

# Medical University of South Carolina Weight Management Center

## Recruitment methods

# Successful recruitment for previous clinical trials

TRIAL	# GOAL	# ENROLLED
52 week non-medication weight loss trial	50	50
52 or 164 weeks (depending on pre-diabetic status) weight loss trial	20	23
12 weeks non-medication weight loss trial weekly visits	120	132

Public Relations : Newsroom : 2013

## MUSC researchers to examine if vitamin D prevents diabetes

By Dawn Brazell | News Center | November 12, 2013



Sarah Pack

MUSC is investigating if a vitamin D supplement helps prevent or delay Type 2 diabetes in adults who have prediabetes, who are at high risk for Type 2.

MUSC is looking for volunteers to take part in the first definitive, large-scale clinical trial to investigate if a vitamin D supplement helps prevent or delay Type 2 diabetes in adults who have prediabetes, who are at high risk for Type 2.

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The multiyear vitamin D and Type 2 Diabetes (D2d) study, funded by the National Institutes of Health, is taking place at about 20 study sites across the United States and will include about 2,500 people. Its goal is to learn if vitamin D – specifically D3 (cholecalciferol) – will prevent or delay type 2 diabetes in adults aged 30 or older with prediabetes. People with prediabetes have blood glucose levels that are higher than normal but not high enough to be called diabetes.

[Related Stories >>](#)

[Sun Avoidance and the "Sunshine Vitamin" \(Progress Notes\)](#)

Patrick M. O'Neil, Ph.D., director of MUSC's Weight Management Center and the study's principal investigator at MUSC, said this study will definitively assess whether people with prediabetes (who are at greatest risk of developing diabetes) will be less likely to develop diabetes if they receive vitamin D supplementation.

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[NIH Vitamin D Fact Sheet](#)

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### CONTACT US

#### MUSC PR

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# D2d recruitment sources for consented participants

- MUSC broadcast messages: 32%
- Radio ad: 18%
- Email recruitment letter: 14%
- Snail mail recruitment letter: 14%
- T.V ad: 11%
- Google AdWords: 4%
- Newspaper ad: 4%
- Co-worker: 3%

# Site enrollment issues

Of the 30 participants screened only 8 have qualified for baseline

Of the 8 qualified for baseline only 2 have qualified for randomization

**Nearly all screen fails were due to participant's blood levels being below pre-diabetic range**

# New approaches

- New ads and recruitment letters changed to focus on ***risk for diabetes***
- Another repeat mailing and emails of new recruitment letter
- Created an online diabetes risk calculator on our website. Also have incorporated it into our MUSC broadcast messages and text messages

## ARE YOU AT RISK FOR

# TYPE 2 DIABETES?

## Diabetes Risk Assessment

### 1) How old are you?

- Less than 40 years (0 points)
- 40-49 years (1 point)
- 50-59 years (2 points)
- 60 years or older (3 points)

### 2) Are you a man or a woman?

- Man (1 point)
- Woman (0 points)

### 3) If you are a woman, have you ever been diagnosed with gestational diabetes?

- Yes (1 point)
- No (0 points)

### 4) Do you have a mother, father, sister, or brother with diabetes?

- Yes (1 point)
- No (0 points)

### 5) Have you ever been diagnosed with high blood pressure?

- Yes (1 point)
- No (0 points)

### 6) Are you physically active?

- Yes (0 points)
- No (1 point)

### 7) What is your weight status?

Height	Weight (lbs.)			
4' 10"	0-118	119-142	143-190	191+
4' 11"	0-123	124-147	148-197	198+
5' 0"	0-127	128-152	153-203	204+

5' 1"	0-131	132-157	158-210	211+
5' 2"	0-135	136-163	164-217	218+
5' 3"	0-140	141-168	169-224	225+
5' 4"	0-144	145-173	174-231	232+
5' 5"	0-149	150-179	180-239	240+
5' 6"	0-154	155-185	186-246	247+
5' 7"	0-158	159-190	191-254	255+
5' 8"	0-163	164-196	197-261	262+
5' 9"	0-168	169-202	203-269	270+
5' 10"	0-173	174-208	209-277	278+
5' 11"	0-178	179-214	215-285	286+
6' 0"	0-183	184-220	221-293	294+
6' 1"	0-188	189-226	227-301	302+
6' 2"	0-193	194-232	233-310	311+
6' 3"	0-199	200-239	240-318	319+
6' 4"	0-204	205-245	246-327	328+
<b>points</b>	<input type="radio"/> 0	<input type="radio"/> 1	<input checked="" type="radio"/> 2	<input type="radio"/> 3

