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Session: VERDICT (Veterans Response to Dosage in Chiropractic Therapy): A Pragmatic Randomized Trial Addressing Dose Effects for Chronic Low Back Pain: What, Why, and How?

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Dr. Robin Masheb: Good morning everyone. Welcome to today’s Cyberseminar. 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. Today’s session is VERDICT, Veterans Response to Dosage in Chiropractic Therapy: A Pragmatic Randomized Trial Addressing Dose Effects for Chronic Low Back Pain: What, Why and How? We’re very pleased to have this presentation today as it is one of the 11 pragmatic trials from the VA, DoD, NIH Pain Management Collaborative. And this is one in a series of those presentations. I’d like to introduce our presenters for today Dr. Christine Goertz and Dr. Cyndy Long. Dr. Goertz is Professor and Director of System Development and Coordination for Spine Health at Duke Health where she builds clinical research programs and improves non-operative spine care pathways. She is also in the Department of Orthopedic Surgery at Duke University Medical Center. We also have with us today Dr. Cyndy Long who is Dean of Research, Professor, and Director of the Office of Data Management and Biostatistics at the Palmer Center for Chiropractic Research in Davenport, Iowa. This is located in the Office of Data Management and Biostatistics. Our presenters will be speaking for approximately 45 minutes and we will be taking your questions at the end of the talk. Feel free to send those in as the talk is going on using the question panel on your screen. If anyone is interested in downloading slides from today you can go to the reminder email you received this morning and you’ll 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 completing this as it’s critically important to help us provide you with great programming. Also joining us on the call today is Dr. Friedhelm Sandbrink. He is a Neurologist, the VA Acting National Program Director for Pain Management, and Director of Pain Management in the Department of Neurology at Washington DC VA Medical Center. He will be happy to take questions related to policy at the end of our session. And now I’m going to turn this over to our presenters’ Doctors Goertz and Long.

Dr. Cynthia Long: Thank you. Good morning everybody this is Cyndy Long and Christine is also on the line and will be helping as we go through the talk. So we’re talking about VERDICT, let’s see here. Okay. There we go. So we’re going to start by talking a little bit about public, the public health impact of low back pain. Followed by a brief summary of current guidelines and recommendations. Then we will be talking about our preliminary pilot work to evaluate chiropractic care for Veterans that that particular R34 grant was part of the original NIH-DoD-VA initiative followed by the VERDICT Project which is part of the Collaboratory.

So the public health impact of low back pain, number one cause of global disability, 80% lifetime prevalence in adults, 37% global annual prevalence, 7.3% global point presence, 540 million people are impacted by low back pain. Over 54% in years lived with disability. Total costs are as high as 200 billion annually in the U.S.

And getting us to current guidelines and recommendations.

In 2007 the American College of Physicians came out with a clinical practice guideline for low back pain. And then they updated it with this systematic review in, almost two years ago.

The key points in this systematic review were that several nonpharmacologic therapies for low back pain were associated with small to moderate, primarily shorter effects on pain and also effects although a little bit smaller on pain in, on function and most of the evidence was for chronic low back pain. And typical harms reported were temporary increases in low back pain or other local effects.

There are quite a few guidelines applicable to low back pain now.

The one that we’re going to briefly describe here is the one that came out in the Spring of 2017, again an update from the American College of Physicians.

The primary recommendation here were that physicians and patients should treat acute, subacute, and chronic low back pain with non-drug therapies.

Acute and subacute low back pain, the recommendations were heat, massage, acupuncture, and spinal manipulation. For chronic low back pain it was exercise, spinal manipulation, and progressive relaxation. And only for chronic pain, low back pain that doesn’t respond to non-drug therapies should drugs be used with obviously opioids as the last resort.

So our first study was evaluating chiropractic for Veterans with low back pain. This was our preliminary pilot work.

We finally called this study Collaborative Care for Veterans with Spine Pain and Mental Health Conditions, COCOV.

The background and rationale as we all know U.S. Veterans have musculoskeletal pain conditions, lots of chronic low back pain, and mental health comorbidities and obviously opioids and psychotropic medication overuse. We have poor outcomes with current treatments. In particular with respect to quality of life and long-term disability and opioid-related overuse or death. So this is the perfect place for chiropractic to be looked at because in the VHA pain model there’s a stepped-care model that includes complementary and integrative approaches.

