

Alzheimer's Talks Transcript Could Coconut Oil Really Help with Alzheimer's? with Dr. Mary Newport and Jill Smith

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Note: This transcript has been edited for content and clarity.

George Vradenburg: Welcome to <u>Alzheimer's Talks</u>, a monthly teleconference series presented by <u>USAgainstAlzheimer's</u>, where we bring you the latest research and breaking news on the path to the cure for Alzheimer's. We connect you with the leaders in research and policy who are working to stop this darn disease. Thank you so very much for joining us today.

My name is <u>George Vradenburg</u> and I'm Chairman and Co-founder of USAgainstAlzheimer's, an entrepreneurial and disruptive organization of engaged and enraged individuals who are transforming the fight against Alzheimer's. Our organization, USAgainstAlzheimer's, is made up of networks of people from all walks of life, in particular: <u>researchers</u>, <u>women</u>, <u>caregivers</u>, <u>CEO's</u>, <u>clergy members</u>, <u>African-American activists</u>, <u>Latino community organizers</u>, and everyone in between because this disease affects everyone, hence our name USAgainstAlzheimer's.

We've been pretty busy since the last call. Strikingly next week there will be 40 nations at the first World Health Organization ministerial on dementia and there they will commit to enlarging the global fight against this disease across so many different nations. And just this week the members of the Advisory Council on Alzheimer's Research, Care, and Services to the U.S. Department of Health and Human Services recommended a series of action steps by the U.S. government to step up the fight. In particular, they recommended a minimum of 2 billion dollars a year in financing against this disease. From the current level of 500 million, that's a significant step-up but we have succeeded in the last 3 years of raising additional money for Alzheimer's disease through the NIH and we are pressing to do that in significantly additional steps. Senators Collins and Klobuchar from the United States Senate have introduced a resolution calling on Congress to double Alzheimer's funding for this year and ramp up investment to 2 billion a year over the next several years. So if you want the latest updates on that score please go to https://www.USAgainstAlzheimers.org.

Today we have 580 people registered for this call from 47 states plus the District of Columbia and Puerto Rico and well over 4,000 people who can't make the call because it occurs during the day but ask for the recap materials and the transcript which we will send to everyone who registered for this call, including those on the call today.

Remember if you have a question during the call please press star 3 on your phone. By pressing star 3 you'll be placed into a question queue. Please have your question ready to share briefly with a member of our staff and we'll try to get you on live with our guest today as soon as possible when we open it up for questions. If you're listening to us online, you can type your question in the box and we will get to as many questions as possible after the opening presentation.

Today we're going to focus on a fascinating subject, on a clinical trial that is currently enrolling at the Byrd-Alzheimer's Institute at the University of South Florida. They are running a randomized Clinical trial to test the effectiveness of coconut oil against this disease. On previous Alzheimer's Talks calls we've had several questions about the possible use of coconut oil, so we wanted to bring you information from the people who are looking into it. We will first hear from Doctor Mary Newport. When her husband was diagnosed with Alzheimer's disease she started searching for a treatment - much like so many of us and so many of you on the call. She believes that coconut oil worked to improve his memory. She's an adviser to the study at the Byrd Alzheimer's Institute. Then we will hear from Jill Smith who's the Assistant Director for Clinical Research at the University of South Florida Health Byrd Alzheimer's Institute to discuss their clinical trial, including how you can enroll if you're interested in participating in the trial. So Doctor Newport, would you please describe your experience with the use of coconut oil?

Dr. Mary Newport: Thank you George. For those who don't know, I'm a physician. I'm a neonatologist, which is the care of sick and premature newborns and my husband, Steve, worked from home as an accountant for my practice so that he could be there for our children. Right around age 51, this is in 2001, he started having problems with accounting and missing payroll deadlines and he was depressed. Then he started having difficulty remembering if he had been to the bank and the post office and things continued to deteriorate. He was followed by a neurologist, and he was diagnosed with early onset Alzheimer's in 2004, when he was 54 years old. This was confirmed when we looked for a second opinion at the Byrd Alzheimer's Institute in Tampa in 2006. So by 2006, he could no longer drive, he couldn't even turn on a computer or use a calculator so he had deteriorated a great deal during that time and in 2008 there had not been many trials available or any that he qualified for up to that point.

