Cyberseminar Transcript

Date: October 1, 2019

Series: Spotlight on Pain Management

Session: SMART Care for Chronic Low Back Pain in a Military Health System: Development of a Clinical Trial to Evaluate Stepped Care

Presenter: Julie Fritz, PT, PhD, FAPTA; Don Rhon PT, DPT, DSc, OCS, FAAOMPT

**Dr. Robin Masheb:** Good morning everyone. And 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 SMART Care for Chronic Low Back Pain in Military Health System: Development of a Clinical Trial to Evaluate Stepped Care. I would like to introduce or presenter for today, Dr. Julie Fritz. Dr. Fritz is a distinguished professor at the Department of Physical Therapy at the College of Health University of Utah in Salt Lake City, Utah. She is also the Associate Dean of Research. Her clinical background is in physical therapy and her research interest is in non-pharmacologic interventions for musculoskeletal pain, particularly low back pain. 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 you’re 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 completing this as it is critically important to help us provide you with great programming. Also on our call today is Dr. Bob Kearns, Director of the NIH-DoD-VA Pain Management Collaboratory Coordinating Center. He is also a professor at the Yale School of Medicine. He will be on our call today to take questions related to policy at the end of the session. And now, I’m going to turn this over to our presenter, Dr. Julie Fritz.

**Dr. Julie Fritz:** Thank you and good morning everyone. Before I get started I want to just acknowledge my co-PI on this particular project, Dr. Dan Rhon. He’s not with us today but this project is a collaboration between he and I. Dan is recently retired from active duty in the Army and works now for the DoD and this collaborative work, obviously, wouldn’t be able to take place without him and his colleagues.

And as a brief outline for what I want to cover today. I want to talk briefly about shifts in pain management both in society as a whole as well as within the military health system and working with Veterans and active duty military personnel. I want to spend a little bit of time talking specifically about pain management considerations that are somewhat unique to the military health system. And as was eluded to, I’ll talk a little bit about a rather unique partnership that this particular project is one part of which is the NIH-DoD-VA Pain Collaboratory. And then finally talk about the particular project that we’re doing as part of that collaboratory looking at Stepped Care Management for individuals with low back pain in the military health system.

And I also want to acknowledge just a larger scope of who all is involved with this particular project in this partnership between myself at the University of Utah and Dan at the Department of Defense. This isn’t even an exhaustive list of all the people who have been working on this project and will continue to work as we begin to put the particular research project into operation.

So as many of you know, the management of pain and the way we think about pain management both as a society and as practitioners has been undergoing a rather dramatic shift, I would say, in the last decade. And I want to talk about a couple of landmark publications and policies that have really represented what that shift is about and really brought about the collaboratory that my particular project is a part of. One particularly foundational document was a report from the Institute of Medicine in 2011 that really sounded an alarm about the burden of chronic pain in the United States and, in particular, the inadequacy of the way that we deal with pain across multiple domains of educating practitioners, of educating the public, and of the actual practice of pain management.

A particular recommendation out of that IOM report was for the Department of the Health and Human Services to develop a strategy to address the multi-faceted need for a new way to think about pain and to manage pain in society. So this document, which was released in its final form in 2016, again covered a number of different areas where pain management is challenging and where there are gaps that need to be filled. The particular area that our project addresses and that we focus on in this particular presentation, really revolved around service delivery. And to sum up a lot of work that goes into this document the particular challenge is related to service delivery is that too often care is not evidenced based, too often it’ not coordinated, and there’s an over emphasis on pharmaceutical and procedural based often invasive care. And the pain strategy recognized that there was a need for greater investment both in basic, but also in clinical research, to overcome these particular challenges as well as a whole host of other issues that are identified within the report.

And a bit more specifically, the National Pain Strategy recommends that care delivery adopt a more population based and biopsychosocially informed pain care management strategy that is interdisciplinary and also tailored to individual patient needs. And that’s a lot to accomplish within any delivery model. There was also a call to fund and to conduct research demonstration efforts that looked at developing new knowledge and, in particular, developing different delivery systems that could accomplish this rather ambitious goal.