In particular in that stepped-care model tier one, are these modalities which also include chiropractic care which is spinal manipulation but also active exercise and other therapies. We currently in the U.S. have 108 chiropractic clinics in VHA facilities, 180 chiropractors, and we can see that over 52,000 chiropractic patients in VHA settings with another over 200 Veterans having chiropractic visits as outpatients.

So our early work first looked at qualitative interviews at three research sites; Iowa City VA, Minneapolis VA, and Connecticut VA. And interviewed patients, multidisciplinary team members and the Doctors of Chiropractic at those sites identifying stakeholder viewpoints. With respect to preferences and perceived need for chiropractic care, chiropractic integration into PACTs. Current policies and processes to support integration. And barriers to inclusion of chiropractic in VHA guidelines and clinical practice settings. And we really looked at, you know three separate sites here where West Haven was really an innovator coming on with chiropractic very early. Minneapolis was an early adopter and then Iowa City was the early majority where they came on, came on last. So perspectives from those three different areas.

We developed an integrated care pathway for chiropractic treatment for low back pain in Veterans as part of a Delphi consensus process and you can see this paper that was published in the JMPT in February of 2018. And this guided our future work.

We conducted a pilot clinical trial. I guess we started it about two years ago. You can see here that we had six months. We were able to, in that six months enroll our target 40 Veterans with chronic low back pain. This was a [unintelligible 10:06] trial so everyone got pragmatic clinical care from the chiropractor and we were able to enroll about 43% of those that we phone-screened. So that certainly gave us a good indication for future planning. We also assessed you know how, we’re using REDCap for primary data collection from the Veterans at baseline, at five weeks. And ten weeks we were able to assess how complete that data collection effort was. You can see here that the number of these DC visits over those ten weeks was only at 4.5 ranging from one to seven. And very important for the next trial we’re going to be discussing. This is average, the average number of visits for, the DC visits for patients visiting the chiropractic clinic in VA is about five. And so you’ll see that that’s an important consideration with the trial that we’re going to describe, the design of it coming up.

So our participants were 40 VA patients, age 18 to 55. We didn’t have an upper limit but this is our actual sample with chronic low back pain. We used that integrative care pathway that I showed the publication of. You can take a look at that and see several pathway charts. They could have chiropractic care up to ten weeks. We did assessments at baseline, weeks five and ten again via electronic data capture with REDCap. We also did qualitative interviews for patients and providers talking about really the feasibility and acceptability of chiropractic in these environments. And then you know we did descriptive statistics to estimate effect sizes and in particular variability for planning a larger trial.

What we were able to do is, is demonstrate the feasibility of participant recruitment. That really was very, very good. And collecting outcomes via REDCap from Veterans in this environment. Early on we saw that we were not getting the ten-week assessments completed. We were having some drop up of that anyway. So we really, we really went back and refined our data collection protocol. In particular our reminder protocols. And so for the first half we were lower percent. We ended up with 83% with week five assessments and 80% with week ten. But after we, about partway you know a third through when we instituted these more rigorous follow-up and reminder protocols we were able to get 90% of assessments after that. So we feel like we’ve got a good hold on that. And so these recruitment and data collection methods as well as many other things we learned in this pilot study were incorporated into the protocol for full-scale, multisite four VA clinics pragmatic trial for Veterans with chronic low back pain which is the study we’re going to talk about, VERDICT. That is part of the Pain Management Collaboratory, the NIH-DoD-VA initiative.

So obviously for this early work we have lots of investigative team members at all of the sites as well as the University of Iowa. And it was our you know acknowledging NCCIH’s R34 grant that supported that work.

So this is, going to talk about the VERDICT dosing study.

I think the Pain Management Collaboratory is something I think a lot of you are familiar with. This is the demonstration projects are, the 11 projects of which we are one that is funded through this initiative. We have obviously program officers and project scientists from all three of the federal organizations. We’re funded by NIH so we have a project scientist on our team as well as program officers. We have a steering committee which is a very large steering committee, I think probably over 50 people with the PIs and of the studies, as well as the key people from the government agencies that are part of this. And work groups which have been really instrumental in developing the protocols and finding as many things that we can harmonize over the 11 projects to really leverage the information that, the data that we collect throughout our separate pragmatic trials.

