Welcome to session T2006, problem solving treatment for service members with mild TBI, a randomized control trial. My name is Dr. Felicia Qashu. It is my pleasure to introduce Dr. Wesley Cole. Dr. Cole is one of our own at DVBIC. He is the senior clinical research director and neuropsychologist at our Ft. Bragg site.

This presentation will discuss how military duty demands, access to resources and the stigma of treatment, are various disservices to service members receiving care. How health approaches can be affective in overcoming treatment barriers. A sample of 356 service members with deployment sustained, mild TBI were recruited and given one of two interventions; telephone based problem solving treatment or TBI education only. Findings suggest, problem solving treatments resulted in significant improvements in emotional health, quality of sleep and depression. Please join me in welcoming Dr. Cole.

Thanks, Felicia, that pretty much covers it. So I will be taking questions at this time. So there is a title that Felicia mentioned, problem solving treatment to service members with Mild Traumatic Brain Injury randomized control trial. This research was conducted by the Intrust Consortium and supported by a grant from PYMC.

University of Washington was the core study site with Dr. Kathy Bell the PI. Data was collected at both Madigan and Womack army medical center, but I was the PI for that Womack site. There is a standard disclaimer just to let you know, I have no financial or other conflict of interest. Everything I am going to say or my views are not those of the Army or the Department of Defense. Another disclaimer, I am doing this at home due to some webcam network access issue, so the disclaimer is that there may be an interruption from a dog, hopefully not. I did make a deal with my wife, that if she entertained the dog for this hour, I would take her out for frozen yogurt later. It is a win-win for everybody in my book.

The learning objective, what I have done is I have broken this talk up into three primary parts. First I am going to discuss some of the challenges that services members face when they have sustained a TBI on deployment. These challenges are what guided the development of this intervention. The second part, I am going to review the intervention in detail, to build into a combination telehealth and problem solving intervention. In the long run, it is our hope that this intervention can be another tool for providers treating service members. Finally what I am going to do is discuss the results of a randomized control trial looking at this intervention, as compared to an education only treatment.

So some background, at this point in the summit and given most of your professional backgrounds and what you do day to day, it probably comes as no surprise that service members that sustain a TBI, including mild TBI, while deployed are at increased for experiencing persistent post concussive symptoms as well as emotional distress. The problem is that today there really are no standardized treatments for post concussive symptoms and it's common [inaudible] such as emotional distress. That's not to say that there are no treatments. Most of you who are involved in the summit, are treating this issue. There is not one standardized or a couple standardized treatments that we can turn to when dealing with these issues.

In addition there are numerous barriers that potentially interfere with service members receiving the needed treatment. For example there are duty demands placed on service members that make it difficult for them to seek out and receive treatment. I know a lot of times at Womack, we have service members that to cancel their appointments because the unit requires them to do, even though they are not supposed to, or even more annoyingly a service member will get multiple phone calls from someone in their unit when they are aware why they are not there and where are they. You can have those sorts of barriers, or if a service member is in the National Guard and is far away from medical center, or if they are stationed at a post without a without a large treatment center. There may be access to care issues.

Similarly, and especially those from the National Guard, there may be a financial issues related to the copay or paying for travel to service centers, or that prevent seeking care off coasts and outside of the military medical system. There is also the unfortunate fact that a stigma exists in the military surrounding
receiving care, especially for mental health issues. We fear a lot of support for our soldiers may be called dirt bags or worse because they have received [inaudible] for shirking their duties while they are seeking out care, regardless of how ill they may be.

Along with is stigma, is the concern that seeking out care may impact their careers. Due to impacting future promotions or medical discharge. Dr. Bernie discussed this exact point in his talk, that service members admitted as much to his study team. The goal of our intervention and subsequent study really stems from these two issues; the lack of standardized treatment and the potential barriers to receiving care. Specifically we sought to create a standardized treatment for post concussive symptoms that could be widely disseminated in its usual manner and was well accepted by service members.

So that was our goal, then what? We chose to take a cognitively based approach, as cognitive and cognitive behavioral treatment have been shown to potentially increase long term resilience. This is consistent with information that Dr. Reigler reviewed in her talk earlier. In a nutshell, cognitive and cognitive behaviorally based treatments both have found non-adaptive patterns of thinking and replacing them with healthy patterns of thinking that improve emotional well-being and increase positive behaviors. It is less of a touchy-feely feelings based approach and it can include components that are more solutions focused.

