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Session: Internet-Based Pain Self-Management for Veterans: Feasibility and Preliminary Efficacy of the Pain EASE Program

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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 Internet-Based Pain Self-Management for Veterans: Feasibility and Preliminary Efficacy of the Pain EASE Program. I would like to introduce our presenter for today, Dr. Diana Higgins. Dr. Higgins is the Director of Pain Psychology in the Anesthesiology, Critical Care and Pain Medicine Service at the VA Boston Healthcare System. And is an Assistant Professor in the department of Psychiatry at Boston University School of Medicine. She is a clinical psychologist who provides behavioral pain treatment at the VA Boston Pain Clinic. And she is a researcher who’s current research involves clinical trials for pain conditions use to increase access to evidence-based interventions for chronic 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 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 completing this as it is critically important to help us provide you with great programming. And now I’m going to turn this over to our presenter, Dr. Higgins.

Dr. Diana Higgins: Thank you Dr. Masheb, and thank you everyone for tuning in for this talk. Hopefully it will be informative and enlightening. Whoops. Let’s see here. There we go. I have nothing to disclose. No one pays me any money, unfortunately. I’ll tell a little bit about what I’m going to cover today. Hopefully this will touch on things that are relevant for clinicians, researchers, policy folks. I’ll very briefly talk about pain self-management in the VA. I think that’s important and for those of you who are unfamiliar with it I will talk about what that entails. Also challenges with accessing pain self-management. That’s one of the reasons that we developed the Pain EASE program. Talk about using internet to deliver treatment. And then at the end I’ll talk about how that works. Or at least based on my experience in the VA. I think there are others out there who have had experiences as well. I will describe the Pain EASE program how we developed it, how we tested it. And at the end I’ll also talk a little bit about where we’re going with it. It is still an active program in research in particular but may actually roll out clinically at some point. And I will talk a little bit about some considerations for implementation. I think that’s really important as we move toward technology delivered care for our Veterans and non-Veterans alike. Limitations of the data that I’m presenting. And then some future directions including like I said the study that Pain EASE is part of at the moment.

All right, so let me just close this really quickly here. So many of you may be aware you’re on the Spotlight for Pain Management Cyberseminar. But chronic pain is very common in the US. Even more so in Veterans. The VA has promoted for a long time a cognitive behavioral therapy-based pain self-management for chronic pain program. We call this CBT-CP. It’s evidence-based, it’s a non-pharmacological option. It has goals of reducing pain, improving functioning and quality of life. It’s usually six to twelve outpatient visits. It really depends on the forum in which it’s being delivered. So it might look different in primary care versus a group format versus what somebody like me might deliver in a pain clinic setting. But it contains cognitive skills. These are things like developing coping self-statements, diverting your attention, it contains behavioral skills, something we call activity pacing, relaxation training. And then the version the VA uses has a little bit of a light approach to physical activity. The version that I’ve used in the Pain EASE program and that my close colleagues and I use tend to have a little bit more emphasis on the physical activity part. I think that’s an important part of the program. Particularly for the chronic pain. So that’s largely what CBT for chronic pain entails. The VA has what’s call the evidence-based practice roll out program for mental health treatments that have strong evidence to support their efficacy and effectiveness. And CBT-CP is part of that program. So there are likely CBT-CP trained providers or should be actually in virtually every facility across the country for VA. And so that may be delivered in your facility and it may look different in place to place as we’re learning in some of our other studies. Sorry about this here.

Some challenges with accessing pain self-management. So there are some patient level barriers. A lot of you who are clinicians might be familiar with patients have trouble with transportation to the VA especially if they live fairly far away. Caregiver responsibilities. They might have children they’re taking care of, or older parents that they’re caring for. Their own health and mobility can be a challenge. I know I often here from patients that they’re in too much pain and they couldn’t come to the pain clinic for their scheduled appointments. And then certainly the time commitment. A lot of our patients have regular jobs and it’s very difficult for them to come for regular appointments during the week, during the workday. So that’s a bit of a challenge. System level barriers. In some places and in particular for patients as well, adopting a biopsychosocial model hasn’t been universal. So patients are quick to ask for a medication for pain and may not know a lot about using a psychological type treatment. There’s stigma associated with seeing a psychologist for something that patients might often consider to be just a physical problem for example. And then there may be limited trained providers or availability in their clinics to see patients who have chronic pain.

And so it’s not always easy to get that care for patients. One way we’ve tried to work around that is using technology to deliver pain care and of course we use technology to deliver other types of care too. What these technology assisted deliver systems, things like telehealth which I think most of you are familiar with now we have the Veteran video connect, we have smartphone applications. There’s interactive voice response, or IVR, and then certainly internet. And that applies to lots of different types of treatments. From managing diabetes to hepatitis C to in this case chronic pain. Some colleagues and I did a systematic review of technology delivered pain care maybe three years ago. And overall we found that patients with chronic pain do demonstrate some significant improvements after they have engaged in an internet-based pain management program with 29 studies of internet-based pain self-management in that systematic review. And this was CBT as I mentioned, but also a similar type of treatment called acceptance and commitment therapy. Challenges with those studies is that the data quality were very variable. So some of the studies weren’t as strong as others. And the samples were pretty homogeneous. Some of it depended on which countries the studies were being conducted in. But they were predominantly white and female samples. Which is not really what our Veterans look like.