There became two clinical trials for two new drugs that were available and we had scheduled back to back screenings to see if we could get him into a clinical trial. Just as a complete accident I was online looking at the risks and benefits of these two drugs and I came across a press release for medical food that was making progress towards FDA-approval, or recognition as a medical food, but it was still about a year away from that. It said that their studies showed that it improved the memory and cognition of almost half the people in their studies who had taken it, and this is not something you normally hear about Alzheimer's medications. So I became very curious and I was able to find their patent application online and what I learned from it was that Alzheimer's is a type of diabetes of the brain. There is a deficiency of insulin and insulin resistance in the brain of people with Alzheimer's disease that becomes progressive and severe during the course of the disease. What this means is that you basically have difficulty getting glucose into the brain without adequate insulin or insulin working effectively. This company had developed a product that would work as an alternative fuel to glucose for the brain and what the product turned out to be was medium-chain triglyceride oil. I happened to be familiar with that type of oil, it's called MCT oil for short, because as a doctor who took care of premature newborns we use this extensively in the newborn intensive-care unit to help our tiny newborns gain weight and it's in basically every formula. What I didn't know, up to that point, was that MCT oil is extracted from coconut oil and with this product being more than a year away I thought well maybe we could get some benefit by giving Steve coconut oil. And it just happened I was reading this the night before he was screening

for the first clinical trial and it was like 1:00 AM and I didn't have time to go out and buy any coconut oil much less research it any further. But he did not qualify for the study that day. He needed to get a minimum score of 16 out of 30 points on the Mini Mental Status Exam and he had qualified with all the other criteria so this was a big blow to us he had drawn a clock that day for the doctor there, he just threw a few little random circles, few numbers that was not organized in any pattern that resembled a clock and that doctor has advised me that he was on the verge of severe Alzheimer's.

So I thought what do we have to lose? And I went to a store and bought coconut oil, researched what the fatty acids were in coconut and learned that it's about 60% medium chain triglycerides and calculated that to give him the equivalent dose to this medical-food that was not out yet that he would need to take a little over 2 tablespoons. And so the next morning he was scheduled to go to the Byrd Institute coincidentally to screen for a clinical trial and I thought I'll just put some coconut oil in his oatmeal and I gave him a little over 2 tablespoons. He tolerated it amazingly well looking back, but this time his score increased from 14 the day before to 18 and he actually qualified for the study. At that point I didn't know if it was the coconut oil or just very good luck but regardless we were thrilled he got accepted into the study because to get into a study it's really the only hope at this point. I decided to continue the coconut oil and I kept researching it and eventually we increased so that we were cooking with it throughout the rest of the day and ultimately he started getting it for all three meals. Basically the reason being that what happens when you take MCT oil is that your liver converts part of it to ketones and ketones serve as an alternative fuel to the brain and this happens naturally during a period of fasting or starvation that your body will use up the glucose in the body very quickly within 36-48 hours and will switch over to burning fat and in that situation the liver converts fat to ketones and the brain very efficiently moves to burning glucose for fuel to starting to use ketones for fuel and the ketones can provide up to 60% of the fuel for the brain during prolonged starvation. So this seemed logical on a scientific basis to me and so I just started trying to provide enough MCT oil to Steve so that he would hopefully have ketones available to him 24/7.

What we saw was just really over the first few days after we started using it that instead of being very sluggish and very poor conversation and unable to find utensils and things like that, in the morning that he had more energy, he was making conversation right away, his sense of humor came back very quickly. He could find the utensils, get water out of the refrigerator, and about 2 weeks later he drew another clock and it was amazingly different it had the full circle, it had all the numbers in the correct order, it was very messy, he had drawn with a ruler a lot of spokes through the clock, that I think represented the hands of the clock, so there was still obvious confusion there, but it was tremendous improvement. He had a couple of other Mini Mental Status Exams over the next 2 months after that and he increased to as high as 20 on the Mini Mental Status Exam during that time. We also saw physical improvements almost right away, his tremors which he had in his hands and his jaw virtually disappeared, he had a weird gait where he would pick up his legs very slowly and he couldn't physically run and over probably about 3 months that completely normalized to the point where he could run again and no longer looked weird when he walked. He had an eye disturbance that had kept him from reading, he couldn't even explain it to me until after he improved, but about 3-4 months after starting coconut oil he told me, 'you know I can read again'. He explained that the words would move around in little boxes on the page he said it was like pixels on a screen they would move around and that's why he couldn't read, plus comprehension was an issue, but that stopped and he could read again. His conversational skills improved very significantly he started recognizing family members that he couldn't remember their names a year earlier. Then probably somewhere around 9 or 10 months into this he started bringing up things that happened 2 or 3 weeks earlier like a volcano that erupted somewhere else in the world and commenting, oh

maybe that's why the sunset is so glorious tonight, that type of thing and remembering something he had read about Einstein in the doctor's office waiting room several hours earlier, he would tell me about it. So just a pretty marked improvement over the first year then he stabilized probably for close to 2 years, with a couple little setbacks. I wish I could tell you that he remains stable but he has had setbacks since then and in spite of that we can only be happy that we got several extra better quality years for Steve. I just wished that we had known about something like this much earlier when he was much earlier in the course of the disease.