So chiropractic care for Veterans, a pragmatic randomized trial addressing dose effects for chronic low back pain, is what we refer to as VERDICT. And that is the study that we’re just getting ready to launch here.

So to give you a sense of the team we have here it looks rather complicated and I think it is. We have the coordinating center for the Pain Management Collaboratory. We also in addition to NCCIH at the NIH we have the Office of Research of Women’s Health on our study. We are trying to oversample at least 20% of our study as women. We have a project scientist from that office. We have our program officer from NIH. Palmer College is the clinical trial coordinating center for this. We are doing all of the primary data collection via REDCap, as well as the analysis. We have four academic research partners; Palmer where we have both a qualitative project lead and clinician training lead. We have experts in pragmatic trials at Dartmouth and the University of Iowa. Anthony Lisi at the Yale Center for Medical Informatics and his team are going to be leading the EHR data extraction activities and analysis. And then we have four VA clinical research partners which include VA Connecticut which is at, we’re going to be recruiting from the West Haven clinic, the Iowa City VA, the Minneapolis VA, and then we added a fourth one to our earlier work and that’s VA Greater LA. And we have site PIs, great site PIs at all of those institutions. So I think we need to back up here a little bit and talk about dosing. I mentioned earlier that our COCOV pilot trial had approximately, or it had an average of about five visits for all of those, of all of those research participants which is average for VA. So VA you know has very long waiting lines for chiropractic care and that’s the average of our visits. They do not have any kind of extended care or some people call them maintenance care. So patients go through an initial course and if they get, if they get, when they get discharged they do not have, they may come back for another consult but they do not have any kind of extended care or follow-up treatment beyond that initial care phase.

So our pragmatic\_

Dr. Christine Goertz: If you don’t mind, just before you get started. This is Christine, I’ll just jump in here a little bit that this is a, a number of the dosing of chiropractic or the number of visits is obviously an issue within the VA but it’s actually an issue that has broader implications as well. If you look at the, right now we really don’t know how many times a person needs to get in a car and drive to a chiropractic office in order to have an optimal outcome. And if you look at the existing data Cyndy already mentioned that the average number of visits is about five in the VA. The average number of visits for a large payer groups is around six. But the median is one. And the, when we, there is one clinical trial looking at dosing for low back pain that came up with 12 but that was not a highly pragmatic trial. So this is an area that is, that is of a lot interest to patients, to providers, and to payers as well.

Dr. Cynthia Long: Right. Christine do you want to, why don’t you describe the pragmatic aspects of this with this slide. And then I’ll pull it back.

Dr. Christine Goertz: Certainly. I’ll be happy to do that. So the question of dosing is one that, for chiropractic is one that’s particularly well suited for a pragmatic, you know clinical trial design. And, however if you look at this [unintelligible 21:03] diagram you’ll see that there are, that a number of areas where we’re able to be very pragmatic you know particularly in terms of outcomes and how relevant they are to participants, our primary analysis, et cetera. But there are also areas where we’re less pragmatic. We’re certainly going to be following participants much more closely as, in terms of patient-reported outcomes and other outcomes then they’re followed clinically within the VA right now. And also the regarding that organization, what expertise and resources are needed to deliver the intervention. Though chiropractic is currently in, is currently offered at all four of our clinical sites and at many VA’s sites as Cyndy already mentioned. But the fact that we’re having more visits which will, Cyndy will get into a little bit later about exactly what the groups are, means that we are delivering care that’s a little bit different in terms of the number of visits both in the short-term and the long-term, then is currently ongoing in the VA. And regarding flexibility about how the intervention be delivered. We are, you know for the most part clinicians are in fact following the normal protocols for how they treat chiropractic patients but we are, the trial does have an impact on the number of visits. And we are also following our clinical care pathway that we developed in the previous study as a guidance throughout this effort.