**Score:**

6

### If you scored 5 or higher:

You may be at increased risk for developing Type 2 diabetes. Of course, only your doctor can tell if you actually have Type 2 diabetes, or prediabetes (high blood sugar that is not yet in the diabetes range, but often leads to diabetes).

**Here are some things you can do if your score puts you in the high-risk range:**

- Talk to your doctor to get more information about your condition
- To learn about a **diabetes prevention study** at the MUSC Weight Management Center click here: <http://www.muschealth.com/weight/research%20for%20patients>

# New approaches cont.

- Sent ads to Cell-u-Lite users (daily weight loss text messages)
- Dr. O'Neil spot on local t.v channel. Will be aired soon
- Internal Medicine Grand Rounds
- Dr. O'Neil presented at the MUSC Endocrine division faculty meeting
- No direct access to EMR, but are working on gaining access





# Atlanta VA Medical Center Recruitment

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<b>PI</b>	<b>Lawrence Phillips, MD</b>
<b>Sub-I</b>	<b>Mary Rhee, MD, MSCR</b>
<b>Manager</b>	<b>Louise Savoye, MD, MPH</b>
<b>Study Coordinators</b>	<b>Rincy Varughese, MS Radhika Mungara, MS</b>

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## **KEY CONCEPTS:**

- 1. Focus on finding prediabetes –  
agreeing to participate is secondary**
  - 2. Aim for the A1c “sweet spot”**
  - 3. Leverage the PI**
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# Atlanta VA Medical Center Recruitment

Screened	42	<p>We suggest that each site consider measuring their yield = (randomized) as a percentage of (screened - pending)</p>
Screen Fail	12	
Baseline Fail	8	
Randomized	14	
Withdrawn	1	
Pending	7	
Screened - pending	35	
<b>Yield (14/35) =</b>	<b>40%</b>	



# Atlanta VA Medical Center Recruitment

## **Prescreen 1. Finger stick A1c in primary care clinic**

- Approach patients who appear eligible (age >45, BMI >25)
- Use “script” – do they have diabetes?
- If not, explain diabetes is a huge problem – would they be interested in being in a vitamin D prevention study if they knew they had prediabetes?
- If yes, then get informed consent, do fingerstick A1c (DCA-2000; machine is free, cartridge costs \$10)
- If A1c is 5.9 to 6.4% , then schedule for D2d study screening visit.
- One day = approach 20 = 5 sticks = 1-2 for screening



# Atlanta VA Medical Center Recruitment

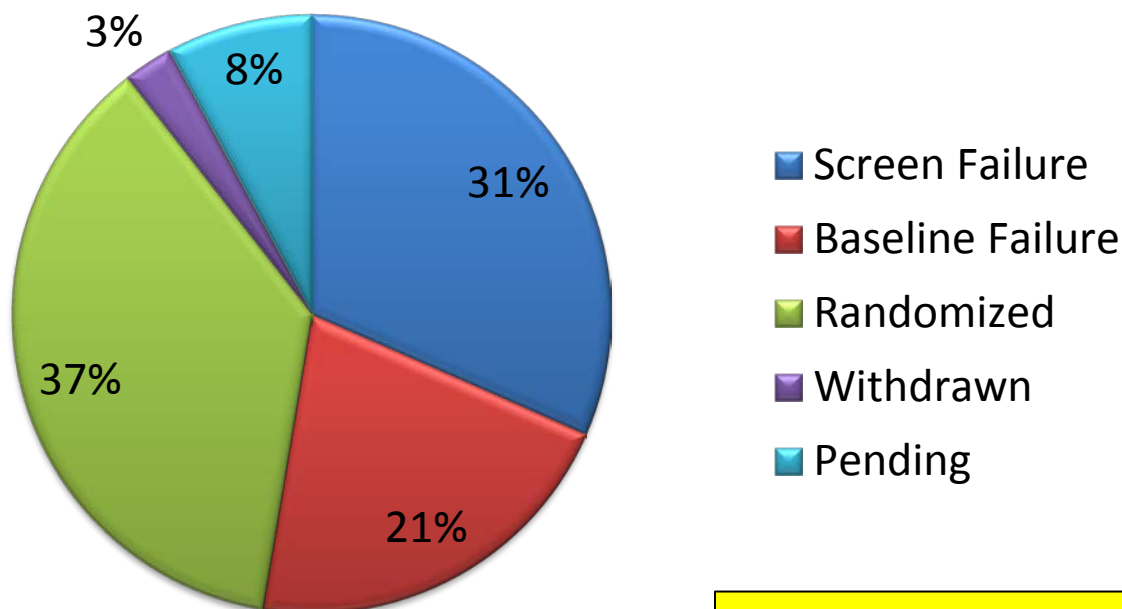
## **Prescreen 2. A1c in patient database screen in VINCI**

