Cyberseminar Transcript

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Session: An RCT of a Primary Care-Based PTSD Intervention: Clinician-Supported PTSD Coach

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Molly: With that we are at the top of the hour. So I'm going to introduce our speakers. In speaking order we have, Dr. Kyle Possemato. I did it right during the practice but, I messed it up just now. Sorry about that Kyle. She's a Clinical Research Psychologist and Associate Director for Research and Clinical Associate Professor at the Center for Integrated Healthcare at SUNY Upstate Medical University. And joining her today is, Eric Kuhn. Dr. Eric Kuhn, he's a Clinical Psychologist at the VA National Center for PTSD and Clinical Associate Professor at Stanford University School of Medicine. So, Dr. Possemato, I would like to turn it over to you at this time.

Dr. Kyle Possemato: All right, thank-you, Molly. I'm going to share my screen. All right, so Eric and I are very excited to be able present our line of research on Clinician-Supported PTSD Coach today.

We're going to start the presentation by giving our rationale on why it's important to address PTSD in the primary care setting. And then will describe how we developed our Clinician-Supported PTSD Coach intervention and some of our early findings in testing the treatment.

And we’ll complete the presentation in describing our HSR&D multisite randomized trial that is currently underway to test the effectiveness of Clinician-Supported PTSD Coach. Sorry, I'm trying to advance slides and there we go. Okay, back over to Molly for our first poll question.

Molly: Thank you. Sorry about that, I stole the screen share back just a minute too early. So for our attendees you do have the first poll up on your screen. Please go ahead and select the response. So we would like to get an idea, what is your primary role in the VA? We understand that many of you wear many different hats within the organization, so we’d like to get an idea of what your primary role is. The answer options are clinician, researcher, administrator, manager or policymaker or other. You can go ahead and click the circle right there on your screen that corresponds with your response. Please note, if you are selecting other you can type in your exact job title into the questions section and I can read that over the call. Or at the end of the presentation I will put up a feedback survey with a more extensive list of job titles, and you might find yours to select there. We've got a very responsive audience. Already 70% have replied. I'm going to give people just a few more seconds to get their responses in. Okay, and with that I'm going to close out the poll and share those results.

So 50% of our respondents selected clinician, 24% researcher, 5% administrator, manager or policymaker and 21% selected other. So thank you to those respondents and Kyle did you have any comments before I move on to the next poll?

Dr. Kyle Possemato: No, not yet.

Molly: Okay, we’ll go ahead and move on to the second poll question. So for our attendees this one is select all that apply. So we would like to get an idea, how do you use mobile applications in your VA role? So again you can select all that apply. The answer options are; I recommend that my patients use them on their own, I incorporate apps as part of the service as I deliver, I conduct research with mobile apps, I do not use mobile apps in VA, I use mobile apps in another way in VA. So take a moment and read through those answer options and again you can select all that apply. And the responses are just starting to come in now, so will give people some time to get those in. Okay, it looks like about half of our audience have replied, so we’ll give people some more time to get those responses clicked. Again, just click the square right next to the answer options you would like to select. Okay, and it looks like the answers have stopped streaming in. So I'm going to go ahead and close this poll out and share those results.

Forty-two percent of our respondents recommend that their patients use them on their own. Thirty percent incorporate apps as part of the services they deliver. Seven percent of respondents conduct research with a mobile app. Forty percent do not use mobile apps in VA and 2% use mobile apps in another way in VA. Thank you again to those respondents and I will give you the screen share one more time.

Dr. Kyle Possemato: All right, thank you, Molly. And I will go past the poll questions. Thanks for answering the poll questions, it really helps us understand our audience in a way some folks are using apps and others not as much. Now back to the rationale and why to address PTSD in primary care. The rates of PTSD in primary care clinics vary a lot based on the location of the clinic and the population it serves, but at any given clinic about 1/8 to 1/4 of primary care patients will have PTSD. So, it's a significant problem both in VA, but both in community clinics as well. And we know that PTSD is associated with a number of negative health outcomes. And these include physical conditions that are commonly addressed in primary care, such as cardiovascular disease or diabetes. And also comorbid with many other significant mental health concerns like depression or substance use. And we know that PTSD is associated with a host of functional impairments, everything from unemployment to poverty and relationship difficulties.