Dr. Cynthia Long: Thanks Christine. Okay so talking a little bit about the design of VERDICT, we are intending to recruit 766 Veterans across these four clinical sites. Initially we will be aiming for about 25% at each site but we will be monitoring that very closely and making changes where needed. Anyone 18 years or older is eligible and they must have self-reported chronic low back pain which we’re using the NIH task force definition of that, that low back pain has persisted three-plus months with pain on at least of the half of the days in the past six months.

Our primary aim one is sort of the short-term, the ten-week course of clinical care. And we are evaluating the comparative effectiveness of a lower dose which is one to five visits. Determined pragmatically within that visit range. Which is again consistent with what is currently given in VA and really outside the VA as well. Of chiropractic care against a higher dose which is eight to 12 visits. Some of that coming up with the 12 visits was partly based on our primary work in our clinical care pathway that was really 12 visits for chronic low back pain Veterans was what was really recommended from that work. And so we’ve given a range there that really is outside of typical care in the chiropractic clinic at VA. Again these participants all have chronic low back pain.

We have a second objective. This is really two, you know two interlinking trials. The first trial looks at the endpoint at ten weeks but then we want to get this idea of chiropractic chronic pain management or extended care for chronic low back pain patients. Which is defined as one scheduled chiropractic visit per month. So our second aim is to evaluate the comparative effectiveness at 52 weeks of chiropractic chronic pain management compared to no chiropractic chronic pain management following the initial treatment. So for about ten months. So we look at all these participants are in the trial for a year. Certainly all other care that they are seeking in the pragmatic sense whether it be for low back pain or other conditions is allowed in this trial.

Those are our primary objectives. We also have two secondary objectives. One is to evaluate the impact of that chronic pain management on health services outcomes compared to just usual care.

And finally we are, through interviews of a random selection of patients and the clinician, the study clinicians at the sites we are evaluating their perceptions of the non-specific treatment effectiveness, the effectiveness of the study interventions. The impact of the varying doses of standard chiropractic care and the CCPM, the extended care on clinical outcomes across these facilities. And this will be using a mixed-method process evaluation approach.

So you can see this is our study flow. We are, we will enroll and randomly allocate 766 Veterans. We have three key recruitment methods that were also tested in our pilot study. We will be enrolling or approaching folks who are all, Veterans who are already consult\_, have been, are on the consult list for the chiropractic clinic. We will be recruiting outside as well looking for other areas that see low back pain patients in the VA to refer patients to the study. We will be doing some letters to people who have not been to chiropractic care clinics in the last year but have a diagnosis of low back pain in their record. And we will also be just doing standard posters and other kinds of outreach to let Veterans know that this study is available. We will be randomly allocating participants first in phase one of this study to either the low dose over ten weeks or the higher dose over ten weeks. And then our primary aim is at the week ten endpoint for phase one. Then we will randomly allocate them again. We know that some people may have dropped out, some people may opt not to go into that or their clinicians may not want them to continue on this study so we’ve put adequate number of participants at the front end so we end up powered at the end of phase two. And in phase two within both the low dose and the higher dose they will be, participants will be randomly allocated to either of the chronic, chiropractic chronic pain management or no chiropractic chronic pain management. And our aim two endpoint is at the end of one year, at week 52.

Our primary outcomes, our primary outcome for both the phase one and phase two is a Roland Morris Disability Questionnaire. We will be looking at in phase one at relative risks whereas in phase two we will be looking at the continuous variable of the actual scores. We have lots of secondary outcomes as you might imagine. Again the primary and secondary outcomes are being collected with, via data capture directly from participants. We are collecting the PEG-3 data. That has actually been harmonized across most of the 11 studies so we will all be collecting that at various times. The PROMIS certain domains of the PROMIS Pain Interference is obviously a very important one, pain function, fatigue, anger, self-efficacy, general health are all part of the PROMIS and we will be using the adaptive measures there. We will be using the Legacy items PHQ and GAD to assess depression and anxiety. As well as the updated PCL-5 to assess PTSD. And the number of days per week with low back pain. So the primary and the secondary outcomes will be collected at baseline, at week five, at week ten, and then quarterly through one year via REDCap. We are also doing a weekly data collection via text messaging of just the PEG-3 and the number of days each week with low back pain. And those will be definitely secondary analysis but we think that that you know with a condition like pain, low back pain, that shifts across time that that will give us valuable information. And we have used that in some other studies as well. Health services that is, so Palmer is going to be collecting the primary data and analyzing it. The Yale Center for Medical Informatics will be doing the health services side where they are collecting from the EHR prescriptions referrals, clinic visits, hospitalizations, anything that’s happening for participants outside of the chiropractic care. In particular for low back pain but really for all conditions. And importantly here our group, our colleagues at Yale developed a specific template in the EHR, I think it is in CPRS to collect visit specific data that are not typically in EHR, relative to the chiropractic visits. And that was developed over the course of a year and has been tested at all, three of our four sites. Maybe all four sites actually and so we feel that that will give us lots of valuable information that we have not been able to get thus far. About exactly what’s happening at each of the chiropractic visits. And then finally I already mentioned that we have a qualitative aspect for a random sample of our patient participants.

