Zoom In on **Dementia & Alzheimer's**

Alzheimer's Research Opportunities: How to Participate
Thursday, April 3, 2025 | 1 p.m. EDT
Transcript of Zoom with Michelle Papka, PhD
Director and Founder of Cognitive Research Center of New Jersey

The information provided in this transcription is a public service of BrightFocus Foundation and is not intended to constitute medical advice. Please consult your physician for personalized medical, dietary, and/or exercise advice. Any medications or supplements should be taken only under medical supervision. BrightFocus Foundation does not endorse any medical products or therapies.

Please note: This transcript has been edited for clarity and brevity.

NANCY KEACH: Welcome. Good morning. Good afternoon. I'm just going to wait till a few more people are in and we'll begin. OK, let's get started. So welcome. I am Nancy Keach. I am at BrightFocus Foundation--BrightFocus Foundation funds research worldwide for Alzheimer's disease, macular degeneration, and glaucoma.

We've invested over $300 million globally in research, and we provide information programs like this one to help people hear what the most current researchers and clinicians are doing in the Alzheimer's and cognitive disease fields. I want to thank Biogen, Lilly, and Genentech for supporting this educational program in part, although the content is solely BrightFocus'.

So before we jump in to a great subject today, a very practical program today about things you can actually do and participate in, also and last thing here, if you sent questions that don't relate specifically to clinical trials and current drugs or interventions that are in clinical trials, please refer to this whole body of prior episodes that I'm sure will answer the questions that you're asking. So if you have a question about genetics or

Leqembi or Kisunla or frontotemporal dementia or how to get a diagnosis, all of these very specific things, you can refer to our website brightfocus.org/zZoomiIn. And all of those episodes are there for free. There's tremendously great information there, if I do say so myself. And I am going to introduce our guest today, and it's great to see all of your faces.

So for over 30 years, Dr. Michelle Papka has served as a researcher and clinician specializing in the field of aging, Alzheimer's disease, and dementia. She has practiced as a neuropsychologist, psychotherapist, and for me, she's served as a psychotherapist, casually, I should say, and a researcher, and has served as principal investigator on clinical trials for Alzheimer's disease, and age-related cognitive impairment for over 15 years. Dr. Papka founded her private clinical practice in 2001, and she founded the Cognitive and Research Center of New Jersey in 2009. The New Jersey center was recently acquired by Pinnacle Clinical Research, and Dr. Papka now serves as the scientific director of central nervous system conditions for the full Pinnacle network. Dr. Papka is known for her passion to the field, her dedication to her patients and their causes, and as an educator in the community. And I will back that 110%. Dr. Papka always gives her time for people. So welcome, Dr. Papka, and thank you so much for being with us today.

DR. MICHELLE PAPKA: Thank you so much for having me. Thank you.

NANCY KEACH: Before I ask about some specific trials that you are running actively and that have sites available all over the country. So if you get a diagnosis of mild cognitive impairment and we have a couple of episodes that are how do you go and get an early diagnosis? You want to get diagnosed as early as possible, which is a problem in itself because there's so much stigma to going and getting a diagnosis. But if you have gone to your primary care doctor and/or a neurologist and gotten a diagnosis of mild cognitive impairment or early AD, what's the first thing to do if you've been diagnosed and you want to participate in a study? You want to participate in research and get involved somehow.

DR. MICHELLE PAPKA: So if you have been diagnosed and you want to participate in a study, there are several ways to find a study. So you could speak with the health professional who gave you the diagnosis to see if

they can point you in the direction of a clinical trial research institute that is near you. You can also check different sources, including the BrightFocus website, which has a link to clinical trial match so that you can see what clinical trials are going on in your area.

And once you are linked to a clinical trial site, you should be able to, number one, learn what they're doing that you may be a candidate for then. But also, most clinical trials centers maintain databases of patients who are interested in trials so that even if they don't have a trial currently, they will contact you with trials as they come in their pipeline to see if you're interested at some future date. And that future could be a month from the day that you contact them or several months out. But I would say the first step is to get connected with a program that specializes in Alzheimer's clinical trials.