George Vradenburg: That is an amazing story and a very powerful one. So I'm going to ask Jill Smith if she might now speak and hopefully give us an insight as to whether this might be totally idiosyncratic or whether there is something really going on here that might be more widely applicable?

Jill Smith: Thank you George. I am so excited to be on the call today and I thank everyone for calling. Doctor Newport has stimulated so much interest in our crowd here, that is exactly why we sought out to do the firstever, as far as we know, clinical trial studying the use of coconut oil and medium-chain triglycerides as a treatment for Alzheimer's patients. We literally got thousands of phone calls from people saying: Does it really work? How we should take it? What should we expect? and we didn't have those answers because it was something that had never been studied before. We actually were able to get private funding to conduct the clinical trial. Pharmaceutical companies, as I'm sure we can all guess, are not that invested in because there's not a whole lot of money to be made off of coconut oil since it's so readily available, but we were able to get private funding to do a clinical trial. What's really interesting is we've been trying to enroll for a year or so now and I can't deny we've had lots of setbacks in enrollment because so many people are interested in the results of the research study that they put their loved ones on it and we are not able to find individuals who are not being treated with it to study. But I continue to get dozens of calls a week from throughout the country, I've actually gotten calls from a gentlemen from Ireland who calls me every couple of months to get updates on where the study is. We are studying specifically subjects with mild to moderate Alzheimer's disease, and as I think Doctor Newport did a great job pointing out, there's certainly possible benefits to anyone experiencing other forms of dementia that it could possibly give them some benefit as well, but as we specialize in Alzheimer's disease here at the Institute that was the criteria that we decided to do the research study under.

We're doing a 6-month trial looking at participants with mild to moderate Alzheimer's disease, and if you're familiar with the Mini Mental State Exam scores, subjects with a score somewhere between 16 and 26. We have a very broad age range from 55 to 90 and we are looking for people who are in reasonably good health. Our study is actually characterized as a crossover study, which is very interesting. If you have ever participated in a clinical research study before or are familiar with clinical research for any health problem, you're aware that they generally will use a placebo product and while we didn't want this to prohibit or diminish our enrollment capacity, we decided to use this crossover feature which allow the participants to receive both the active treatment and the placebo during their single participation in the trial. So of the 6 -month study that we are doing, we have broken it up into two 3-month treatment periods. So participants will receive the active treatment either the first 3 months or the second 3 months and then they'll receive the placebo during the other. Now to make sure that we are collecting unbiased information, we do not know who is receiving what treatment at any given time and that way we can make valid assessments on the possible benefit of the coconut oil. The product that we're using, I know that was a question that a lot of people had e-mailed in, it is a product that's currently available and I will disclose I get no money for telling you about this, it just seemed to be a quality product, it's called Fuel For Thought and it's provided by Cognate Nutritionals. It comes in bottles of 2.5 ounces and so our participants take half a bottle twice a day and they will do this with both the active treatment and the placebo product that we're using, which is identical in taste and in texture and how it looks. It's actually a canola oil product that Fuel for Thought, the company, had provided for us. So there's two 3-month treatment periods and they take one bottle during the day and we recommend that they take half usually in the morning and half in the afternoon. What's really important that I'll point out is to always take the product with food. I think Doctor Newport had talked about how they added it in throughout meals throughout the day. One of the most common side effects that we have seen reported both through anecdotal evidence and what we've also collected through the trial is mostly gastrointestinal symptoms as far as possible side effects and that usually includes like bloating, nausea and diarrhea. So we recommend that they take it with food and we often will see a decrease in those problems.

During the 6-months trial, similar to other clinical research for various treatments for Alzheimer's, is we do a lot of safety testing as well as efficacy testing. We do regular physical and neurological exams, we repeat blood work throughout the trial including fasting blood work. There's a lot of interest in how coconut oil can affect cholesterol, triglycerides and glucose and that's one of the things that we're testing very closely throughout the trial. As far as people who might be good candidates for it, we are looking for people who have normal levels of cholesterol, triglycerides and glucose prior to enrolling and then we follow to make sure they don't become elevated once they start receiving the product. As far as efficacy testing, we also do questionnaires with participant and we ask that they have a study partner who can do reporting for them throughout the trial. I know there were some questions submitted for this call about genetic testing. We are testing for the ApoE4 gene, which we know is somehow linked to Alzheimer's disease, about 40% of Alzheimer's patients have that gene. Because of limited funding, we're not currently doing any kind of amyloid PET imaging or anything like that but we hope to possibly include that in the future. But those are some of the procedures that we're doing throughout the trial and we're measuring ketones as well to see how much it elevates individuals' ketones, both on the treatment and off because that seems to be the main feature of the coconut oil that is giving the benefit. So the actual study ends up being about 8 months long including the screening period and we also do a one-month follow up.