We also chose to use problem solving therapy, which is cognitive behavioral in nature. I'll explain this in more detail over the next few slides, but for now just know that problem solving therapy has been shown to affective at addressing a variety of psychological problems, medical problems and chronic pain. In fact I used to approach with adolescents with ADHD. So if you have ever been around an adolescent with ADHD you know if something can work with them, it is going to be pretty promising. I have to admit I was excited to see Dr. Sherry Wade mentioned by Dr. Reigler as a lot of the work I did when I worked with adolescents with ADHD was based largely on her work.

The other benefit of problem solving therapy it is patient centered. What this means is that the patient is very involved in guiding the direction, therefore it is usually well accepted by patients including military and veteran population. Finally we chose a telehealth approach, so this really marries well with the early process that Dr. Reigler did. Telehealth is a promising approach to treatment and it can help overcome some of the access to care barriers that are previously discussed, and again Dr. Reigler touched on this and really had a nice wide comparing telehealth versus face-to-face treatment in her talk. I will quickly touch on those again.

The telehealth allows for an element of anonymity since the service member does not have to go to a physical location, such as a mental health clinic. Second it can be scheduled at times convenient for the service member rather than being held within clinic hours or during their regular duty hours. We chose telehealth over web based and video based interventions since virtually everyone has access to a telephone. So again, it is overcoming some of the access to care barriers. In past studies by Cathy Bell and the University of Washington have established the feasibility of telehealth approaches in civilians with TBI, even when their injuries are more severe or even in the presence of cognitive impairment.

All this taken together, led to the decision to develop and manualize telephone delivered, problem solving therapy based intervention, and so that you don't have to hear me say manualized telephone delivered problem solving therapy based intervention a thousand more times, I am just going to call it PST for problem solving therapy from this point forward. The reference you see here is a protocol paper published in the journal Contemporary Clinical Trials, and this reviews the intervention and our study design in detail.

I also want to take this opportunity to let you know that most of this information can also be found on our relatively new website www.contact4TBI.com, that is four as in the number four, contact4TBI.com. I have it over my shoulder here, I am not sure if you can see that, it may also be inverse due to the webcam.
That is the website, it was not active when I finalized and submitted these slides, apologizes for the web address not being listed here. It was just put out in the last couple of weeks.

Each service member was randomized in the PST and was assigned a concussion support specialist or CSS. This was a masters level individual who received extensive training in the intervention and was supervised by a licensed psychologist. The CSS conducted up to 12 bi-weekly phone calls over a six month period, with each call lasting 30 to 45 minutes approximately. Using didactic information and concrete examples PST would talk to the participants. Then once PST was ready to be implemented, the problems of focus were selected by the participants, with some additional structure and guidance provided as needed.

Let's talk more specifically about problem solving therapy. Dr. Reigler had a slide where there was an image of the steps. I will go into detail about those steps now. It is a great intervention to teach to patients because it's broken down into six steps labeled A through F. I think Dr. Reigler's slide had A through E, we added an additional step, F. That makes it really easy to remember and it's also great because it can be applied to a wide range of issues.

I am going to use and example off of the contacts4TBI.com website. The problem is, and I have to admit this hits a little too close to home, I need to get in shape and get more exercise. Also, since I didn't include interactive poles in this talk, please feel free to make this the interactive portion of the presentation and choose a problem for yourself and walk yourself through the steps with me.

The first step, A, is for assess, and specifically to assess the problem. So in other words, participants were encouraged to clearly define the problem, characterize it, and truly understand it. Saying I need more exercise is not specific enough. How many times per week, and for how long would you like to exercise? Is there any barriers to the goal, such as access to a gym or exercise equipment? For those of you doing this as an interactive activity, you can pick anything like time management or organization, finances, eating habits, whatever. Really think about what the true core of the problem is, for example if you problem is I don't have enough time to spend with my family, maybe the true problem is that I overload my schedule, or I don't manage my time well, or I am too tired by the end of day because I don't sleep well.