NANCY KEACH: And we have a link in the chat. The first link is to the trial finder on BrightFocus' website. And I'm going to just qualify what Dr. Papka said that the better sites and the better doctors, if you don't qualify for a trial that you apply for, which may be for any number of reasons, it could be age, it could be some other disease, or you've been on a medication prior, not all of them will refer you to a different trial or put you in a registry. So if you volunteer for a trial and they just say to you, oh, sorry, you don't qualify. Go home now. Don't give up because there are many other sites like Dr. Papka's who will make sure that you get put into a system that will recommend a trial to you if it's suited to you because there are a lot of different types of trials, which is part of what we'll cover today.

So there's a lot of questions. And I see the first one in the chat is about this, but a lot of questions about if you're already in a trial or you're already taking a drug, does it disqualify you from other trials? So let me read a couple of them so that you can answer holistically. The one in the chat here from Anker. "I am in the Trailblazer III study and in the observation stage. Once this study is done, what other studies can I participate in? I would like to participate in a tau study." And before you answer, I'm going to just do throw in a few more. I am currently-- this is from John in Des Moines. "I'm currently in two months into monthly

fusions of Kisunla. Are there clinical trials that a person can be included in that are already in treatment as I am?" I know these are different questions, but I'm just going to throw them all out because we can't answer every single one individually. "How to be sure I don't participate in a trial that will exclude me from other trials? For example, if I participate in a vaccine trial, might that exclude me from amyloid and tau clearing interventional trials?" That's from Bonnie in Parkesburg, Pennsylvania. I'll just do one more. "I found that participation in one trial, a dosage trial for donanemab, is preventing me from qualifying for anything else. I'm getting frustrated, but I don't want to give up." And that is from Carol in Moseley, Virginia. So let me stop there because we had quite a few of these.

DR. MICHELLE PAPKA: OK, so these are great questions. So I'll try to give an answer that will address all of those questions. So for one, you can only be in one clinical trial at a time. So if you are enrolled in a trial you cannot simultaneously be enrolled in another trial. And that's really it's for your safety because you may be given an experimental drug and you really shouldn't be taking another experimental drug at the same time. And so for your safety and also for the quality of the scientific data that's being collected in these trials, you can only be in one at a time. So that's the first thing.

The second is that each clinical trial has its own inclusion and exclusion criteria, and part of the inclusion, exclusion criteria are the allowed medications. So we have lots of clinical trials for Alzheimer's that might allow somebody to be on drugs like Aricept or Namenda and also be in a clinical trial. But every trial is different. And it would really just depend on the trial that you're looking to be in.

With regards to taking drugs like Kisunla and Leqembi, unfortunately, right now, most clinical trials will exclude people who are currently taking a monoclonal antibody treatment. And while we need to get away from that as these monoclonal antibodies, these anti-amyloid drugs start to become standard of care for patients who qualify for those medications, currently, they really tend to be excluded from most trials. And hopefully over time, we're going to come away from that because we agree in the field that a

person is going to need probably a cocktail that is going to include anti-amyloid, anti-tau, anti-inflammatory, a cocktail of drugs that are working by different mechanism of action. But before we can get to that safely, we really have to have an understanding of the individual effect of each type of drug, both in terms of what it does, its efficacy and also its safety, and how safe it is to give these drugs at the same time.

Now, the question of if you had been treated with a monoclonal antibody, whether it is one that has been approved by the FDA, or an experimental drug that did not come to be approved by the FDA, while that may be exclusionary for many trials, sometimes for some trials, if there is a certain washout period, so a period of time since you were last given that drug and then starting a new experimental medication, sometimes that is allowed. It could be a whole year. Sometimes I've seen studies where it's been six months. But in some cases that could be allowed.

The other thing I would suggest for somebody who has been in a trial and given one of these types of medications and then want to go into another trial, you may be able to find out if you were given the drug or given placebo because if you were given placebo, then you would qualify to be in another study because you were never given that monoclonal antibody. So usually, you can find out your group assignment at some period of time after the study has closed. Not after you've completed the trial, but after the study has closed.

NANCY KEACH: That's something I didn't know, actually. So that's a great thing to know that after it's closed, you can ask.

DR. MICHELLE PAPKA: You can ask. In most cases, the sponsor does provide that. There may be some cases where they don't. But in my thinking of it, I've received that list for pretty much every trial I've done. And when I receive the list, I get on the phone and start calling people to tell them what their group assignment was because people always want to know. We're always guessing. But if that's something you can find out, and if you were given the placebo, then it really is a non-issue or it should be.