What's important about participating in research is that product that we are using for the study is provided to participants at no cost and none of the study procedures ever cost anything either. Unfortunately, we're the only one's participating in this at this time I know there's people all over the country who are very interested, and I just got an e-mail today from a group in Canada who would like to add on to our study, but at this time it's limited to the University of South Florida in Tampa. I think that kind of briefly covers it, a lot of information in a very short period of time.

George Vradenburg: Thank you. I think it was very clear and very straight forward, so thank you so very much. I have a few questions myself, but I want to remind people that if you do have a question star 3 on your phone you get into a question queue. Have a question ready for our staff who will try and get you on with Mary or Jill.

Let me ask you just a couple of technical questions. In terms of ascertaining the inclusion criteria, that is who should be included. Do you have any other assessment of inclusion other than MMSE between 16 and 26? Do you have to be either ApoE4 positive or negative? How do you know that people in your trial actually have Alzheimer's?

Jill Smith: So we are looking for somebody who has a documented diagnosis of Alzheimer's disease, you do not need to be ApoE4 positive. I'm sure a lot of your callers are aware that dementia is an umbrella term, Alzheimer's is the most common form of dementia. So every day I encounter people who have been diagnosed with dementia but are not really sure as to if it's a vascular dementia or Alzheimer's. So we do request medical

records just to document that they've been diagnosed. Some of our participants actually came from our own clinic, which is wonderful. As far as the testing criteria, the one memory test they have to pass is that Mini Mental State Exam and they are looking for a score of 16 to 26, which typically characterizes mild to moderate Alzheimer's disease. We also at the screening visit collect information about their health, so we're hoping they're in relatively good health. Everybody might have a little bit of a blood pressure problem and they take a treatment for that. We are not excluding individuals who are on cholesterol treatment, so long as it is controlled with the treatment, but we do the labs as well to make sure that they're not showing significant levels of cholesterol triglycerides and glucose before we enroll them. Another thing that I'll point out that I hadn't mentioned before is we're looking for people who are not currently on coconut oil or Axona, which is sort of a similar medical food product, within the last 30 days and then all of their other medications we want to be stable for about a month or so.

George Vradenburg: And, Mary referred to this in a vernacular of 'diabetes of the brain'. My question is, whether diabetes is an exclusion criteria or you're willing to take people who actually have diabetes?

Jill Smith: We don't want people with a history of diabetic ketoacidosis. If they have exercise and diet control diabetes that's okay but we are a little reluctant at this point just because we're so early still in our pilot study to take people who are currently on treatment for diabetes. We just don't want to put them at risk for something until we've got more data collected on those types of labs.

George Vradenburg: So we're going to open it up to some questions now from people who are calling in. I'm going to have Lois ask you a question that certainly came to my mind, Lois?

Question: Okay. Wouldn't canola oil and coconut oil put on a lot of weight for someone?

Dr. Mary Newport: If you just add it to the diet that could be a yes. So what I usually recommend to people is that you start substituting it for other fats in the diet, other types of oils in the diet, and also potentially cutting back on carbohydrates, which could be beneficial in general just to try to substitute it for something in the diet instead of adding it. If you add it to then yes you could gain weight just like anybody who eats too much, too many calories in a day.

Question: Thank you.

Dr. Mary Newport: You're welcome.

Jill Smith: And I'll add as well, it is a couple hundred more calories that you're consuming a day. So we have actually had participants withdraw from the study because they noticed they were putting on a few pounds and they didn't want to adjust their diet otherwise, that is an interesting question.

George Vradenburg: So I'm going to turn to Gloria. Gloria, want to ask your question?

Question: Yes I had a question about the diagnosis from the doctor about Alzheimer's. My mom was diagnosed with Alzheimer's but I don't remember that the doctor's really... what kind of test is required to get diagnosis? And my second part was I have also heard the canola oil was not very healthy that it was originally used as an insecticide, just had a question about that?

Jill Smith: The product is being produced very similarly to the way the coconut oil product that we're using in the studies is produced and canola oil is something that people still readily can purchase and use at the grocery

store. I would assume in high quantities that there are always effects of all things that are possible but to that I've not heard any concerns or had any issues.