So where we are right now. As all of you that work in research know that we have IRB approvals, is what we’ve been working on for about a year and a half. We just got our annual renewal for our VA Central IRB in December. And because we have four academic sites we also need an academic IRB. And so Yale is our IRB of record and we were approved in May for that. We have hired study, we will be hiring study coordinators at all four sites. Three of the sites have hired them. Our first two sites that we’re going to begin at are the two that we’ve done the most work at; the Iowa City VA where we did our pilot study will be the first and we’ve had that study coordinator with us for a year probably, working with us here at Palmer. We’re, you know we’re only an hour from Iowa City. And we know those Doctors of Chiropractic at that site very well. They have been here for training and we’ve been there for training and so we’re ready to go at the Iowa City clinic and anticipate starting in the very near future, within, in January. We also have our study coordinator hired and trained at VA Connecticut at the West Haven clinic. And the doctors of the study, Doctors of Chiropractic have been chosen there and they went through training late in last year. So they, we anticipate them starting before the end of the month. And so we will have two sites up and going, anticipate in January. Our other two sites Minneapolis has hired their study coordinator. Will be onboarding so in February we’ll have them travel to Palmer for the week of training. In particular on the REDCap system that we use for data collection but we also use for a lot of trial management across those sites. And VA Connecticut is just getting ready to post their study coordinator. But the Doctors of Chiropractic at both those sites have by, for the study have been identified and we will be beginning training with them as well. We have you know lots of direct posters and such that we will be posting at those sites and if you’re at any of those sites we hope you take a look and appropriately refer participants or your patients to this study.

Most recently, we, I think just off the press at the end of December we have a paper out by some of our team here at Palmer where we developed a clinical decision aid. Christine do you want to talk about this a little bit more?

Dr. Christine Goertz: Sure. Just as you were, one of the issues that we face for, always when studying a multimodule treatment such as chiropractic that can include so many things. In addition to the signature spinal manipulation that you might all be already aware of Doctors of Chiropractic also commonly work with patients regarding you know exercise advice, dietary advice, physical therapy modalities such as heat and ultrasound and muscle stimulation. You know rehab. And as general education about good back hygiene are common treatments. And so it can be difficult to know what’s, what approach a doctor should take and what certainly in the context of a clinical trial and how are we able to then describe what actually happened to the patient sufficiently enough that a person would be able to replicate the study or would be able to use the, our treatment approaches in an actual clinical practice. So to address this issue we engaged in a, this is the, really a follow-on for the paper that Cyndy mentioned earlier about a, about treatment for a clinical care pathways for people that, in the VA that have both back pain and mental health comorbidities. We followed a similar process here for looking at how clinical decisions can be made in management of common conditions that cause low back pain for Veterans. And this right now both, actually I think that the paper that we mentioned earlier is in the public domain and this paper is not quite. It is supposed to be in the public domain, I think it takes the Journal just a little bit of time to actually make it available. But\_

Dr. Cynthia Long: Well actually it is available in the common domain right now.

Dr. Christine Goertz: Is it now? Okay great. Then it’s, that’s\_

Dr. Cynthia Long: Follow this link and you will find it.

Dr. Christine Goertz: Oh that’s great. Because earlier in the week I was not able to pull it up actually in the public domain. It was saying that I had to pay for it. So I’m glad to know that that’s actually happened now. But this is, I think this will be important you know not only for Doctors of Chiropractic but those of you who are working with Doctors of Chiropractic to better understand what, what the clinical decision process is for DCs and what the recommendations are as the result of this consensus process.