NANCY KEACH: And there are trials that are not for drugs. For example, for what we call lifestyle interventions, they might be for courses of

exercise or types of diets or even sleep studies or those types of trials. So if you wanted to participate in those types of trials, is that an option if you're excluded from a therapeutic trial, a drug trial?

DR. MICHELLE PAPKA: It should be. And again, it depends on the actual trial. So even lifestyle factors, those controlled studies will have their own inclusion, exclusion criteria. But definitely there are lots of options. And I'm glad that you're pointing this out for people to consider in addition to the anti-tau anti-amyloid drugs that these lifestyle factors, these pillars of brain health, which are being studied empirically in clinical trials, but also that are being encouraged in people's everyday lifestyle and health are also very important factors in and moderating the course of the disease process.

NANCY KEACH: We have one more question before we go to the actual trials. And this is from Catherine. "I see on Facebook many opportunities to participate in studies. How do you know what's legit? Some are from nonprofits or associations, some from drug companies and universities."

DR. MICHELLE PAPKA: So that's a very good question. So utilizing websites like the BrightFocus website that will connect you and provide you with information on clinical trials that are being conducted will be very helpful. You could also contact the site and learn more about it. There are many organizations and clinical trial sites that will use Facebook to advertise. So just because you're seeing it on Facebook, I wouldn't discredit it. We do Facebook advertising because a lot of people are on it and are getting connected and getting pieces of information.

But legitimate studies have a lot of regulatory documents that you will see. And so once you contact the site, if you actually went in and entered into the consent process, you would see that those documents have been approved by an IRB. You could ask who the sponsor is.

NANCY KEACH: What's an IRB? What does that mean?

DR. MICHELLE PAPKA: Yes, sorry. An IRB is an institutional review board. So all studies that are being conducted in the United States have to have approval from an independent institutional review board. And this is a board that will approve not just the protocols. So the actual study,

in terms of its safety and legitimacy to be conducted, but any patient facing material, public material. Actually, including the advertising that you see on Facebook has to be approved by one of these institutional review boards. So the content has to be approved so that it is accurate and also not overly coercive. It has to be-- the language has to be easy to understand and honest and straightforward. So studies that are being conducted in the United States all have to have what's called IRB approval. And they are very particular about the language of these advertisements. And also, if any of you who have been in a study or consented to a study, everything that you see and read is approved by this institutional review board before it can be utilized.

NANCY KEACH: OK, thank you. And I'm just going to add, and I've never really thought about this before. But you should not be asked to pay money.

DR. MICHELLE PAPKA: Yeah, you should not ask to be paid money.

NANCY KEACH: Don't give money. You don't give money to participate in a trial. If anything, you get compensated sometimes. Correct.

And I'm going to thank Gloria for making the segue for me. She put in the chat. "Are there any results yet from the HOPE study?" And I know you are running the HOPE study at your site. And also the HOPE study was the very first clinical trial we featured when we started this Clinical Trial Zoom In program. And everyone who participated was very excited. And then we realized that their website had crashed during download and people were trying to get involved. So can you give us an update? Where are we with the HOPE study? What is it, and can people still participate and are there any results?

DR. MICHELLE PAPKA: So the HOPE study is a study that is being conducted by a company called Cognito. And they have a medical device that people utilize. It has a headset, which has just picture. This is how I describe it. Like sunglasses, it almost looks like glasses that have a flashing light and the person wears headphones that, to me, sound like static. And this device is giving off a-- the active device is giving off a 40 hertz signal, whether it's a visual signal or an auditory signal. And based on previous

studies, this 40 hertz signal helps induce certain activity in the brain that seems to be helpful for cognitive symptoms, and it also seems to be doing something that is helping to maintain brain mass. And some of the thought about how it's maintaining brain mass is that this type of stimulus, this signal is helping to keep neurons interconnected in a way that maybe it is not they're not getting interconnected without this intervention.

And so the HOPE study is a phase III study that was open to people who were diagnosed with either mild to moderate Alzheimer's disease, and it is still ongoing, and it is open to people who have moderate symptoms of the disease. So people who have more mild symptoms that cohort has closed. But it is still open for people who have moderate symptoms, which is really a wonderful opportunity because we don't always have clinical trials for people who have more progressed symptoms. There's a lot of emphasis towards early diagnosis and early treatments. And so this is a great opportunity for people who have more progressed symptoms.