- Select patients without diabetes who have A1c 6.1-6.4%
- Encrypted email to PCP – IRB approved letter explaining study, letter to send to pts, letter for them to send to pts who inquire, list of their patients who appear to be eligible
- For pts not crossed off list, mail IRB approved letter to patients who appear to be eligible – call if not interested; call if interested; if we don't hear from you, we'll call you
- Call interested patients first, if eligible → screening visit
- If patients haven't called back in 1 to 2 weeks, follow up by calling those patients



# Atlanta VA Medical Center Recruitment

## Recruitment with Finger Stick A1c



**Yield% = 14/35**



# Atlanta VA Medical Center Recruitment

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## **Recruitment with VINCI database query**

Total screened 4

Screen Failure 0

Baseline Failure TBD

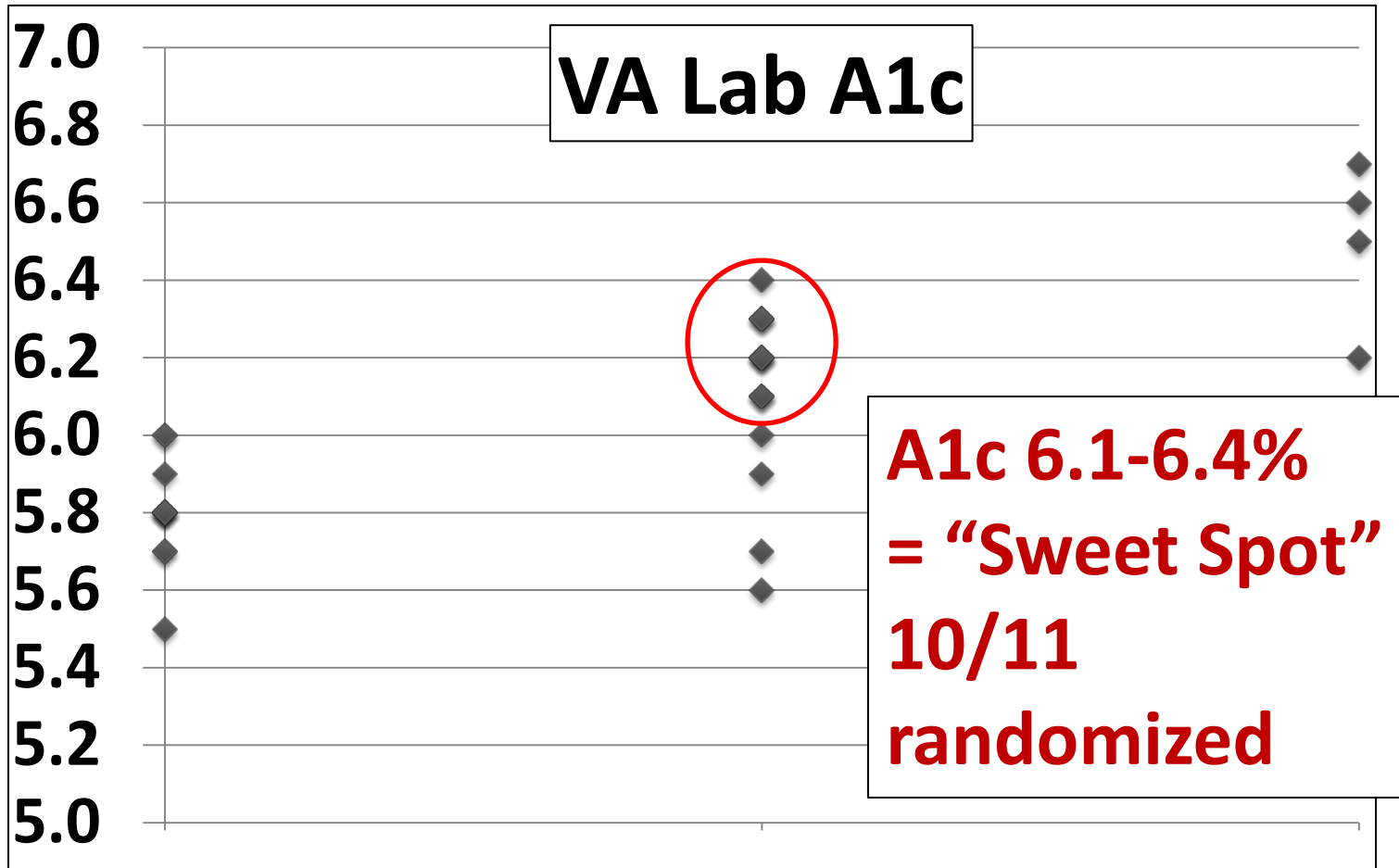
Randomized TBD

Pending 4

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# Atlanta VA Medical Center Recruitment





# Atlanta VA Medical Center Recruitment

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## **D2d Recruitment Challenges - Finger stick A1c**

- 1 Difficulty in finding patients with prediabetes
  - 2 Labor-intensive – one day in clinic = 1-2 patients scheduled for screening visit
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## **D2d Recruitment Challenges – VINCI Query**

- 1 Just began this method
  - 2 272 patients had VA lab A1c 6.3% - we have contacted and scheduled some, some have been screened but there are many no-shows
-



# IMPORTANT SITE ACTIVITIES

- 1. Find prediabetes – (i) fingerstick A1c in primary care clinic, (ii) VA database A1c based on query in VINCI**
- 2. Aim for the A1c “sweet spot” – A1c levels most likely to randomize = local A1c 6.1-6.4% (in our site)**
- 3. Use the PI – to facilitate recruitment/retention:**
  - study is important to medical science**
  - being run by the government, NIH – not by pharma**
  - if study is positive, it will help millions of people**