So one of the primary reasons to address PTSD in primary care is that individuals often will seek primary care services when they are hesitant to engage in mental health services. So it can be maybe one of the only opportunities to engage folks in care. Many researchers have described primary care as a de facto mental health system and some research has found that the majority of primary care visits are often related to mental health concerns. Also, the treatment barriers that are often associated with mental health don't always apply to primary care services. So for instance, many individuals have more negative beliefs about mental health treatments, such as the treatment doesn't work or they won't receive the type of care they want. There is also more stigma associated with mental health care and for people who are already getting services at a primary care clinic it can be a barrier that’s often reported as trouble navigating through a system to go to a new mental health service provider. Past research also shows that physicians can struggle to recognize and treat PTSD. There is reason to believe that physicians in VA struggle a lot less than other physicians, but I think there is still a big role for behavioral health providers to play a role in primary care to help with recognition and treatment of all mental health disorders. And within VA, VA recommends a combination of two assessments to really screen for PTSD in primary care and for all the VA folks these will be pretty familiar. So, the primary care PTSD-5 screen is one of the annual mental health screens that are given to most primary care patients. And when people screen a three or higher it should be followed up with the PTSD checklist 5 and these two screens together are pretty efficient and simple strategy for identifying PTSD in primary care.

So I think most those in VA tend to understand the integration of behavioral health in primary care well. So this slide just gives a very brief overview of what this is and I'll go through it quickly, especially seeing how many clinicians we have in the audience today. So when behavioral health is integrated into primary care, behavioral health providers like psychologists or clinical social workers function as a member of the primary care team, or what we call in VA the patient aligned care team, the PACT. There's many important features of the treatment that’s provided in primary care. Probably one of the most important is these providers, when functioning in an ideal model, has at least some open access slots throughout the day. And this is crucial to help primary care patients engage in care while they’re at their regular primary care appointments, that they can meet the behavioral health provider and begin receiving services. Primary care behavioral health treatment often tends to be brief, in that the appointments are often 30 minutes long and typically only one to five sessions. And it uses a step care approach, where people receive lower intensity treatment at first and then are stepped up to higher levels of care as needed if they don't improve with less treatment. The treatment focus tends to really be around what the patient’s primary concern is and what the provider’s reason for referring the patient is. And no comprehensive intake is done to understand all problem areas, but instead focus on what the patient and the provider are most concerned about. Treatment is focused on the step present concern, tends to be solution oriented and patient self-management is really encouraged including the use of mobile apps. And a key aspect is that the behavioral health provider communicates regularly with the primary care team so the treatment plans can be coordinated for the patient. And it was with this framework in mind that we developed the Clinician-Supported PTSD Coach to fit into the system.

So, as we were approaching this line of research and starting to think about what was needed, we took a look at what type of services were currently being provided in VA primary care by behavioral health providers for individuals with PTSD. And what we found in medical record reviews was that treatment tended to be highly supportive and that oftentimes things like psychoeducation in normalizing of symptoms was included. We did not find a lot of evidence of specific evidence-based strategies, but less frequently people would also use things like relaxation training. Or often the treatment would focus on things that were related to PTSD but, not specifically on PTSD symptoms, like anger or insomnia., which is a nice way to use a brief primary care treatment if that's what the patient is most concerned about. We saw referral management used a bit too, and what we mean by this was not just referring people to specialty care but helping people actually get to specialty care by problem solving any treatment barriers that came up. And we also wanted to mention here that although it didn't come up in our medical record review, because we're really focused on counseling services and brief psychotherapy, all of us know that anti-depressants are commonly prescribed in primary care for PTSD. And there is some evidence that combining anti-depressants with nurse care management can be effective. This is especially true for individuals with depression and there’s been some research on combining care management with anti-depressant prescriptions for individuals with PTSD and the research is more mixed on that.

So within this landscape that of seeing that there wasn't a lot of, kind of specific strategies being used to treat PTSD in primary care that we developed the Clinician-Supported PTSD Coach treatment. And we knew that many providers working in, behavioral health providers working in, primary care were interested in more structured and manualized approaches. So our approach really seeks to support patients in learning about PTSD treatment options and using symptom management strategies. And Eric and I will talk about much more about what this is but I also want to give a plug for prolonged exposure for primary care which is another brief primary care based treatment that is currently being researched. And it is four 30 minute appointments that includes written Imaginal Exposure, In Vivo Exposure, mostly assigned for homework but then discussed in sessions. And there is also some good preliminary efficacy on this. And if anyone is interested in learning more about it, especially Primary Care Mental Health Clinicians, there’s resources in VA to be trained on that now. And if people email me afterwards I can get them directed to that. Okay over to you, Eric.

Dr. Eric Kuhn: Thanks, Kyle. So I'm gonna just briefly go over what PTSD Coach is, hopefully some of you have heard of it. It is VA's first publicly available mobile app. And we launched it in 2011, actually April of 2011, so really it is our Happy Birthday month 8 years ago. It's been downloaded over 450,000 times at this point in over a hundred countries. So it's gotten good uptake. And it's available on both platforms, so both of them, the major platforms, Android and iOS, for free download to anybody and you don't have to be a Veteran to be able to download it. It's been versioned for several other countries at this point, including Canada, Australia, Denmark, Sweden, the Netherlands, and a few others. And it's also been versioned for cancer survivors, because oftentimes cancer survivors have PTSD like symptoms, with some partners at Duke University. Next slide please.