We don't have the results of the HOPE study yet because they're ongoing. But the results that I spoke of were from the prior study, the phase II study, that led to this larger phase III study. I think that they are looking for, I don't know how many more people, but they're at the tail end of recruitment. But the recruitment is still open. And then probably it'll be a year or so out before we have the results of that study. But it looks promising and it's an exciting possibility because this is something that is not-- so far it's been shown to be pretty safe, very inclusive in terms of who is able to get it. We do have people who don't want infusions or injections, so it's not invasive compared to these other types of treatments. So it has been very popular for people to try to participate. And I think it's an exciting addition to the other opportunities and options that are out there.

NANCY KEACH: Yeah, and as you know, I reached out specifically because it is exciting. We get so many questions from people who say, my husband or my wife or my significant other is in moderate stage. Is there anything for them to do?

DR. MICHELLE PAPKA: Yes.

NANCY KEACH: Because everything for either early or even before you

have symptoms now. And so when you told me that they're looking specifically now for people who armed the moderate stage, that's fantastic. It's not a drug. And from what I know, the earlier stage results, which you mentioned from the earlier stage of the trial, a smaller group were very surprisingly positive, as far as my understanding is.

DR. MICHELLE PAPKA: Yes. Yes.

NANCY KEACH: And I believe-- let me also ask, although I'm surprising you with this. So I don't know if you're familiar with this study. But I think there was a study called the SMART study that was also testing this type of device that's more of a headset and more of a frequency type of device. I don't know if you're familiar with it and want to say anything about it, if you do know.

DR. MICHELLE PAPKA: Well, I'm not familiar with that particular study, but I can say that I know of and have heard about and hear about other types of medical device studies using different types of stimulation to induce activity and effects in the brain. And I think it's an exciting addition to the various types of treatments that we're exploring. And some people are just more comfortable and maybe it's more suitable for them to consider this type of an intervention versus other type of intervention.

And again, getting back to the cocktail, I'd like to see a time when it's not necessarily one or the other, but this could be an added benefit or have an added effect to other types of interventions that are being tried.

NANCY KEACH: Thank you. And so if you have more questions, anyone about the HOPE study in particular or this class of interventions, this stimulation I guess is how it's referred to in general, please either raise your hand or put them in the chat. And I'm going to move on to actually a study I was not that familiar with that I know you are posting at your site called the ReTain study. Can you describe the ReTain study for us?

DR. MICHELLE PAPKA: Yes, so the ReTain study is a study that is being conducted by Janssen, Johnson & Johnson. And this is a study for people who have preclinical Alzheimer's disease. So by preclinical these are people who have not been given a diagnosis of Alzheimer's disease. I

tend to call them the "worried well." They may be concerned because they have a family history or maybe they're noticing something. They're not sure if this is normal aging or something else, but they don't have symptoms that interfere with daily functioning or that would warrant a diagnosis, including a diagnosis of mild cognitive impairment.

However, if tested with different types of biomarkers, have underpinnings of the development of plaques and/or tangles that are still very, very early on and maybe not yet significant enough to cause these kinds of overt symptoms. So that is the population that the ReTain study is seeking. And their medication is an anti-tau medication. So it is geared towards trying to prevent this tau protein from creating tangles in the brain. And so that is it's an injection. So it's a medication that gets injected.

The screening for that study is actually currently on hold because they are modifying their protocol a little bit. But it will reopen. I'm not sure of the exact date but sometime in the near future. So we have a number of preclinical studies for anti-amyloid type drugs. This one is an anti-tau drug. So it works by a different mechanism of action. And that's a very exciting program as well.

NANCY KEACH: I've have a couple of questions. First you said it's an injection, so it's not an infusion and it's not a subcutaneous?

DR. MICHELLE PAPKA: Yeah, it's a subcutaneous injection. So some of these drugs are infused where you get the needle in your vein and you're hooked up to this pump, and it drips in slowly. And most of our infusions that we're doing take somewhere around 45 minutes or they're injected subcutaneously. So it's like getting a shot. You get a shot and it's injected. And then usually you stay at the site for a period of time just for an observation period.