So a word about the Military Health System and many of you are probably quite familiar with the structure and really the scope and breadth of the military health system. But needless to say, it serves a lot of patients, both active duty personnel as well as dependents and other individuals and provides care to a large number of individuals across varied settings. I’ve personally been able to do research within the Military Health System and in a couple of different projects and it provides an interesting, somewhat unique, but also there’s a lot of generalizable ideas and information that can come out of doing research in the MHS.

So specific to low back pain and pain management for low back pain in the Military Health System, the first project that I got involved with that really began to look at this was based on data that was gathered from to 2007 to 2009 which I would put as a date range a little bit before the sort of paradigm shifts that are going on currently and have been going on say for the last decade. At that particular time we used the data resources in the MHS to look at new individual consultations for back pain that occurred in that system. And you can see some of the data here in terms of how many of those consultations resulted in specifically opioid pharmaceutical management. And how many resulted in non-pharmaceutical management, specifically physical therapy in our analysis and physical therapy that occurred early within 30 days of that new consultation. As others have found, we identified that for patients where early use of physical therapy was put into place there was some positive impact on outcomes that were observed. The last data point there was just a sense of the overall burden to the system in terms of costs that low back pain causes. So in this particular study with this 750,000 cases of back pain, over two years that accounted for almost a billion dollars in direct low back pain related costs. And that doesn’t even take into account costs that would be related to lost time on duty, lost time at work, and other sorts of more indirect costs.

Concern about pain management overall and low back pain management in the military health system specifically has only grown since the time we extracted that particular dataset. And the interest in this area, the concern in this area, grows out of several different issues that have come to the forefront since that time. One is just the overall prevalence of back pain as the diagnosis most associated with chronic pain. And the impact that low back pain has on readiness and evacuation from deployment. Finally the graph, particularly on the right of the screen, recognizes also the over utilization of opioids for pain management for individuals who have particularly been combat deployed who are active duty military. And highlights that the issue is even more of a Military Health System than general public estimates have been and the data related to back pain only reinforces this concern as one of the most common reasons why opioid use is initiated.

And the issue of deployment also brings with it a whole host of comorbid conditions that complicates the management of any chronic pain condition including chronic back pain. This is a couple of different datasets from publications looking at the comorbidity burden specific to individuals who’ve returned from deployment. And again, you can see, that even that Veterans who’ve been deployed and experience persistent pain often come with a host of other comorbid conditions that certainly complicates the management to a large extent.

And then finally, with respect to prevalence, this was an interesting analysis that was published a couple years ago looking at the post deployment health assessments and the prevalence of back pain specifically in these particular assessments. You can see that in 2013, from 2012 to 2013, the numbers changed quite a bit. The issue there is that the question was changed. And you can see that in the more recent data from 2013, 2014, the key change was to reference the past month. And with this type of question that the individual’s experiencing back pain was up in the neighborhood of 40% of people returning from deployment.

And there’s also been additional work looking at management of low back pain and particularly with the focus on what’s done initially before individuals who present to the Military Health System with this complaint. So this was a more recent study by Mary Jo Larson and her colleagues looking again at new low back pain episodes. They focused on ones that were more persistent then in our prior work. And again, the utilization of opioids was examined as well as the proportion of individuals who received non-pharmacologic management, again, within 30 days. And you can see how that broke down in terms of who received what in the chart on the right.

And similar to previous reports, they found associations between early non-pharmacologic care relative to opioid use with respect to long term opioid use, risk to be on limited duty, and to be hospitalized for some pain related cause. Also of interest in helping us to form our project was what non-pharmacologic treatments were used within the first 30 days for those particular individuals who used them. Most commonly it was some type of physical therapy or exercise therapy and you can see the other modalities that were reported in this particular study in terms of the non-pharmacologic care that was available and taken advantage of for these individuals.

So with the respect to the concerns that’s raised within this body of research, a few important policy statements have evolved since some of this work has come out. And I want to cite a couple of the things just to set up the project that we’re working on and the overall goal of the pain management collaboratory. So the Office of the Army Surgeon General set up a pain management taskforce to begin to address some of these problems with the final report being released back in 2010. And of particular relevance to this presentation, one of the recommendations that was cited here was to adopt the Veterans Health Administration Stepped Care model for pain management. And this had not previously been a policy within the Military Health System to use a Stepped Care model and to try to implement that type of care.

