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United Spinal Webinar

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>>CART Captioner: Standing by.

>> Female Speaker: Good afternoon. Thanks for joining the United Spinal webinar, "What is the Vibe?" Presented by Ms. Jennifer French, MBA, and Doctor Kimberly Anderson-Erisman. I will be your moderator for today's presentation. Today's webinar is one of a

continuing series that United Spinal Association will be hosting, and all of our webinars are archived at WWW.spinalcord.org. Use the question's window on the control panel to post any questions that you may have and we'll do our best to get to them today. If we do run out of time during the question and answer session, you may pose your question directly to the presenters for later follow up. And I would like to call attention to the handouts section of your control panel, will you find today's PowerPoint presentation as well as closed captioning instructions as needed. Jennifer French, MBA, became a quadriplegic from a C6/7 incomplete spinal cord injury in 1998. She is an active user of the functional electrical STIM relation implantable expand and transfer system. She first received in 1999. That's a mouthful.

As a user of neuro technology, who has reaped its benefits, she is a cofounder and Executive Director of the nonprofit organization NeuroTech Network. She currently serves on several advisory boards in the neuro tech field and an accomplished speaker -- TED Talks, the World Science Festival, and the National Academy of Sciences. Jen is an author of "On My Feet Again: My Journey Out of the Wheelchair Using Neuro Technology" and eye on Ike pioneers. Blaze the trail to new therapies. Doctor Kimberly Anderson Erisman is the research professor and Director of Education for the Miami project to cure paralysis at the Miami School of Medicine. Her research is focused on the translational investigations bridging the gap between basic

science, political science, and the public community living with spinal cord injury. Her training spans the spectrum of spinal cord research. Cellular, molecular study, whole, animal, behavioral studies in human clinical research as a faculty member of the University of California, Irvine, and now the University of Miami. Her current projects focus on aging related changes in bladder health after SCI. Determining the minimum amount of exercise and loco motor training required for clinical trials targeting chronic SCI, and identifying the factors and barriers to clinical trial participation from the SCI consumer perspective.

In addition to pursuing her own research regarding chronic injury, she serves as a scientific interface to the public for the first array of research being conducted at the Miami project and is also now managing the first cellular transplant patient clinical trial. Doctor Anderson Erisman is a member of the United Spinal association's medical and scientific advisory committee. And now, I would like to hand it off to Ms. Jennifer French to begin today's presentation.

Jennifer?

>> Jennifer: Thanks, bill. That's a great introduction. Thank you all for attending our webinar today. I know Bill mentioned that we have the handouts there in the control box. You are more than welcome to download that. The PDF is also available on the NeuroTech Network website as well as the Miami project website. So feel free to

download that and follow along, add any of your notes. We have all of the active links in the PDF. Please don't feel that you need to write down a lot of notes from each slide, we have that available for you to download. Let's also start to dig into the questions too. As Bill mentioned, we have a question box in the control panel. We'll be happy to address questions at the end. We'll have plenty of time for that. If you have any questions, type them in, and we'll try to address them at the end of the webinar. If there's not enough time, we'll attempt to address them individually as well.

So moving on, we want to first introduce you to both Kim and my organization. So first, I would like to hand it over to Kim. If you can introduce the Miami project to the folks that are on the webinar.

>> Kimberly: Yes. The Miami project is located at the University of Miami. And their mission is dedicated to finding more effective treatments and ultimately a cure for paralysis resulting from spinal cord injury.

>> Jennifer: Thanks, Kim. NeuroTech Network, a nonprofit focusing on the education dissemination of neuro technology, devices, therapies, and treatments for people with impairments and their caregivers and the front line medical professionals who care for them. So that explains what our two organizations are. We're very focused on education and with spinal cord injury as well.

We do have to add a little bit of our disclaimers involved with this webinars. The information that's presented is not meant to replace

any advice from a medical professional. You should consult your healthcare professional familiar with your specific case, concerns and conditions. NeuroTech Network and its representatives do not endorse, rate, sell, sell, prescribe, administer, or recommend any product, procedure, or services. Again, we highly suggest that you take the information that you are getting from this webinar and share it with the medical professional to discuss the options that are very specific to you. We also want to point out what we will be presenting today is a lot of under clinical trials been some of the devices and therapies we'll be talking about really should be used under some type of super-advisory condition. We wanted to make everyone aware of the precaution if you were going to be using this type of technology at home.

