



## **Baylor College of Medicine Site Specific Recruitment Plan & Materials**

### **RECRUITMENT STRATEGIES**

Recruitment efforts (especially pre-screening) will be targeted towards populations and communities at greater risk for diabetes. The following are associated risk factors that will be considered during recruitment:

1. Family members of people with type 2 diabetes (adult children, spouses).
2. People who are overweight.
3. Ethnic groups at highest risk: African Americans, Hispanic Americans, Asian Americans, and Native Americans.
4. Women with a history of gestational diabetes.

**Strategies to be employed include:**

#### **Departmental Databases**

- **E-mail (or other promotional mailings)**.....to people who have previously participated in Baylor College of Medicine Behavioral Medicine Research Center research, or expressed an interest in participating in such research studies. Will include link to D2d study webpage ([www.D2dstudy.org](http://www.D2dstudy.org)).

#### **Research-specific Websites**

Research specific websites that will be used to recruit potential participants include:

- *clinicaltrials.gov*

#### **Referrals from Primary Care Providers and Other Clinicians**

- Promotion to primary care providers will be limited to physicians already associated with the Baylor College of Medicine Behavioral Medicine Research Center (i.e., current or past co-investigators, etc.). Will promote through distribution of physician letters.
- Social Service Agencies
  - Harris Health System
- Other collaborative institutions

#### **Referrals from Participants (“word-of-mouth”)**

Participants from past and current studies will be encouraged to refer other potential participants such as family members or friends who may be at high risk for type 2 diabetes.

## **Publicity and News Media**

### ➤ **BCM public relations department**

- Distribute BCM PSA's/press releases to news outlets in the area (*see appendix for sample press release – modify to site*).
  - Potential opportunity for live interviews on local TV, radio (to promote study)

### ➤ **Flyers/Brochures (Targeted towards study population) - See appendix for samples; modify to site.**

- Baylor Clinic (selected departments)
  - Kirby location included
- Local gyms
- Local YMCA's
- Libraries
- Church wellness centers
- Front waiting room (Baylor Behavioral Med)

### ➤ **Presentations to:**

- Outreach to religious organizations
- AARP (local chapters)

## **Print and Media Advertisements**

- Newspaper advertisements
- Organization newsletters
  - Nonprofit groups
- Direct mail postcard

## **Web-based**

### ➤ **D2d Public Website**

- General study information will be presented to the public on the D2d public website, [www.D2dstudy.org](http://www.D2dstudy.org). Potential participants can review the information on the website and obtain site-specific contact information for a site in their area.

**Website URL ([www.D2dstudy.org](http://www.D2dstudy.org))** will be included in printed advertisements & other promotional materials such as e-mails to past study participants. In addition, provided verbally to any interested potential party.

### ➤ **BCM Institution Website**

- Study will be promoted on BCM Institutional website. (*See appendix for sample ad*)

### ➤ **Craigslist**

- Will post study participant volunteer recruitment ads on Craigslist. (*See appendix for sample ad*)
  - <http://houston.craigslist.org/>
  - Will post under “Community” section → “Volunteers”

- **BCM Facebook**

### **Recruitment from “Within” Baylor**

- Consider the following for posting recruitment fliers:
  - employee newsletters
  - intranet
  - employee health services
  - bulletin boards

### **In-Person Community Outreach**

- Health fairs, community events, and community organizations & religious gathering places
  - Community Organizations
  - Community Events
  - ADA (American Diabetes Association) Walk

## **5.4 APPENDICES (TOOLS AND MATERIALS FOR RECRUITMENT)**

**Appendix 5.4.1 Brochure, general info**

**Appendix 5.4.2a Letter to physician, general info**

**Appendix 5.4.2b Letter to patient from non-D2d physician**

**Appendix 5.4.2c Letter to patient from D2d site (with primary care provider permission)**

**Appendix 5.4.2d Letter to volunteer from D2d**

**Appendix 5.4.3a Ad text**

**Appendix 5.4.3b Ad flyer vitamin**

**Appendix 5.4.3c Ad newspaper 1/12 page**

**Appendix 5.4.4 Sample Press Release – NOT READY YET, CC will provide official press release and will coordinate with NIDDK**

## Appendix 5.4.1 Brochure, General Info

*(No changes. Using as provided by Coordinating Center.)*

### Appendix 5.4.2a Letter to Physician\_General Info

INSERT DATE

Dear Colleague,

I am writing to inform you and your patients about the D2d study, which is a clinical trial that will test the safety and efficacy of oral vitamin D<sub>3</sub> supplementation to reduce the progression from pre-diabetes to diabetes in people at risk for diabetes. The study is supported by the National Institutes of Health and is being conducted at twenty locations across the United States and we are very excited that *INSERT NAME OF SITE* has been selected to serve as a D2d site.