So we looked toward what kinds of programs have done particularly well. And we found self-guided, which means no clinician involvement. So a clinician doesn’t call and check in, doesn’t help the patient through the program. These internet-based programs for chronic pain are promising. They have some additional benefits that we hypothesize, although people are looking into this more systematically now. Including reducing operating costs. And greater access. So because we’re not relying on training clinicians we don’t have to worry about those time and availability barriers. And it most likely costs quite a lot less to deliver treatments using technology so. One of the things that we didn’t know is that these self-guided CBT-based pain self-management programs that were delivered using internet have not been developed for Veteran samples. We’ll make a caveat for that in just a second because I will talk about one that has, although it got developed slightly after Pain EASE did.

So I’m going to go through three, because I think these are important programs and one, two of them are still out there, actually all three of them are still available. They just look a little bit different. So the first is called Living Well with Fibromyalgia it’s now called FibroGuide. So is you want to Google that and see what that’s about. This was a great study. They basically gave these patients six months of access to the program. Their patients were mostly female, they had fibromyalgia, they got the CBT skills delivered by the internet. No clinician contact and their results suggested improvement in pain, physical functioning and global improvement. So patients did well in this study. The second one if you Google, Pain COACH you’ll come up with the papers that were published on this. It’s now called painTRAINER. For hip and knee osteoarthritis. Again no clinician involvement or minimal. CBT format. Again predominantly female sample. These patients were patients who showed improvements in self-efficacy, pain related functional interference, anxiety and positive and negative affect which are mood symptoms largely. And they were really satisfied with the program. The interesting thing to me about this program is they had very low attrition. I think their dropout was around 3%, don’t quote me on that, but I think that’s what it was. It was very low. Not consistent with what other programs had reported, but wonderful outcome there.

And then this third one is called Health eRide, which now also has a new name, and is in process of becoming perhaps another grant. This was developed for Veterans with chronic pain. It was developed outside of the VA with the Pro-Change company. So they published a pilot study. This was, had some CBT skills as part of the program but was more using this transtheoretical model of behavior change to tailor the pain treatment to the patient. So it’s very theory based, it based on the stages of change. Many of you may have heard of that. And it did include the CBT skills of course. They had found some statistically significant reductions in pain and pain impact. But only used a 30-day follow-up period, so the patients didn’t engage with the program for very long. This program was developed like I said maybe I feel like it was a couple of years after we got funded to start the Pain EASE program.

So let’s talk about Pain EASE. The word EASE is an acronym. It’s really hard to come up with these acronyms sometimes. It took us like a month to do this, but it stands for e-health for Activity, Skills and Education program. And that’s just the content of the program largely. It’s internet-based, it’s interactive, it’s a CBT for chronic pain intervention that was developed specifically for Veterans with chronic pain low back pain. This was a rehab R&D funded study, although I will talk about implementation in this presentation, so that might be helpful. And myself and Dr. Bob Kerns were the co-PI’s for that particular Merit Award. This is no clinician involvement. We actually developed this somewhat based on the Living Well with Fibromyalgia study. One of the PI’s for that study is a co-investigator on this particular grant. So his guidance was especially helpful. And we decided to do a feasibility and preliminary efficacy trial. Because we hypothesize and we were right that it would take quite some time to do the development phase of this particular program for a host of reasons that I’ll talk about in a bit.

So we had a couple of aims. One of course developing this program that we named Pain EASE. The other testing the feasibility and preliminary efficacy, we were maybe overly ambitious with sort of saying, okay patients will report clinically meaningful reduction in pain related functional interference. We were really probably not powered to do that, but I’ll talk about that more in a minute. And we hoped that patients would also really like the program, right? They’d think it was credible and useful and they’d be satisfied with it.

So let’s talk about phase one. We used content for this program that was derived directly from Dr. Alicia Heapy’s COPES program. COPES has been part now of a number of different studies and has been published, so the original trial is published. So the content of Pain EASE is very, very similar to the content of COPES. We also engaged, we hired an informatics expert to collected our behind the scenes data that I’ll talk about in a minute how patients used the program, super important. And we hired a usability engineer who was also trained as a graphic designer. This comes in handy and I will talk about why also in a moment. But they were our development team. And we had this expert panel of clinicians and researchers who had a whole variety of expertise that helped us make decisions about what the program would look like, what it would contain, and how it would function. We thought, all right, during this development we’re going to collect some feedback from patients which I’ll tell you about in a second, and that we’ll use that to modify its original prototype that was developed and put that into the feasibility and preliminary efficacy trial.

So for phase one we collected, we enrolled 15 patients, we collected a lot of information from these patients. I’ll tell you about our qualitative data in just a second, but our quantitative data was just based on this post-intervention questionnaire that I made up that largely asked them very specific questions about what they liked about the program, what they wanted changed, and we just used a Likert scale. So largely most people liked it. They thought the material was easy to follow, it was the right amount, they found it helpful for their pain problem, and everybody sort of said all right, I could access the internet no problems there.