Who what are we talking about today?

What we're going to be talking about is introducing you to Vibration Therapy but focusing on a rehabilitation tool. Now I will point out that Vibration Therapy is available for other use and continues such as sexual function, and there's a lot in the literature about that, but for the purposes of this webinar, we're going to be focusing on Vibration Therapy as a rehabilitation tool. So we're going to introduce you to the difference between rehabilitation and exercise. Define what Vibration Therapy is. Help you understand the difference between partial, focal or segmented. There's a lot of different terms for that. Vibration, versus whole body vibration. And talk about some of the

supporting research and evidence that's available to support Vibration Therapy as a rehabilitation tool. Introduce you to some of the active clinical trials going on, particularly in the United States, and also giving you an overview of the technologies that are available today and available on the market. -- the technologies that are available today and how do you access those technologies.

We'll end the webinar with resources where you can learn more about the technologies and be able to access them.

So with that we want to introduce you to the difference between rehabilitation and exercise. Sometimes people use them interchangeably, but really the definitions of them are very different. When we think about rehabilitation, it's really a treatment or a combination of treatments that are really designed to facilitate the process of recovery from an injury and illness or disease to as normal as a condition as possible. Again, rehabilitation really focuses on restoration or recovery. On compensation. Maybe compensating for some muscles that are no longer working to or no longer have full voluntary function, to identify the limitation and what adjustments you need to make in your life with a new condition and a new injury, and also to focus on independence. That's what rehabilitation really is. It's the focus of restoration and recovery, and how do you live a full active life with the condition that you currently have.

Whereas exercise is really different because exercise is really focusing on an activity that is planned, that is really repetitive and the purpose

is for conditioning the body. So the focus of exercise is different from rehabilitation in that its focus is on improving your condition, maintaining or improving your health, and prevention and performance. Sometimes the lines can be blurred, but when we are talking about using Vibration Therapy as a rehabilitation tool, compared to using as an exercise tool, you will see that in some sophomore the Vibration Therapy therapies were -- some of the Vibration Therapy therapies were gained from the use of the exercises comparable to rehabilitation. With that, I would like to hand it over to Kim to go into more detail about Vibration Therapy. Kim?

>> Kimberly: Yes. I am going to tell us a little bit about Vibration Therapy. And what are some of the benefits. So, first of all, just by definition, vibration is mechanical, repetitive movement or an oscillating movement, which is basically a back and forth type movement, and oscillating. And around an equilibrium point. It's a forced oscillation where vibrations are generated by motors transmitted to the person either in a specifically targeted area or across the whole body.

Now one example you can see with this old image right there of using a belt to shake the abdominal area. When it comes to using vibration as a therapy, it was actually first study was published in 1969 and it was using vibration as a therapy tool for those that had survived strokes.

And it gained popularity more recently in the last several years when it's been used by professional athletes. I am sure many people probably have seen the vibrating platforms at stores or gyms and they are used in combination of exercise that way. What we want to look at is how it's being used with therapy. The effects of vibration are really thought to be a result of muscle excitation or spinal motor neuron excitation. And the benefits that we'll talk about as we go along may be attributed to either of those. We're not really sure exactly which one it is a true mechanism. It may be a combination. Like I mentioned, can you do partial vibration therapy or you can do whole body vibration therapy. If you look at the first image, it's an example of partial or focal vibration using a little device. For example, vibrating just the knee area.

Another example is with whole body vibration. And you can see who figures here. One where the person is standing on a platform and vibrating straight up and down or using an alternating pattern. I can tell you a little bit more about this alternating pattern versus the up and down vertical. It's called oscillating or linear.

And oscillating you can kind of imagine as if you were standing on a teeter totter. Each side of the platform goes down in an alternate mechanism. If you spread your feet further apart on the platform, you will actually move at a greater magnitude than if you have your feet closer to the center. That is called amplitude. The distance by which the platform moves. Alternatively, you can also do linear, the

whole platform moves up and down at the same movement. There's really no clear evidence as to whether or not one is superior to the other, so it's just a matter of preference and the particular machine. So there is some evidence already published in the literature, which is what we are focusing on today, and I am going to tell you about different dose orders. So for strokes, for example, it's been shown that when used in the upper extremity, it can reduce spasticity in the arm or the hand. It can also be used to improve proprioception which can involve balance and can help improve global awareness. Importantly, it can help improve the dexterity of the arm. That's getting at functional, and motor.

