

PS2-26:

Recruitment Costs for a Multi-Center, Randomized Clinical Trial for a Behavioral Intervention Study

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Background and Aims: The pace of recruitment impacts resources, planned study tasks, timelines, and ultimately, costs. The Journey for Control of Diabetes: the IDEA Study, a randomized trial conducted in two healthcare settings (Minnesota and New Mexico) utilized different recruitment methods at each site. This presentation compares these recruitment methods with respect to recruitment efficiency and costs. **Methods:** Study inclusion criteria were patients with sub-optimally controlled type 2 diabetes, an A1c=>7, and diabetes education-naïve within the last one to two years. Recruitment databases at each site were developed using electronic health data to identify potential participants. All patients were mailed recruitment letters and study brochures inviting them to participate. Site 1 mailed letters with an enclosed response form for the patient, if interested, to return to the study site; Site 2 mailed letters and subsequently attempted to contact all patients by telephone. Six months into the recruitment period, Site 1 also incorporated follow-up calls to potential patients who were mailed recruitment letters. **Results:** The enrolled sample was 623 patients: 147 (Site 1, Method 1), 190 (Site 1, Method 2), and 286 (Site 2). Recruitment efficiency rates based on number of enrolled participants per total recruitment letters mailed were 3.8% (147/3995 for Site 1, Method 1), 3.7% (190/5199 for Site 1, Method 2), and 6.9% (286/4128 for Site 2, Method 3). Cost of enrollment per patient ranged from \$71.45 for Method 1 (\$10,502/147), \$81.90 for Method 2 (\$15562/190), and \$87.57 for Method 3 (\$25,046/286). Total staff hours per patient were 1.58 for Method 1 (232.3/147), 2.51 for Method 2 (477.5/190), and 3.46 for Method 3 (990.4/286). Site 1, when combining data for Methods 1 and 2, recruited more subjects (337) within the 11 month recruitment period than Site 2 (286). **Conclusions:** Although recruitment efficiency rates were higher for Site 2, fewer staff hours were used at Site 1. Using the Site 2 methodology of contacting each patient may be more effective for studies with a higher risk of participation. Future studies should consider including a recruitment response form with the recruitment letter to save time and cost.

Keywords: Recruitment methods, Patient participation, Behavioral intervention

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PS2-27:

Lifestyle Choice, Education and Risk of Dementia Among Older Americans

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Background: The United States is in the midst of a profound demographic change: the rapid aging of its population. Dementia is one of the most common diseases at this age cohort. The cause of dementia is unknown and there is no effective treatment. Identification of lifestyle related factors that influence the risk of developing dementia, however, may provide insight into its cause and offer potential strategies for prevention. **Aim:** The primary objective of this study is to examine the association between a set of lifestyle characteristics and the likelihood of dementia among older Americans. **Methods:** The Aging Demographics and Memory Study (ADAMS) dataset is used to examine a set of potential protective or risk factors for dementia among older individuals in the U.S. The ADAMS is a cross-sectional data of a stratified random sample of 1,770 individuals of age 70 and above, selected from the Health and Retirement Survey -2000, based on the self-or-proxy reported cognition score. The ADAMS is the first nationally representative sample of individuals with dementia in this country. The generalized ordered logistic model is used to examine the impact of lifestyle related risk factors on the likelihood of dementia and other cognitive impairments not dementia (CIND). **Results:** For one year increase in age the odds of dementia versus

the combined outcomes of CIND and normal increases by 1.11. Compared to all other genotypes, APOE-e4 is associated with an increased risk of dementia. An each year increase in education, the odds of dementia against the combined outcomes of CIND and normal is decreased by 0.90. Among chronic health conditions, an incidence of stroke is the significant risk factor for dementia. **Conclusion:** The finding that higher education lowers the risk of dementia has important implications as education can be viewed as a 'preventive medicine' for postponing the onset of dementia. From a policy perspective the causal relationship is important in order to evaluate the effectiveness of public expenditures on education. Further research can investigate whether a re-allocation of resources can be welfare improving if the impact of education on dementia risk is larger than the impact of healthcare on dementia.

Keywords: Dementia, Lifestyle factors, Education levels

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PS2-28:

Online Consenting in the Simulated Diabetes Training (SDT) for Resident Physicians Study

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Background and Aims: The main purpose of this NIDDK-funded group-randomized trial is to evaluate the effect of teaching resident physicians fundamental principles of diabetes management using an interactive computer simulation program called SimCare. A minimum of 20 primary care residency programs with up to 700 residents total will be randomly assigned to either (a) an early SimCare Diabetes learning program group or (b) a delayed SimCare Diabetes learning program group. This presentation will provide an explanation of and justification for using an online informed consent process to facilitate informed consent for a national trial of this scale. **Methods:** Resident physicians interested in participating in this study will be asked to read an online informed consent form that fully details the study procedures, potential risks and benefits to participating, the study's voluntary nature, and issues surrounding confidentiality. As they move through each page of the online consent form, they will be required to confirm their understanding of the page's content by clicking an "I understand" check box before they can proceed. Reviewing the online consent and enrolling in this study confers their informed consent. **Results:** The online informed consent process for this study has been developed and IRB-approved. To enroll, a resident will create a user name and password and provide contact information to be used to communicate with them during the study. A link to the principal study staffs' contact information will also be clearly posted on each page so that if a resident has a question or concern, they can contact the study staff prior to completing the form. At the end of the form, a resident has the choice to agree to participate and enroll in the study and print a copy of the consent, ask questions to the study staff prior to consenting, or decide not to participate. **Conclusions:** It is difficult to coordinate informed consent for a national trial, but an online informed consenting process such as this provides an efficient avenue that meets internal review board standards.

Keywords: Online consenting process, informed consent, national trial enrollment

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PS2-29:

Optimal Lifestyle Adherence and 2-Year Incidence of Chronic Conditions

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Background and Aims: Adherence to an optimal lifestyle, defined as adequate physical activity, no use of tobacco, moderate alcohol use, and eating five servings of fruits and vegetables per day, has been associated with as much as 14 years of increased longevity and improved functional health status. Unfortunately, adherence to these optimal lifestyle behaviors is relatively low among the population. Furthermore, the extent to which adherence to multiple lifestyle behaviors is associated with specific disease