Most of you are familiar with this. This is a visual that Dr. Kearns and others have used in trying to provide an idea of what Stepped Care involves but essentially it’s the idea of beginning with lower risk, lower cost, evidence based care and escalating care as needed based on either the patient’s need or the lack of response to prior treatment. And by implementing this type of a stepped process limiting care escalation only to those individuals who need it and, hopefully, avoiding inappropriate care escalation which would be represented by things like early use of opioid pain medication, particularly on the first consultation. And this has been implemented in a couple different chronic health conditions with evidence that’s it beneficial in achieving those goals, particularly within the VA.

More recently, the Department of Defense Military Health System came out with their own model which visually looks a fair bit different. I think it’s an over simplification. But it essentially is highlighting the same issues in terms of what Stepped Care is and what it should help to provide which really focuses a lot on when to escalate care. I think importantly added in here is when to deescalate care and how to go through a logical process of limiting more higher risk and higher cost care in the tertiary management level to those individuals who clearly had been resistant to recovery in earlier steps.

So another key landmark along the lines of shifting the paradigm of pain management, particularly in the Department of Defense, was a working group convened that involved the NIH, Department of Defense, and VA to examine specifically the effectiveness of various mind-body, non-pharmacologic practices for pain management.

And the report out of this particular group, which was 2015, really formed then the basis of the pain management collaboratory initiative. So this particular initiative, this joint strategy by the NIH, the DoD, and the VA to improve pain management and partner together to look at better ways to integrate non-pharmacologic management, really began in 2017 with a good deal of financial resources committed across these different groups.

So the goal of this particular collaboratory effort is to develop the capacity to implement large scale pragmatic research projects in military and the Veteran Healthcare delivery organization. And our focus is on non-pharmacologic approaches to pain management and the comorbid conditions that come with it. So this particular collaboratory has been underway now for about two years.

If you’re interested in more information on the details, Dr. Kearns and his group, who serve as the coordinating center for this initiative, recently published in *Pain Medicine* a very nice description of the structure of this particular initiative. You can see the components depicted on the left hand side there in terms of the involvement of the various agencies, the coordinating center, and then demonstration projects. And the project that I’m going to describe for you here as we continue, is one among, I think 14, demonstration projects; some of which are based in the Military Health System, some of which are based in the Veterans Administration.

Now I want to describe our particular demonstration project in this collaboratory. And a word about the arrangement of the collaboratory, in terms of the timeline here. Our collaboratory, really got going, as I mentioned, about two years ago and these awards for our demonstration projects are phased awards. So each one of these demonstration projects are beginning or have reached a state of transitioning from a planning phase where the input of the entire collaboratory was really key in helping us to establish our procedures, to harmonize some of our data elements, to learn from each other in terms of setting up our projects, and we’re now transitioning to actually doing these studies. So the project that I’m going to describe for you that we lead is in that point of transient where we anticipate actually enrolling subjects in this study in about a month. So what informed our study in response to the concerns that had been raised is we wanted to look at a very pragmatic examination of various non-pharmacologic options for back pain that were consistent with the Stepped Care approach that has been advocated for implementation in the Military Health System. And in doing that, that obviously required us to have a strong consideration of what resources are available within the Military Health System. Who’s in the workforce in term of non-pharmacologic providers. What the strategic priorities and other initiatives going on around this area are within the MHS. And fortunately we have good stakeholders within the Military Health System that can help us try to keep aligned with other priorities that are going on and are always emerging within the MHS. A key question that we wanted to be able to address was really two fold. One is, what works best for whom? Which is a challenging but key evidence gap within pain management generally, and back pain management specifically. That sorting through the heterogeneity of the outputs, or excuse me, the effects that you get from any particular non-pharmacologic treatment has proven to be quite challenging. Our other primary objective was to develop our study in a way that we could address the sequencing of care which we felt was consistent with the Stepped Care model and the idea of how to step up care when individuals are not responsive to an initial effort at pain management.

