



diabetes prevention research matters

Volume 05, 2017

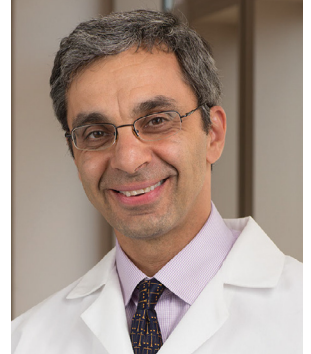
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A Note from the D2d Leadership Partners in Research

Dear D2d participant,
Happy New Year!

At the dawn of a new year, I wanted to thank you for your continued contribution to D2d and to share the exciting news that the study achieved its recruitment goal on December 16, 2016. This is the perfect time to pause and reflect on this accomplishment. Completing recruitment is a major challenge for every clinical study and we are thrilled to have met this major milestone.



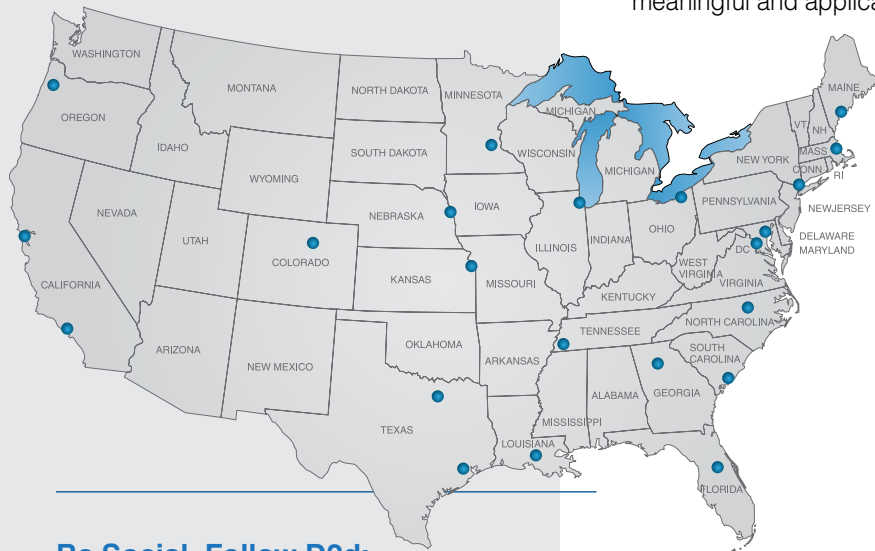
As of today, D2d has enrolled 2,419 wonderful participants in 22 cities across the United States and we are expecting a few more to join before the end of the January. The D2d participant community is a diverse group, in terms of age, gender, race, ethnicity and socioeconomic status and we expect results to be meaningful and applicable to the diverse U.S. population at risk for diabetes.

The next phase is to ensure that as a vital participant, you stay engaged in the study. Please continue to take your study pills, return for all follow-up visits to complete all necessary testing, and notify your research team of any changes to your health. In relation to this, I am proud to report that 99% of participants continue in D2d and 97% of you continue taking study pills. Both numbers are higher compared to the average clinical trial and higher than we expected when we planned the study. This reflects the commitment of the D2d participants and the productive partnership you have established with the research staff at your site. Please remember that even if you have stopped study pills for any reason, you are still part of D2d and your coming to study visits is very important.

I recognize that your time is very important and I am most grateful for your contributions and dedication to D2d. I wish you a healthy, fun, productive and meaningful New Year and will continue to provide you with updates on the study. As always, feel free to reach out to our study staff with any inquiries and please let us know if there is anything we can do to enrich your experience.

Thank you for making D2d possible!

Anastassios G. Pittas, MD MS - Principal Investigator, D2d study
Professor of Medicine - Tufts Medical Center



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Meet the D2d Champions at the National Institutes of Health (NIH)



In prior issues of the D2d newsletter, we introduced you to staff from the D2d Coordinating Center at Tufts Medical Center, the study lead investigator, Dr. Anastassios Pittas, and a fellow D2d participant from the Maine site. In this issue, we are excited to introduce you to the D2d champions at the National Institutes of Health (NIH), the United States' medical research agency whose mission is to improve health and save lives. The NIH provided the funding to conduct D2d and assigned two talented scientists, Myrlene Staten, MD and Saul Malozowski, MD to the D2d team. Dr's. Staten and Malozowski advise the study leadership, monitor the study to ensure it stays on track to meet objectives and utilizes funds in an efficient way.

D2d: Dr. Staten and Dr. Malozowski, can you each tell us about yourself and how you ended up working at NIH?

Dr. Staten: I studied and became a dietitian before going to medical school. I have always had an interest in the impact of nutrition on our health, which led me to become an endocrinologist. I spent over a decade working in the pharmaceutical industry, conducting clinical studies on new drugs for diabetes, obesity, and heart disease. Then I had the opportunity to work at the National Institutes of Diabetes and Digestive and Kidney Disease (NIDDK), which is part of NIH, focusing on research that could have a major impact on the nation's health.

Dr. Malozowski: I trained as a pediatric endocrinologist and first conducted clinical research in children and adults at the NIH. Then I worked at the US Food and Drug Administration reviewing information on new drugs to treat diabetes. There I was exposed to all steps of drug development and evaluation, and I was responsible for the oversight of large clinical research studies. In 2001, I returned to the NIH to work on studies exploring ways to delay or cure type 1 diabetes.