Great. And so, PTSD coach was designed really to be a public health tool, really. Just out there for folks to use as they see fit in the moment as needed. Not really a comprehensive intervention, just something to give them some psychoeducation, to learn about PTSD. Some ability to track symptoms and monitor their symptoms overtime. Some self-help tools, so very low level self-help tools, like relaxation, and breathing, and those kinds of things. And really these tools originally, this is an original screenshot of PTSD Coach, were based on what was wrong. So what kind of symptoms the person is coming in with and we put it into these eight buckets based on what we know from factor analysis of PTSD, as well as what patients want when they come into our system. And then lastly, they can quickly find support, so getting professional help or using their support networks to be able to reach out for support knowing how important support is in PTSD recovery. Next slide please.

So these are just some examples of the tools in the manage section of the app. There are many tools like this that include things like deep breathing, positive imagery, soothing pictures. And some tools that require making, for example, making a plan or doing something in the future. Really the idea was that giving folks tools in the moment when the distress arose. And we didn't really call it PTSD, per say, but just distress that they’re having and there is a little thermometer that we put in there, a distress thermometer, where folks can rate how much distress they’re having whether it's anger, or anxiety, nervousness, whatever it is. And then they would be offered a tool to help them cope with that distress in the moment. What's not included in PTSD Coach is Exposure Therapy. So, no Imaginal, no In Vivo, although there is a tool in there called the RID Tool; the relax, identify, and decide tool, which encourages folks to kind of stay a little longer in those situations when they are naturally exposed out there and when they’re out and about. To help kind of them cope better in those situations rather than escaping immediately. Next slide please.

Great. So to date there's been a number of studies on PTSD Coach. Our first study was just kind of going into the men's and women's trauma recovery program here at the Menlo Park VA. We originally went to the men’s trauma recovery program to ask them for help with the future set. What we were gonna put in the app, and we got a lot of input. We originally had kind of thought, “oh, we could do all of this cognitive therapy stuff.” And as psychologists we thought we could pack it full of all of this stuff and really what they were saying was, “when I'm at the supermarket with my girlfriend, I just want to get the hell out of there. It would be nice to have something that I could use in the moment to kind of cope with that situation.” So we kind of went back to the drawing board based on their feedback and we then built PTSD Coach. And then our first study was to go back to the men and women in our trauma recovery program and have them try it out and see if we kind of hit upon what it was they were wanting. And so we had them use the app for a weekend. We gave it to them on a Friday and then we met back up with them on a Monday. And we got a sense of if they thought it was satisfying and did they think it was helpful. So it was through a series of focus groups and questionnaires. And indeed it was rated as being acceptable, I think 89% of folks said it was moderately to highly satisfying to use, and they had a number of things they said that was helpful for including managing PTSD symptoms. So we were encouraged there. Our second trial we went out to the community with our colleagues from Stanford and we did a pilot study. Sorry, can you go back out? There is a lot in that slide.

We went with our colleagues from Stanford and we did a small scale, sorry, can you go back out one? And we did a small trial with 49 community trauma survivors. And we showed that it looked like it was acceptable and feasible and potentially could be helpful as a stand-alone intervention with these community trauma survivors.

That encouraged us then go back and do a third trial where we did a full-scale trial with community trauma survivors where powered it up to detect the effect if it was there. And what we found was that indeed PTSD symptoms were reduced. There was a treatment effect for PTSD symptoms, there was a treatment effect, as well, for depressive symptoms, which we often find with PTSD. And that psychosocial functioning seemed to be improving as well over 3 months of PTSD Coach relative to a Wait List Control. The last thing we did, is we used novel data. So, when we were thinking about the version 2.0 update, we, as a team, got together and said, “let's find all the data we have”, including aggregate data. That instead of being collected from the app it's aggregate anonymous data. It's kind of an analytics tool that's embedded in the app. That we were able to look at the first 150,000 plus downloads, and see if we could get any information on the reach, the reception, the impact, and the use of PTSD Coach on this really limited data that we had.

As well as, going into the App Store and getting the reviews from both the App Store and Google Play. And seeing if we could do qualitative analysis to see if these reviews are telling us anything about the reach, reception, use, and impact. And so what we've found was that we were having a substantial and sustained reach in the population based on the numbers of downloads that we were getting. It was being used as intended. So we could see that the paths that we had laid out in the app, people were actually following through and using the paths. They were doing assessments on their first use of the app. We also saw that when using the distress thermometer, folks were actually coming down when they went into the tool and when they came out the other side. Their distress was coming down an average of about 2 points. So that was kind of cool, just totally anonymous aggregate data of only single sessions. So we don't know overtime what’s happening with these folks. And then, lastly, the App Store reviews were really favorable overall. We were getting high ratings in terms of the stars that we were getting. As well as, in the reviews themselves. And it did look like, a number of reviews mentioned that they were Veterans and the Veterans were satisfied with it. So it's kind of interesting data that we looked at. What we, next slide please?