In terms of the qualitative methods, we used what’s called a Think Aloud methods. We sat each of these 15 folks down for two, two and a half hour sessions and we asked them to click through the program and just talk. Give us all the verbal feedback they could about their experiences with the program. We also had them logon one time form home between those two visits. And we got a lot of information from them. What should we change? So we had a pretty diverse sample for these 15 folks that we enrolled in the program. And actually a large percentage of women for a Veteran population, but they had, they were older, they had a fairly long duration of pain. Moderate pain intensity. And they gave us some feedback that we incorporated into the program and made it a bit improved for the second phase. Just some style changes, this color is too bright. One thing that people did say is they didn’t like the mix of photographs and sort of created images. And I’ll show you what I mean in a second. And I’ll talk about also what the challenges were with that. They thought some of the content was too long for the models. So we cut some. And then the other interesting thing that they gave us for feedback, we thought we’d try this concept that Dr. Heapy used in her COPES trial of giving sort of little test your knowledge quizzes to patients just to make sure they understood the material. We put one in for the sleep module and patients almost universally said that they wanted them for every single one. So we developed all these test your knowledge quizzes for all of the modules for the second version of the program.

So as I mentioned it’s self-guided, it’s internet delivered but we had the foresight and I’m going to credit our usability engineer with thinking through this to make this what’s called device-agnostic. So apparently we were ahead of the curve on this. But this program you don’t have to just sit down at a computer and use, that was really important because we suspected strongly that people wouldn’t use the internet the same way in 2012 that they’re using it in 2020 and we were right. So this is designed so that instead of having to go to a browser and click through things if you’re using your smartphone for example, an iPad or a tablet, you can swipe. So it’s much easier to use and it modifies itself visually to be viewed optimally on those types of devices. So it’s helpful for patients use that. I actually suspect, although we haven’t collected the data, that most people are using a smartphone to login. So the program is device-agnostic. It’s self-guided. There’s an ability to login and be recognized by the program. This matters because we did put in options for patients to save some particular data. One of which is responses to their self-assessment, which I’ll tell you about in a sec. The other is if they wanted to enter step counts we gave them pedometers for this program so that they could engage in a walking program. Sleep tracking, relaxation practice, all that. The program would save that information and display it to them either numerically or graphically as they decided. So the beginning of the program people login and we said, you know maybe we can try to tailor this for patients if they want it. So they have the option of taking a self-assessment. This is based on the Chronic Pain Coping Inventory. That’s a series of questions, I believe eight, that ask about a patient’s number of days patients use adaptive coping skills for managing their chronic pain. And their responses to this generated what we call the personalized plan. So these were just coping skills modules for the Pain EASE program that were based on low scores for CPCI items. So if you said to me, you know I don’t ever distract my mind from pain, then we might suggest behavioral activation as a coping skill, which we call planning meaningful activities. So different things that patients responded to would be in there. The other thing that was consistent for each personalized plan was the first module, which was pain education. We didn’t have a coping skill that corresponded to that. And we thought that that was particularly important because it sort of gives an overview of the program for the patient. So we included that in everyone’s personalized plan. Now even if we generate that personalized plan, it doesn’t matter patients can access any of the skill modules that they wanted to. However they found that they wanted to use the program we let them use it. We put no restrictions on it. Some programs restrict you to one module access per week. They’re in a sequential order. You can’t go back. We didn’t do any of that. We just left this an open program and said here, have at it in any way that you’d like to use it you can.

So these are the skill modules. They’re standard for cognitive behavioral therapy for chronic pain. And as I mentioned they’re based largely on Dr. Heapy’s COPES program. And based largely, they’re derived from it directly. They’re all of the modules on the Pain EASE program have some brief content, I’ll show you what that looks like in a second, presented with graphics or audio. And then it’s next round we’re going to add some gifs so that we can have some sort of semi-video demonstration of some things. There’s a little self-assessment that tests your knowledge quiz I talked about at the end. And that provides automated feedback to patients depending on what their responses are. There’s a little popup that says you did great or you missed a couple, go back and look again. And there were other tools that are imbedded in the modules. Things like instructions for how to use a pedometer. Self-monitoring forms if patients want to track things, we want them to use those forms to understand the skill. The skills are pain education, setting personal goals, planning meaningful activities I mentioned that one. Physical activity. We have a pedometer based walking program for back pain in this one. There’s also a section on stretching and another body mechanics. We thought those were really important. We had a physical therapy type expert who helped us develop some of that information. We provide them with relaxation as well as downloadable MP4 tracks so they can keep right on their phone or their computer. We do a section on what’s called cognitive restructuring or developing healthy thinking patterns. Time-based pacing. There’s a sleep section. It’s communicating effectively both with people in your life and with your healthcare providers. And then preparing for the future, so helping people manage pain flairs in the future.

I mentioned the self-monitoring feature and that you can, the patients who entered those data can have those data numerically displayed or graphically displayed and it will change the timeframe on the graph depending on what they choose. Sort of like if any of you use Fitbits or if you have an Apple watch and you’re looking in your activity app, you can see graphically displayed data and you can kind of change the timeframe for that. There were also some tracking forms in a section of the program called tracking your progress. And those are commonly used in CBT for chronic pain just to guide patients in the use of pain coping skills. A little form for creating some smart goals, for balancing unhealthy thinking, for tracking relaxation practice. They could also access all the test your knowledge quizzes if they wanted to go back and take them. And then the program finally has a resources section which gave us an opportunity to provide links that are evidence-based and sort of helpful, help literacy type things about chronic pain so education. Comorbid problems as well, we know PTSD and depression are highly comorbid with chronic pain so there were official links to VA and other sites there. And a suicide hotline is there as well. And then any smartphone applications that were developed for Veterans, CBTI for insomnia for example were listed there. So patients would know what other resources were out there for them that were kind of vetted.