As far as the diagnosis question, and Doctor Newport can add if she'd like, people will always ask, how do you get your memory problem diagnosed? I'll try to abbreviate as quickly as I can, is your primary care doctor is really good, they're sort of your gate keeper for health but to really have something diagnosed that's a special problem like memory loss you should really go to a specialist and so these are often neurologists or even like our practice, geriatric psychiatrists here, and they understand the proper way to diagnose. Many of you who's loved ones have been diagnosed with Alzheimer's disease, if it came from a primary care doctor you can often relate to them just asking a couple of very simple questions like what's today's date and who's the President, and that's the extent of the memory evaluation but doing simple labs to rule out other causes for memory loss is extremely important and some type of brain imaging should always be utilized to differentiate between the different types of memory loss.

George Vradenburg: A number of people with a similar question here, Linda Moye and Phillippe Berthoud online but there's also one that's called in with the same question, Ethelle Lord would you like to go live and ask your question?

Question: Yes thank you. This question is for Doctor Newport and I know Doctor Newport we've corresponded before.

Dr. Mary Newport: Yeah, hi Ethelle, how are you?

Question: I'm good. I'm so glad to hear from you and be part of this important program. My husband started on coconut oil after I read your information, I saw your clip on YouTube in 2011 but then he had to stop and recently when I moved him last August until about the first of January they reduced the coconut oil that he was taking. So my question is, is it just as effective to start slowly, go to the two tablespoons per meal three times a day, then reduce it and then return months later to the actual two tablespoons a meal and get the same results? Because I'm really excited, and he's in an advanced stage, of the results I'm getting even after I had to slow down for 6 months.

Dr. Mary Newport: That I do not know the answer, I have heard of people that had to stop it or that some family members decided that they were worried about cholesterol and they stopped it and they lost the benefits and when it was restarted they started seeing the benefits again. But I don't think that's actually been studied. This is just really anecdotal from people that I have heard from. Your husband had an extraordinary, if I recall, response to it and I don't know if you want to say something about that but I do think there is a potential that if he responded before that he would again.

Question: Yes he did. In 2011 he hadn't spoken for a year, or a little bit more even, and within 24 hours after, and I didn't know not to start so quickly I did give him the two tablespoons per meal and then he get diarrhea after 48 hours, but after 24 hours at three tablespoons per meal his first word was Ethelle which I hadn't heard as I said in over a year. And then when I brought him to his room his question was to me, are you happy? Isn't that profound? And the other day after not using it for months and giving it to him again at two tablespoons because I kept the small amount at least two teaspoons to carry him through because he was adjusting from a move, a physical move, and I didn't want to really add to the problem and so he started the two tablespoons and within less than one day, less than 24 hours, there was a conversation going on at the table and his question to the person because they were threatening to arrest the other fellow if he didn't drink his juice and

my husband listened to all this and right out of his mouth was well did he do it? He was very concerned that he might to go to jail if he didn't drink his juice. So I can't say enough about the coconut oil.

George Vradenburg: Thank you Dr. Lord. I appreciate that.

I'm curious just to go back to what the dosage is that you're using in the trial and whether increased doses other than the side effects you describe are a problem or that lesser dosages might be as effective? Are you doing any dose variations in your trial?

Jill Smith: Because this is a pilot study, we are trying to keep to the standard 2.5 ounces daily for the participants. For individuals who are trying it at home, I think clearly there could be some benefit at whatever level you are able to give your loved ones.

We've talked briefly about the different types of products, and I just wanted to point a few things out that Doctor Newport can add to. As far as coconut oil I know some people take it as a pill, some people get the oil itself, which at room temperature kind of looks like lard, and I always get questions about the type of product that people should use. And perhaps you're not in the Tampa area so I can't assist you with the research study, if you want to put your loved one on it, it's important to buy an extra-virgin non-hydrogenated formula. It is not something I would recommend purchasing at your grocery store or at a drugstore, I think the higher-quality products that you can buy if you're looking for something locally are probably like at a health food store or even a vitamin store. Then to start with low doses and work your way up and I think that's been discussed a bit and you just find the dose that your loved one can tolerate. The other question I get very frequently is if I cooked with coconut oil are we getting the same benefit? And unfortunately when you cook with it you are pretty much burning off all the benefit that you'd be getting as far as the ketones and so forth. So cooking with it, it's a healthy oil to cook with but you're not getting any cognitive benefits from that, and Doctor Newport I think you'd like to add to that?

Dr. Mary Newport: Yeah I was just going to say that because some people do get diarrhea if they try to take too much too fast, I usually recommend that they start with like maybe one teaspoon, two or three times a day with food and that they kind of gradually increase every two or three days from that point. Some people just are very sensitive to it. We were very lucky that Steve didn't have a problem with two tablespoons right away, but a lot of people do. So just kind of take it slowly, people are eager to see the effect but if the person with Alzheimer's has diarrhea you might never be able to get them to take it again or you might not even want to give it to them if there's an accident so I just recommend taking it slowly.