But, what we also know is that, stand-alone self-help suffers from high attrition, low adherence. If you build it they will come but, they will not stay, and they will not use it routinely. And the outcomes will be weak because of that. It's all of the same content that we deliver in person, but if they are not exposed to the content they don't use it, they're not going to benefit. So we realized that guided self-help, or self-help with some type of Supportive Accountability, as David Mohr would put it. Where you would be working with a trustworthy, helpful, experienced other Clinician or a Coach could actually improve outcomes in terms of both the adherence as well as the impact that the intervention, the self-help intervention could have. And so what, as Kyle mentioned we did is, we decided that we should build an intervention that could fit within the parameters of the VA primary care. So it needed to be brief, 30 minutes or so. It needed to be between one and five sessions. So we had four sessions that it needed to be time limited. And so we built something that takes place over 8 weeks. And as Kyle said, it really is a model where you focus on a specific issue. So what we decided we’d do is just focus on one concern at a time, kind of a foot in the door technique I think as we think about it. Working on one concern at the time and assigning the patients use the app daily to manage that concern. So really focus. And so over 2 weeks we want you to work on this one concern which you select together, for example, unable to sleep. It's a very common one we see in the study. And then the second important outcome is, that we are trying to help folks transition to other care if their symptoms are still high at session four. So we don’t believe that this is the end all be all, especially for a lot of the Veterans that we see. But for some Veterans they might be well on their way with their PTSD symptoms improving. For other Veterans they're going to need more. And so this is kind of another way of getting them comfortable with doing some bridge psychotherapy before they go off, hopefully into a mental health treatment. So some early studies that we’ve done, and that Kyle will go over shortly, is gathering stake holder feedback on treatment development. So going in and getting all the stake holders together and finding out what they would like to see in an intervention like this. Trying to find out if Clinician-Support increases the efficacy of PTSD Coach, and I'll cover a study we did on that, and this is where we did a randomized control trial comparing Clinician-Support to self-managed PTSD. So we’ll go over those studies shortly. Back to you Kyle.

Dr. Kyle Possemato: All right, thank you Eric. And sorry if the slides got a little off. I lost my audio and we’re having computer issues but I think I’m okay now. Okay. Our first study we sought to gather stake holder feedback on how to fast deliver, sorry, to look at the feasibility and acceptability of delivering Clinician-Supported PTSD Coach in Primary Care. And we also wanted to gather factors that could support or hinder implementation of the intervention, as part of the research study. And we also used the feedback to develop and refine our clinician manual.

So what we did is, we enrolled both primary care providers and mental health providers who were both front line folks and had an administrative role in leadership and asked them to complete a survey in a follow-up interview regarding implementation barriers and facilitators. And this is based on the consolidated framework for implementation research or CFIR. And then we also interviewed the clinicians who delivered the intervention as part of the small RCT, we’ll talk about soon and interviewed 9 patients who received it and gathered feedback on the intervention and the implementation process as part of this first early study.

And so what I have on the next few slides is a few themes that came up with barriers and facilitators, and understanding how best to both develop this intervention and then research it. So for primary care and mental health folks several facilitator themes came up. And you can see in these slides, I'll go over the main themes and their link to the CFIR construct for those who are interested in how this links back to the model. So the intervention was thought that it would help Veterans overcome common barriers to receiving PTSD treatment. And the most common barrier that folks in primary care mentioned, was that not being able to get people to go to specialty care. People also had feedback that they thought it fit well in the primary care mental health structure and in the primary care as part of primary care services. And that it addressed an important gap in care. And I'll actually read a quote here that relates to several of these themes. So one of our primary care providers who was in this study said that, “I think it's good for primary care providers who are very frustrated with PTSD, because we recognize how much it impacts patients’ physical health. Unlike depression or anxiety where we feel like we have some capacity to make interventions in primary care, we feel totally lost when it comes to PTSD. We are not aware of any interventions that are really successful that primary care providers can do. We know we prescribe SSRIs that maybe has some benefit. I think we are aware that the people who have been successful with PTSD treatment are the ones who fully engage in it and we just can't get people to the treatment.”

So a few themes came from, the facilitator themes, Veterans and clinicians as well. So things that Veterans highlighted were that they thought the intervention had an effective design, which included the amount of information, the tools used in the app, the number of sessions. And they also highlighted that the clinician support was important to help it help them engage in the app. So many specifically said, “I would have checked out the app once or twice, but, I really don't think I would have used these strategies on my own.” And Veterans also mentioned that they liked the flexibility with session format and spacing. So one Veteran specifically said, “It is the right number of sessions. It gives you the independence but also doesn't leave you on your own.” So we felt we were striking the right balance between people who needed some support but not a lot of support. And clinicians most also liked the flexibility of the protocol the most. And the comments around this were related to PTSD is such a complex disorder and people have different presenting concerns and the manual really allowed them to focus on which concern was most important for the patient.