So again, we were trying to really be consistent with a Stepped Care approach and we felt that the design that best fit this goal was what’s been labeled as a SMART design, so a Sequential Multiple Assignment Randomized Trial. We wanted to be pragmatic and we felt this fit with a pragmatic approach. And in particular that SMART designs can inform adaptive treatment strategies. In other words, strategies that respond and change based on the outcome of an individual patient.

So this is a busy diagram but this is the overall view of the project that we’re getting ready to start that uses this type of a SMART design. So you can see on the left hand side we have four separate implementation sites; three of which are based in the Army, one Air Force. And you can see, also, the way that we’ve developed phases of treatment that represent steps of care. And I’ll come back to this to explain a little bit what these interventions are. But from a study design standpoint, the way that this is constructed is that within phase one we have essentially a fairly typical parallel group randomized trial of two options that we conceptualized as appropriate initial phase interventions for pain management; physical therapy and Move to Health, which I’ll explain a bit more in a moment. Patients are re-assessed. We operationalized how to define a treatment responder or a non-responder. And then consistent with a Stepped Care framework, a treatment non-responder is re-randomized. And in particular, what we are using as options for that second randomization for non-responsive patient is to either combine the PT and Move to Health intervention so that we make phase two care more intensive by combining these two phase one treatments. Or switching to a really different approach to care which is a fairly intensive eight session mindfulness approach. And then we have long term follow up.

So take out the detail or our particular trial and to just think of this conceptually this is really what’s at the core of a SMART design. Are these multiple randomization steps based on some kind of operationalized tailoring variable that then dictates what care will be received beyond that step.

So why use this design? Why did we particularly use this design? It’s an attractive design for interventions that require a decision about what to do next if a patient doesn’t respond which is actually a fairly common question in chronic disease management and it certainly is the case in chronic pain management. But even evidence based non-pharmacologic treatments that we know have relatively small-to-modest treatment effect sizes. So it’s not unusual that any individual patient may not be responsive. What this design allows us to do is to look at the sequencing effect, recognizing that the effectiveness of a treatment may very well be impacted by what comes before it or what you are going to move a patient onto after it. So this is the idea of an adaptive intervention which gets away from just a traditional randomized trial where a patient is assigned to a particular treatment and remains in that treatment until your follow up is completed. And we know there’s high heterogeneity, as I mentioned before, in response to any one particular non-pharmacologic treatment. And this design has some features that allows us to try to get at this, particularly in our phase one treatment where the sample size is adequate to begin to look at some moderating variables.

So we felt this was consistent with a Stepped Care model. We had to and we think this is actually a positive thing to think about. Define a tailoring variable that drives the adaptation. In other words, how do we operationalize whose a treatment responder? The powering of this allows for a fairly rigorous evaluation of heterogeneity’s affect with respect to phase one care which allows us to get to who responds to what treatment question. And then overall we can evaluate these two phase adaptive treatment regimens and their effectiveness in a way that’s adapted to individual patients.

So if you think about, in general, what are the specific aims that are associated with this type of design? There’s a few things that probably come to mind and this is what we built in to our specific aims for this project. Which is first to compare the first stage treatments, that’s pretty straight forward. To look at our second stage treatments which is, of course, conditional on what happened in phase one and to look at sequences. And then make an effort to develop more personalized treatment regimens based on potential moderating factors assessed at baseline.

So to spell that out coming back to our specific design, we have the primary aim to make this initial comparison between physical therapy and Move to Health. And to do so with [unintelligible 29:53] that relate to pre-specified sub-groups defined by moderator variables. We have another primary aim to look at the effectiveness of our phase two treatments which is either the combined treatment or mindfulness conditional on what came first. And additionally, to look at the effectiveness of our phase one interventions based on what will happen in phase two. And this, in particular, allows us to look at the sequencing versus combined effects of Move to Health and PT which we view as broadly available or potentially broadly available sort of population based strategies for non-pharmacologic care.

Few more details about our project just to fill in some gaps. We will recruit anyone basically whose a TriCare beneficiary and receiving care at a participating Military Health System facility. So that would include, again, active duty as well as dependents. You can see the other inclusion/exclusion criteria. Essentially we’re trying to be pragmatic and get a broad spectrum of patients with non-specific back pain who are chronic in nature.