So the drugs like Kisunla and Leqembi are infused drugs. So people who are on those, they have to go to an infusion center or potentially have an infusion nurse come to their home and have an infusion. Really, I think if we can move towards subcutaneous injections, that's really a game changer just in terms of the practicality. As and if these drugs get FDA approval, it's very difficult to find and have enough infusion centers to

accommodate all the people who are going to want and need to be on these drugs. But just imagine if you can do use one of those autoinjectors at home and autoinject the medication, it makes it much more accessible and available to people. And so in clinical trials, a lot of these companies are trying to develop injectable forms versus infusion forms just for long-term practical use.

NANCY KEACH: So the ReTain study-- and you mentioned other preclinical studies. So meaning before people are actually seeing symptoms. Is the ReTain study only for people who have not been diagnosed or don't have symptoms, or is it also for mild people?

DR. MICHELLE PAPKA: It's for people who don't have symptoms. Yeah.

NANCY KEACH: So here's the million-dollar question. If people have no symptoms, how are they finding out if they have the biomarkers which you can find in a scan or through blood, the amyloid, tau, or cerebrospinal fluid testing. How will they know if they have no symptoms?

DR. MICHELLE PAPKA: Yeah. So I want to be a little careful about saying that people who have preclinical Alzheimer's disease have no symptoms, just because research has shown that they may show some symptoms. It's just that this would not warrant a diagnosis even of mild cognitive impairment. So they don't have symptoms that warrant a clinical diagnosis. But some of them may be noticing something. Others may be not at all.

And so that's what makes it so difficult to find these people to participate in a research study, but also for people to think of themselves as somebody who maybe should come and participate. So this is where education and outreach is so important. And even some of those Facebook ads, why we're putting these things on Facebook to try to educate and let people know that you could be a candidate simply by, first of all, age. So a lot of these studies start if your age like around 50, 55, sometimes 60 or 65, depending on the study. And the people who tend to come in first are ones who may be concerned because they have a family history, or because they've seen it in someone else, or because

they're educated and maybe hyper vigilant about what they're noticing, or just want to come in and get this biomarker just for their own so that they know that they either have a mark or they don't.

But I think that what may happen over time is as blood biomarkers become used more and more in mainstream clinical practice, and as we have treatments that we know can help prevent the progression of the disease in people who are identified as preclinical, I think this is going to start to become standard of care in the future.

So I don't know if everyone listening knows that we have blood tests that can help detect remnants of amyloid and tau in blood. And a lot of these blood tests are really very highly sensitive, even more sensitive to earlier stages than some of our specialized PET scans. And so these blood tests and blood biomarkers are being used in these preclinical studies.

So there are actually three preclinical studies that we're doing right now at our centers. And the first step is to come in and to be consented. So learn about the study, give consent, and then get a blood draw. And we're using a blood biomarker for these studies as a first step to determine if you qualify. And the purpose of these studies is to see if we give these drugs really, really, really, really early when someone may have the very beginnings, but not really the accompanying symptoms yet, can we prevent this person from getting the progression of the disease all together? And if we can, that's a game changer. That's a game changer. Then I can foresee a time when, just like you get your routine blood work, that once you hit a certain age, this is going to be part of your routine blood work. And if you have the biomarker, you'll be given your course of medication. And then we really may have a cure for this disease. And I think that's just an incredible progress and hope.

NANCY KEACH: Yeah, we talk about it these days like cholesterol for heart disease. If at some point you can screen in your blood for amyloid and tau, it doesn't mean you're going to get Alzheimer's or a heart attack. But you can now look into these trials and interventions. So it's very exciting. And Kimberly in the chat asked, "what are the three studies that you just referred to for the blood draw, where the blood draw is the first step?"

DR. MICHELLE PAPKA: So one of them is this ReTain study from

Johnson & Johnson. That's an anti-tau study. And then we're doing two other studies. They're both sponsored by Eli Lilly. One of them is called Trailblazer III. It's an addendum study they had added to an ongoing Trailblazer III study. And that is for people who have preclinical Alzheimer's disease. And they will be given Kisunla. So Kisunla is an anti-amyloid drug. It has FDA approval. And so we want to see if we give this to people really early, can we prevent the progression of the disease. And so that is currently enrolling and screening. And if you're interested I recommend finding a site close to where you live to see if you can screen for that. There's actually no placebo group. So everybody will get Kisunla if you qualify for that study.