So this an example of what the Pain EASE homepage and then on the second screen shot personalized plan look like. And the Pain EASE homepage we sort of described the program, you can’t really see much of it there because I of course had to screenshot it but it describes the program for them. The photo of the members of the military there rotates every second or so there are a bunch of different photos that kind of scroll through so it’s not always looking at the same thing. If someone logs in the personalized plan they can do their self-assessment, it highlights everything in a sort of darker green color. But again they can choose anything that they want to. They’re not stuck to just the personalized plan that was developed for them. And you can see across the top that they had the access to the tracking progress and the resources sections.

And then this is an example of time-based pacing one of the skills. This is just two I’m going to call them frames, they’re actually pages, of that particular module. You’ll notice that we have some instead of using photographs as we did on the homepage, we have sort of graphics that were created for this program. One of our challenges is that the VA will not allow people to use anything that’s copyrighted. Turns out a lot of photos on the internet are copyrighted and we had a very difficult time finding quality images that we could imbed in this program that were consistent that made sense in the context of the program. And so again, fortunately we hired that usability engineer who was also a graphic designer and he created all of the graphics in the program so that it’s consistent. And that was one of the bits of feedback that we had from patients in the development phase of the project. They didn’t like photos and then these sort of graphic images interspersed. They wanted some consistency. And so we did our very best with that in the program.

Okay. So that’s the development and that’s the program overall. Let’s talk a little bit about how we tested this program. Does it work? We had a bunch of feasibility outcome measures modules completion, usability. We used that PIQ that I showed you that I sort of made up about the feedback for the program satisfaction and credibility course.

And then our preliminary efficacy outcome measures. We wanted to make sure that this would work, at least to some extent. And it was not a randomized control trial. So a single-arm trial, we only tested people pre- and post- with ten weeks access to the program. Our primary outcome was pain interference. We used the WHYMPI interference scale for that. And then of course we tracked other typical secondary outcomes that you might find in a pain treatment or a pain clinical trial. Pain intensity being one of those. Emotional functioning, we used back depression inventory and something called a profile of mood states. That’s a whole bunch of mood symptoms that has different subscales that are created. We looked at fatigue, because fatigue tends to be one that we hear a lot. At least as a clinician I hear a lot from patients that that’s a big part of their chronic pain experience. And then certainly we hear sleep disturbance, so we measured sleep as well.

Descriptive statistics did a lot of our work, and then we used some mixed models regressions to look at change within subject change from baseline to 10 weeks post-baseline on our measures of interest. We had a total N of 59. One person enrolled and completed the consent form, but didn’t complete the baseline assessment. So we ended up with a total of 58. Forty-one people completed post-treatment, that’s a 29% attrition at 10 weeks post-baseline. That seems really high. It’s actually super consistent with the studies that reported their attrition rate in that systematic review I described earlier. And with that range from about 20 to 50% so we were kind of on board with that there, so that was good. We were mostly male sample, unlike a lot of the samples that are reported in literature. We had quite a bit of racial and ethnic diversity compared in again to many of the samples in the published literature. We were certainly older folks, the average age was 55. Moderate pain intensity. Long pain duration. And then about 15% of these patients were prescribed an opioid pain medication at baseline. So we did a little bit with medication use as well.

This is a big table. I don’t want you to have to strain your eyes on it, but I wanted to put it in here because we, this is something that I’m very interested in now that this part of this trial is over. I want to know how patients use this program and what can we do to increase their use? We know from lots of different types of technology delivered treatments and for lots of different problems that patients largely don’t use these programs very much after the initial sort of login. That includes apps. That’s one of the big issues people have with healthcare apps. So we have very skewed data here. Some patients used the program a ton and others barely used it at all. So in this particular table there’s untransformed and transformed data. Overall I was most interested in number of logins, on average it was about 5. Again that average means that the data were pretty skewed. And a little over than three modules accessed on average. That matters to us because we consider three sessions, or three modules if you want to call them to be a dose of treatment in some of our other studies from myself and my colleagues. So at least we’re fairly certain that people accessed three out of the ten modules, so that’s a good thing. We looked at a bunch of other things here too. Including we had some weekly check in calls with a research assistant. We did this for a couple of reasons in the study. One we wanted to make sure people didn’t forget their password or have access, you know had trouble accessing the internet. Two, we actually collected their pedometer steps data. We were curious to see if they were using that. And three, we asked them which modules were they accessing during the previous week. That was a validity check, because we knew we’d have these data collected behind the scenes, using SQL databases for the program. And so we were able to compare, we have not done that yet in full disclosure, so I don't know what those data look like. But patients did pretty well taking those calls. So they would have received a total of 10 calls and it was maybe five minutes or so of data collection. This was not a clinician it was a research assistant really just troubleshooting with the patient for technical reasons and then collecting those bits of data that I just described.

So for predictors of engagement we’re looking a little bit more at these data and I, we have an abstract that was accepted to the Society of Behavioral Medicine which is occurring in April. And we had to look at what predicts engagement in the program. Now overall, people didn’t use the program a lot which is challenging. But we also wanted to know, hey is there a difference? Are there people that are really good at this and people who really need some extra assistance, right? We found in particular that our non-white participants, remember about 40% of our participants were non-white, logged in fewer days. They accessed fewer modules, they were less likely to fill out those self-monitoring forms than our white participants. But there was no difference between the number of phone calls that our non-white participants took and our white participants took which we thought was really interesting. We also noticed that older age was positively associated with number of days logged in and modules accessed. So the older the patient was the more likely they were to log into the program, the number days and the more modules they were likely to access. And then we looked at gender as well. We had mostly men in this particular phase of this study, and we didn’t find that was significantly related to the variables. So I’m going to come back to this information in a minute or so because I think it’s important. It speaks to how we engage patients in these technology delivered treatments. And I think as more people are turning their attention to using technology it’s going to be very interesting for us to see how to improve their engagement in that.