In the lower extremity, it's been shown in some studies that Vibration Therapy can increase walking speed after stroke or possibly improve Dorsiflexion, and plantar flexion, where you lift your ankle in a situation called foot drop, and also been shown to improve knee flexion and extension. It's important to know that the particular studies have all been somewhat small studies. There is some controversy in the literature where some studies that used larger sample sizes or used a placebo or a control. And they have shown there is no benefit. But like I mentioned, you really need to go with different variety of injuries and types of functional or reduction changes and see whether or not that is actually applicable to the individuals.

As in spinal cord injuries, stroke has a great amount of variability

between people's injury. That may be similar to the contributions, the findings. Alternatively, the improvements or changes may be small, so they're washed out when you use a larger sample.

There's also evidence for benefit in multiple sclerosis and Parkinson's disease.

And for multiple sclerosis, one of the benefits has been a partial decrease in fatigue. Also a decrease in tone. Tone is somewhat similar to spasticity. Some studies have shown improved muscle force and sensation, or improvement in postural control. But there's again a variability in the magnitude of the benefit

When it comes to Parkinson's disease, there's improvements in walking speed, stride duration, and cadence. It doesn't change it 100%. Just partial improvement. There's also been some improvement, i.e., reduction in tremor and rigidity, which is a similar concept to spasticity, a similar mechanism. Some small studies demonstrated improvement in gait and toe turn. A larger double blind study -- posture. And a larger double blind study shows a different.

In evidence for spinal cord injury, there's been improvement. Upper extremity it's been shown to decrease spasticity, and improvement sensorimotor function, or motor function by reducing spasticity it can help improve the range of motion. There's been some demonstration that improved functional gain can be combined

with repetitive motion therapy and get a larger effect than with just Vibration Therapy by itself. For the lower extremity, after spinal cord injury there's been some documented improvement in blood flow and circulation with vibration. Again, a decrease in spasticity. And one study has demonstrated an improvement in walking function in individuals with motor incomplete after an injury.

I'm going to go into this just a little bit more, spinal cord injury.

So if you notice, from where I have been talking about with the benefits and all the different disorders, the biggest effect of Vibration Therapy seems to be that it can reduce spasticity either in the upper extremity or the lower extremity. Now I mentioned focal vibration, versus whole body vibration, and for spinal cord injury, there's evidence that the folk value vibration effect, in the reduction of spasticity can last for a maximum of 24-hours.

However, if you do whole body vibration, those effects can last 6 or 7 days. It's something to think about when considering for your use.

The focal vibration can elicit step-up behavior in motor complete or motor incomplete injuries, but those behaviors need the vibration.

For example, if you take the vibration away, the step like behaviors go away. What the vibration does is a temporary effect. It modulates the information in the spinal cord and the muscles but doesn't permanently change that. It's connection. So some precautions and risks to be aware of. Like Jen mentioned in the beginning, everything that we're reporting here is based on what is reported in the literature.

So in the literature, there have been no serious adverse events reported. So that's good. And some of the most frequently cited side effects are in the lower extremity you can get reddening of the skin, you can get an itchy feeling over where it's being vibrated, and anecdotal reporting of negative side effects in the musculoskeletal system, the digestive system, the vascular system, re-productive system, visual, and vestibular system. What that means is that there's anecdotal reporting of negative effects. But as I mentioned, there have been no serious adverse events reported in the literature. Now, in order to try to figure out what you are supposed to do with the vibration, unfortunately, there's no consensus. So there are certain parameters that are common in the literature. So, for example, the frequency -- now the studies that I have reported, the frequency ranges from 25 to 50-hertz. And then the amplitude, the height, or the distance of the movement, ranges from 2 to 10-millimeter. It's a very short, very small amplitude. Then the duration of the Vibration Therapy ranges from just 30 seconds to 10 minutes. There's all kinds of varieties in those parameters where it may just be done once or it may be done multiple times over a set period of time or multiple days a week or for multiple days, multiple week, so it really depends on what the question is that is being asked.

So now we're going to hand it over to Jen, and she's going to talk about some various clinical trials.