And then Lilly also has another preclinical study that we're doing. It's called LAKI or I think they call that one the TRAILRUNNER-ALZ 3 as well. And that one is for people who have preclinical Alzheimer's disease and even a little bit MCI. That kind of early phase. And that is also an anti-amyloid drug called Remternetug. It's a different drug than Kisunla and in this case, this is an injectable form of the drug. And there is a placebo group for that one. But that is another preclinical study that we're doing. So those are the three that we are enrolling for now. So there are a lot of opportunities for people who are in preclinical category.

NANCY KEACH: So the Remternetug also removes amyloid like the Kisunla trial. That's so that's Trailblazer III is Kisunla and TRAILRUNNER-ALZ 3 or LAKI is the newer drug, Remternetug. And that is a subcutaneous injection and not an infusion, Remternetug.

DR. MICHELLE PAPKA: Yes.

NANCY KEACH: However, in the Remternetug trial, you may get drug or you may get placebo, whereas in the Trailblazer III if you qualify, you will definitely get Kisunla. Is that correct?

DR. MICHELLE PAPKA: Yes. You just won't know for the Trailblazer III. We're testing different titration doses. So how you titrate the drug up to the maximum dose, you won't know which dosing you're on, but you will be getting active dose of the drug.

NANCY KEACH: I'm going to ask a question from Pam on YouTube. "Are there clinical trials for people that are in the later stage of dementia who are not very verbal? Assuming imaging and/or blood tests to assess efficacy."

DR. MICHELLE PAPKA: There could be agitation or trials of neuropsychiatric, different types of neuropsychiatric symptoms that are associated with Alzheimer's disease. Currently, we're not enrolling for any studies of people who have severe symptoms. We have had those in the past and I'd like to see more. We do have two studies. The HOPE study being one, and we have another study that will be starting for-- it's called the Ono trial, which is for patients who have moderate symptoms. So currently there are studies for people with moderate symptoms.

More severe symptoms get difficult because especially if someone's not verbal, unfortunately, because a lot of how we test whether or not the drug works in terms of cognitive symptoms generally involves some kind of verbal testing. But the point of could you test to see whether it helps physiologically with the underlying mechanisms is a good one. And we do have trials where we're doing that, but not in patients who have severe symptoms. But that doesn't mean, just to get back to where we started, that there won't be in the future. And so you may want to get connected to a clinical trial center near you and let them know that you're interested and should there be a trial for patients with severe symptoms that you're interested in learning more about it because the pipeline is always changing.

NANCY KEACH: That's a very good idea. And Sandy in the chat wrote, "You mentioned that the typical age range for the preclinical candidates." She says, "I'm 74 and have a strong family history of Alzheimer's father, sister, brother. Would I be able to participate in a preclinical study, potentially?"

DR. MICHELLE PAPKA: Yes, definitely. So when I said in the 50s, that's the lower age range. So for the J&J study, the lower age range is 55. And then it goes up to age 75. For the LAKI study it's 55 to 80. And for the Trailblazer III study it's 65 to 80. So someone who's 74, you would meet the age criteria for any of those studies.

NANCY KEACH: Yeah. And you can, again, you can either Google the name of a study, or you can go on the Clinical Trial Finder match on our website, and it will tell you like the age range and what we'll allow you. What's an inclusion and an exclusion criteria.

We have a YouTube question from JK, and we did have a question about this submitted in advance. Are there specific trials for people-- This one is from Celeste in Madison, Wisconsin, and one of the chat is from JK, for people who are APOE4 homozygous. Are there specific trials for people who have APOE or APOE4 positive?

DR. MICHELLE PAPKA: There are trials for people who have two APOE4 alleles. I can't name you what they are, and those are also changing. So there are trials specifically looking at that particular population. But I also want to say that just because a person has two APOE4 alleles, doesn't mean that they're not also a candidate for all the other trials. So having two APOE4 alleles doesn't necessarily exclude you from being in all of the other clinical trials. So I can tell you that all the studies that we're doing would allow somebody with two APOE4 alleles to participate.