Our primary outcome. We’re using pain interference as our primary outcome that we powered the trial on and that we’ll use to evaluate the result. We have a host of secondary outcomes across different domains that are typically impacted by chronic pain. With respect to our tailoring variable, we looked a good bit in the literature at changes in our primary outcome. The PROMIS pain interference score, and what was associated with not just a minimum clinically important improvement but really with a large effect because our tailoring variable, essentially flagging a patient that we deem as a responder and the implication of that is that they won’t escalate care beyond their phase one care. So we wanted it theoretically and conceptually to be a fairly high threshold where a patient would be likely to endorse that they’re recovered to the extent that they can self-manage at that point.

Now I want to say a few words specifically about the phase one interventions and how we’re conceptualizing them. And the design here, again, is to be pragmatic. So we’re trying to balance that with also making sure that we’re providing evidenced based care within our various treatment categories. So with respect to physical therapy, the key components that we view as CORE to evidenced based physical therapy are first a risk stratification to basically help the physical therapist determine the intensity of physical therapy care based on an individual patient’s risk for not recovering rapidly. This is based on, for any of you who may have worked in this area, based on a tool called the Start Back Tool which has been validated in terms of looking at these various risk categories. And this is a fairly brief instrument and it’s intended to help guide the physical therapist in the intensity, not so much the content, but the intensity of the care to be provided. You can see that we view standard, or we view educational materials including back pain materials, educational materials that are produced by the DoD/VA as part of standard care. And then exercise in manual therapy specific to the particular patient’s needs.

And then our other phase intervention is Move to Health. And this is an initiative that came out of the Army Office of the Surgeon General a couple of years ago and is very much based on and sort of an analogous to the VA Whole Health Initiative. But it’s really intended to be a change in the way the patient provider interaction occurs and the way health and well-being is approached at a very high level. So this is the model that the Move to Health program uses.

Again you probably see some similarities with what maybe some who are on the podcast, or on the call here, are more familiar with which is the VA Whole Health program. And again, I don’t want to go too much into details here but I think most folks understand the goal here is to really help individuals focus on the components of well-being and health, which the Whole Health Program lists out eight of them. And to help individuals take a personal inventory of these factors and areas where they want to make changes to improve their well-being and their health.

So Move to Health, as I said, is a fairly analogous strategy within the Military Health System that has very similar goals.

And also really utilizes a personal health inventory to guide an individual into this process of identifying areas where they want to set goals and work towards improving their overall health. And these are the components and the visual that the Move to Health Initiative uses and, again, it’s fairly analogous with what the VA has done.

So one of the things that we’ve spent a good bit of time in the last two years on is taking these concepts and tools within the Move to Health initiative and operationalizing it to be more specific to the needs of individuals who are dealing with chronic low back pain. And both the Whole Health initiative, Move to Health, it’s well recognized that the approach is very appropriate for individuals who are dealing with chronic pain issues. But we needed to operationalize even more specifically what it looks like to leverage this paradigm and this framework, specifically for people with chronic pain. So we, first of all, established sort of what our theoretical basis was for operationalizing this and then looked to incorporate evidence based elements for behavior change into the process of using the Move To Health framework to intervene with patients with chronic low back pain.

So again a bit more complicated than I want to go into here, but essentially this is a diagram of the way we’ve viewed this. That we’re working with the person who will sort of guide the patient we’ve labeled as a health coach. We are providing training to those individuals across several domains including motivational interviewing. And it’s the job of this health coach to help engage the patient to identify a domain in the Move to Health model that they wish to address specifically because they relate it to their experience of chronic pain. And then identify goals within that area. We’ve developed both general and domain specific education materials. And then we have a follow up process for, which may include referrals depending on a particular domain a patient identifies, and additional assessments that we may use with the patient. So we’ve developed a fairly detailed manual to help operationalize what this looks like in working with a patient.

A couple of additional points on this. We decided to simplify the Move to Health wheel from eight to five domain; 1) To make it a little more manageable and, 2) To really try to increase the extent to which, hopefully, the patient perceives the relevance of the domain to their experience of back pain. And then, as I said, develop management algorithms to guide further assessment and intervention within each domain and establish goals and use referrals as necessary.