Jill Smith: Yeah start low and go slow, that's what we say.

Dr Mary Newport: Right.

George Vradenburg: So there are a number of questions online about whether or not one can get into this trial from anyplace else in the country. I think you answered no, at least right now, but you've gotten inquiries. Is there any indication that any other center might pick this up and extend your trial other than you mentioned the inquiry from Canada but any place in the States?

Jill Smith: Not at this time. I mean this is a pilot study and the sooner that we can get through this, we would love nothing more than to be able to apply for some NIH funding to do a multi-center trial across the United States and have multiple sites participating in this. But people who've done clinical research in Alzheimer's will tell you we have to keep everything as standard as possible which means our staff, who is trained, administers all the memory assessments through the trial, that all the information is collected by the same group of

people, so that our results we know are accurate and true. So unfortunately at this time, you would have to come to Tampa for the visits but I've actually had participants in our various research studies who have family in Tampa and they use it as a reason to come and visit. So if that by chance is an option that could certainly be viable.

George Vradenburg: Here's a question from Pat in Illinois, which I think it reflects a number of other questions that I've seeing coming in online.

Question: Hi, thank you George. My question is my mother has dementia and we were wondering, my siblings and I, is this something that would be beneficial for us to take at this point before we have any symptoms or is this strictly for when the symptoms occur?

Dr. Mary Newport: There's some actually interesting research that's going on in Canada and it's <u>Doctor Stephen Cunnane</u>. He has a ketone PET scanner and he has been studying MCT oil in Alzheimer's disease and basically what he has found is that the higher the level of ketones in the plasma the greater the percentage of energy those ketones provide in the brain. What he has learned is that from taking MCT oil which comes from coconut oil, but they use MCT oil in this study, that you can provide as much as 8 - 9% of the energy requirement of the brain just by taking a dose very similar to what they're using in the Byrd study and it just happens that people who are at risk for Alzheimer's fairly early-on have a deficit of energy in the brain of about 5-10%. Basically the conclusion is that it could potentially be beneficial for preventing Alzheimer's disease.

Question: Thank you.

George Vradenburg: Question from Christina online. How does MCT oil affect diabetes? If you have diabetes is the use of MCT oil not recommended?

Dr. Mary Newport: I think it might actually be beneficial for people with diabetes. What I've seen, and this is anecdotal again, and there has been a little bit of study at another Department of USF, when you take MCT oil it lowers the blood sugar. So that could be beneficial for a diabetic. Also if you think about it, in this case with Alzheimer's we're talking about alternative fuel for the brain but in diabetics other organs are affected with insulin resistance and ultimately there's so much damage to kidneys and eyes and poor circulation of the skin and people end up with amputations and if you could provide an alternative fuel, such as ketones, since they're not using glucose effectively, one question is could you prevent some of this damage to other organs that occurs in diabetics over time? My gut feeling is that it is beneficial to people with diabetes.

Question: Let me ask you are there other versions or other kinds of products that have ketones in them other than coconut oil? Is there another source of ketones that one can get on the market?

Dr. Mary Newport: Yeah, well not quite on the market yet, but there are in development ketone salts they are called, they're ketone mineral salts where the ketone is bound to sodium, potassium and they are working on a calcium and magnesium product. Right now it's only available for research purposes but I know that they are trying to advance it very quickly so that it can be generally available to the public. Ketone esters are another big area.

Very early on when I first learned that these seemed to be benefiting, I made contact with <u>Doctor Richard</u> <u>Veech</u> at the NIH in Washington D.C. and he for years has been working on a ketone ester to try to help people with Alzheimer's and Parkinson's and some other neurodegenerative diseases and traumatic brain injury. A ketone ester can raise levels of ketones much higher than what you can get from MCT and coconut oil and the

big problem after all these years, I've known him for 7 years now, he is having difficulty getting funding from the NIH or any other source to mass produce this and get clinical trials going. Hopefully soon that will happen, that's a very promising area that has yet to even have a pilot study. There are a couple of other ketone esters also that are in development that are trying to get FDA recognition. So yes, there are products on the horizon but unfortunately none of them are readily available to the public yet.

George Vradenburg: This is a question from Jenny Janssen. Jenny your question?

Question: Hello. My question is we have a significant amount of Alzheimer's in my mom's side of the family. My mom had Alzheimer's also. Most of my cousins have gotten it, and my sister has started rubbing coconut oil on her skin and I wondered if that can create the same effect as ingesting coconut oil?