So a few barriers also came up and we really used these barriers to inform parts of our study implementation plan and also revised the manual around this. So from primary care and mental health leadership, it was clear that they anticipated that not having strong leadership support or clinic champions could be a barrier to the study and also that primary care staff needed more education about how to talk to their patients about PTSD in order just to get people referred over to the study. Clinicians mentioned several things that we were able to fix in our manual. That our manual lacked detail on collaborative goal setting, which is a really important focus towards the end but we didn’t have enough detail. They also recognized that our homework was too complicated so it got greatly simplified. And they discussed how important it was to be able to do phone sessions because patients really said they needed these in order to complete the treatment. But that it could be tricky because they weren't in the same room and looking at the app together. And so we provided a lot of support in the manual around how to do phone sessions. Next slide\_

Dr. Eric Kuhn: So\_

Dr. Kyle Possemato: Back up to you Eric. Yep.

Dr. Eric Kuhn: Okay, cool. So the study that we did, this pilot randomized controlled trial in VA primary care, we recruited patients who scored 44 or more on the PTSD checklist 4. So this is the clinical cutoff of the old version of the PCL. And we excluded those who were receiving, or who were interested in receiving, specialty mental health care. So they were not part of our target population. If they wanted to go on and get treatment right away we were happy to refer them. We really wanted the folks who were reluctant to seek treatment and wanted their PTSD addressed in primary care. We had two conditions, one was Clinicians-Supported PTSD Coach. So this was our brief manual before four sessions, 20 to 30 minutes each. And they were provided over 8 weeks. And I don't know if we said it explicitly, but we did allow folks to complete phone sessions if they wanted those. So it's patient preference for that, and as Kyle said and we've experienced, doing a phone session while somebody's navigating an app can be tricky. But we did that. We also had a condition that was just self-management knowing what we know about PTSD Coach and how it can helpful on its own. This was just a one in-person 10 minute session on how to use the app, just an anchoring session to get them going and go use it however you would like to use it and we’ll talk with you in 8 weeks about it. But we thought that both conditions would lead to some improvement of PTSD symptoms, obviously we don't have a Wait List Control or a no treatment condition. So we can't really established whether they both led to improvements in PTSD symptoms. But it was a small trial. And then the Clinician Supported PTSD Coach would be to greater reductions in PTSD symptoms, and would increase the uptake of mental health care initiation compared to self-managed PTSD Coach. Next slide please.

So we recruited these twenty patients. And as you can see here, they were our Veteran kind of population. So predominantly male, 95% male. They were OEF-OIF predominantly. I think we selected for, or we actually had 90% OEF-OIF Veterans. So they were 42 years of age on average. They were predominantly white, about half were employed. And you can see there their PCL totals were fairly high, although not maybe as high as what we would see in a specialty PTSD clinic where commonly it’s in the upper, in the mid 60’s. So next slide please.

In terms of outcomes of our treatment by time interaction, so self-managed versus clinician supported. We got a modest or a moderately sized (d) which was not significant. We had 10 and 10 in each condition, so we weren't really expecting to see much other than a good effect size, which is we got. But then if we drill down and just look at the pre-post within condition changes, we see that the PTSD Coach alone condition, had an effect size of point 4. So it decreased the PTSD symptoms on the PCL. So about 6 points or so. But if we look at the Clinician-Supported PTSD Coach, we see that we’re showing a very strong effect size for that, with over a 10 point decrease on average in PTSD symptoms on the PCL. So we looked at this in terms of clinical significance so, the next slide please.

And so if we look at the first couple of bars there, clinically the clinical significance and this would be those meeting, or the percentage meeting, 10 point reduction on the PCL over those 8 weeks while they were in the trial. And in the Clinician-Supported PTSD Coach condition we're seeing that 70% of those participants, 7 of the 10, had a reduction of 10 points or more on their PCL compared to about 37.5% in the self-managed group. So pretty encouraging data overall. Then if we look at the other outcome that we were most interested in, accepting a mental health referral, 90% of those who got Clinician-Supported PTSD Coach accepted a mental health referral. So this really does seem like a foot in the door kind of getting comfortable talking with somebody on a low level, just on a few different issues that you're having, can actually increase the likelihood that they're going to accept a referral to mental health treatment. But, really there's a lot of folks who accept mental health referrals from primary care, but then they don't show up. And so if you look at the next couple of bars, and the couple of bars after that. Attended mental health, attended PTSD treatment, you can see that actually they are showing up and they are showing up at higher levels than the folks who had self-management alone. So very encouraging data obviously very, very, very, small sample size, but it looks like there's something going on here with the Clinician-Supported PTSD Coach. It also looks like, as you can see, although again, we didn’t have a Wait List Control to test it, that maybe PTSD Coach alone could be helpful if the person is saying they don't want anything else. So next slide please.