But yes, there are also studies and have been historically and I'm sure will be in the future specific to people who have two APOE4 alleles. And in many studies they are checking for your APOE status. So to know whether you have a 2, a 3, or a 4, sometimes they're telling you based on the research results, and sometimes it's just something that the clinical trial team, the central team, is looking at, because we want to understand how your APOE status affects the efficacy and the safety of the drug. And some of what we're learning is that some drugs seem to be more or less effective or more or less safe, depending on what your APOE status is. And that's why we're looking at that information so that we get more details about that.

NANCY KEACH: Lots of questions about this. Do research centers do that genetic testing or how do you get that genetic testing?

DR. MICHELLE PAPKA: So at a research center like ours, for example, we will do the genetic testing if it is part of a protocol. So if you come and screen for a study that includes genetic testing, and part of the protocol

is to give the results back to you, then we would do it. And that's probably true of a lot of dedicated clinical trial research sites that they will do it as part of a protocol.

And again, keep in mind and if you're screening for a study and you're being told that they are going to do genetic testing, it would be in the consent form whether or not you're going to get the results back. But you may just want to ask about it because sometimes people do it and expect to get the results back. And then that's not part of the protocol and you won't get the results back.

You could also go to your healthcare provider and you can ask to get this type of testing. It can be done through saliva or blood. Or you can also-- I know of people who go through things like 23andMe or there are other vendors, whether through saliva or blood, that will provide your APOE status. So you can get it.

NANCY KEACH: And for early onset Alzheimer's, we have a question from somebody with a really strong family history who's 52, Kimberly. Are there specific trials that you know of that people can participate in that focus on early onset Alzheimer's?

DR. MICHELLE PAPKA: Yes, there are trials for people who have early onset. And a lot of those are being done at the academic medical centers. So if you live near an academic medical center that has an Alzheimer's center, I would contact them. There's also a website that off the cuff, I can't tell you what it is that I think you could probably look for those early onset studies, but those are people and populations that are being followed very carefully and have opportunities to participate in studies involving different diagnostic tools that we have, and also all of these different types of interventional treatments.

NANCY KEACH: The questions are coming fast and furious, and we only have, I can't believe, six or seven minutes left. But so let me go to two of them. One is because I know a lot of people are hearing about this. Are there GLP-1 Alzheimer's prevention trials? So these are the weight loss and diabetes drugs that are all the rage right now. And they seem to hold promise potentially for Alzheimer's disease. Are there active trials at this

point?

DR. MICHELLE PAPKA: I think that Novo Nordisk does have a trial, but it is not yet. I mean, I think it is closed to recruitment right not. But those are coming down the pipeline. So my sources tell me that these are things that are going to be tested in the future. The effect of the GLP-1s on memory, different types of neuropsychiatric symptoms and also the Alzheimer's disease process. So we don't know how-- these GLP-1 seem like miracle drugs. They help so many different systems of the body, and it's not clear fully whether or not the positive effects are because it's secondary to something else. Like if you bring down somebody's body mass index into a healthy range, is the benefit of that also better brain health because now they're other things like they have better cardiac health and so on and so forth.

NANCY KEACH: Yeah. We don't know if these are—

DR. MICHELLE PAPKA: Yeah, if it's secondary or if it's doing something directly that is benefiting the brain and different systems of the brain. And those things are coming down the pipeline to be studied and very exciting possibilities as well.

NANCY KEACH: I'm only going to ask this because more than one person has asked because we try to escape from anything political here. So Gloria and Lynn and others, how is research being impacted by the federal cuts?

DR. MICHELLE PAPKA: Well, in terms of NIH research, I'm hearing from colleagues of mine at NIH and colleagues at academic medical centers who are funded through NIH research, worry about cuts in funding for that research. In terms of industry-sponsored research so far there hasn't been an effect on our center or centers like ours. The industry this is coming from pharma sponsored trials and so it's private money. It's not government money. And so we haven't seen that effect on the industry-sponsored trials so far.

NANCY KEACH: And I guess on behalf of BrightFocus, because we fund young researchers, I'll add that the field in general is deeply concerned that the cuts will slow down research and that we will lose researchers

to other countries, et cetera. So I think I can speak on behalf of the whole field that there is a tremendous concern that we will lose a lot of the momentum that we've gained in Alzheimer's research over the last decade.