Patients overall found the program very credible. These are numbers out of a maximum of 10. Those people thought it was useful and appropriate for their pain problem.

This is a collection of some of the questions on a treatment satisfaction measure. Overall, 80% moderately to very satisfied, 85% said they were moderately to very satisfied with the Pain EASE program specifically. Most people said that they thought the amount of treatment they received was good. And about half of the patient, well more than half the patients said hey at least some of my needs were met and then the other bits most of the most part said most of my needs were met in terms of addressing their chronic pain problem.

And then this is that post-intervention questionnaire that I showed you for phase one same for phase two. Again most people thought that they, the website was good, they liked the content, the self-tests all this kind of stuff. The interesting thing about this data is question number nine, I would prefer to complete the program by the internet rather than in person with a counselor. That was about 50-50. So I was very interested to see that. Not 100% sure what to make of it, we’ll talk about it in a second.

I’m just posting here some, the preliminary efficacy results. This is the portion of a very large table that would definitely not have fit on this slide and would not have made any sense. These are the significant results. So our primary outcome was the WHYMPI pain interference. Significant, statistically significant reduction in that measure. We thought about well it’s almost clinically significant too, it would have been minus point six, but we can’t necessarily say that because we didn’t have the comparison condition for control. And then we found positive effects of the program on a depression symptoms. Tension total mood disturbance which really just means mood symptoms and I don't know what to make of the snoring subscale of the medical outcome study sleep scale, but it was significant as well. And our effects sizes are medium effect sizes for all of these. So that was very promising.

And so change from baseline to 10 weeks post-baseline non-significant results for pain intensity. Fatigue, the additional profile of mood state, subscales and those additional sleep scale subscales are a bunch of those. And we did do some clinical improvement calculations. We had a very small sample of only 58 participants. So about 25% or so improved at least 30% from baseline on pain interference and then about 20% improved about 30% from baseline in pain intensity.

All right, so overall for the study portion, statistically significant reductions in pain interference, mood, depression symptoms and tension, seems to me that the patients found that the Pain EASE program was feasible, was a satisfactory method of receiving pain management, seems to suggest that Veterans in particular with low back pain might benefit from internet-based interventions. And that this in particular could reduce symptoms of comorbid depression. This reduction in both pain and depression is not universally reported in these internet-based self-management programs. So a lot of the programs do not find change in depression, so we were happy to see that.

We have some limitations for this study. I’m just going to be mindful of the time here, I have about 10 minutes, I think that’s good. The first of course is that it was largely a pilot study and so the preliminary efficacy is really just preliminary. And we had a small sample, so that makes it a little bit difficult. 29% attrition is of course a limitation, it’s not an outlier among similar studies but it’s not the best outcome. We did not have a control condition. And the login data was very variable among the participants. We had some super, super users of the program and in fact one that we was such an outlier that we had to remove from those data analysis. And others who maybe logged in one time, changed the password, maybe clicked on one module and then that was it. And so their engagement was much less. And so we have to think a little bit more about how to expand that.