So our big conclusions from this early work is that PTSD Coach in PC is feasible especially with our clinician supported protocol, and possibly helpful based on the outcomes that we've collected. We believe that adding that clinician support is super important and it probably improves both the outcomes and the initiation of mental health services. And as Kyle said we think that PTSD Coach could strike as good balance between convenience and self-autonomy, so really getting the patient activated in primary care to work on self- management. And that having the mobile intervention could be helpful in that. And so that then kind of leads to our larger scale randomized control trial, where we set out to study this with some HSR&D funds and I’ll hand it back to you Kyle.

Dr. Kyle Possemato: All right, thank you. So we are currently in, just started year three I believe of our two-site, two-arm pragmatic randomized clinical trial, which is funded by HSR&D, as Eric said. And when we say pragmatic here, really the goal was to keep everything as close to real world as possible while still being able to answer our study questions. And what we have in the next few slides explains how we did that.

So we enrolled people, our two main inclusion criteria, was that they had to be a primary care patient at the sites we were recruiting from, and they had to have endorsed a traumatic event on the Criterion A screener, and have at least a 33 or higher on the PCL-5.And when I mentioned the two health care systems we're are recruiting from, I will mention that this includes two medical centers and we're currently at 5 CBOCs. So we’ve continued to expand a bit location-wise to keep our enrollment numbers up. Our exclusion criteria, we really tried to minimize because it is a pragmatic clinical trial. So we excluded people with gross cognitive impairment if they had current symptoms of mania or psychosis or other more pressing concerns that needed to be addressed first such as, a recent suicide attempt. And in this case we really just get people engaged in suicide prevention services in VA and then once they’re engaged in those we enroll them in the trial. The last three bullet points here are about excluding folks who are engaged in other types of either mental health services or mental health counseling or changing doses of psychotropic medication or just want to go directly to VA specialty care, go to PTSD treatment. And that's really because this study is for people who aren't currently engaged in other types of mental health treatment. And so people who aren’t a good fit and people who just want to go directly there we just refer them there.

And so this slide shows our flow through the study and we recruit people randomized, they go to the intervention or our control group; which in this study is primary care mental health treatment as usual which means, we place a referral to the primary care mental health treatment in their home primary care clinic. So everyone does get some sort of treatment. So we’re really comparing a structured approach versus a non-structured approach in this study. And we assess them at post treatment, which is 8 weeks after baseline, and then we assess them again at 16 weeks follow-up and 24 weeks follow-up.

And our specific aims in this study, we have two co-primary aims and these flow directly from the, what we found in our pilot study, which Eric just presented on, is we are investigating the impact of the intervention both on PTSD severity but also engagement in specialty mental health care. And we’re also interested in just understanding patient and provider satisfaction around this intervention. We’re also exploring mediators and moderators a bit as exploratory aims and this figure here shows conceptually how we're thinking about this. So we see PTSD Coach as leading both reductions and symptoms and also more engagement and treatment. And things that we might, that we think may be moderating these changes, excuse me, mediating these changes, include more app use and also increases in coping self-efficacy. And then a few moderators we’re exploring of the treatment effect includes baseline PTSD severity and comorbidities like depression or substance use at baseline. All right, back to you, Eric.

Dr. Eric Kuhn: Sure, so as Kyle mentioned we are in year 3 of this trial. And as of this morning we have 116 patients enrolled. This just shows that as of our most recent BSMB report we are doing really well with the randomization where we’re not seeing any differences between our treatment as usual and our intervention conditions or our experimental condition. So that’s really encouraging. Next slide please.

In terms of outcomes we did not break the blind yet, so we do not know if PTSD Coach with Clinician-Support is superior to PCMHI. But what we do know is that it looks like in aggregate the interventions that we have in our trial are showing reductions in PTSD symptoms in terms of both the clinician and administer PTSD scale 5, the interview measure that’s our primary outcome at week eight. And then also in the PCL over time and so we’re seeing as a whole those hundred people who have completed as of, I believe it was, the end of the year they’re showing pretty large reductions in their PTSD symptoms that the second fall looks like something that like 11 or 12 points on the PCL-5. So, that’s encouraging. Next slide.