>> Jennifer: Thank you, Kim. Kim set the basis of what evidence is

available, what are the precautions we need to take. Now we're going to go into what we are studying, what are we trying to see from a human curriculum trial standpoint from understanding kind of the next steps, if you will, for the Vibration Therapy. Before going into the specific clinical trial, I will note that they're all listed at clinicaltrials.gov. We'll give you an identifying number. An NCT number, and that's an easy way to look up that specific clinical trial. And there's a lot of other clinical trials going on, but we're only focusing on those that are active and recruiting. First I would like to highlight some of the curriculum trials going on with stroke patients.

So the first -- clinical trials with stroke patients. The first one, impaired leg or lower limb for chronic stroke patients or stroke survivors. That's that have impaired ankles which with a substantial impairment. AKA, known as drop foot, which Kim mentioned earlier. The interesting thing about this clinical trial is they're look at not just Vibration Therapy, but from a rehabilitation standpoint how it compares to conventional therapy. That's a multi-centered trial. Oregon Health and Science, and northwestern University, and rehabilitation institute of Chicago. There's the NCT number to be able to look up the clinical trial. Another interesting one is using Vibration Therapy for stroke survivors. This is for the upper extremity and for the arm, if you will. They're really looking at how vibration therapy affects the improvements of the proximal in terms of arm. They're looking at two areas, and a combined therapy. Not just vibration,

they're looking at bio feedback and assistive movement, and seeing what kind of impact and functional gains the people in the studies are gaining from that. Again, there's the NCT number to look it up in clinicaltrials.gov. A single center trial being held at Oregon Health and Science University. The third clinical trial that we would like to highlight is in regard to balance. For a lot of stroke survivors, balance becomes an issue, particularly if they've hemiplegia or paralysis on one side of the body. This trial is taking place in France. They're looking at Vibration Therapy and how it impacts balance and the impact of that balance on daily living. So very interesting trial that's going on. This NCT number to be able to look up that trial. Those are kind of three highlighted trials for stroke. We also want to highlight some key clinical trials for spinal cord injury.

The first one is a clinical trial taking place in the Kessler Foundation. They are looking at the effects of whole body vibration on spasticity. As Kim had mentioned when she was going through the evidence, there's a lot of evidence in supporting the advantageous effects of Vibration Therapy to spasticity. What makes this clinical trial different is that they are combining the whole body vibration withstanding on a tilt table. So the people that are in the trials are actually on a tilt table to stand up. They are actually standing on a vibration platform in the tilt table. And so they're looking at what the impact is of approximately 14 minutes and 3 sessions on 3 separate days to see what the impact is. Typically, for complete and incomplete spinal cord

injury below the level of T10. If you are interested in that, there's the NCT number where you can find the clinical trial on clinicaltrials.gov.

Another clinical trial is looking at leg rehabilitation. Obviously, you are seeing a pattern. Oregon Health and Science University is very active in clinical trials going on for Vibration Therapy. This one particularly is looking at incomplete spinal cord injury. And looking at how they can improve their walking ability. So it's looking at the treatment of using a robotic therapy device along with Vibration Therapy to see how people living with chronic spinal cord injury that are incomplete, how it can improve their strength, sensation in their legs and the functional gait and functional walking for those treated limbs.

This is a study out of Oregon Health and Science University, and that's the MCT -- the NCT response number p.m. The final, is the dose-response effects. How much therapy is beneficial, is there a point or threshold where it's too much therapy where you might do some damage, so this is focusing on whole vibration therapy for spasticity and walking. For people with incomplete, or complete spinal cord injury -- sorry, incomplete spinal cord injuries with AIS, level C and D, and see how it can impact the walking ability and increase spasticity. The study is really kind of comparing doses. They're comparing on low and high frequency, and short and long-term sessions so that they are really kind of pinpointing what is the best design for therapy in using whole vibration and what are the

doses they can give to give the most optimal effect. And if there's a threshold that takes too much. This is taking place at the Sheperd Center, and there's the NCT number where you can look up this specific clinical trial. We have gone over the clinical trials going on, and some of the active study, but let's introduce you to the devices clinically available, and commercially available. These devices can be used under supervision. Some can be used at home. Again, in looking at the devices that are commercially available, some are FDA cleared, some are not. Some are classified as exercise machines. Some are classified with the FDA as being therapeutic devices. So I think it's really important if you are looking at these different types of commercial devices to use at home or to use privately, what device might be best for you.