We are looking to enroll adults (age ≥ 30) with **pre-diabetes** and a BMI between 25 (23 for Asian) and 40 kg/m<sup>2</sup>.

⇒ *We recognize that your time is very valuable and we would be grateful if you made the enclosed pamphlets and flyers available to your patients for their review, simply by placing the pamphlets in the waiting area of your office.*

During the study, we will follow participants for development of diabetes but will not manage diabetes or other health problems that may develop during the course of the study. Therefore, it is essential that participants maintain their relationship with their primary care provider. We will foster this relationship by obtaining a medical release from participants at enrollment that will allow us to share with you results of study-specific laboratory tests.

As you are aware, recruiting for participants is challenging and we are most grateful for your assistance and support.

Sincerely,

**INSERT NAME**

Principal Investigator, D2d study

**INSERT NAME**

Coordinator, D2d study

## Appendix 5.4.2b Letter to Patient (from non-D2d Physician)

*INSERT DATE*

Dear *INSERT NAME*

Doctors that I work with at *INSERT NAME OF SITE* are studying the relationship between vitamin D and type 2 diabetes, to determine whether taking vitamin D can prevent type 2 diabetes in people that are at high-risk for diabetes. The study will likely help answer an important question that may help many people who are at risk for diabetes.

I believe you would be an excellent candidate for the study (called the D2d study), so I have enclosed a brochure for your consideration.

During the study, you will have glucose tolerance testing and the results will be given to you to discuss with me and other physicians of yours.

The study will be done at the following address, which is easily accessible by *DESCRIBE TRANSPORTATION INFORMATION*.

INSERT ADDRESS  
INSERT ADDRESS  
INSERT ADDRESS  
INSERT ADDRESS

If you are interested, you may call the study site at ###-###-### or send an email to *INSERT EMAIL*. For more information, you may also visit the study's website at [www.d2dstudy.org](http://www.d2dstudy.org).

Sincerely,

*INSERT PCP NAME*

## Appendix 5.4.2c Letter to Patient from D2d Site (w/ PCP Permission)

Date INSERT DATE

Dear INSERT NAME

We have the permission of your doctor, INSERT NAME OF PHYSICIAN, to invite you to participate in the Vitamin D and Type 2 Diabetes (D2d) study. This research study is supported by the National Institutes of Health and is conducted at [INSERT SITE NAME]. The study will examine whether taking a daily vitamin D pill can prevent or delay the onset of type diabetes in people at high risk for diabetes. Enclosed is a brochure that provides information on the study.

We are looking for people age 30 and above who are above their ideal body weight and are at risk for diabetes. If you are receiving this letter, you may be eligible for the D2d study. Participation in the study will require 12 scheduled visits and additional visits may also be needed.

During the study, which will last up to 4 years, you must agree not to take nutritional supplements or other preparations containing vitamin D in excess of 1000 units per day or calcium in excess of 600 mg per day from all sources combined.

During the study, you will have testing for glucose (sugar) and the results will be shared with your medical care team. Participants will receive a stipend for their time and effort during the study and for transportation costs.

The study will be done at the following address, which is easily accessible by *DESCRIBE TRANSPORTATION INFORMATION*.

INSERT ADDRESS  
INSERT ADDRESS  
INSERT ADDRESS  
INSERT ADDRESS

If you are interested, you may call the study site at ###-###-### or send an email to *INSERT EMAIL*. For more information, you may also visit the study's website at [www.d2dstudy.org](http://www.d2dstudy.org). We may also contact you by phone in the next 2-3 weeks to see if you would like to learn more about the study. If you do not want to learn more about DDM2, please call or email and ask to have your name removed from our list.

Please feel free to share this letter and our contact information with any friends or family members who are at risk for diabetes and would be interested in learning more about this study

Sincerely,

**INSERT NAME**  
Principal Investigator, D2d study

**INSERT NAME**  
Coordinator, D2d study

## Appendix 5.4.2d Letter to Volunteer from D2d

INSERT DATE

Dear INSERT NAME

We would like to invite you to participate in the Vitamin D and Type 2 Diabetes (D2d) study. This research study is supported by the National Institutes of Health and is conducted at [INSERT SITE NAME]. The study will examine whether taking a daily vitamin D pill can prevent or delay the onset of type diabetes in people at high risk for diabetes. Enclosed is a brochure that describes the study.

We are looking for adults age 30 and above who are above their ideal body weight and are at risk for diabetes. If you are receiving this letter, you may be eligible for the D2d study. Participation in the study will require 12 scheduled visits and additional visits may also be needed.