When I started in this field, which is actually 16 years ago. But I remember in around 2012, the government was spending $400 million on Alzheimer's, as opposed to over $6 billion for cancers and so on. And recently, I believe, before the cuts, that spending on Alzheimer's research recently went to over $3 billion. And I think that most of the people in the field would say, that is why we're seeing all of these exciting advances, like blood tests and improved drugs and newer drugs on the horizon. So I think it's fair to say that may, not tomorrow, but over the next several years, slow down the pace of these exciting new discoveries and our ability to continue to look into them. And as Dr. Rossi, who directs the Alzheimer's grant portfolio at BrightFocus, thank you, Sharyn, says many Alzheimer's disease research centers have lost their funding and many more will by the end of April. And that will definitely impact trials.

DR. MICHELLE PAPKA: Yes. And we need NIH funded research for some of this basic science and other types of trials and discoveries that are not being done in pharma, even things related to lifestyle factors or what we call nutraceuticals. These are things that may not be-- pharma may not invest in it because these are not necessarily things that they can capitalize on. And so we need NIH. We need government funding to test these things and to have the seedlings for new ideas and growth. And if you think about all the resources that went into building these Alzheimer's disease centers and these academic medical centers, we really don't want to dismantle that.

It is very difficult to find specialists. I don't know if all of you are experiencing this that even if you want to go get a diagnosis or a workup the waits at some of these places can be like eight or nine months. There just aren't enough specialists and specialty teams in our country. So we certainly don't want to discourage them. We want to encourage them. And so I would agree with that.

Yeah, and I know we're out of time. But there is just one thing I want to

say because some of you have mentioned wanting to participate in a trial. And that is, and I say this to everybody who I meet with who comes to our center, thank you. Thank you for your interest in participating in a clinical trial and volunteering to be in a clinical trial because without people who are willing to participate in clinical trials, we will not have new treatments. So the only way to get to new treatments is through clinical trials. So for anyone and everyone who is doing something about it, thank you. And don't give up if you're not eligible for one study, ask about other studies because we need you. And it's important to have everyone's participation so that we can find the cure. We have to find the cure.

NANCY KEACH: Thank you for having us close on that note. And I'm also going to close on the note that our organization, for example, charities, philanthropies there are some like BrightFocus that do not depend on government money. We do not take government money. And I think reiterates how important philanthropic funding of research is because at times like these, when government investment fluctuates, it's the private philanthropies like ours that depend on donor donations that will continue to fund the research and in our case, continue to try to bring young researchers into the field. Because if there's no funding for postdocs to go into the field, they are not going to go into the Alzheimer's research field. They're going to go into oncology or some other field. So thanks also to all of you for participating in our webinar series here and for your donations because I know a lot of people participating are donors.

And with that, I want to give a huge thanks to Michele, to Dr. Papka. Thank you so much. Your service to the field and to families is fantastic.

Here's the website on the screen to search for a clinical trial, www.brightfocus.org about clinical trials. If you would like some free publications, they are also available on our website. And we can go to the next. If you have suggestions for future topics-- and I apologize because this was one of the times I know I didn't answer a lot of the questions we got an advance, so I hope you'll come back Dr. Papka. And because I also know there are other trials that haven't been announced yet and other therapeutics. There was an article about in November about Genentech's trontinemab, which is going to get into the brain more directly from

a brain. So many really interesting upcoming trials that we hope for upcoming trials to talk about. And so if you have suggestions for future topics or things that we didn't cover today that you really wish we would have, please email us at reply@brightfocus.org.

And I will close knowing that Dr. Papka has promised to come back by saying to everybody, thank you for staying with us and hug all the people around you that you love. I'm going to close on that note. And we send hugs to you, Dr. Papka, for being there for everyone in this terrible situation. So everyone have a wonderful rest of the week and weekend, and we will see you soon.

Resources:

- BrightFocus Clinical Trial Finder: https://www.brightfocus.org/about/clinical-trials/
- HOPE Study: https://www.hopestudyforad.com/
- ReTain Study: https://clinicaltrials.gov/study/NCT06544616
- TRAILBLAZER-ALZ 3: https://trials.lilly.com/en-US/trial/302480
- TRAILRUNNER-ALZ 3: https://trials.lilly.com/en-US/trial/548297