  - the study drug is convenient, safe, and cheap**
  - we will oversee your prediabetes care**
  - (we pay you for your visits)**
  - at end of the study, we will give you a personalized recommendation for your management**



# Atlanta VA Medical Center Recruitment

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## **D2d Future Recruitment goals**

- 1 Screen 12 patients per month using database query in VINCI
- 2 Focus on patients having A1c from 6.1% - 6.4% from the database query
- 3 Randomize 6 patients per month

**TULANE UNIVERSITY**

**D2d  
Recruitment**

# PREVIOUS RECRUITMENT METHODS

- **Local News interview with Dr. Fonseca**
  - Received over 200 phone calls
    - Only 50 were non-diabetic patients that we could contact
      - About 10 were screened
- **Flyers everywhere!**
  - In Tulane buildings- we received a few phone calls, a couple people were screened
  - In clinics- Tulane and community clinics
    - Maybe 1 or 2 phone calls, unless the doctor hands the flyer/brochure to the patient is less likely to call.
- **Health Fairs**
  - We have been to over a dozen health fairs with very little response
    - Generally people will talk with us and seem interested but will not call us or are hesitant to give us their phone number to contact them.

# NEW RECRUITMENT METHODS

## ■ Tulane Primary Care Clinics

- We have gained access to primary care clinics and can alert these physicians to patients who may qualify and approach them in clinic
  - This has been difficult when patients most of the time are unaware of their A1c level or elevated glucose, it is hard to convince them to join a study when their doctor may not have told them they have prediabetes
  - Thus far we have prescreened over 600 patients in the last 2 weeks
- We are working on gaining access to cardiology and neurology clinics

## ■ EMR search

- We have submitted forms for an EMR search at Tulane Medical Center. Then we will send out recruitment letters; still working on this list.