So challenges. This has been a real learning experience I think for both Kyle and for me. We have kind of overcome or encountered and partially overcome many of these challenges. We’re still working on making it work. But our biggest challenge, like with any or most clinical trials is recruitment. We are as Kyle said recruiting at our primary medical centers here at Palo Alto and at Syracuse, but we had as backup plans if we weren't able to recruit the numbers we needed that we would be reaching out to the CBOCs around us. And so here at Palo Alto, we are at our primary medical center and we are also at the Fremont Clinic and also at the San Jose Clinic where we are recruiting from right now. At Syracuse, as Kyle commented, they are also recruiting and at their outlying CBOCs. So they have multiple CBOCs engaged now which is really cool. What's interesting as a pragmatic trial we have to kind of go with what's there, so the primary care mental health integration at the different CBOCs might look a little bit different. So we kind of go with whatever is there and have to deal with it, so we are dealing with challenges of keeping consistency among research staff at multiple sites. We are really good at kind of meeting every Monday morning, making sure we check in and we go through our numbers and just stay well aligned. I think we could, you could really feel the kind of a tension where there could be drift pretty quickly given the differences between sites, and so we're trying to minimize that, to hopefully reduce the noise and actually test this in earnest. And so really we also have to kind of be flexible, though where if things are not working at one site because the context just doesn't allow it we have to kind of flex there and deal with it. And I think we joke often that this is a pragmatic trial and we do our best to try to keep everything standardized across the sites.

Maintaining staffing across a four year study. So I think this is particularly a challenge for Kyle’s site where she has interns and practicum students and you know we don't have that many of those here at our site. But, she get some good input there, and so there's a lot of churn. And so getting folks trained up, whether it's with the CAPS assessments or with doing the Clinician-Supported PTSD Coach, it can be a lot of management there. And then lastly, having such a small team with everyone wearing different hats we have to be really super careful about blinding of all material. So we need to always be aware of who's in the meeting, is it somebody who might be a CAPS assessor. We have to be careful what we talk about in meetings and we have to kind of be explicit to ask folks in some meetings to step out or we partition the meeting in a way that we don't compromise that as we go through. And I bet I could fill about 4 or 5 more slides with challenges but we’ll stop there. So, you can go to the next slide, Kyle. Thank you. I guess we're going to open up the floor then for questions, right Molly? You’ll be reading them off?

Molly: Yes I will, thank you so much, to both of you. So for those of you that joined us after the top of the hour to submit your question or comment please go to the GoToWebinar control panel on the righthand side of your screen, click the arrow next to the word Questions, that will drop down the dialog box and you can submit it there. The first question we had come in, is the PTSD Coach available in Spanish?

Dr. Eric Kuhn: Oh what a timely question. I wonder if it's somebody from our team who’s asking about that. Just for me to, for me to, yes it will be. We are working on version, I think, 4.0 at this point or 3.0 and it will be available in Spanish. So I believe through internationalization or localization, whatever they're calling it now. If your device is in Spanish the app will be in Spanish. Good question.

Molly: Thank you. The next question is, what role does social class or status play in Veteran retention in these programs? Isn’t Palo Alto a pretty high class region?

Dr. Kyle Possemato: That's an interesting question.

Dr. Eric Kuhn: Yeah.

Dr. Kyle Possemato: Yeah it's been interesting, to run a study out of Syracuse, Syracuse is in Upstate New York and serves largely a rural catchment area and Palo Alto is very different. So we're getting a very diverse sample. But I don't know if we have our results yet to understand if what role social economic status, if any, play in retention or treatment gain. But we have people from all walks of life in this study.

Dr. Eric Kuhn: Yeah and even though Palo Alto, you know it's very, very, very expensive to live out here compared to New York State, anyway. We do have folks who are coming from our kind of hinter regions like in the, further off into the Eastbay where things are in air quotes “a little bit more affordable”, and so our Fremont Clinic we’re getting folks from closer to like the Central Valley. And we do have a lot of folks, given that we serve a lot of homeless Veterans and folks in transitional housing, that we've had quite a few of them in the study. And a number of our older Veterans they probably would be considered, given that they have been living in the area for a long time before the boom with the Internet and then with all of the stuff going on now with social media and with Google, etc., Apple, we do have a number of those folks who are in the study and they seemed to be engaging like anyone else. And I think in terms of smartphones there doesn't seem to be disparities based on socioeconomic status, so it seems like everybody has smartphones at this point in time regardless of SES.

Dr. Kyle Possemato: Although we do get, let people borrow smartphones if they don't have them. We’ve had a few participants like that in the study.

Molly: Thank you both. The next question, how do you recruit and get buy-in from primary care clinicians in order for them to refer patients to your study?

Dr. Kyle Possemato: You want me to take that one Eric? Or do you want to?

Dr. Eric Kuhn: Yeah go for it.

Dr. Kyle Possemato: Okay so, great question. So we use, we largely rely on a system where we extract data from the VA medical record looking for people, looking for indicators that someone has current PTSD symptoms, like a positive PC-PTSD screen and aren't engaged in other types of mental health treatment, and then we go back to the primary care providers and ask them to refer those people to us. So we elicit referrals that way and then when the primary care providers say, “yes, you can recruit that person”, we send them an invitation letter and call them on the phone.