So let's dig into some of them that are available. One that is available is a device that's -- devices that are out of Europe. They're distributed in the U.S. by STIM design. They have a couple of different types of platforms. The classic platform, whole body vibration device. They also have one for -- that's a chair. It's on a vibration platform. For those who are not able to stand. There's a chair alternative. To be able to use this vibration therapy.

They also have a device that is kind of a dumbbell, if you will, but more of a partial or focal point vibration, as Kim mentioned earlier. And that's primarily focused on upper extremity. There's a variety of those devices. Galileo by STIM Design and that's the website. The

direct link. And that direct link is in the PDF file to download.

The other device is a VibePlate. You stand on and/or you are able to sit on it. They have a couple different sized platforms, as you can see from the bottom picture, and have one that's available to be able to stand with a pedestal with it. Again, this is a whole body vibration system. By VibePlate. This is the link to be able to go to the website to learn more about the device.

Some other whole body vibration tools that have really been born out of the exercise world but are now gaining ground in terms of rehabilitation Tools is something called the Power Plate. They have a couple of different types of categories of devices that they offer. Again, it's a pedestal where you stand on the machine and, again, this is the website to be able to link to a Power Plate device.

Also, the WAVE. It looks very similar. They have some different features that are on it. But, again, it's a whole body platform.

This is the website to be able to find that device -- it's a whole body platform. And another device, Juvent health platform. It's

a -- JUVENT health platform. It's a little bit different because it's just a platform. It doesn't have the pedestals that come along with it.

But, again, it's available commercially available device that you can see the link there to be able to learn more about that specific twice.

And, again, there's the -- the specific device.

And, again, the AMES Technology device. The Oregon Health and Science University. This is what the device as born out of, that

university. They are conducting several active clinical trials at this point. And the device is available mainly through clinics.

Again, this is the website to learn more about that device.

So that introduces you to the commercially available devices, but we talked about a lot of those platforms and standing platforms for whole body. What are options for people who can't stand?

So one of them, this one that we're showing over here on the right hand side, is a tilt table. It's a tilt table and you will go up into a standing stance but you will be standing on a vibration platform.

There's an active clinical trial going on right now, and early published research about using a tilt table with a vibration, whole body vibration platform. Another option for those who can't stand independently would be to use a whole body suspension system above a platform to be able to be above a whole body platform and be able to put your feet on it to have that type of therapy. So that's another option for those who can't independently stand.

So how do we access these devices?

There's a lot of ways to access them. As we mentioned earlier, there were devices that are FDA cleared and those mainly used for exercise. That leads to a wide array of being able to access the devices, and it's very different to the classification of the device. You can learn about the device through a physical therapist or a rehabilitation center.

There's quite a few that offer there. There's the extended rehabilitation facilities or programs. Those extended therapy

programs that we're seeing around the country that are popping up. A lot of them offer Vibration Therapy as one of the tools that are available to people that belong to those types of programs.

Now, again, in those two settings earlier are under some type of supervisory use. Something to think about when you are trying to choose if that's the right option for you. They're under supervisory use.

And exercise facility, as Kim mentioned, some therapy devices were born out of the exercise, or became very popular out of the exercise and fitness world. You might be able to find some in exercise facilities or gym, if you will. And there are devices available for sale for home use. Again, we caution. If you are thinking about getting a device like this to use as home to be sure you are being supervised or consulted with a therapist or a trainer who is familiar with the device in your case. Just as a precaution if you are looking for it as a home-use device. And, again, consult your medical professional who is familiar with your case to see if that is something appropriate for you. So here are some resources for you when you are thinking about the Vibration Therapy.

We have some past webinars when we talked about some post rehab programs that offer Vibration Therapy, and they can be found through this spinalcord.org website. One is that "Rehab Is Over. What Now." And the Therapy Programs and What Kind of Devices They Offer. And "Paralysis and Exercise" a webinar conducted earlier, and cutting

edge technology for with wheelchair users.

We highlighted six clinical trials. And we only highlighted those that are currently active or recruiting. So you can find a lot more on clinicaltrials.gov. We recommend that when you search you search for Vibration Therapy. Make sure you put and in capital letters, AND, and whatever condition you are looking to search. Spinal cord injury, stroke, MS, Parkinson's Disease, et cetera, that's where you will find extras.