## ■ Mass Mailing of brochures

- We developed a brochure for both D2d and GRADE to mail out a brochure to a random sample of 20,000 addresses in 5 zip codes in the New Orleans area.
  - The brochures are being mailed out.

# UPCOMING METHODS

- **VA Approval**
  - We are in the final steps of approving D2d at the local VA and will be able to recruit from this population
  - Should have final approval in the next week or two. We already have IRB approval for a HIPAA waiver so we can search the database for potential patients.
- **Tulane Hosting a Health Fair**
  - We are planning to host a Health Fair with a local Whole Foods for research promotion and offer A1c screenings.
    - This will occur in June or August 2014
- **Refining recruitment at Tulane clinics and community clinics**
  - Being more effective in our prescreening efforts as well as making sure we are able to be present in the clinic and approach the patients in a positive and encouraging manner
    - We will start to use the ADA risk assessment test to get the attention of the patient prior to going into detail about the study.

# JUMPING OVER HURDLES

- We have had many hurdles and are still attempting to jump over them!
- Restricted access to Tulane Medical Center patients, we have reached a data use agreement but are still having a few obstacles in terms of getting remote access for all staff.
- VA Approval is a long process but we are nearing the end of the tunnel!!
- Staff! We have had a change in study coordinator and working on getting students to help us prescreen and do data entry to free up the coordinators to recruit patients.
- Lastly raising awareness for research and diabetes prevention.
  - Most people have not been told they have prediabetes or are aware that they could be at high risk. This is a significant challenge in how to word the study and convince them to participate.

# UT Southwestern Medical Center

Dallas, Texas

## Meet Your UT Southwestern

### D2<sub>d</sub> Team

Philip Raskin M.D.



Chanhaeng Rhee M.D.



Naim Maalouf M.D.



Brenda Brightman – Study Coordinator





# Recruitment Strategies

- ❖ UT Southwestern Employee Homepage
- ❖ Health Fair
- ❖ Local News Channel - Health Segment
- ❖ Campus Flyers
- ❖ Pre-Diabetes Nutrition Workshop
- ❖ Physician referral
- ❖ Subjects from past pre-diabetes study
- ❖ Physician presentation of D2d study during weekly physician meetings
- ❖ Mailing of D2d study packets to metroplex physicians
  - ❖ (consisting of D2d study letter, brochures, article on Vitamin D, Pre diabetes & copy of UT Southwestern MED magazine with D2d study article)
- ❖ UT Southwestern MED magazine
  - ❖ (UT Southwestern magazine sent out to the public)
- ❖ Internet – Yahoo Health & Dallas Business Journal

# Recruitment Outcome



27 Screening visits

18 Baseline visits

8 Randomized

## Most Successful Tools

- ❖ Employee homepage
  - ❖ 3 Randomized (most overall response, most were unable to take time off)
- ❖ UT Southwestern MED community magazine
  - ❖ 3 Randomized (best overall quality respondents)
- ❖ On line Sources
  - ❖ 1 Randomized - Dallas Business Journal
  - ❖ 1 Randomized - Yahoo Health page (link to “Clinical Trials in Dallas”)

# Sweet Success in the Making

## (Future Recruitment Strategies)



- ❖ Electronic medical record system



- ❖ (long process, very time consuming – approval needed, still waiting and waiting...)

- ❖ Placement of D2d brochures in clinic waiting areas



- ❖ ( this too has an approval process & we're still waiting and waiting...)

- ❖ Dallas Heart Study



- ❖ data base of subjects from all around Dallas that volunteer to give information, family & medical Hx, medications, blood, etc. for Cardiovascular research – this data can & has been used to help identify subjects for other types of research. From the database, we would identify those with pre-diabetes, contact them with study information and ask if they are interested in participating in the D2d study - (Of course! This too has an approval process that is long & time consuming, and we are still waiting and waiting...)

**We shall overcome!!**

- ❖ UT Southwestern MED - D2d article for Summer issue