Dr. Eric Kuhn : And\_\_

Dr. Kyle Possemato: Although we love direct referrals too, it's just hard to run a big study off of direct referrals.

Dr. Eric Kuhn: And out here in Palo Alto where we’re not as integrated into primary care as Kyle's team is in Syracuse, we had to go reach out to those clinics and go through the medical director of the clinic and then present at staff meetings and kind of give them the pitch about what this study’s about and what we're trying to accomplish. And it was across all 3 clinics that we’ve entered so far it’s been received so well, and that they just are so supportive of us coming into the clinic and helping with this. They really do see the need and they think that this could potentially help a lot of Veterans. So we didn't have much problem with getting buy-in and we often when we're sending these emails to the providers of the PCPs they might give us a call and talk with us about a patient, or they might be excited that this is available their patient. So I think that bodes well, potentially if the trial is successful for implementing this across a system, that there does seem to be a need and maybe a demand out there for this.

Molly: Thank you. Have you considered measures of patient health literacy and patient activation as mediation and moderating variables respectively?

Dr. Kyle Possemato: So we haven't in this study. I do a lot of research on folks with PTSD in primary care and we have in other studies. I have in other studies, and specifically with patient activation we have found, I've actually found it as a moderator in some studies. So folks with decent activation at the beginning do well and folks with a very low activation don't benefit from some interventions. But I think it would be interesting to think about it in the context of this study, too.

Dr. Eric Kuhn: I’m not as familiar with the patient activation literature. I think it's been developing over the time since when we originally kind of put this grant in and where we are today. But what we do have is we do have, which might be closely related, the measure of self-efficacy. Maybe if that's related in some way then maybe we’ll be able to look at that.

Molly: Thank you. While we wait for any further questions to come in I'd like to give you opportunity to make any concluding comments that you'd like to. Dr. Possemato?

Dr. Kyle Possemato: Well, I’ll just thank everyone for calling on and their interest in this study . We hopefully will have a good last year of recruitment and we'll be sharing study results after that.

Molly: Dr. Kuhn, did you want to add anything?

Dr. Eric Kuhn: Yeah, so I'm really super encouraged that we got a lot of clinicians on the call. We’re going to be presenting on the Tech into Care call on Wednesday of this week, which is going to be largely the same as what we've done today, maybe a little more emphasis on the clinician stuff. But I just encourage folks, if you're interested in not only PTSD Coach, but all of our other mobile apps, to reach out to us. You can find many of them on the National Center for PTSD’s website. Or you can just reach out to us. We have a number of materials that we've developed over the last year or so to support the implementation of these other apps and PTSD Coach if you want to use it in care. So we’re hoping to get the word out that these resources are available and that we do have some support at this point and we are building communities of practice around bringing Tech into Care. More to come, but reach out if you want some resources we’ll be happy to help out.

Dr. Kyle Possemato: And Eric’s plug of his apps reminded me of a plug I want to do too. So for those people who are interested in brief intervention to deliver in primary care. We, the VA Center for Integrated Health Care has a brief intervention protocol portal. We have a portal where people can go and download a number of manuals. This one's not up there because it's still in the midst of research but we have many others up there and if people email me I can send them the link.

Molly: Thank you, we have one last question that came in. Is there an age limit for this app?

Dr. Eric Kuhn: Not that I am aware of. We don't have an age limit in the study and I've had Veterans who are in their 80’s who have participated. I think we have to be careful to kind of assume that if somebody’s older that they're not going to be able to use the app. I’ve had younger Veterans who've had some difficulty using the app. In general it's very easy to use but some of the older Veterans are some of the superusers, where they've never had an intervention like this, and they really go get gung-ho about it. And so, I don't think there’s an upper limit. We do build all of our apps to be 508 compliant. So folks with visual, hearing and other types of impairments they can use our apps. So there's not that I'm aware of any upper limit. I think it might be a matter of kind of using it on an iPad or another larger tablet than on a smartphone. But with an orientation to the smartphone and to the app it seems like anybody of any age could use it.

Molly: Great. I'd like to thank you both very much for coming on and sharing your research and lending your expertise to the field. I'd also like to thank our attendees for joining us. I am going to close out the session in just a moment. Please wait while the feedback survey populates on your screen and take just a moment to fill out the questionnaire. It's just a few questions but we do look at your responses very closely. And with that I would like to also send my regards to Julie Craybuel [phonetic] who helps us organize this and each of the Spotlight on Mental Health Cyberseminars. Yeah, so thank you very much Kyle and Eric. Thank you to our attendees. And this does conclude today’s HSR&D’s Cyberseminar. Have a great rest of the day everyone.

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