I caution you to educate yourself on the risks that are associated with clinical trials when you are looking through them, and become an educated participant. And clinicaltrials.gov offers some fantastic educational tools. You can learn what it means to be a participant in the clinical trial, and what are the expectations going into it and what are some of the risks and precautions you need to be aware of as well.

With that, I wanted to highlight some of the references that are available so the clinicians that are out there, that might be interested in what we discussed today, there's some references from the literature. And that concludes our webinar. We wanted to let you know that both Kim and I are available to answer any questions. We're giving you our e-mail addresses here on the final slide, if you want to contact us directly with anything further. At this point, I would like to hand it over Bill to see if we can address any further questions that our audience might have

>> Bill: Great information, Jen, Kim and Jen. Especially until my

view the review of the current research, current clinical trials.

Yes, we have quite a number of questions. Let's get right to that.

First: Where can I find a vibration plate withstanding frame?

>> -- if one exists.

>> Jennifer: Sure. As far as I know there's not one for a specific standing frame. I am assuring that the person asking this is not able to stand voluntarily. The ones that we highlighted have a standing platform with a rail to hold on to. If you are able to independently stand, you can use that. But those that are commercially available with a standing frame, there is not something that's combined available on the market commercially. However, as you saw from the clinical trials that they're highlighting, they're looking at combining a tilt table with a Vibration Therapy. That is an option for you as well as the whole body suspension but, again, you would have to buy those devices separately. If you are looking at using it for home use, and/or in the clinic. Again, those are two separate devices, but they can be used together in unison. I hope that answers your question

>> Bill: Okay and the next is a combination of questions here. I will read it as is. Wouldn't it be logical that Vibration Therapy should be contraindicated for people with kidney stones, but you are saying this has not been documented in the literature? Has that been or not been documented in the literature, and whap could we know at this point about contraindication for people with kidney stones or

susceptible to kidney stones.

>> Jennifer: Sure. In looking at the literature, when we look specifically for Vibration Therapy for the conditions that we highlighted today for stroke, spinal cord injury, MS, and Parkinson's Disease, we really didn't find anything that was very specific to kidney stones. With that being said, there may be evidence in the literature, if we just look up Vibration Therapy and kidney stones separately from any other condition. So we did not do that search. There might be some evidence in the literature. If that person that asked that question would like to get ahold of me or Kim, we can do a quick search in the literature to see if there's anything for you specifically

>> Bill: So, yes, for the originator of the question. Reach out to Kim or Jen directly, which is also nice that we have the handout there. You can download that and save that. We have a lot of other question, and they're pouring in.

How long after SCI injury is this practical, is Vibration Therapy practical, I take is.

>> Jennifer: Kim, would you like to address that one?

>> Kimberly: Sure. The bottom line answer is that there's no data yet. But surely in patient therapists will do standing therapy and they'll do body weight loco motor training. And those are being used in combination in many different research studies. So there's no, nothing really to say that you couldn't use Vibration Therapy in, during

patient rehabilitation therapy, but there have not been any studies published on it. So the final word that we would need evidence to show whether or not it was beneficial or detrimental.

>> Bill: Okay. Very good. The next question is -- and there's some great questions -- we have a number of get to. We'll try to get to as many as we can.

Osteoporosis, is there anything for that, and the benefit of Vibration Therapy for osteoporosis?

>> Kimberly: I know in general vibration and weight bearing is the best combination for reducing and preventing osteoporosis. There's a lot of literature out there for aging women in relation to osteoporosis. Whether or not the same thing holds true, been demonstrated for neurologic disorders like we discussed today, spinal cord injury, Parkinson and stroke, that's not been demonstrated in the literature. For spinal cord injury, particularly, it's reducing and preventing osteoporosis, there's been a number of things tried. The results have been somewhat non-impressive.

But there is a large literature in general for vibration and weight bearing reducing osteoporosis in the normal aging of women.

>> Bill: Okay. Next question. Does Medicare cover Vibration Therapy?

Jen or Kim. Who wants to tackle that one? If you have evidence on

that?

>> Jennifer: Sure. There are some reimbursement codes that you can find with some of the commercially available devices. Now whether you're Medicare, because Medicare can change from state to state, whether that specific one will cover it is based on in which state you live. But, again, there are reimbursement codes for some devices. Again, these need to be devices that are not classified as exercise equipment, but cleared for the FDA, that's typically what we find. So when you looked at the commercially available devices, some of the commercially-available devices do offer reimbursement codes so you are aware of those. Those are more than likely ones that you can make a case for reimbursement

Otherwise, many of these devices are paid for out of pocket.