Dr. Cynthia Long: Right and we will be using this decision aid in the trial.

Okay. So you know as we mentioned earlier in addition to our four VA clinics we have Christine at Duke, we have the, all of the, my colleagues here at the Palmer Center for Chiropractic Research who will be doing primary data collection and analysis. We have all of our colleagues at Yale who will be doing the EHR data extraction and analysis. And then we have our colleagues at University of Iowa and Dartmouth who have also been the key in this process. You know we’ve spent a lot of time together on the phone. I think we can say.

And you can see all of our investigative team members from those sites and of course we need to acknowledge our funder. We, this particular grant mechanism we had a two-year, so we were funded in the end of 2017, we had a two-year planning period to get the protocol up and in, and reviewed by many, many levels of, for us NIH reviews, as well as all of the IRBs and so we transitioned in September to be able to move forward with actually doing the trial. As I mentioned we have two sites that are ready to go and so just waiting for some final IRB approvals and we will be moving. And then in the Spring we will be launching at our other two sites. Thank you.

Dr. Robin Masheb: Thank you both for such a wonderful presentation and it’s really unbelievable the number of different institutions and people that are involved in a project such as this. So kudos to the two of you for pulling it all together. I just want to remind our audience to feel free to type in your questions and I’d be happy to field them to our presenters. But I’ll just start off with one. I was wondering if maybe you could talk a little bit more about your recruitment and things like your inclusion and exclusion criteria and maybe you know what obstacles you think you might encounter in trying to get a sample size of this magnitude.

Dr. Cynthia Long: Yeah, I’ll start Christine and then you can, you can jump in. So we’re trying to be as pragmatic as possible so that the key things are just above 18 and chronic low back pain. Of course there are contraindications certainly. We need patients, we can’t use a proxy. We need patients to be able to understand and sign the informed consent and understand the processes. And any other, you know some contraindications to chiropractic care. But those are the primary inclusion/exclusion criteria. Recruitment I mentioned a little bit. You know we really think certainly in our pilot study and working with our colleagues we think our primary recruitment source will be patients who have already been referred to chiropractic and are in the queue and you know we have a process where we will be sending letters to those patients inviting them to the trial if they’re interested. And you know but the key thing and the challenge we will have is likely will already have been scheduled for chiropractic visits. So we need to have that baseline visit where we do the consent process and collect all baseline data before their chiropractic visit. Christine do you want to jump in here?

Dr. Christine Goertz: This, the obviously recruitment and retention are always a challenge. Especially in a trial of this magnitude. We, in previous studies with you know similar treatments we’ve had really good luck with both recruitment and retention. And so we’re hoping that the same is, is true in this study. But I think our biggest chal\_, well we have several challenges but one challenge that we have in this trial is, is actually making sure that we’re able to offer the appropriate number of visits within the dosing groups. With the primary concern making sure that we’re able to offer more visits than the average of five that is currently occurring. And we’re going to address that, we’ve already addressed that issue by expanding capacity at each of the sites adding clinical, adding additional FTEs of chiropractors so that, that the sites are able to handle this, the increased dose. But in addition we’ll be paying very close attention and making sure that our participants are in fact receiving the doses that are, that they are, have been allocated to. So that we’re able to address issues that, any issues that we run into you know, in very quickly in real-time.

Dr. Robin Masheb: Another question is are you, did you experience this in the pilot study and I’m curious about how you might handle it in this pragmatic trial, although it is a pragmatic trial so I assume you want people to go ahead and you know, they’re going to do whatever they do to get other care, is what if people like you know the chiropractic care and they’re like I want more of this. And they have the opportunity to get it on the outside, outside of the study. Are you doing things to keep track of that? Are you discouraging people from getting additional chiropractic care outside of the protocol?

Dr. Cynthia Long: Well that’s definitely an issue you know. It’s harder to keep track of because it’s obviously not in the EHR. We will, we do ask participants about all kinds of self-care as well as outside chiropractic care at those assessment times. We mostly want to know. I think that during, we don’t anticipate really during the actual ten-week active care that we’ll see many participants going to outside care. We didn’t see that in our pilot study. You know, some might but in that you know, continuing on I think they’re going to do whatever they’re going to do and I think we hope that we can capture that both through what we’re getting in our EHR as well as what we’re getting in our patient self-report regularly on, on all things that they are seeking in terms of relief from their low back pain.