Dr. Mary Newport: I think it would be interesting to measure levels of ketones after that type of thing. I know of some instances in which people are doing this, there's a group of people with ALS or Lou Gehrig's Disease, that used coconut oil massage as part of their protocol. And I know of one lady who was taking it orally, she had improvement but she had diarrhea even with a small amount, and she lost her improvements when they stopped it. Her daughter started massaging it and she regained her improvements again. So that's just an anecdote, but I researched this a little bit with infant massage and there are actually studies out there where they showed that with infant massage that did increase those particular fatty acids in the blood when they measure before and after the massage. So apparently it is absorbed and it does increase those fatty acid levels. So it's possible, it just need to be studied.

Question: Well thank you very much.

Dr. Mary Newport: You're welcome.

George Vradenburg: What's so striking about all this is that the anecdotes, aside from the side effects, all seem to be positive. It will be intriguing to hear the results of your trial, Jill. So when is your trial over and when are we likely to see publishable results using this scientific process, the gold-standard of a randomized control trial?

Jill Smith: Well we're hoping to get 65 individuals who we dose with the treatment, and we're quite a long ways from that. So we're hoping to have the results in the next 12-18 months. Each individual's participation is 8 months long, so you figure if it takes us a few more months to enroll the number of individuals we are looking for, for everyone to complete their participation, and then it always takes several weeks to analyze all the data after. So I'm optimistic and hopeful, as I say, within the next 12-18 months.

I of course realize everyone wants those answers now. So the faster we can meet our enrollment goal, the faster we can get those results out. And you point out something really important George. We're hearing lots of positive anecdotal stories and that's exactly why we wanted to do the clinical trial. I'm sure there are stories out there of people who have tried it and had side effects or people have tried it and haven't had any effect, but we don't always hear that information.

So we're trying to get the truth out, we hope and think it's going to be viable and a certain benefit to Alzheimer's patients and their families, even if only to give a few more months of higher level functioning. I mean Doctor Newport mentioned, even that limited amount of time was certainly worth the effort.

Dr. Mary Newport: I have heard from people who said they saw absolutely no benefit. So that medical food that I learned about was Axona, it just wasn't out for another year, but in their studies almost half of the

people responded and the other didn't. So not everybody is going to respond to it. I've heard from over 400 people who have had a positive response probably 40 or so people that felt they had no response or very limited response or they just had too many side effects and they decided to stop it. So I'm thrilled that there is a clinical trial because such things really do need to be studied.

Jill Smith: You're absolutely right Doctor Newport and it'll be interesting to see in sub-analysis if there was a difference in effect on people entering at the various MMSE scores, or whether or not they were ApoE4 positive or not. So we're trying to collect as much side information as we can try to determine who this best benefits.

George Vradenburg: It will be interesting even if you get ambiguous results it may be because we have not yet figured out which sub-populations can benefit and which sub-populations don't get the benefit. So the ApoE4 could be one characteristic or there could be others as well. So this may be one of what will become a family of studies on this score.

Jill, how many persons do you have participating in your trial right now? I mean actually recruited.

Jill Smith: We have screened 20, but a significant number didn't qualify based on eligibility criteria. So their score was outside of the range, they had another health condition that they hadn't reported to us that ended up being something we didn't think during the pilot study would be in their best interest to participate. I want to say we've had maybe somewhere between half a dozen and maybe 10 participants actually go through the treatment study itself but we're trying to get 65 so that we have a real good number of individuals to try to analyze the data on.

George Vradenburg: This is a question that came in online from Pamela. Do you disqualify patients that have been in another study for Alzheimer's, for example deep brain stimulation or other study?

Jill Smith: No we usually wait what we refer to as a wash out period since participation in another intervention. For anyone who's had any involvement in pharmaceutical clinical trials, a lot of times participating in a study previously will prohibit or not make them eligible for a new research study that's being done. In ours that's not the case, we just usually (depending on what the intervention was) wait a certain period of time to make sure they've gone back to their normal status and then we would screen them for the coconut oil study.

George Vradenburg: So, a question from Linda Moye online. What signs do I look for to determine if the oil is helping? It's a general question and more precisely what are you looking for in your trials? Is it just the MMSE improvement?

Jill Smith: We are doing a number of different assessments, various cognitive measures, the MMSE is just kind of a drop in the bucket for the number of memory tests that we're doing. We're also monitoring for changes in day-to-day activities, their ability to do what we refer to as activities of daily living. We're also monitoring for changes in an assessment called the Neuropsychiatric Inventory, which is different behaviors and moods and so forth. We've heard evidence in the past that the coconut oil has given people different mental state as far as it having benefits on agitation, depression and so forth. So we're monitoring for those as well and we're collecting those throughout the trial and that way we can compare before they were ever on any product and then on the two different products the Fuel For Thought and then the placebo product.