>> Bill: Okay. Any clinical trials available for C level, Asia B. I am assuming cervical level of injury [indiscernible] B. Completeness.

>> Jennifer: Sure. There is the one study that we mentioned for spinal cord injury, that was the first study that we highlighted in terms of spasticity. They were looking at both complete and incomplete spinal cord injuries that are above the T10 level. So for that particular person, that clinical trial might be something you would like to look into. Those are, again, only the actively recruiting clinical trials. There are a lot of other clinical trials listed on clinicaltrials.gov that might be in the works but not actively recruiting at this time.

Meaning, they are gearing up for the clinical trial. That might be something you would like to search when you go into clinicaltrials.gov when you look for Vibration Therapy and spinal cord injury. You could even put in as a search tool, as AISB and see what kind of clinical trials are available, and/or those that are upcoming

>> Bill.

Am okay. Understood.

Any clinical trials addressing persons living with MS?

>> Jennifer: There are clinical trials for people living with MS. But they really not currently actively recruiting. So that's why we didn't highlight them on the webinar today. But, again, you can go on to clinicaltrials.gov, use the search terms that we showed you in this webinar, and you will be able to see the clinical trials. Keep in mind, something may have come up in the last few weeks that turned from recruiting to -- not recruiting to recruiting. When we created this slide show and presentation, it was a few weeks ago. I would encourage the people asking the question to go to clinicaltrials.gov to search through for the trials that may be ongoing for MS, may not be recruiting but you may want to follow for your own personal interest

>> Bill: Thank you, yes, and the clinicaltrials.gov lists are typically fluid, are they not?

>> Jennifer: Yes, they are.

>> Bill: Okay. I have a question. My client is a paraplegic and is able to walk using a walker. Has lower extremity spasticity. She's wondering if a sleep-number bed that vibrates, would this possibly have the same effect as the vibratory therapeutic tools.

>> Kimberly: I can try to answer that one. I don't know that laying down would give you the effect on the muscles that you need, for the Vibration Therapy. But there's some very good evidence in the clinicals that is already published as well as ongoing clinical trial that is Shepherd, that Jen mentioned, it's enrolling people with motor incomplete spinal cord injury, such as you mentioned with your client. Those individuals typically have leg movement but their spasticity can be so strong that it impairs their ability to voluntarily move their leg, because of the spasticity. And inhibit their motion. And it's been noted that the Vibration Therapy can reduce some of the leg spasticity which enables the voluntary muscles to actually work better. But that's always done when you are upright and bearing weight on the muscles and tendons.

I am not sure that laying down in the bed that's vibrating will give you the same effect.

>> Jennifer: Just something to add on Kim's response to the question. If you are looking at the vibration bed, you really need to look at parameters that the vibration is taking place. Earlier in the presentation, we showed you some very common parameters. That

might be something you need to check into as well. To see what the amplitude, what the frequency is, of that bed to see if it would come into any of the ranges that have been studied previously.

>> Bill: Thank you. Interesting question, because the adjustable beds with vibratory feature are out there. There's a lot of those in use.

The next question. Have you heard of bio density?

Biodensity machines?

Kim or Jen?

Bio density machines.

>> Jennifer: I have not. I am not familiar with those. Kim, have you come across a bio density be?

>> Kimberly: No, not in regards to therapeutic. The only thing I am aware of is machines that can measure bio density, for example, a DEXA machine, measuring bone density. But I am not aware if there's a bio density type of therapeutic machine.

>> Bill: Okay.

I have a question from a PP. Have MS drop foot. I guess probably from the individual. Have MS drop foot. PT tried TENS, but seemed to make it worse.

Is this therapy similar?

We have one of those machines at the gym. Have MS drop foot. PP

tried TENS but seems to make it worse. Is that similar. We have one of those at my gym.

>> Jennifer: TENS units have very different from Vibration Therapy. There are some studies looking at using electrical stimulation and vibration. What I would suggest to the person asking that question, if they want to investigate to see if their drop foot might be improved with this type of vibration platform is to try it -- discuss with your medical professional, and try under supervisory. If you are on the platform, and an adverse effect happens, you want to be sure there's someone there to assist you. That would be my recommendation for that. Kim, do you have anything else to add?