Moving onto the next step, B is for brainstorm solutions to help with your problems, and this is an anything goes step. So no matter how crazy the solution may seem, put it on the list. This really should be a fun step, the more fun you have with it, the more uninhibited you will be in coming up with solutions, and the more likely you will be able to create a really great list of solutions. For those of you doing this interactivelly, think of a few things to address your problems and remember, anything goes. For my problem related to exercise, perhaps I could go to the local high school track and run if I don't belong to a gym, and that is going to be free, or I could find a community center with inexpensive exercise classes that I could join.

So C is -- I almost said C is for cookies. It is not for cookie but for consider and choose. You can see Sesame Street you know it sticks with you for a long time. This involves determining the pros and cons of each solution. So consider and choose. Think about the handful of potential solutions you may have been able to come up with quickly. What are some of the potentially positive outcomes, what about some of the potentially negative outcomes? So for my exercise problem, the pros of a high school track is that it is free, it is convenient, it is close by. The cons is that if the weather is bad I won't be able to use it, and also it pretty much limits me to one type of exercise, running or walking. For the community center, the pros are it may be inexpensive, I could get a variety of different exercises, but the cons are that it might not be as close to me as the high school track, and it may still cost me money even if it is inexpensive. Although that could be a pro because if I pay for it I may be more likely to use it. You can see that it really takes a lot of fleshing out to do.
So once you have identified the solution that will maximize pros while minimizing cons, you choose that one. Remember it may not be what initially may seem like the best solution on paper, because perhaps one of the cons of the best solution would be that it is difficult to implement, or it is difficult to sustain. So perhaps you go with an easier solution at first. Even though the community center seems like the best solution on paper, maybe I try the track first because it will be a little bit easier to do.

D is for do it. So on the website it is listed as develop, as in develop the plan and then do it. Implement the solution, or solutions using a concrete plan with detailed and operationalized steps. That is really the key. It should be concrete, clear, and ultimately feasible. Also it is recommended that you develop a backup plan. You really want to set yourself up for success. For those of you playing along, you actually can't move forward with your example because I don't want people leaving the talk to go try their solutions. Unless your problem was staying awake during the talk, then by all means try your solution. For the example of exercising that I have been using, I have to sort of plan a workout three days of the week, stopping on my way home from work. I will enter a reminder into my phone, so that I don't forget to take my gym bag and my workout clothes, and I don't forget to stop on my way home.

E, that is for evaluation. So after a period of time, determine if you are satisfied with the progress and outcome of implementing the solution. Did you have success? Were there short comings and if so why was that? What can you do to overcome those shortcomings?

Finally, F is or fight on. Keep on going with the solutions if they seem to be working, and if not return to earlier steps; the brainstorm step, the consider and choose step. It is the problem solving equivalent of rinse and repeat. Go back to the earlier steps and try again. Remember that success doesn't come overnight. It is unlikely that something is going to work the first, second or even third time. So you need to fight on and persist to meet your goals. Just quickly some of the examples brought up by my participants included a lack of time to complete responsibilities and irritability or short-temperedness, financial problems, and inter-personal conflicts.

So in addition to the steps of PST, modules were also available to the concussion support specialist. These modules have anticipated common problems, such as depression, post-traumatic symptoms and anxiety, sleep disturbances, and headaches. These modules included an initial assessment view, an educational component, and therapeutic strategies that CFS could walk the individual through.

But strategies were based on principles of behavioral activation, cognitive behavioral therapy, and problem [inaudible]. They are a bit more structured and guided than using PST alone on the participant-selected problems. Each module is designed to last two to four sessions, and after completion of a module, it is determined if a referral for additional treatment is warranted.

That notion about referring for additional treatment brings us to the busiest slide. Don't worry, I'm not going to go through this entire slide. Focus on the top couple of boxes, definitely to box if you can see it. If not, I will tell you what it says, and then the bottom boxes. Basically what it says at the top is that a problem area was reviewed, and if no concerns were identified, they proceeded to an exit interview, which is right there on the left. That was not a common occurrence, because we were recruiting from a clinic. Those were the clinical population, they had problems. If concerns were identified, then the severity was clarified, and the determination for the level of care was made.

