



Welcome to a special edition of the RealTalk MS podcast. I'm Jon Strum, and each week on RealTalk MS, we talk about the news, the views, and the breakthroughs that people living with MS should know about. You can find out more about the podcast by visiting www.realtalkms.com.

Today, we're talking about stem cell therapy & multiple sclerosis. I get a lot of email and private messages on social media asking about stem cell therapy, and I can understand why -- there's just a lot of *conflicting*, *incomplete*, and sometimes just *incorrect* information out there. that's why I'm so pleased to share this episode of RealTalk MS as part of the MS Society's stem cell week. I hope it helps to bring a little bit of clarity to the conversation about stem cell therapy & MS. And, just a reminder, you can find a transcript of the podcast below.

When you google the phrase "stem cell therapy for MS", it's easy to feel like you fell into a black hole of conflicting information, misinformation, and dodgy information that can be full of promises that have been designed to speak directly to someone who is anxiously and sometimes desperately looking for a miracle cure for a debilitating condition. And there's also plenty of good, credible information that's available online...but how do you go about separating the wheat from the chaff? We're going to try to jump start that process for you today, and look at the current state of stem cell therapy & MS.

And since this is the beginning of our conversation, we should start with a few

differentiations and definitions...because there are different *kinds* of stem cells. And different kinds of stem cells have different properties -- they aren't all capable of doing the same things. And that may, *already*, be new information for some of you.

There are *haematopoietic* stem cells. These adult stem cells are found in bone marrow and blood. And the term "adult" refers to the stage of growth of the cell, not the person. Haematopoietic stem cells can produce the cells that make up our immune system.

There are *mesenchymal* stem cells. These are adult stem cells that can be found in several different places in the body, including bone marrow, skin, and fat tissue.

There are *neural* stem cells. These can be derived from other stem cells, including mesenchymal stem cells, and these stem cells can repair myelin in the brain.

There are *human embryonic* stem cells. And these are stem cells that are derived from donated human embryos.

And there are *induced pluripotent* stem cells...which are *engineered* from adult cells to produce many different types of cells

I should also point out that one of the issues that's been identified in working with human embryonic stem cells and induced pluripotent stem cells is that both of these types of stem cells have been shown to cause tumors, which can limit their therapeutic value.

There's obviously a tremendous amount of interest throughout the research community in stem cell therapy. It holds some real promise...along with real complexity. Today, there are no FDA-approved stem cell therapies for MS. But there

are a few promising avenues of research that are being explored.

Some researchers are focusing on trying to reboot the immune system using hematopoietic stem cell transplant, or HSCT, to essentially build a new immune system in an effort to stop MS disease progression.

HSCT has been used to successfully treat diseases originating in bone marrow cells, like leukemia. And because immune cells are formed in bone marrow, scientists have expanded their research efforts to include other diseases that involve the immune system, like MS. Some of these approaches have involved completely wiping out the existing bone marrow -- called *ablative* treatment. And other approaches have involved only partially destroying the existing bone marrow, and this is called *nonablative* treatment. In both cases, a person is given an intravenous hematopoietic stem cell transplant so that new bone marrow will be created, and the hope is that the healthier bone marrow will create a healthier immune system...an immune system that won't attack myelin.

One HSCT clinical trial was conducted by Doctors Mark Freedman & Harold Atkins at the Ottawa Hospital and the University of Ottawa. In this clinical trial, bone marrow stem cells were isolated from 24 people with early, aggressive, relapsing MS. The 24 study participants received ablative treatment, followed by hematopoietic stem cell transplant -- or HSCT. The study participants were followed for the next 4 to 13 years, and 23 of them had no clinical relapses, nor did they develop any new brain lesions. 14 of the participants had absolutely no disease progression, and 10 had long-term improvements in their vision, muscle weakness, and balance issues. One participant in the study died from the procedure. If you know someone who's had extensive chemotherapy to treat cancer, you might already be familiar with how risky it can be when they completely delete your immune system. And, keep in mind, this was a small study, but it certainly made the case that more research should be conducted in this

area.

So, Dr. Richard Burt, the chief of the Division of Immunotherapy at Northwestern University's Feinberg School of Medicine in Chicago, is in the midst of conducting an HSCT clinical trial. This study involves 110 participants with relapsing remitting MS. Half of the participants received HSCT, and the other half stayed on their MS disease-modifying drug therapy. A difference in this study was that the participants who received HSCT were given the nonablative treatment...so their immune systems were knocked down but not completely deleted.

And a few months ago, Dr. Burt shared some interim results of this ongoing study. One year after enrollment, no deaths had been reported among the participants who received the hematopoietic stem cell transplant. One MS relapse had occurred in the transplant group, compared to 39 MS relapses in the group that was kept on their medication. And there was already a reported improvement in disability among the transplant group.

Dr. Burt's team is already planning additional clinical trials to better understand who will respond best to HSCT, and which approach to HSCT is best for treating MS. Research to date indicates that the strongest candidate for HSCT is someone who is 50 years old or younger, has had MS for 5 years or less, has active relapsing-remitting MS, but is still walking, and who isn't responding to the available disease-modifying therapies.

So, hematopoietic stem cell transplant is one of the very promising stem cell therapies currently being investigated. It's already being offered as a treatment for MS in other countries, and we'll talk about what you need to know and the questions you should be asking if you're thinking about traveling abroad for this treatment.