>> Kimberly: No. Actually I would ditto your response

>> Bill: Thank you, Kim and Jen. This is somewhat similar but slightly additional question on reduction of spasticity. Is there documentation of reduction of spasticity medications? I think you addressed a reduction of spasticity per se, provided for hydration therapy -- Vibration Therapy but is there documentation that you came across with reduction of spasticity medication needs?

>> Kimberly: That would probably require large clinical trial. And have a couple different groups in it. You would have to have people with similar degrees of spasticity on similar dose of anti-spasticity medication. And then in one group --

>> Jennifer: To continue with Kim's response, in one group there would be those that are using the therapy, and staying on the spasticity medicine. And another compare it to another group that is taking the Vibration Therapy and coming off the spasticity medicines and see what the effect is. So there really isn't anything in the literature that has published data on reduction of spasticity medication related to this therapy. Now that being said, we did find several anecdotal responses that people can reduce their spasticity medications in association with Vibration Therapy.

>> Bill: Okay. Thank you both.

What about decreasing pain?

That's the next question today. Jen?

What's the next question?

>> Jennifer: Decrease of pain. Pain is a complex matter. And you would encourage the person asking that question to go back into the archivings. There's been several webinars hosted by United Spinal addressing pain. That being said, how does it relate to Vibration Therapy? We didn't find anything very specific in the literature that relates to pain.

Again, as I mentioned earlier, pain is complex. Could be neuropathic, muscular skeletal, or diabetic pain, and there's lots of different types of pain, and being able to pinpoint the pain reduction, that could be something to look into.

Again, we have not found anything very specific in the literature for that broad area of pain.

>> Bill: Okay. Thank you. The next question. Has there ever been any evidence or indication that Vibration Therapy could be harmful to the hardware associated with spinal fusions?

>> Jennifer: to the question, I am assuming, is related to the spinal rods where, or those types of stabilization devices that are implanted typically with people with spinal cord injury, or directly the spinal cord injury. Again, we didn't see any of those adverse effects in the literature published specifically for spinal cord injury, so if anything it might be anecdotal. Again, there's nothing in the literature that says whether it can be harmful or whether it's not. So, again, that's one of those risks you need to consider if you are looking at a Vibration Therapy. And it might be something that if it's a concern to you to make sure that your medical professional is monitoring, if you decide to go into a Vibration Therapy regimen.

>> Bill: Okay. Thank you. I think this will be the final question of the day. And a unique angle. Good question. What a pacemaker pose a problem with Vibration Therapy?

>> Jennifer: That's a very insightful question. As we know with a lot of medical devices and even exercise devices there are a lot of warnings regarding pacemakers. Now pacemakers can be from an individual basis. Again, we didn't find anything in the literature that was adverse and/or beneficial. But what I would say is that if this person who is asking the question, touch base with your cardiologist and introduce the fact that you are thinking about this type of therapy and what your cardiologist might say specific to your case. So, begin, we didn't find anything in terms of the literature that we searched. Now, again, that being said, we searched for the specific conditions that we covered for this webinar, stroke, spinal cord injury, MS, and Parkinson's disease. Now we can, again, I would encourage the person asking the question if you would like us to search the literature, we can search the literature for Vibration Therapy specific to pacemaker. Now that would open it up to people without neurological condition, as Kim mentioned earlier in addressing osteoporosis, but, again, it would be something that you would need to consider. If you have a neurological condition combined with a base maker. I would encourage that person asking the question to get ahold of Kim or me and we can find some specific answers for you

>> Bill: Would like to thank the audience for insightful questions today. I would like to thank Ms. Jennifer French, and Doctor Kimberly Anderson-Erisman, for their experience and knowledge for us on vibration as a rehab tool. Jennifer and Kim, thank you again on

behalf of our audience today, and United Spinal association.

>> Jennifer: Thank you. On behalf of Kim, she had a pleasure of being here as well. We would like to thank all of our audience for attending as well as United Spinal for sponsoring this webinar.

>> Bill: Thank you, Jen. To sign up and receive the newsletter, sign up at spinalcord.org. Check out the magazine which covers everything that wheelchair users need to know. Visit spinalcord.org to see what we're all about. This will end today's presentation.

Thank you.

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