George Vradenburg: Question here from Alanca in Washington D.C. Do you have a question?

Question: Is it possible that coconut milk can be of an asset, or even hopefully piña coladas?

Dr. Mary Newport: Coconut milk actually is loaded with coconut oil. So yes it could be, it's probably about a quarter of a cup maybe a little bit more than that is equal to about a tablespoon of coconut oil. So yes I mean it's basically the same composition as coconut oil but it just has the other components in the milk.

Jill Smith: And I think you just have to pay attention to what other products are in it that could affect your health in other ways as well.

George Vradenburg: I'm changing my vacation drink.

Dr. Mary Newport: Yeah sometimes you'll see sugar added, some of the products that are in cartons on the shelf are very diluted with water too, but if you get it as the whole coconut milk concentrate and look for one that doesn't have chemicals in it and sugar added then I think you could get some benefit from that as well.

George Vradenburg: So I've got a question on that very subject of sugar from Linda Keith. Linda, what's your question?

Question: Yes, hi. Last winter, we went on a diet where we took all sugar out of our diet and my husband who had had a stroke, his brain thoughts immensely improved and when you were mentioning that it is a form of diabetes of the brain, I was just wondering if sugar were to be eliminated along with the coconut oil if that would be beneficial?

Dr. Mary Newport: Actually I think it could be, and one of the reasons why he may have improved is just because when you go on that type of a diet a very low carbohydrate diet you go into ketosis, which means your ketone levels become elevated. And a very strict form of that diet is used for epilepsy to treat children and adults who are not responding to medications and it's effective. Probably about 25% of them will have a complete elimination of seizures as long as they stay on that kind of a diet, about another third will have some improvement, and those studies have been done. So basically the low carbohydrate does raise ketone levels and personally from a lot of things that I have read we do probably consume way too much sugar in our society these days and my gut feeling is that has something to do with the increase in diabetes, and diabetes of the brain as Alzheimer's.

Question: Yeah okay. I just spent the weekend with my brother and he's only 72 and it's terrible, I've seen how he has changed in the course of the year. He asks questions after questions the same questions, and it's very hard on my sister-in-law. This is a terrible disease.

Dr. Mary Newport: It is a terrible disease.

Jill Smith: Diabetes is a huge risk factor for developing Alzheimer's. People who have diabetes have somewhere between 50 to 100% increased risk for developing Alzheimer's. People say what can I do to try to prevent it? Well definitely try to prevent getting diabetes.

George Vradenburg: And cardiovascular deterioration, so diet and exercise that helps your heart will help your brain too.

Dr. Mary Newport: Right.

George Vradenburg: So thank you very much, Jill and Mary. This was most fascinating. A lot of anecdotes out there, of course a lot of desperation out there as well to find something that will improve either the cognitive

or functional ability of somebody who has been diagnosed with Alzheimer's. So this is clearly a topic of an enormous interest as you have found from all the calls you've been getting and this call has shown it as well.

So thank you very much both of you for being here with us today. I'm sorry there are still some questions outstanding, but if your question wasn't asked in precisely the words that you asked I think you got the information that should answer your question. So thank you all for being on the phone today. In about a week we'll have a copy of this recording and a transcript on our website which is <u>usagainstalzheimers.org</u> so you can share it with your friends. As I said, there are well over 4,000 people who have asked us to send them the recap and the transcript, we will do that but obviously you can all get it on our website in the next week or so.

Just as a little tease, a promo, <u>our next call is going to be on Friday, April 17th from 3 - 4 PM Eastern and will feature Greg O'Brien</u>. Greg O'Brien has been diagnosed with Alzheimer's. You may have heard from this real life Still Alice <u>on our website</u>, <u>Facebook page</u> or <u>through his NPR series</u>. He's going to be with us to discuss his experience and his book <u>On Pluto: Inside the Mind of Alzheimer's</u>. I recommend the book, it's fascinating and to join us next month to understand sort of the mind of somebody that's going through this, the Still Alice movie is out there I urge all of you who have not seen it to go see it, but that's a fictional story there are people around this country in large numbers who are experiencing it in their life and Greg O'Brien will be on our call in April to really describe what he feels, what he can't do that he used to be able to do as a professional journalist, what he can do still and the efforts that he is making to try and press upon Americans the experience of going through this damned Alzheimer's journey. <u>So join us Friday, April 17th from 3:00-4:00 PM Eastern</u>.

As always, please stay on the line if you'd like to leave us a message with a question or comment. We're particularly interested in what you would like to see discussed on future calls.

So thank you Jill, thank you Mary, thank you all for joining us today and have a great afternoon.