And I think we’ll talk about that in just a second here. So I want to spend a little bit of time talking about implementation. Because even though this particular program is not at the implementation state it’s I think this is relevant for others who might be considering using technology to deliver self-management programs but other aspects of healthcare for our Veterans and for non-Veterans as well. This engagement with the program I think is kind of a hot topic because there are lots of app developers out there. And internet-based is maybe a little bit behind the scene, or behind the times sorry. Although what I will say is that I think that the reason we chose not to do an app is that apps are a little bit more limited in the amount of information you can convey. And even though we’ve come quite far in the functionality of apps, I thought that it would be better serving the patients to use internet-based as a platform because I thought that it would be more universal and at the time remember this was 2012, a lot of our Veterans didn’t have smartphones. Now it seems that most people do. But I wanted to do something that I thought would still have some longevity. This is important in the world of technology, eight years is a lifetime. And fortunately we are still using the internet. It might look different how we use it. Most people don’t have desktop computers anymore. And even this laptop that I’m using seems to be something that’s a little bit outdated. But we do still use the internet, so I think that’s important. And trying to study how people use these kinds of programs is particularly fruitful for researchers and clinicians. If you’re going to recommend an app to your patients, and that’s something I routinely do in my clinical practice both in the VA and my private practice, how are they using them? Are they logging on one time to it, putting in you know, whatever a little bit of information and trying it out one time and that’s it? Some of the data suggests on average, people use apps twice and then they don’t return to them. Even if they’re paying for them. They’re not very good at using them. So we have to think about ways to better engage patients in these technology delivered treatments. We also need to and I think this is particularly important and I’m going to give some extra props to Dr. Heapy who with her COPES program did a non-inferiority trial. So she directly compared interactive voice response delivered CBT for pain and in person delivered CBT for pain, which of course is kind of the standard, and found they were equally effective. So efficacious. So that’s important. We don’t have a lot of studies of internet-based pain management that does that direct comparison. So I think that that’s maybe a place for some future thought but in particular related to Pain EASE, how do we engage these folks? Our user data are not that promising. Even though the results are quite good. Now one caveat here is we don’t have great data on the amount of time that they spent on the website. We have some data it’s missing a lot because if people close the browser and didn’t log out we don’t have those data. So what we have, patients spent about 17 minutes on the program. Now I showed you a couple of, we’ll call them frames, but pages of the time-based pacing module. You can get through one of these modules in less than 5 minutes, so it’s possible that even if they didn’t logon a bunch of times, that they actually covered a lot of the content in the program. We would like them of course to continue to come back to it and keep practicing it, but maybe they had more exposure to it than we’re giving them credit for because we just didn’t collect that information. In particular with what we found so far, our younger non-white Veterans with chronic low back pain, we need to focus on to figure out how to better engage them. Is time a factor? Do they find the content is not relevant? And we, and remember I mentioned that there were no race ethnicity difference in these check in calls. Everybody depending, no matter what race or ethnicity they were, took about the same number of calls which was about 6 or so out of 10. And I’m curious to wonder whether or not the calls are being taken because somebody is calling from the VA so the number pops up on their phone and it’s familiar, or they think it might be about something else and so this has nothing to do really with how they use the program, but it’s just kind of a function of how they receive their healthcare. It’s hard for us to know. The other thing that we think quite a bit about is the role of clinical support for internet delivered pain care. So I gave out a few examples at the beginning of programs that are out there that are not for Veteran, or two of them are not for Veterans that did not include clinician support. They were self-guided. But there are many, many more that have some clinician support. Whether it’s clinician check ins by email, they use the internet-based program as a support for the in person treatment. There are all kind of methodologies out there. And I’m wondering if that wouldn’t help in boost engagement in the program, even if it’s quite limited. Like a clinician checking in with them three times over the program or sending them a text or something to that effect. There is a group who have looked at clinician involvement and to different extents and have I think largely found that the amount of clinician involvement didn’t matter, but that clinician involvement was helpful. We also think for implementing these kind of programs, creating these device-agnostic programs is very important. Although we didn’t collect data on this particular study on how patients were using the program. Are they using a laptop or a tablet or smartphone? We surmised that they probably were largely using a smartphone. And so we were very glad that we made this easy to convert for smartphone use. That’s not universal. And I know people are sort of starting to realize now that that’s really important. And I think that’s an important consideration, because people don’t sit at a computer anymore in a way that we used to 10 years ago for example. And the other thing I thought was really interesting was the patients were kind of equally divided on their preference for in person pain management treatment compared with technology delivered. Again, this was 10 years ago. There were very fewer of these things in VA at that time, now there are more. And so maybe that was part of it. They just didn’t have access to it. Maybe they missed the personal connection. Maybe our sample was quite a bit older. Maybe they did not have some of the barriers to accessing care that I’ve mentioned that maybe are more relevant for younger patients. It’s kind of hard for me to pin that down but I guess we can hypothesize if any of those things are true. So it may be that having a little bit of that clinician contact will offset this, and that patients might still prefer doing something that’s technology delivered. One of the things that we also ran into is Veteran access. VA is doing a very good job especially with this VVC, video appointment program. Giving patients internet access on iPads. And I know I’ve been able to get iPads to a few of my patients on the clinical side so that they can do the VVC. But this I think is important. With these kind of treatments largely shut out patients who might be in rural areas who don’t have great internet access, or patients who just don’t have smartphones. Either they’re older and they’re not sure how to use it, or they’re limited in financial means and so they don’t have these. So that’s important. The other thing I wanted to mention is data safety and technical considerations. This matters to VA in particular. They’re very stringent about data safety and privacy. I think our biggest challenges with developing this program were around contracting for one took us about 12 months to get a contract approved for a usability engineer and graphic designer. And then also trying to convince the VA that it would be okay to deliver treatment using technology delivered methodologies because they were concerned about patients data being somehow absconded, whether hacked or what not. So the Pain EASE program collects no PHI whatsoever, and I think that helped.

We are using Pain EASE program, I’ll actually just move down one slide in, another funded study which I’ll talk about in a second, and we are going to use either Amazon Web Cloud services or Microsoft Azure which have separate government sanctioned Cloud-based storage partitions that meets the government’s guidelines for data safety. It’s not easy to access and you have to find a vendor who can specifically do that. But I think that it’s doable now and actually there’s probably a more widespread way for people to do that. But I think these interventions are important. They promote maintenance of treatment effects. They might facilitate treatment fidelity so it doesn’t matter how the treatments are delivered, it's the same across the board. They’re potentially affective as a first line as we’ve showed with our preliminary data or maybe an adjunctive treatment for chronic pain and other comorbidities. Depression. We didn’t look at this in the study, but maybe substance use like opioid use disorder. Maybe PTSD. And so also important again to study that participant engagement. Pain EASE is going to be part of the VA cooperative study’s program study called the SCEPTER Trial. This might be coming to a VA near you, it’s going to have I believe about 20 sites enrolling patients. Pain EASE will be offered as the first step of a two step comparative effectiveness study and this is aimed at trying to figure out what’s the optimal approach to treating chronic pain with nonpharmacological interventions. We have lots of those out there. There’s chiropractic, and yoga, and acupuncture, all kinds of different things. And so we’re trying to figure out which things should go for which patients. And so Pain EASE will be compared to treatment as usual. Compared by itself and then a third arm of this first step, Pain EASE will be partnered with a tailored exercise program prescribed by a physical therapist. And then those who don’t achieve clinically significant reductions in pain interference at the end of step one will be randomized to one of three other nonpharmacological interventions. So you may hear about Pain EASE again in the future at your facility if you’re one of the ones who will be recruiting for this SCEPTER Trial. So I think we’ll have much more opportunity with this very large CSP study to really look at this engagement piece. And we’ll also be modifying the program a bit, so hopefully we’ll be able to address some of the limitations that we’ve found with the initial trial.