During the study, which will last up to 4 years, you must agree not to take nutritional supplements or other preparations containing vitamin D in excess of 1000 units per day or calcium in excess of 600 mg per day from all sources combined.

During the study, you will have testing for glucose (sugar) and the results will be shared with your medical care team. Participants will receive a stipend for their time and effort during the study and for transportation costs.

The study will be done at the following address, which is easily accessible by *DESCRIBE TRANSPORTATION INFORMATION*.

INSERT ADDRESS  
INSERT ADDRESS  
INSERT ADDRESS  
INSERT ADDRESS

If you are interested, you may call the study site at ###-###-### or send an email to *INSERT EMAIL*. For more information, you may also visit the study's website at [www.d2dstudy.org](http://www.d2dstudy.org).

Please feel free to share this letter and our contact information with any friends or family members who are at risk for diabetes and would be interested in learning more about this study.

Sincerely,

**INSERT NAME**  
Principal Investigator, D2d study

**INSERT NAME**  
Coordinator, D2d study

# Worried about Diabetes?

If you are over the age of 30 and are:

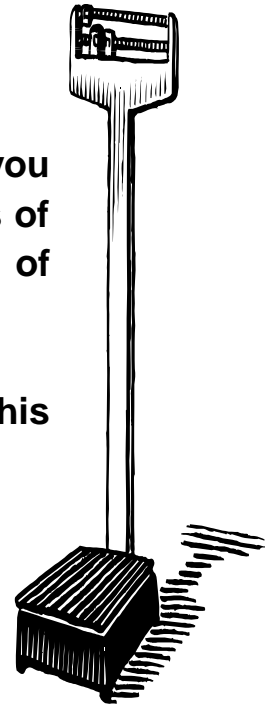
- Overweight?
- Have a parent or sibling with diabetes?
- Had diabetes during pregnancy?

If you answered yes to any of these questions, you may be eligible for a research study on the effects of a daily vitamin D supplement for the prevention of type 2 diabetes.

Please call 713-798-#### to see if you qualify for this diabetes prevention study.

Please call for more information.  
6655 Travis St., Suite 320,  
Houston, TX 77030  
713-798-####

BCM



**Appendix 5.4.3a Ad Text**

**Volunteers needed to study vitamin D and prevention of diabetes.**

HOUSTON – Researchers at Baylor College of Medicine are recruiting volunteers over the age of 30 for a study on the effects of vitamin D and prevention of diabetes. People who are overweight, have a relative with diabetes or had diabetes during pregnancy are at greater risk for developing diabetes and may qualify for this study.

Eligible women and men will receive valuable information on diabetes prevention. They will be asked to take a vitamin D pill daily. Volunteers need to be available for 12 study-related clinic visits for up to 4 years. Financial compensation will be provided upon completion of study visits following study enrollment; parking provided for all visits.

For more information, call the Behavioral Medicine Research Center at BCM at 713-798-3741.

## Ad Text (Multiple versions)

*The following advertisements will appear as text (e.g. postcard, Craig's list, newspaper)*

### Text #1 (Diabetes & Supplement)

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**Overweight adults age 30 and above, who are at risk for diabetes are needed for a research study on a dietary supplement.**

During the study, participants will obtain information about their health, will receive educational information on the prevention of diabetes, and will be required to take a dietary supplement daily. Participation in the study will last for up to 4 years. Financial compensation will be provided upon completion of study visits following study enrollment; parking provided for all visits. People diagnosed with diabetes, with kidney stones, or with kidney disease are not eligible. Other exclusions apply.

**For more information or to see if you qualify,**

**Call 713-798-3741**

**Email [VitD@bcm.edu](mailto:VitD@bcm.edu)**

**Visit [www.d2dstudy.org](http://www.d2dstudy.org)**

Sponsored by the National Institutes of Health

### Text #2 (Diabetes & Vitamin D)

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**Overweight adults age 30 and above, who are at risk for diabetes are needed for a research study on vitamin D and prevention of diabetes.**

During the study, participants will obtain information about their health, will receive educational information on the prevention of diabetes, and will be required to take a vitamin D pill daily. Participation in the study will last for up to 4 years. Financial compensation will be provided upon completion of study visits following study enrollment; parking provided for all visits. People diagnosed with diabetes, with kidney stones, or with kidney disease are not eligible. Other exclusions apply.