Dr. Christine Goertz: Right, if a Veteran decides that they want to get chiropractic care outside the VA they basically have two choices. One is to basically request that, that care that they have access to community-based chiropractic care which is something that Veterans do have access to. That is perhaps a little bit easier for us to track because there are processes that have to be followed there. You know what, where it’s more difficult as if people just access chiropractic care you know on their own and pay for it on their own and we anticipate that that will be you know not as, not common but it’s something that we definitely need to track as closely as we can.

Dr. Robin Masheb: Mm-hmm. So we have a number of questions coming in about the actual delivery of the care. So I’ll just kind of throw out a number of different things. Maybe could you talk a little bit about the training of the chiropractors. Do you have some sort of manual? Is there some sort of systematic way that the number of, the dosage is delivered? So you know both the low dose and the high dose is delivered in ten weeks is there like a frequency set of you know a visit every once a week, two weeks, how does that work? And what are you doing also to ensure that the care is delivered uniformly across the four sites and even within each site within the different clinicians? Do you have some sort of fidelity assessment and that’s kind of the general area of the questions.

Dr. Cynthia Long: Christine do you want to take this?

Dr. Christine Goertz: Well, yes. Well I’ll start with the last question first, but. So we’re not really because this is a pragmatic clinical trial, we’re not looking at fidelity to a standardized protocol in the same way that we would in a less pragmatic trial. So though, so what we’ve done, we’ve done two things so that, that it doesn’t end up just being a mishmash of care that we’re not really able to evaluate. The first is coming up with the clinical decision aid that we are training the DCs on to make sure that they understand that clinical care pathway. And you know to try to out, funnel patients down a similar treatment road. And then the other thing that we’re doing is Cyndy mentioned earlier about the development of a data collection tool within the EHR to, in order to collect more detail on the treatments, the chiropractic treatments that the patient is actually getting. Because what we’ve learned in previous trials is that in spite of our best efforts we weren’t able to, to really get down to the level of granularity that we’d like to in describing the treatments that that individual patients had. We have done a pretty good job in the past of describing overall what treatments were delivered but not for particular patients and we’d like to have the opportunity to do some secondary analysis looking at whether you know some treatment protocols or some approaches seem to be more effective than others. Since we will have a pretty large sample size. So we’re, we are trying to, so we’re both trying to direct that, the care you know within some broad parameters and then also we are, we are going to be carefully collecting the data on what’s actually happened to the patient. As far as the training goes and a manual, we, all of the, all of the DCs are going to be trained in the overall study protocol and what is and is not, what does and does not fit within the boundaries of this particular, of our particular protocol et cetera. And we can actually, the person that would be best able to answer that question Dr. Robert Vining is not on the call today but if anyone wants to, really wants more details you could reach him at Robert.Vining@palmer.edu and I’m sure he would be glad to provide a lot more detail about what that training entails.

Dr. Robin Masheb: Great. Thank you. I just wanted to give Dr. Sandbrink, you know a couple of minutes, if you had anything you wanted to reflect upon?

Dr. Friedhelm Sandbrink: Yeah. Thank you. So first of all I want to thank Christine and Cynthia for the presentation and actually doing the work, right. This is so important. I think actually. And it’s important that it’s a pragmatic trial, right? Because we want this to somehow represent what we would expect as we send the patient you know from our clinical side whether it’s from primary care or pain clinics to chiropractic care and spinal manipulation and that we, we have an assessment here that will help us to guide in, particularly in regard to the intensity of the intervention, right. And how is that appropriate. Now I was just wondering a little bit more you know, you have basically a comparison to being a low dose, whether it’s the higher dosage application of chiropractic care, how do you see this in comparison to let’s say physical therapy. And the question was among earlier was, was raised, you know what about patients who get other kind of chiropractic care outside or continue this may be in the group that was not meant to continue. But the question is also for clinicians often is like how, what’s the framework of how chiropractic care compares to physical therapy. Which patients would I send for chiropractic care versus physical therapy and also are you tracking whether patients may be engaged in physical therapy on the side or separately and any kind of comparison in that regard?