This is just an example of a couple of the general patient education materials we’ve developed for patients who would be randomized to this particular arm.

And then, finally, within phase two the one other treatment we’re examining is a mindfulness program and, again, there’s a lot that can be said for this particular mindfulness protocol. This has been developed by one of my colleagues here at the University of Utah. He’s worked with military personnel specifically with this particular approach which we label as MORE as an acronym. It’s a bit different then MBSR or what you may be more familiar with as sort of traditional mindfulness. But this is a fairly it asks a lot of patients, it’s fairly intensive, it involves eight sessions and a fair bit of self-work on the part of the patients. And that’s why we can see this is a phase two interventions for people who don’t respond to what are perhaps less intensive and more broadly accessible interventions.

So to close, let me again just kind of give you an idea of where this particular project is at. Probably the most relevant thing to say is that very first bullet which is where we’ve transitioned from planning this project to actually doing it. So what that has entailed is making sure that we have all of our regulatory approvals and data sharing agreements finalized. That we’ve established our data collection infrastructure which relies heavily on both red cap and the military data repository. Our study protocol has gone through multiple levels of reviews thanks to the collaboratory involvement. And what we’re involved in right now is finalizing our personnel training and continually engaging with our stakeholders at the various sites.

So I will conclude at this particular point. As I mentioned, there’s a lot more really excellent work going on in the pain management collaboratory. And if you’d like more information on that and some details on some of the other projects, the website is here. And there’s a lot of resources there that can be used to learn more about everything that’s going on. So I will stop at that point and take any questions that anyone might have.

**Dr. Robin Masheb:** Thank you, Dr. Fritz. This was a wonderful overview of the collaborative and then more specifically about this Stepped Care SMART design study that you’ve laid out. It’s an enormous project and so exciting to hear about the development of it. If we have more questions please feel free to write in and I will field these questions. I’ll get us started with one which is, could you tell us a little bit more about how the initial evaluation is being conducted with the back pain in addition to some of the measures that you talked about? Are you also assessing other comorbidities like depression, PTSD, generalized anxiety, alcohol or substance use? And how might some of those things factor into your analyses that you’re planning on conducting?

**Dr. Julie Fritz:** Yeah. So we will collect most of our comorbidity data through administrative sources identifying relevant comorbidities like the ones that have been listed as well as through patient self-report at the baseline evaluation. I think, you know, the fact that those comorbidities that were listed, as well as some others, are so prevalent as part of the rationale for the Move to Health as a phase one intervention that at least conceptually could more directly address some of these comorbid issues that patient’s may be dealing with and that may be barriers to recovery. So we’ve pre-specified a few things in terms of moderating variables, particularly for that phase one treatment comparison of physical therapy and Move to Health. And one of the key things we want to look at is prior opioid use. But the other mental health variables that were mentioned may also be interesting moderators of effect, particularly in that first split and first treatment comparison. The other thing I would say is that our outcomes assessment, and we rely heavily on PROMIS tools here to be efficient and robust in collecting this information, but we’re using as secondary outcome, a number of these domains that we can look at longitudinally; so anxiety, depression, sleep disturbance, some of these comorbidities that are very common with chronic pain conditions.

**Dr. Robin Masheb:** And along the lines of characterizing the sample, can you give us an idea of how many people you’re looking for? What the gender breakdown is going to be? And what do you do about people who have had treatments, you know, different components of the treatment that you’re looking at? Or I don’t know, maybe in some of your preliminary data you have an idea of whether they have used different mindfulness interventions, if they’ve done things like MDSR or things like cognitive behavior therapy and how you might take that into account? Because it seems like there are different treatment components that are used in other non-pharmacologic treatments that people might have been exposed to.

**Dr. Julie Fritz:** Yeah. That’s a, it’s an excellent question. It’s actually been something that our collaboratory has been talking a fair bit about which is the ability to collect information on other non-pharmacologic strategies that individuals have used across a longer time frame. So some of this data we can examine administratively by looking at, you know, well prior physical therapy is perhaps the easiest one because it shows up in the electronic health record, there’s a cost associated with it. But so many of the non-pharmacologic treatments that patients may seek out don’t get represented within an electronic administrative source. And so, and I’ll invite Bob to maybe speak about this, developing an instrument than can collect that very piece of information. What have patients used before? And to get some understanding of that is something that we’ve been working on developing both as a way to characterize our cohort at baseline but also potentially across some projects as an outcome variable for how some patients are managing their pain. And Bob do you want to speak to that issue any further?