Here is where I attempted some animation. Let's hope it works. I'm a little bit hesitant, given how some of the other presentations have gone. For most participants, what we saw -- hey that looks like it's working well, so you're getting that. We basically saw yes, concerns were identified. It was a low level of concern, and we deemed that a level one care, which basically was the PST, including the modules, was sufficient. Low-risk PST was good.
However, if the risk was higher, then they would go down the other side of that graph, and we'll see if it works here. There was a higher level of concern, therefore, more intensive treatment is indicated, such as an out-patient clinic, or even emergency care in some situations. That would then be recommended and coordinated with the local site.

That's your crash-course on the intervention. Again, there's a protocol paper published that provides more information. This is another shameless plug for the website. Contact4TBI.com, again the number four. This includes information about PST, about our study, links to additional information and resources, and links to relevant publications. Content's going to continue to grow in the study of -- on this website. It's not even been up and active for a month yet. It's going to grow the content, it'll continue to be refined. Hopefully we can get a link from the (inaudible), hint hint.

Let's turn our attention to the details of the randomized control trial. First, service members who sustained a mild TBI while deployed to OAF, OEF, or OND within the past two years were eligible. They were recruited from, again, both Womack and Madigan Army Medical Centers' TBI clinic. As the shadow, all my friends at Womack now watching this. There had to be an affirmative mild TBI screening at the post-deployment health exam, and a positive screening on the clinic's respective questionnaire measuring TBI symptoms. It's pretty minimally restrictive criteria, and we did that for a reason. We wanted to capture the "typical" service member dealing with issues after deployment-sustained a mild TBI.

Participants were then randomized into the PST group, or into an education-only group. I will explain what the education-only group is on the next slide. It is important to note that usual care was not interrupted at any time during our intervention. Those randomized into the education-only group were provided with twelve informational brochures upon enrollment. These brochures dealt with common problems after mild TBI in deployment. You can see the complete list of problems on the slide, but they include things like stress, headache, sleep disorders, finances, anger, and post-traumatic stress. These brochures were based on peer-reviewed literature, and reviewed by the Madigan Education Coordinator for military-appropriate content. Additional copies were mailed out to the participants throughout the study. I also want to note that the PST group also received these educational brochures. So essentially, the PST group was the education plus the problem-solving therapy.

Outcomes were assessed by obtaining a baseline assessment at time of enrollment. An in-person assessment collected demographic information, injury history, and medical history. Then we turned the participant over to an outcomes examiner, who completed the rest of the baseline assessment by phone, and they were located at the call center at University of Washington. This outcomes examiner was different from the CSS, the person that walked me through the intervention that I had talked about earlier, because they had to be blind to the participant's group.

Follow-up assessments were conducted at six months post-enrollment, and I want to clarify that later in this call I call it six months post-treatment. It's six months into the study, so it's really a six month post-treatment-initiation, which also corresponds with the end of the active treatment period. Assessments at twelve months post-enrollment were also conducted, and both of those follow-up assessments were conducted by the blinded outcomes examiners.

Our hypotheses. The primary outcomes were related to the six-month follow-up period, that initial post-treatment period. This typically comes shortly after treatment was completed. We hypothesized that PSP would result in lower levels of post-concussive symptoms and emotional distress in the education-only group. We also hypothesized that PSP would result in greater improvement than education only across areas of physical and emotional well-being at the six-month follow-up. We expected PSP to be well-received by participants, as indicated by a satisfaction survey. Finally, we expected those gains to be maintained at the twelve-month follow-up time point.
Here’s how we measure those outcomes. Post-concussive symptoms were measured by the Rivermead Post-Concussive Symptoms Questionnaire, or RPSQ. Most of you are familiar with this. It’s a well-established, commonly used questionnaire of post-concussive symptoms. It includes things like headaches, dizziness, sleep disturbances, fatigue, irritability, and other emotional symptoms and cognitive symptoms.

To measure emotional distress, we used -- Oops, went too far there. To measure emotional distress, we used the Brief Symptom Inventory Eighteen, or BSI Eighteen. This is brief measure of psychological factors. These are the two primary measures, but there were many other assessments that we conducted. This allowed us to look at a host of factors. I’m not going to read off the list of measures, they are all listed here for you to see. As you can see, we measure things such as quality of life, symptoms of PTSD, sleep, resiliency, alcohol use, functional abilities, depression, and suicidality. We also collected information about other medical services that participants were receiving, as well as their satisfaction with the intervention that they were receiving throughout the study, whether that was PST or education-only.