Dr. Christine Goertz: So those are really good questions. But there are a number of ways that we’re recruiting patients for the study including you know potentially sending out letters letting patients know about the study and, but the primary way that we’re recruiting patients for this study are among those who have already been referred to a doctor of chiropractic in the VA for treatment. So the decision has already been made by a primary care doctor or other you know initial triage person within the VA that this person is, is it suitable for chiropractic care. So by the time they get to that point in the process somebody other than us has already made the decision about whether chiropractic or physical therapy is the most appropriate treatment.

Dr. Friedhelm Sandbrink: Yeah. Thank you. And I’m wondering are you tracking whether patients you know how much chiropractic care they’ve received before and whether they had prior you know success in the past or whether they received physical therapy? Often what we find is that you know we have to re-refer our patients even if they’ve felt like a prior, you know attempt maybe wasn’t successful. And that’s why it’s so important I think with what we often experience clinically that if patient tried, try an intervention that it’s well done. Right. I mean an intervention that isn’t done the right way often leads to frustration and obviously unsuccessful attempt to treat. And it’s, that’s why it’s so important that it’s done the right way when we make referrals so that patients aren’t discouraged to trying it again.

Dr. Christine Goertz: Right. So we won’t know, I think we asked some questions and Cyndy can clarify this about the type of treatment that they’ve used in the past but we’re not retrospectively going back into the clinical record to take a look at that. However once they enroll in the study we will be carefully tracking all the treatment that they receive. So we’ll know if they go, if they see primary care or a physical therapist or anyone else that’s within the system. And as we mentioned earlier in addition to that we will be asking them about self-care and other treatment modalities that they may have access outside the system. So that we are able to look at that question.

Dr. Cynthia Long: And you’re exactly right. We will, we do have a self-care instrument that the Collaboratory developed that we are giving, as well as we’re giving a lot of other self-care so we are asking about physical therapy you know from the patients but we won’t know necessarily in the EHR until they enroll in the study [unintelligible 56:46] for that entire year we will be following that very carefully.

Dr. Friedhelm Sandbrink: Yeah, so thank you so much for doing this work. I think it’s so important for us to know this clinically. So my last question of this regard is Cyndy when do you anticipate you will see the first results as we’re looking forward to this.

Dr. Cynthia Long: Well\_

Dr. Christine Goertz: That is the question isn’t it.

Dr. Cynthia Long: Right. We anticipate, you know recruiting through 2022 for the sample and then we have of course the one-year follow-up. So you know 2023, you know would like to have that analysis done. Certainly by the end of the year, maybe by the end of the summer. Depending on how recruitment goes according to plan.

Dr. Friedhelm Sandbrink: Right. Thank you.

Dr. Robin Masheb: This is really exciting. I’m assuming this is going to be the largest trial for chiropractic care with chronic low back pain, is that correct?

Dr. Christine Goertz: In the United States, it will be. We actually, but we did a study with a different question in the DoD with 750 participants at three sites. This study will be slightly bigger than that and encompass four sites which we’re excited about. Because we think it enhances generalizability.

Dr. Robin Masheb: Yeah. It’s amazing. Amazing work and we’re so appreciative that you are on the call to share it with us. And I hope we can reach out to you again in the future as you’re you know finding results and eventually your final results to share it with the VA audience. This has been really wonderful and thank you to people for you know coming on the call today. We had some great questions. Please hold on for just another minute or two as we get the feedback form out to you. If you’re interested in downloading the PowerPoint slides from today or any other ones you can go to VA Cyberseminars archive, just by Google searching on that and scroll down the filters for Spotlight on Pain Management and you’ll have access to this and all of our previous seminars. Our next Cyberseminar will be on Tuesday, February 4th with Dr. Diana Higgins. And the title of that talk is Internet-Based Pain Self-Management for Veterans: Feasibility and Preliminary Efficacy of the Pain EASE Program. We will be sending registration information out around the 15th of the month. And I just want to thank everyone for attending this HSR&D Cyberseminar and we hope that you’ll join us again in the future.

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