**For more information or to see if you qualify,**

**Call 713-798-3741**

**Email [VitD@bcm.edu](mailto:VitD@bcm.edu)**

**Visit [www.d2dstudy.org](http://www.d2dstudy.org)**

Sponsored by the National Institutes of Health

### **Text #3 (Diabetes/Family History & Supplement)**

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**Overweight adults age 30 and above, with a family history of diabetes are needed for a research study on a dietary supplement for prevention diabetes.**

During the study, participants will obtain information about their health, will receive educational information on the prevention of diabetes and will be required to take a dietary supplement daily. Participation in the study will last for up to 4 years. Financial compensation will be provided upon completion of study visits following study enrollment; parking provided for all visits. People diagnosed with diabetes, with kidney stones, or with kidney disease are not eligible. Other exclusions apply.

**For more information or to see if you qualify,**

**Call 713-798-3741**

**Email [VitD@bcm.edu](mailto:VitD@bcm.edu)**

**Visit [www.d2dstudy.org](http://www.d2dstudy.org)**

Sponsored by the National Institutes of Health

### **Text #3 (Diabetes/Family History & Vitamin D)**

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**Overweight adults age 30 and above, with a family history of diabetes are needed for a research study on vitamin D for prevention diabetes.**

During the study, participants will obtain information about their health, will receive educational information on the prevention of diabetes and will be required to take a vitamin D pill daily. Participation in the study will last for up to 4 years. Financial compensation will be provided upon completion of study visits following study enrollment; parking provided for all visits. People diagnosed with diabetes, with kidney stones, or with kidney disease are not eligible. Other exclusions apply.

**For more information or to see if you qualify,**

**Call 713-798-3741**

**Email [VitD@bcm.edu](mailto:VitD@bcm.edu)**

**Visit [www.d2dstudy.org](http://www.d2dstudy.org)**

Sponsored by the National Institutes of Health

#### **Text #4 (Gestational diabetes & Supplement)**

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**Overweight women age 30 and above, who had gestational diabetes (diabetes during pregnancy) are needed for a research study on a dietary supplement for prevention of diabetes.**

During the study, participants will obtain information about their health, will receive educational information on the prevention of diabetes and will be required to take a dietary supplement daily. Participation in the study will last for up to 4 years. Financial compensation will be provided upon completion of study visits following study enrollment; parking provided for all visits. People diagnosed with diabetes, with kidney stones, or with kidney disease are not eligible. Other exclusions apply.

**For more information or to see if you qualify,**

**Call 713-798-3741**

**Email [VitD@bcm.edu](mailto:VitD@bcm.edu)**

**Visit [www.d2dstudy.org](http://www.d2dstudy.org)**

Sponsored by the National Institutes of Health

#### **Text #4 (Gestational diabetes & Vitamin D)**

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**Overweight women age 30 and above, who had gestational diabetes (diabetes during pregnancy) are needed for a research study on vitamin D for the prevention diabetes.**

During the study, participants will obtain information about their health, will receive educational information on the prevention of diabetes and will be required to take a vitamin D pill daily. Participation in the study will last for up to 4 years. Financial compensation will be provided upon completion of study visits following study enrollment; parking provided for all visits. People diagnosed with diabetes, with kidney stones, or with kidney disease are not eligible. Other exclusions apply.

**For more information or to see if you qualify,**

**Call 713-798-3741**

**Email [VitD@bcm.edu](mailto:VitD@bcm.edu)**

**Visit [www.d2dstudy.org](http://www.d2dstudy.org)**

Sponsored by the National Institutes of Health

Ad newspaper 1/12 page

**Are you at risk for Type 2  
Diabetes?**

You may be at risk if you are overweight,  
you have a parent or sibling with diabetes  
or you had diabetes during pregnancy.

**You may qualify for a research study on  
vitamin D and prevention of diabetes**

Participants will receive diabetes testing,  
information on diabetes prevention,  
and a stipend for participating.

**Please contact us at: 713-798-3741  
VitDstudy@bcm.edu**

or go to [www.d2dstudy.org](http://www.d2dstudy.org) to learn more  
about the study and type 2 diabetes

# Are you at risk for Diabetes?

## You may qualify for a research study

If you are older than 30 years and answer yes to any of the following questions:

- You are overweight
- You have a parent or sibling with diabetes
- You had diabetes during pregnancy
- You are willing to take a daily supplement

Volunteers are needed to participate in a research study (12 visits, up to 4 years) on the effects of a daily vitamin D supplement on the prevention of type 2 diabetes.

**During the study, you will receive:**

1. Information about your health, and educational materials on lowering your risk of getting diabetes.
2. Regular monitoring for development of diabetes.
3. Financial compensation for completing study visits.

For more information, call (713) 798-3741  
or visit [www.d2dstudy.org](http://www.d2dstudy.org)

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