diabetes prevention research matters

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In This Issue

Partners in Research1
D2d Timeline2-3
Meal Plan Basics
D2d Clinical Sites
Reminders

A Note from the D2d Leadership **Partners in Research**

Dear D2d participant,

The idea for D2d was conceived around 2002 when Dr. Pittas, the study's principal investigator, and his team became interested in the association between vitamin D and risk of diabetes. Over the next decade, Dr. Pittas' team and other research teams reported that people with low blood levels of vitamin D have higher risk of developing diabetes. However, these studies do not prove that vitamin D is directly related to diabetes. It is possible that other factors can explain why people have both diabetes and



low vitamin D levels. For example, it is known that people with high vitamin D levels have a lower weight and a better lifestyle and they are healthier overall, which could be the real reasons behind their lower diabetes risk. The D2d study was designed to test the idea that vitamin D supplementation lowers risk of diabetes in adults at high risk for diabetes. The D2d research team (see picture) considers you, the study participants, as important partners in this research. As we are coming to the end of D2d, your participation today is just as important

as it was when you joined the study. D2d has been a very ambitious undertaking. Together we will find the answers to important questions about vitamin D, prediabetes and diabetes. We are all eagerly waiting for the final results, which will depend on your continued participation.

We would like to thank you for making D2d possible and we look forward to seeing all of you through to the end of this study. We wish you all the best for the New Year.

- The D2d Research Group

Be Social, Follow D2d:





D2dStudy.org



D2d News diabetes prevention research matters

3

We would like to stress the importance of taking the study pills every day and returning for your final few visits.

The D2d Research team is fully committed to working around your schedule.

Whether you have been with D2d for four years or one year, your continued participation will shape the future of diabetes prevention and will complete the final bullet in the timeline.

2018

Date to be determined

D2d is successfully completed The first phase of D2d comes to a successful end.



2016

June

D2d enrolls 2,000th participant

A participant from the Pennington Biomedical Research Center site was the 2,000th participant enrolled in D2d.



November

D2d publication

Management of Hemoglobin Variants Detected Incidentally in HbA1c Testing: A Common Problem Currently Lacking a Standard Approach.*

2014

August

D2d enrolls 500th participant

A participant from the Atlanta VA Medical Center site was the 500th participant enrolled in D2d.

September

First D2d publication

Rationale and Design of the Vitamin D and Type 2 Diabetes (D2d) Study: A Diabetes Prevention Trial is published.*

December

Sharing the D2d experience

The magazine Diabetes Forecast features a D2d participant who shared his experience about being part of the D2d Study. Read the interview at d2dstudy.org/in-the-news/

2012

June

U01 cooperative agreement grant is submitted

The D2d team submits a 1,140 page U01 grant application to NIH for funding to conduct the D2d study.



2010

January

NIDDK Large Studies Committee reviews preliminary concept of D2d

The justification and the preliminary concept of D2d goes through multiple internal reviews by NIDDK.



September

Association between blood level of vitamin D and Diabetes Risk in the Nurses' Health Study is reported

An observational study in the Nurses' Health Study strongly supports an association between low blood levels of vitamin D and development of diabetes.

2002

July

Idea is conceived

The idea that vitamin D is linked to risk of developing diabetes is conceived.



2017

February

D2d enrolls last participant

The 2,423rd and last participant enrolls in D2d. Congratulations to the amazing staff for recruiting a wonderful group of dedicated participants.

August

D2d publication

Assessment of a National Diabetes Education Program diabetes prevention toolkit: The D2d experience.*

September

Interim analysis results

The D2d Data and Safety Monitoring Board reviews the results of the interim analysis and

the interim analysis and recommends that the D2d study proceed to completion as planned.



2015

June

D2d enrolls 1,000th participant

A participant from the MedStar Community Clinical Research Center site was the 1,000th participant enrolled in D2d.

July

First time research participants

Joanne and her husband are first time research participants and among the first participants to be featured on the "Meet D2d Participants" page in d2dstudy.org. To share your experience as a D2d participant, submit your story at d2dstudy.org/share.

November

D2d enrolls 1,500th participant

A participant from the Northwestern University site was the 1.500th participant enrolled in D2d.