Some references there and then I think I’m, I just went over maybe one or two minutes, sorry about that Dr. Masheb, but I will open this back up and see if I can answer any questions that people might have.

Dr. Robin Masheb: Thank you, this was a wonderful presentation and thank you for kind of letting the audience in on what research was done leading up to this project, and what your thoughts are for the future, and what their plans are for future directions. I just want to encourage our audience to write in with their questions. It makes for a really interesting interactive experience with our presenter. And I thought I would start off with the first kind of big picture question, which is, I would imagine that it’s hard to compete with different software programs. Whether they’re apps or web-based programs that are kind of out there in the market outside of the VA. And that other companies don’t have the kinds of obstacles that you might have in terms of developing and rolling something like this out there. So what do you think works or how do you use this so that it is very Veteran specific so that people want to come and use this type of program as opposed to maybe something else that’s out on the commercial market?

Dr. Diana Higgins: I think that’s a really good question. This is a very competitive market because there’s money to be made for certainly not for the VA, but for some of these commercial companies. And I think I’ve looked at a lot of the programs that are out there, there are some very good programs out there. A lot of them seem to find, seem to have some aspects that I found were a little bit lacking. The other thing that I think that’s important here is that this was developed for and with feedback from Veterans. So I mentioned the content was from Dr. Heapy’s COPES study. The content for that study, the COPES study was extensively developed with Veteran feedback. And so it’s really geared toward our Veterans with chronic pain and actually that was back pain as well initially. And so I think that the content here can speak to the Veterans. It’s not novel in the sense of it’s CBT for pain and that’s somewhat standardized, but I think the way that we present it is very helpful. I think using particular graphics can be helpful. I think marketing is a big tool and the VA of course is interested in vetting things that are developed specifically for Veterans, and if it’s marketed in such a way will get behind it and then patients will know more about it. The disadvantage that I think we have is we are on a research grant. Right? We have a very limited, very limited amount of money to develop these programs compared to some of these other programs that I’ve mentioned, developed in conjunction with big pharmaceutical companies. Well they might dump a million dollars into developing these programs, that’s not unusual. And so if you’re doing an regular RO1 or a Merit Award, that’s your whole budget you’re not going to be able to do that, right?

Dr. Robin Masheb: So\_

Dr. Diana Higgins: To get very\_

Dr. Robin Masheb: Right, because I asked this question because I think it must be just tremendously difficult to compete.

Dr. Diana Higgins: It can be. It can also be I think one of the other challenges is trying to get vendors, and the VA calls them vendors. People who are contractors approved through the contracting process who you think are going to meet your needs as someone who’s developing these programs. And that can be really difficult to tease out. You’ll get a lot of people who are interested in a government contract, but may not have any, and who may be website developers but don’t have any experience with developing technology delivered treatments. Which looks very different of course. So I think that’s one of the other challenges. But I do think that these things can compete because the things that are out there are a little bit different. The apps for example for pain most of them are pain tracking apps. And I’m not sure that that’s the best thing for our patients with chronic pain. I think they’re better served by having access to some treatments.

Dr. Robin Masheb: Right. Were there, is there any information that you got from people in your qualitative interviews that they felt like was extremely helpful, or is there a way that you feel like it speaks to your patients? So I’ll give you an example because my area is more about weight and eating. Is that when we in our interventions try to get people and Veterans to exercise. Their first reaction is, oh I guess I’ll join a gym. And then when we ask, well when was the last time you belonged to a gym, and do you regularly go there, there are many obstacles in terms of the population that we treat. They’re very medically complexed, psychiatrically complexed, at least the Veterans who show up here in person, and yet they’re holding on to these preconceived notions about what exercise is and based on kind of their military experience. And so being able to do interventions there’s like a psychoeducation piece about that, that I feel like is very specific to the Veteran population. Do you have similar types of things that you experienced? Maybe about working through pain or different things like that that you feel like your treatment does a better job than say things that are out there in industry?

Dr. Diana Higgins: I think we, so I think a couple things and again I’m going to, although I was part of this too, but I’ll credit Alicia Heapy with thinking about this is, putting an emphasis on things that we know are important to Veterans. They were at some point very active people, right? They were in the military, they had to get through basic training, and most of them have a goal of being more active. So really heavily emphasizing that I think is important. We have a discussion of what’s called kinesiophobia as part of the program which is fear of movement. Because that’s what a lot of patients tell you they experience. They don’t want to get out and exercise because they’re afraid they’re going to hurt their back in some way. And it will reinjure their back. So we have that component. We also I think really talk about ways of managing pain that do speak to patients including using things like pacing, right? What happens when you overdo things? What happens when you push through pain? And we use a lot of graphics that I think can help explain those concepts in a visual way for patients who are maybe not so interested in reading long lines of text. And I’m hopeful that that’s helpful as well. And really just trying to understand, our patient population is going to be a little older, they’re going to be predominantly male. And so we tried to tailor the look of the program to that population.