That’s the [inaudible] analysis you use to make the vector regression analysis. This is a form of linear regression. It's ideal for repeated measures, which is what we did. It takes into account both fixed and random effects that may be driving groups differently. If analysis determines that the outcome scores from the measures I just reviewed are different between baseline assessment and fixed month assessment, and if so, if that difference was driven by which group the participant was in, PST or education-only.

These analyses were planned to control the variables that were unbalanced between the PST and education-only groups that base-line. This ensures that demographic variables aren't driving anything. We also wanted to look within the PST to determine if there was any imbalance between those participants who dropped out before the intervention was completed, and those who were labeled completers of the intervention. The remaining participants in the PST are going to receive up to twelve calls in a six-month period. Not everyone needed that many calls, so we [inaudible] completers as those individuals the took part in at least four intervention calls. We did see that those contacted for follow-up assessments across both groups typically were older and more educated than the entire baseline group, so those variables were controlled well. Again, we repeated this analytical approach for the exploratory variables.

 Enough about stats, let's get into some numbers here. Before we get into specific results, here are the numbers for our participants. Across both sites, we enrolled three-hundred and fifty-six individuals, with fifty percent randomized into each of the groups. I have sixty-seven percent of the PST group completed at least four sessions, so those were our completers. The mean number of sessions was six point five and median was seven, so we'll call it seven sessions. At six months, seventy-eight percent of the original PST group completed post-intervention assessment, and ninety-three percent of the education-only group completed assessments at the at same point. About eighty percent of the PST group completed twelve-month follow-up assessments, but eighty-eight percent of the education-only group completed assessments with [inaudible]. I just think it's worth congratulating the outcomes examiners at University of Washington for those incredible follow-up numbers, those are pretty remarkable. They did a fantastic job with that.

I'm a little bit of a liar. Earlier, I said that was the busiest slide in the presentation. This is clearly the busiest slide, don't worry, I'm not going to spend too much sign on this. Again, I attempted some animations. If it doesn't work, you're not going to miss much. It's just some arrows that are going to pop up and highlight what I'm going to click eventually, so let's try it.

The point was to show you that we evaluated equivalency between groups, and here we've got all randomized subjects, those in PST and those in education-only. We have the T value on the right. We looked at recruitment sites, it was not [inaudible] different between the groups. Age, not different. Gender, not different. Race, not different. Ethnicity, sensing a pattern here. Education status, not different between the groups. Military status, irregular versus a National Guard, not different. Number of deployments to
combat zone, again not different. A lot of equivalency between groups to start out with. That's great, that's what we wanted to see. I just wanted to point out that we did evaluate for that. Basically, the summary of that really busy slide was that PST and education-only groups are generally equivalent across demographic and injury variables.

All right, moving on. Here are the results of the six-month assessments for the Rivermead. A table is up at the top for those of you who like numbers, and a graph on the bottom for those of you who like visual representation data. There was a reduction in reported symptoms. It wasn't huge, it was only a couple of points. It was present across groups, and the difference between the two was not that significant, so the P value there will be --

Let's look at the same slide, but for emotional distress. Again, that is measured by the BSI 18. As you can see, ratings in emotional stress were reduced in the PST group, represented in blue, but not for the education only group, represented in red. The [inaudible] treatment group interaction variable was statistically significant, indicating that PST positively impacted ratings of personal distress.

Well, that was exciting. I'm not going to walk you through slide after side of each of the exploratory variables, so I'm just going to summarize here. To summarize, there were significant differences in that time by group interactions at six months in support of PST on measures of depressions, sleep quality, and ratings of general physical well-being. Additionally, PST was rated higher than education-only on satisfaction ratings with the kind of help, as well as the amount of help received. Some of the exploratory analysis did yield some positive results. However, not all was rosy. The benefits did not seem to hold at the twelve month follow-up.

