San Diego, because Dr. Baxi had started the yoga program even before some of my research, we had some very experienced instructors here to draw from. But in the SCEPTER Study, we really had to decide what criteria we were going to require sites to meet; and so, there's 200-hour yoga training and 500-hour training, there's also the 1000-hour yoga therapist training.

And so, in the SCEPTER Trial, we required the 500-hour as a minimum or greater, or two years' experience delivering yoga to people with chronic pain conditions or health conditions in a healthcare system. But then, we will be--and we did additional trainings going over the manual, explaining why it's important that they not go off on their own; and then we videotape to look at fidelity, and yeah, they know they're being videotaped as well.

Robin Masheb: Thank you so much, Dr. Groessl for sharing your work with us and to our audience, my apologies for not being able to get to everybody's questions, but I think it just speaks to how interested everyone is in the VA about this work and how engaged they were in today's talk.

Just one more reminder to hold on for another minute or two for the feedback form. Again, if you're interested in the PowerPoint slides from today, if you just search on VA cyber seminars archive, you can find any of our past Spotlight on Pain Management sessions.

And just a reminder that our next cyber seminar is going to be on Tuesday, May 4th; we'll be sending registration information out around the 15th of the month. And I just want to thank everybody again for attending this HSR&D cyber seminar and we hope that you'll join us again.