**Dr. Bob Kearns:** Can you hear me?

**Dr. Robin Masheb:** We can hear you.

**Dr. Bob Kearns:** Great. Actually I don’t know if I have anything to add. I think the last phrase or clause you said were right on target. So you know, the measurement is important for both characterizing the sample and for potentially trying to adjust for that prior exposure in the context of the analytic approach, ultimately analyzing outcomes and change. I think I heard it, the question, a little differently then maybe you did Julie. In thinking about in the context of the trials themselves, if somebody has, maybe you know they’ve participated in, they’ve engaged in some of these treatments beforehand, how does that affect what you offer them in the context of the intervention itself?

**Dr. Julie Fritz:** Yeah. Thanks, I think

**Dr. Bob Kearns:** I do think we’ve talked a little bit about that but actually the question prompts me to think, gee, that’s another important challenge for a study like this one that’s really studying essentially a model or a system of care rather than a specific approach.

**Dr. Julie Fritz:** Yeah. And you’re right. I dismissed the first part of that question. So a little bit more information on how we’re dealing with that. So the total sample size, I apologize if I didn’t have that on a slide, that seems like a key piece of information, is 1200 patients. We’ve done a fair bit of clinical trial work in the Department of Defense in the Military Health System. And when we use a fairly broad eligibility criteria like we have and include non-active duty, our gender breakdown gets a little more towards parody. But we’ll still skew a bit more male, so probably 60% to 65% male, just based on my experience working with this population. With respect to prior treatments, from a study standpoint and eligibility, we will exclude anyone, and I think it’s a six month lookback window, whose recently had an intervention specifically for pain. That would be physical therapy or mindfulness, but only within that sort of narrow window. The larger question that you bring up is an excellent point which is we know people do all kinds of things in an attempt to deal with pain. And it’s something that we want to characterize but not, at least in terms of study methods, not restrict or in any way adjust our eligibility criterion based on that. But the other thing I would just ad on this particular topic is I’ve certainly come to even appreciate more the complexity of actually assessing this. And you know, there’s several things that are challenging here. One is, you know, if somebody’s doing yoga because they like to do yoga, is it for their pain or is it not, and how do you operationalize that? How do patients understand how to categorize things in the way that we might do as researchers but they might understand what they’re doing differently depending on, you know, how they learned it or where they picked it up from. So you know, there’s a good bit of complexity in understanding this but it’s been one of the, I think, one of the things that’s been particularly useful about having the input across the collaboratory is to try to deal with some of that complexity to at least be able to characterize what kind of care people have sought and are seeking for pain.

**Dr. Robin Masheb:** Yeah I can imagine.

**Dr. Bob Kearns:** If I may, If I may I could add a couple, this is Bob again. So I think you’re talking about this, you know, you’re showing appreciation and I hope the audience appreciates the complexity of the measurement and also how you use the data in the context of the trial, or many trials. One thing I would add to what has just been said is you might think, an investigator might think, oh the person says they’ve been exposed to massage or CBT for pain, or something else. But without knowing more about the dose of that intervention, it’s affects, you know, Julie was just saying what they were receiving that intervention for, whether it was general wellness or pain or something else. One issue that comes up a lot, in fact many of us think about, is the idea that many people may have brief exposures to interventions that actually kind of inoculate them against the potential benefit of a full dose or a full course of that intervention and that is another dimension that I think makes this all so complex. Back to the measurement approach, of course, they are also lots of different non-pharmacological or even complimentary and integrative health approaches. It’s you know, groups that have been coordinated through the National Center for Complimentary and Integrative Health have developed, and the National Health Interview Survey have developed, measures that are quite comprehensive but probably too comprehensive to be reasonably used in the context of a trial. Others have developed shorter measures that serve their specific purpose, one of that specific trial. What we’ve been trying to do in the context of the collaboratory is develop a measure that could be, you know the core of the items or the approach could be, used across multiple trials and then so that we can have some harmonization so to speak across trials, but allow for some adding on of more specific information or the adaptation for individual trials. So it’s just a, thanks for the question whoever sent it in and it’s really an important one in this context. I’m sure Julie agrees.

