MUSC Recruitment Plan: D2d Study

PI: Patrick O'Neil, PhD
Site: Medical University of South Carolina

Target number of subjects randomized: 150
Average enrollment goal: 6-7 per month

Plans for Identifying Participants:

We will follow the same plan with which we have successfully recruited for scores of clinical trials over many years. Our overall approach to clinical trial recruitment focuses on publicizing the trial in numerous ways, to encourage as many people as possible to obtain a detailed letter which describes the trial and lists the major inclusion/exclusion criteria, to permit subjects to initially self-screen before significant coordinator time is expended on phone calls. Ads, PR efforts and referral requests will all point the potential participant to a website, e-mail address or voice mail number through which they can request the letter.

Advertising efforts will include the following means: flyers, brochures, MUSC broadcast e-mail, electronic/video signage at the MUSC cafeteria and/or in-house video, newspaper ads, radio ads, television ads, Weight Management Center (WMC) website and other websites. We will send letters and e-mails about the study to a database of about 5,000 people who have previously expressed interest in participating in clinical weight loss trials at our Center. We will also send letters to MUSC and local area physicians and other health care providers describing the study and soliciting referrals. Finally, we will utilize MUSC PR resources and our staff's existing media contacts to publicize the study.

**Study-wide** recruitment: Potential subjects may also learn about our site at the D2d study website (http://www.d2dstudy.org). If they feel they pre-qualify they can find the trial site closest to them on the D2d website. The phone number and email address of the study coordinator is listed in the website.

Pre-Screenings:

After reviewing the study recruitment letter and I/E criteria, potential subjects who feel they may qualify for the study will call the study coordinator, who will conduct a brief phone screening after asking the caller to verify that s/he was able to say "yes" to all the statements in the letter describing inclusion criteria. The purpose of this screen is to determine whether it is appropriate to invite the patient for an in-person orientation, nearly always conducted in a group format. The orientation, not this call, is the primary source for detailed information about the study.

Consent process:

After pre-screening, potential subjects who would like to learn more about the trial will be scheduled for an in-person orientation. At this session, subjects will be told more about the

study and will be given a copy of the informed consent form to review. The orientation sessions are structured around a PowerPoint presentation to ensure consistency. Much attention is paid to the I/E criteria. Subjects are encouraged to ask questions about the study at any time during the orientation. Subjects in group orientations are also assured they may ask questions in private after the session.

Benefits of recruitment plan:

Through this multi-stage process (recruitment letter with I/E criteria, phone screen, orientation session) we maximize our ability to inform prospective participants about the trial requirements and benefits, and have them pre-screened by themselves and the coordinator on the phone. Further, by placing an informative recruitment letter in the hands of subjects before talking to them on the phone, and by focusing on the group orientation as the primary venue for discussions about the trial, coordinator time is preserved. The pre-screening call also helps to ensures that the coordinator will bring most qualified subjects to the orientation.

This multi-stage process also maximizes the chances that we will then screen subjects who are not only 1) fully aware of all study procedures involved but are also 2) the most motivated subjects to participate in the study.

Potential recruitment barriers:

1. Potential subjects not knowing their FPG or HbA1c
2. Screen fails due to inconsistencies for FPG and HbA1c criteria:

   FPG 100-125 mg/dL (inclusive) and HbA1c 5.1-6.4% (inclusive) or

   HbA1c 5.7-6.4% (inclusive) and FPG 91-99 mg/dL (inclusive)