Dr. Robin Masheb: That’s great. We have a question about what’s your experience been like enrolling patients who are on opioid therapy with this intervention?

Dr. Diana Higgins: That’s a good question. So our enrollment ended a couple of years ago. And I think largely I have found in this and other studies that I have worked on that patients who are on opioids are maybe less likely to engage in these programs. And I don't know if that’s because they’re pain is optimally treated. I would argue as a clinician that that’s not the case. I don't know if that’s because they don’t see the value in this. Sometimes there’s that secondary gain aspect, okay if I do this program then I’ll get to keep my opioid prescription. Although I think really based on the VA’s opioid policy, the prescribing policies and the changes that we’ve seen in the last several years that that’s less of an issue. I think if I were, so I talked about the SCEPTER Trail which will use Pain EASE, I suspect that we will not have a barrier to enrolling patients based on opioids because there are just frankly fewer patients who are on chronic opioid therapy in VA than there were previously.

Dr. Robin Masheb: Right. And that’s going to continue. That track.

Dr. Diana Higgins: Right. We have you know a fairly small number of patients who were on opioids on this trial anyway. We did collect pre- and post- data. I don't know what those look like because I haven’t analyzed those yet. I don't know if anybody stopped taking opioids in the context of this trial. It was only 10 weeks. My guess would be no, but I could surprise myself. So I’m not sure about that.

Dr. Robin Masheb: But just clinically you didn’t have a sense that that was an obstacle or that was\_

Dr. Diana Higgins: No.

Dr. Robin Masheb: \_incredibly helpful or that painful?

Dr. Diana Higgins: I didn’t have that sense. I did, I do say that it was difficult to enroll patients for this trial. And I’m not sure why that was. We screened a fairly large number of patients and a lot of them ended up not being in interested in enrolling in the trial. And we actually, we gave them monetary compensation for the assessments. The pre- and the baselines and the 10 weeks post-baseline, and it was a hefty compensation for maybe 30 minutes of their time. But a lot of them just weren’t interested and I’m not sure what the, we only recruited from one VA site. There were a bunch of other studies going on there too, so that might have been part of it. But I’ll be interested to see how the SCEPTER Trial goes.

Dr. Robin Masheb: Yeah, yeah. And in future research asking the people who don’t participate. That’s always a little tricky right? If you don’t have people’s consent, just finding out from then what\_

Dr. Diana Higgins: Exactly.

Dr. Robin Masheb: \_was not interesting. If there’s a way that you could get at that, that would be really fascinating.

Dr. Diana Higgins: We do have an implementation piece to the SCEPTER Trial. I’m not sure what she’s going to focus on but I think I suspect that will be part of it. These are all nonpharmacological treatments. So I would imagine that that will be part of it as well.

Dr. Robin Masheb: So I’m getting a few questions from the audience about when this might be available outside the context of a research study and\_

Dr. Diana Higgins: Oh, that’s a good question I think\_

Dr. Robin Masheb: \_ is something like this available now.

Dr. Diana Higgins: It is not available now. The VA does have a VA Pain Coach app, but wait for it, you can’t find it on the app store on your iPhone or on your Android phone unfortunately. It’s available only through this VA mobile website. It’s because it has a login feature that patients are required to do in order to collect their data. I have now never seen it because I don’t have that login feature available to me. I’m not a Veteran. So that’s there, but there is nothing else in VA that’s available at the moment. The SCEPTER Trial is six years in duration. So that’s [inaudible 0:56:43].

Dr. Robin Masheb: Wow.

Dr. Diana Higgins: Yeah, it’s a big study. You might see this program at your VA, as I said. You might, and we’re enrolling 2,400 patients or something in that study, it’s very large. So you might hear patients talk about it if your VA facility is one of our recruiting sites. But right now because it’s part of another very long research study, it won’t be available any time soon. Our hope was to get VA to host it. VA does have a couple of web-based treatments. They are not interactive, they do not collect patient data. They do look a little bit like TMS trainings. But the content is quite good and they’re very professionally done. One is on problem solving, another is parenting help. They’re available to the VA they have been for a few years. And I don’t know of any patients who have used them, although I recommend them from time to time. So I’m not, I haven’t had any feedback on those. My hope is the VA will host something like this as a resource available to patients once we demonstrate that it’s got actual efficacy instead of just preliminary efficacy. And we can make a few extra tweaks to it. So it wouldn’t be specifically to low back pain but rather for musculoskeletal pain, which this is perfectly reasonable for also.

Dr. Robin Masheb: Yeah, thank you so much Dr. Higgins for sharing this work with us and to our audience for attending and writing in with some great questions. It made for a really interesting discussion. Just one more reminder to hold on for another minute or two for the feedback form. If you’re interested in downloading the PowerPoint slides from today, please go to the reminder email you received this morning for the link to the presentation. Slides from all of our past sessions can be found by searching on VA Cyberseminar’s archive and then you can scroll down to get to Spotlight on Pain Management. Our next Cyberseminar will be held on Tuesday, March 3rd with Dr. Kevin Vowles. The title of that talk is, Integrated Treatment for Veterans with Chronic Pain and Hazardous Opioid Use. We will be sending registration information out around the 15th of the month. And I want to thank everyone for attending this HSRND Cyberseminar, and we hope that you’ll join us again.

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