**Dr. Julie Fritz:** Yes definitely.

**Dr. Robin Masheb:** Yeah Bob, you started to touch on another question in terms of the dose. How are you handling that in this study? How long these treatments are and how much of a dose is given?

**Dr. Julie Fritz:** So we defined, yeah, we defined a treatment period for our phase one and phase two treatments. We’ve not, consistent with a more pragmatic design, we’ve not pre-specified a protocol that clearly outlines what that dose is. But there’s some professional judgment that gets embedded, particularly within physical therapy and Move to Health interventions. So you know, it’s guided by the principals that we’ve developed in our protocols. But the ultimate sort of dose will be tailored to the patient hopefully by the principles that we’ve specified. And we’ll track the fidelity with doing that, but we don’t have a pre-defined dosage that cuts across all patients. It’s a bit more standardized in the mindfulness protocol because of the nature of that treatment and the sequencing of the sessions and it’s a bit more of a protocol driven approach just by the nature of the treatment.

**Dr. Robin Masheb:** Right. So do you have some way that you’re going to measure contacts with a professional dose? Any of these concepts, how are you conceptualizing that?

**Dr. Julie Fritz:** Yeah. So there’s two things that we’ll try to address mostly through the electronic health record. One is compliance with attending sessions that a patient has been asked to attend in the context of any one of our study interventions. Then we’ve also developed brief yes/no fidelity checklists for the intervention sessions that are attended where we can look at, not only the compliance with attendance, but the fidelity to the core components of the interventions that we’ve identified. So again, we’re not trying to look at dictating specific types of exercise that have to get used, etc., but within each of our treatments we identify the core components that are involved and look to see that those things have either occurred or not occurred.

**Dr. Robin Masheb:** That’s great. That’s interesting. We just have a couple more minutes. Are there any final thoughts, maybe Bob, you might have?

**Dr. Bob Kearns:** No. I appreciate this presentation and the series of presentations and the opportunity to have our individual projects in the collaboratory represented and presented in the context of the Spotlight on Pain Management and I’m appreciative of the interest of our community. I think there are potentially lots of lessons to be learned from the individual trials and even the collaboratory as a whole. So I also want to show appreciation to Julie’s pointing to our website for the collaboratory. I do think that this can, we’d like to hope that this can, become or emerge as an important, readily available resource to people with pain including Veterans and military service members and their dependents which are the target of these trials, healthcare providers, clinicians, and of course, researchers and even policy makers and administrators. So if you’re any of those kind of folks I’d like to encourage you to take a peek at the website. We are particularly trying to grow our kind of outward facing, you know, interface in order to really serve the broadest aspect of stakeholders in these trials. So it may also ultimately be a resource that you, for example as clinicians, might want to point your patients to for more information about chronic pain or about non-pharmacologic, particularly complimentary integrative health approaches, and the evidence supporting them. So thank you everybody.

**Dr. Robin Masheb:** Thank you. Thank you, Bob. Thank you, Dr. Fritz for sharing this work. It’s so interesting because there’s a lot of complexity in the treatment decisions and also in giving patient’s the opportunity to work on areas of their life that they wish to work on. We want to thank our audience for attending today and writing in with some great questions. Just one more reminder to hold on for another minute or two for the feedback form. If you’re interested in downloading those PowerPoint slides you can go to the reminder email you received this morning and, in fact, slides and presentations from all of our past sessions are there. It’s easily found by doing a google search on VA Cyberseminars archive and then you can click the pulldown for Spotlight on Pain Management. Our next Cyberseminar will be on Tuesday, November 1st with Dr. Matt Bair. His talk will be Sequential and Comparative Evaluation of Pain Treatment Effectiveness Response (The SCEPTER Trial). You’ll be receiving registration information around the 15th of the month. And I want to thank everyone again for attending this HSR&D Cyberseminar and we hope that you’ll join us again.