Let's look into the data with a little more detail. If we look at the Rivermead data, the first two data points are what you previously saw, so I have added in the twelve-month follow-up data. There continue to be no significant differences between the groups. But what's interesting about this graph, is that you'll notice post-concussive symptoms did decline over time across both groups. It should fit PST did not result in a greater decline than educational. I think it is interesting, it indirectly supports the research and maybe [inaudible] that post-concussive symptoms usually do improve with time. And again, this isn't a group that was experiencing these symptoms chronically. I'm not sure, just based on this data, if this is a significant or even a clinically meaningful decline, but there was a little bit of a decline there.

Let's look at the emotional distress data. Again, the first two data points are what you saw before. I've added in the twelve-month data for emotional distress. You can see a significant decline in the PST group at six months, instead of the return of those symptoms over the six-months period, after the intervention. The point that return when there is no significant difference between groups. In other words, when intervention was removed, the symptoms appear to return. That same pattern was observed for the other exploratory variables I mentioned earlier that showed significant positive effects of PST at six months.

To summarize, after PST was completed, we saw benefits for the telephone-based intervention for levels of emotional distress, physical well-being, depression, and quality of sleep. [inaudible] was also well-received be service members. However, the twelve month data was like a big bucket of ice water on the enthusiasm that may have existed for the six month data, because those gains were not maintained at twelve months.

But not all is lost. What we're taking from this, at this point in time, is that we concluded, interventions like telephone-based problem-solving therapy may hold several advantages when treating service-members who have sustained combat-related injuries. Disadvantages include being client-centered, getting around access to care-barriers, avoiding stigma by increasing privacy and not focusing on feelings. They can be adapted for a wide range of problems. I also all hope you saw Dr. See-foo's [phonetic] talk this morning, it was excellent. He discussed the importance of addressing a wide range of problems, including quality of
life and good long [inaudible]. We still got our intervention to be a beneficial part of a treatment program to build in.

Let's talk about limitations and future directions. Moving forward, we definitely see a need to further investigate the impact on post-concussive symptoms. One of the things we wanted to note is that the Rivermead includes a wide range of problems, and we were investigating that bottom-line total score, so that may have masked some of the improvements in more specific areas. Also, it may be that concussive symptoms are going to resolve anyway, so you're not adding a lot by throwing an intervention on top. Most of us should know by now that for the majority of these individuals, these symptoms typically resolve within thirty to ninety days post-injury, and when problems are present beyond that point, it is typically due to psychological distress. Or, as Dr. See-foo [phonetic] discussed, that vicious cycle that starts with post-concussive symptoms that spirals downwards, due to a host of other factors.

Perhaps it's not surprising that positive [inaudible] primarily seen from emotional distress, and those types of issues may be what's driving those persistent symptoms, especially in a group seeing care for chronic problems. However, it is concerning that these symptoms of emotional distress symptoms return when the intervention was removed.

A few other notes. We had a slight larger loss of followers in the PST group, and that could result in bias in either direction, but it's important to know as a limitation to the study. Also, we did not require a minimum level of symptomology to be entered into the study. You may remember from one of the earlier slides, I said that we intentionally kept the eligibility criteria minimally restrictive, because we didn't ensure high levels of symptoms or distress to be present before enrolling, we may have decreased our statistical power, limiting our ability find it. Therefore, I actually think it's kind of impressive that we found several statistically significant effects. But as I noted, these effects were not maintained, and therefore what we need to do is look at the dose effect.

We need to determine if the amount and frequency the intervention was delivered needs to be adjusted, or if treatment should be extended, or if future sessions would help maintain positive gains. Regardless, we feel this approach shows a lot of promise, and could be beneficial to service members. We really encourage you to visit the website. It has a lot more information.

What I wanted to do here was call attention to the many collaborators and contributors to this site. Womack, like Madigan, was a collaborating site, so a lot of the heavy lifting was done by the folks a University of Washington, specifically by Kathy Dawn and her team. We've also received a significant amount of support from folks at UC San Diego, as well as Pee-too, Dee-coh, and Diz-ick, [phonetic] and other folks at the site listed here. That information is available on the website. Again that website is www.contact4TBI.com.