U01 grant to conduct D2d is awarded

Tufts Medical Center receives the U01 cooperative agreement grant to conduct the D2d study. The grant is supported by NIDDK and the NIH Office of Dietary Supplements.

October

Recruitment begins

D2d begins screening people at high risk for diabetes to join D2d in many study sites throughout the United States.

November

D2d enrolls

1st participant
A participant from
the University of

Kansas site was the 1st participant enrolled in D2d.



July

2011

U34 planning grant is awarded

Dr. Pittas and colleagues are awarded an NIH-supported planning grant, which provides financial support to plan the D2d study and prepare for the U01 grant application to seek support for the study conduct.

March

Association between blood vitamin D level and Diabetes Risk in the Diabetes Prevention Program is reported.

An observational study in the Diabetes Prevention Program study strongly supports an association between low blood levels of vitamin D and development of diabetes among people with prediabetes.

2006 September

CaDDM clinical trial

The Vitamin D and Calcium Homeostasis for Prevention of Type 2 Diabetes (CaDDM) study is funded in 2006 by the NIDDK and the NIH Office of Dietary Supplements. Results (published in 2011) support a mechanistic link between vitamin D and diabetes risk among people with prediabetes.



* To see the publications, visit d2dstudy.org/publications

Meal Planning Basics

Meal planning is deciding what you will eat during the week ahead of time. It is a great way to save money and ensure you're eating a balanced diet and meeting your nutritional needs. Some things to consider when planning a week of meals at a time:

- Calendar check: Determine what nights you'll have time to cook and what nights you'll only have time to reheat leftovers.
- Mix things up. Change up your menu by planning some meatless meals or substituting a breakfast for a dinner. Alternate between new recipes and old favorites.
- Save time and use leftovers. Have extra pasta on Monday? That can be reheated for lunch on Tuesday. Leftover chicken on Thursday? Use it to top a salad, fill a sandwich or add to a soup on the weekend.
- Search for sales. What's on sale this week at the supermarket?
- Think seasonal. What fresh produce is available this time of year? Is it salad season or soup weather?
- Recycle your menus. Don't throw away your meal plan at the end of the week. Instead, hold on to it and reuse it later.



Please Keep in Touch! **D2d Clinical Sites**

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California

Stanford University

Palo Alto, CA (650) 485-3910 Stanford@d2dstudy.org

University of Southern California

Los Angeles, CA (323) 980-8446 D2d@usc.edu

Colorado

University of Colorado, Denver Aurora. CO

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Florida

Florida Hospital Translational

Research Institute

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Georgia

Atlanta VA Medical Center

Atlanta, GA (404) 321-6111, ext. 7638 John.Varghese@va.gov

Illinois

Northwestern University

Chicago, IL (312) 503-3413 d2d@northwestern.edu

Kansas

University of Kansas Medical Center/ Truman Medical Center

Kansas City, KS (913) 588-6052 d2dstudy@kumc.edu Louisiana

Pennington Biomedical

Research Center

Baton Rouge, LA (225) 763-3000

clinicaltrials@pbrc.edu

Maine

Maine Medical Center

Research Institute

Scarborough, ME (207) 661-7624 D2d@mmc.org

Massachusetts

Tufts Medical Center

Boston, MA (617) 636-2842 tufts@d2dstudy.org

Maryland / District of Columbia

MedStar Health Research Institute

Hyattsville, MD (301) 560-2943 studies@medstar.net

MedStar Good Samaritan Hospital

Baltimore, MD

(443) 444-6137 / (443) 444-6136 D2d.Baltimore@medstar.net

Minnesota

Health Partners Research Foundation

Minneapolis, MN (612) 341-1950

Nebraska

Omaha VA Medical Center & University of Nebraska Medical Center

University of Nebraska Medical Cer

Omaha, NE

(402) 995-3924 / (402) 559-6244

New York

Lenox Hill Hospital

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North Carolina

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Ohio

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Oregon

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University of Tennessee Health

Science Center Memphis, TN

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Texas

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Dallas, TX (214) 648-2971

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Baylor College of Medicine

Houston, TX (713) 798-5757 VitDstudy@bcm.edu

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).
- Please call your research team if you have any study related questions or to report changes in your health, medications, or supplements.