For more stories, visit d2dstudy.org/participants.

D2d: What are your roles in the D2d study?

Dr. Staten: The opportunity to work on the D2d Study is the culmination of many years of following and overseeing Dr. Pittas' clinical research studies. In my role as the D2d study Project Scientist, I partner with Dr. Pittas, the Coordinating Center and the Investigators at all D2d sites to provide guidance on how best to conduct the study.

Dr. Malozowski: I am the Project Officer for the D2d study. In this role, I oversee the performance of the study, assess the study team's management of the budget, and serve as a bridge to the NIDDK leadership and the Data and Safety Monitoring Board. In addition, I see my role at NIH as a facilitator, providing advice on how to advance the science in specific areas and to strategically develop projects.

D2d: Any final thoughts?

Dr. Staten: For me participating in the conduct and reporting of the D2d study is the cherry on top of my career. Sharing the study results, no matter the outcome, will have a major public health impact.

Dr. Malozowski: I expect the D2d study to answer "the" question: does vitamin D delay or prevent type 2 diabetes in people at high risk? If positive, this will be an enormous contribution to the nation's health. ■

Share your D2d experience!

We'd love to hear or see anything you'd like to share with us about your D2d experience so far! Please visit www.d2dstudy.org/share/ to tell us about your experience.

Do you have a fun, creative or interesting D2d related photo you could share with us?

Did you travel with your D2d item and have a picture to share?

Do you have a healthy recipe you'd like to share for a future issue of the newsletter?

Q&A

Participant FAQs

I have been off study pills, but have decided I want to start retaking them. Is this allowed?

A: Absolutely! Re-starting study pills is encouraged, provided you weren't asked to stop them by the study staff. The success of D2d depends on participants taking the study pill once daily. You can always ask any of our D2d staff about taking study pills at every visit.

What if I move to another state or out of the country? Can I still participate in the study?

A: If you are moving to another state, a D2d staff member can see if there is a D2d site located in the state you are moving to and can look at options to see if you're eligible to transfer to another D2d site. If you moved out of the country, you would have to stop taking your study pills if you were unable to return for scheduled safety assessments. However, phone or e-mail contact would be scheduled every 3 months to determine if anything has changed. If you decided to move back to the US, your full participation would resume.

If I develop diabetes during the study, do I need to start taking medication right away?

A: A diagnosis of diabetes does not mean that you have to take medication. If you develop diabetes during the study, it is very important for you and your primary care physician to discuss the best treatment for you. ■

Featured Recipe

Black-Eyed Pea Salad to ring in the New Year

In the Southern United States legend says that eating black-eyed peas on New Year's Day will bring prosperity and luck in the New Year. There are several legends as to the origin of this custom, and several ways they are served. Texas caviar, Hoppin John, and Black-eyed peas and Ham hock are a few examples. Black eyed peas are actually a bean. By themselves they are high in fiber, low in fat and calories, and a good source of non-animal protein. Although New Year's Day 2017 has passed Black-Eyed Pea Salad can be a healthy side dish or main course anytime of the year. The following recipe has been tweaked over the years by Patty Sheehan, the D2d study Project Manager.

Note: peas need to soak for 12 hours prior to making the salad
Makes 8-10 servings

Ingredients:

- 2 cups dried black-eyed peas
- 2-3 bell peppers finely chopped (I use red, green, and yellow)
- 2 scallions finely chopped
- 1 garlic clove finely chopped
- ½ cup olive oil
- ¼ cup white wine vinegar
- ¼ cup apple cider vinegar
- 1 tbsp chopped fresh parsley
- 1 tbsp kosher salt
- 1 ½ tsp ground black pepper
- 2-3 slices of bacon (optional, but it gives a nice smoky flavor)
- 6 cups low sodium chicken or vegetable broth

Method:

1. Soak peas:

- Place black-eyed peas in a large bowl. Add cold water to cover the peas by 3 inches
- Place in refrigerator for 12 hours.

2. Prepare dressing:

- Whisk together bell peppers, scallions, garlic, olive oil, vinegars, parsley salt and pepper.
- Cover and chill dressing.

3. Prepare peas:

- Drain peas from the soaking water.
- If using bacon, cook it in a large pot so that fat renders (5-7 minutes), but it is still soft (if not using bacon continue with recipe).
- Add peas and stir to distribute bacon fat.
- Add broth and bring to a boil, then reduce heat to a simmer. Simmer until peas are tender, approximately 30 minutes. Stir occasionally.
- Remove bacon and drain peas.
- Transfer peas to a large bowl and add desired amount of dressing (you may have some extra), stir.
- Chill, and serve cold.

Enjoy your 2017!



Please Keep in Touch!

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REMINDERS

- **Please notify your research team immediately if you are told you have diabetes and before starting any medication for diabetes (e.g. metformin, Saxenda).**
- At your next visit, please remind your primary care doctor that you are participating in D2d.
- Please notify your research team if you plan to take more vitamin D or calcium than what D2d allows (vitamin D - 1,000 units per day; calcium - 600 mg per day).
- Don't forget about the next participant event held at your local site. If you have any questions please check with your D2d site staff personnel.