The next three slides are the references or support for the data I presented here. They give you some background information, and also includes the protocol paper we published in a contemporary clinical trial, with Cathy Bell as the first author. We have submitted an outcomes paper reviewing the data on the primary outcomes that I discussed here, and hopefully that's going to be out there in the literature soon. Again, links to these papers and other valuable resources are available on the website.

My gift to you is that it's the end of the day, and I am done with sixteen minutes left. I guess now is question time, and then wrap up time. Thank you.

Thank you, Wes. We will now take questions from the audience here at DHHQ --
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We have a question from the virtual audience. You spoke about this a little bit, but one of the questions was, "Since the treatment effect didn't last to the twelve-month time point, do you think that that would require continued treatment beyond the time point you gave the treatment?"

Yeah, I think -- Possibly. I think that's one of things that we really need to look at. Does it necessitate longer treatment? Does it necessitate more frequent treatment during that six-month time period? Is twelve just an arbitrary cutoff, and should we extend it? Or, could we maintain those benefits with just booster sessions, maybe scaling back. Instead of calling every other week, we call once a month for a few months, and then we call once every other month. But, I think that's a great question, that's a great point, something we need to look at, because we did see some positive effects, and I think we need to figure out how do we maintain those.

Great. Another question that came in, maybe it was on your patient demographics slide. "Did you collect data on rank?"

Did we collect data on rank? I don't know that off the top of my head. Let me go back. I'm scrolling back through these, oh here we go. I think the short answer is, we did. I don't have data on that. We did collect data on rank. I don't have data. We didn't look -- I didn't present data on the equivalency on that. To some effect, that's controlled when you look at education data, and some other data sets that I've done. Education data tends to correlate which rank, and also with the age, but the short answer is that I don't have data [inaudible] rank for my groups. Good question though, thank you.

One more question just came in, I think it was referring to your response to the previous question. "Does that people may need to accept that symptoms will need to be managed rather than being eliminated?"

Yeah, I think so, and I think that's what Dr. See-foo [phonetic] kind of hinted at, that you really need to do a lot of lifestyle changes. You really need to put things in place that manage those symptoms to decrease the impact on your life. Again, I don't think from the data set in this study I can definitively answer that, but I think the experiences that we have, the work that we do, the research that's out there, I think those suggest that you may not ever be able to completely eliminate symptoms. Ideally that's the goal, but you may not be able to, so then it comes down to effectively managing those symptoms. I think that's the case for a lot of people, especially those people who are having chronic issues.

Great, thank you so much Dr. Cole. I hope you can -- Wait, one more question, last minute.

Yeah, I see them coming in there.

"What is your feeling on the differences on telephone-based treatment via the tele-health treatment."

I'm not sure I completely understand the question. Telephone-based [inaudible]. I'm not sure I completely understand that question, I'm sorry.

Oh, maybe I misread it. "What is your feeling on the differences on telephone-based treatment versus the tele-health treatment."

Again, I'm not sure I completely understand what they mean. Is he talking about the treatment that Dr. Reed discussed?

Yes, so perhaps that instead of video tele-health, or even the virtual health --

I see. Like more video-based --
With avatars.

Web based. I'm sorry I didn't understand that. I think they both have benefits. Thanks for clarifying that, that's the difference. I don't know if I have a strong feeling that one's preferred over the other. We chose telephone-based because we anticipated dealing with some National Guard folks who may leave their duty station and go back home and may have inconsistent web access.

Basically, data show that pretty much everyone has access to a telephone, but not everybody has ready access to web-based -- to internet basically, so web-based may not be possible. It's becoming more and more common, but just to potentially circumvent that, telephone was chosen here. There may be a benefit, and now I'm just speculating that talking over the phone and not having that video chat, I have completely avoided looking at myself while I'm doing it, because the window of my video feed is right there staring back at me. That makes me a little uncomfortable, so I don't love the video. I don't think anybody really likes to see how they look on video. But also, there's just that anonymity that could be there, and give some of the stigma that's attached, perhaps it could overcome some of that.

That'd be an interesting question to look at. I think that's a good point, that the viewer there brings up.

Okay, thanks. That's all the questions. Thank you Dr. Cole, and I hope you can give your dog a treat, as well as your wife with the ice cream tonight because -

Frozen yogurt.

[crosstalk]

Thanks everybody, I appreciate it.

[crosstalk]

Thank you.