But before we get to that, we're going to look at research that's been done using *mesenchymal* stem cells. These are adult stem cells that can be found in several different places in the body, including bone marrow, skin, and fat tissue. And a research team at the Tisch MS Research Center in New York reported the results of their Phase 1 clinical trial using mesenchymal stem cells. This clinical trial involved 20 people with *progressive* MS. The research team harvested mesenchymal stem cells from the participants' own bone marrow, and used these cells to derive a specific class of stem cells called neuro progenitor stem cells. Each of the study participants received these neuro-progenitor stem cells in a series of 3 injections into the space around their spinal cord.

So, a Phase 1 clinical trial is undertaken to determine the safety of a specific treatment, and in *this* phase 1 clinical trial, there were no serious negative effects. The most common side effect reported was mild to moderate headache and fever.

And while a Phase 1 clinical trial isn't designed to look at the benefits of a specific treatment, the research team at Tisch MS Research Center observed some improvement in the participants' EDSS scores, (again, that's the score that neurologists use to measure disability), they also noted improvement in muscle weakness, walking speed, and bladder symptoms.

And based on these encouraging results, the research team is moving into a larger phase 2 clinical trial involving mesenchymal stem cells. There is also clinical trial research focusing on mesenchymal stem cells taking place at the Cleveland Clinic, Stanford University, and the University of California San Francisco, to name just a few of the research centers that are looking at this stem cell therapy.

This isn't all that's going on in stem cell therapy research -- *by far*. But there's another important aspect of stem cell therapy and MS that we need to talk about. And that's the

half-truths, the inflated claims, sometimes the out-and-out lies..that are being made by for-profit stem cell clinics. Unfortunately, there are people living with MS who take these claims at face value, and end up spending huge sums of money and risking their health...and even their lives...on really *questionable* procedures.

Literally, as I was working on this podcast episode, I saw a tweet from someone living with MS, and the tweet linked to a website for a stem cell clinic in Mexico, and this individual wrote, "I want this treatment. I need it." When I visited this stem cell clinic's website, I read that they specialized in HSCT for MS, Type 1 Diabetes, Chronic Inflammatory Demyelinating Polyneuropathy, and Transverse Myelitis. They claim to have performed HSCT for more than 20 years, including 700 procedures to treat MS. They claim to achieve positive results in over 78% of their patients, which - they say - include both relapsing and progressive patients. So, the first thing that concerned me about their claims, was that their 78% success rate is measured against all of their patients, not just their MS patients. So we still don't know what their success rate is for MS. Nor do we know what they consider "success". And while they claim to have been successful with both relapsing and progressive patients, those results haven't been achieved under research laboratory conditions. HSCT has been shown to be effective in treating relapsing MS, but these folks are claiming success with *progressive* MS. And that brings us to the first very big - huge - red flag -- *NONE* of these for-profit stem cell clinics -- anywhere -- have provided any medical evidence that their treatments work...or are even safe. And this is important enough to say again -- *NONE* of these for profit stem cell clinics -- anywhere -- including the ones here in the United States -- have provided any medical evidence that their treatments work. And I don't know why that is...but I imagine they have a *reason* for not providing evidence that their treatments work. And as a consumer, that alone should be a deal-breaker.

So, aside from the fact that these for-profit stem cell clinics don't provide medical evidence that their procedures work, there are a couple of other important things to

keep in mind the next time you come across one of their very appealing, very enticing, online or print ads.

In *many* countries, stem cell clinics are allowed to operate without any oversight when it comes to the safety of their procedures.

And if a stem cell clinic offers stem cell treatments for a variety of different conditions -- and I've seen ads that boast treatments for everything from aging to lower back pain, to rheumatoid arthritis to congestive heart failure to asthma to erectile dysfunction to multiple sclerosis -- all in one clinic. Well, you need to be very careful. Because while stem cells can be made to do many different things in the body, stem cell treatments require cells from different parts of the body, and each type of stem cell therapy requires manipulation of those cells in different ways. It's not a one size fits all procedure. Stem cells do *not* automatically know where to go and what to do when they're injected into someone's body.

If you're looking into one of these clinics, ask them for the studies that have been published in medical journals that the same stem cells and the same techniques that they are using have been proven effective. And ask about their safety certifications.

Be sure to ask about the *source* of the stem cells that they will use...because if they aren't coming from your own body, they can pose a *serious* threat to your health.

Ask about the clinic's procedures for handling complications...ask how they define "success"...ask how long they will monitor your condition after the procedure.

And if someone claims that their stem cell treatment will cure your MS...run away as fast as you can. And keep one hand on your wallet while you're running.

Now, if this sounds like I'm coming down against stem cell therapy for MS, nothing could be further from the truth. Personally, I think it's an avenue of treatment that offers incredible promise. But there's still so much to understand...and so much work to be done in making it safe and reliable.

Just in the past couple of decades, we've seen so-called treatments for MS turn out to be pretty worthless. Whether it's bee stings or ProCarin, or CCSVI...thousands of people with multiple sclerosis have turned to these treatments with high hopes, and the only thing that they lost was their money. And in the case of stem cell therapy, that could mean a *lot* of money.

There's some really amazing research on stem cell therapy and MS that's going on here in the United States, in the U.K., in Israel, and in other accredited academic settings. It's going to produce the knowledge and insight needed to determine whether stem cell therapy is a credible treatment for MS, and how to go about it so that the risks are minimized and the outcomes are expected. So you can be sure that we're going to be talking more about this subject on RealTalk MS. But I hope that you come away from today's podcast episode knowing and understanding a little bit more than you did before about stem cell therapy about stem cell therapy & MS .

My name is Jon Strum. Thanks for listening...and we'll catch you next time.