You don't want to be seen as somebody who's forcing a patient... if their provider is telling them this is a good idea you are more likely to get your patient to do it. I think they have to understand what a clinical trial is, first of all, in that it's a trial. Right? We're trying to figure out if a certain treatment is good or not. It may not work. It may work. With many patients, they don't only have medical problems, but significant mental illness that sometimes interferes a lot with just our treatment of them here for their clinical problems. And so, that probably would interfere with someone's ability to understand and consent to a trial. And the patients have the right to make that choice. I don't need to be—I don't mind influencing them on things I know about, I think are invaluable, but I don't need to be a barrier to them. (5) Perceived responsibility in trial recruitment varied substantially, from no involvement at all, to prescreening, counseling, or recruiting patients. Some providers felt that they should have the right to say "no" to recruitment of their patients while others believed prescreening was an unnecessary burden, outside of their role as a primary care provider. if someone prescreens and thinks its appropriate and gives me that judgment call to say, do you think it would be a good fit? I think one of them, they sent, and I said, Oh, I don't think it would be a good fit because of this...So that would be fine. I don't think I need to be a gatekeeper for studies. I mean, if there's people that qualify for a study, and there's a great study that's been approved, and they can recruit them without me knowing, that doesn't bother me in the slightest. I liked how it was—I could do a simple referral ... someone else figured out the qualifications. if we knew of ongoing studies and if we thought a certain patient may qualify for a certain study, we just contact the coordinator, and then they just take care of the rest. I think that appropriate ... from our perspective, would be, "Are you interested?" "This is the number for a person who can sit with you, talk with you about a trial, tell you everything about it, answer your questions, and then you can make a decision." I'm not going to let you go mess up my patient and I'm going to have to deal with the consequences. (6) A clinic-implementation approach that systemizes workflow, limits the number of trials providers are asked to recruit for, and minimizes provider time burden is needed. Suggested methods for informing providers of patient clinical trial eligibility included: email, alerts, in-basket messages, texts, phone-calls, and in-person contact. People are so sick of change, change, change, change ... if there's no stability whatsoever, then people get frustrated and start to burn out. Having my staff remember how to do it correctly and I remember what studies we have going ... it becomes somewhat of a burden... it's hard for us to remember as we are flying through our day. There just needs to be a clear understanding with those roles... Who does the patient call? We don't want to look like we don't know what we are doing. There probably should be a selection committee put together from various people who have stakes in the community, at least who can say, "This would be applicable for xx clinic." (7) Provider Suggestions Providers had multiple suggestions regarding notification methods. (II) Development of item pool and construction of questionnaire The specific items were constructed from literature review on physician's attitudes and results from the focus group. The overarching concern was on readability, brief questionnaire size, and relevance. A large item were constructed and then reduced through piloting. (III) Questionnaire Pilot Results: The 7-item pilot questionnaire was completed by 36 physicians (28% response rate). In this section, we report the empirical results. DISCUSSION/SIGNIFICANCE OF IMPACT: Discussion Relevance of Methods. Overall, the described methods for determining components for a recruitment program in primary care shows early promise. The focus groups that consisted of providers, staff and administrators resulted in insights as to workflows, attitudes, and clinical processes. These insights significantly varied across clinics. This variation supported the need for an individualized clinic-based approach that will meet local needs. During the course of the study, participants were willing to participate in all activities (although some requested payment). We were able to conduct the focus groups as scheduled and obtained the desired input. The analysis of the focus group transcripts was performed using iterative discussions and did not needed any special adaptation for this area of study. The pilot survey response rate was within the expected for this type of study. Focus groups can rapidly provide rich information regarding attitudes and other factors affecting provider participation at the point of care. However, findings from focus groups must always be confirmed through larger studies. It is important to keep the focus groups small and to hold multiple focus groups to offset the more vocal participants that may influence comments of others. This study shows that using our 3-step approach it is possible to gather important information on clinician's and staff perceptions and needs to participate in point of care patient recruitment for CT. The focus groups also provide an important step for survey construction. Designing surveys empirically requires multiple validation efforts, which will be conducted in the future. However, we can draw preliminary conclusions from the results of the pilot study which are quite informative and they are discussed below. Near future work will be to expand the response rate through additional local survey and conduct formal psychometric testing and validation both locally and nationally. A final validation will be proposed through the CTSA consortiums. Variation in responses. There was a lack of normal curves in our survey results. This points to the need to target education and recruitment efforts by provider type (with similar perspectives). Identification of these types would be useful. Some specific points regarding variability that should be considered in program design. Preferences for trail recruitment methods. Many trial recruitment notification methods have the potential to be successful when used judiciously and done well, particularly if the trial coordinator/provider relationship is supported by reciprocal benefits to the provider. Consistency in workflow within seems paramount to success. Providers can pull some notifications at a time they choose, while other notifications interrupt and must be used sparingly. Some allow review of multiple patients at the same time, and some foster easy access to the patient's medical record. Conclusions. The authors recommend that recruitment HIT be customizable at the clinic and provider level by responsibility and interest to allow selection of level of information, delivery method, that is, email, text, in-basket, alert, dashboard, mail; frequency of notification, and an opt out feature. These customizable options will allow for better support of clinic workflow or goals. There is the potential with machine learning technology to monitor provider interactions with trial notifications and for the system to automatically make adjustments to the method and level that best supports each physician. Limitations: The major limitation is the focus on one site only and one delivery system (university based). The low response makes generalization difficult. Efforts to improve the rate are underway. Many populations are under-represented in Utah. Full psychometric analysis was not conducted but will part of the final project.

2294

Do patient comorbidities impact the effectiveness of a COPD self-management program?

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OBJECTIVES/SPECIFIC AIMS: Chronic obstructive pulmonary disease (COPD) is a leading cause of both hospitalizations and readmissions in the United States, and about 1 in 5 hospitalized patients with COPD will be readmitted within 30 days. COPD-focused self-management programs are frequently used to help patients better manage their symptoms and prevent hospitalization. However, while the majority of patients with COPD have at least one comorbidity, most trials of COPD self-management programs either excluded patients with significant comorbidities or did not analyze the impact of comorbidities on patient outcomes. Using data from the BREATHE trial of a COPD self-management program, this study aims to determine if patient post-intervention outcomes differ based on the intensity and type of patient comorbidities. METHODS/STUDY POPULATION: In total, 240 patients hospitalized for COPD were randomly assigned to either a comprehensive self-management intervention or usual transitional care. Primary outcomes for this trial were the number of COPD-related hospitalizations and emergency department visits at 6 months and changes in COPD-specific quality of life. To determine whether patient comorbidities modify the effect of the self-management intervention on readmission and quality of life outcomes, we will compare patient outcomes across groups stratified by comorbidity burden (Charlson Comorbidity Index) and type (baseline diagnosis of congestive heart failure, diabetes, and depression). In addition, we will use regression analysis with interaction terms to test for interaction between comorbidity burden/type and intervention assignment. RESULTS/ANTICIPATED RESULTS: We hypothesize that the effect of the self-management intervention will differ in patients with greater comorbidity burden due to competing medical demands for patients with multimorbidity. DISCUSSION/SIGNIFICANCE OF IMPACT: The results of this study will help clinicians better target disease-specific self-management programs to the groups of patients with COPD who are likely to receive the greatest benefit from this type of intervention.

2287

ECG and echo characteristics in familial partial lipodystrophy: The impact of Lamin A variants

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OBJECTIVES/SPECIFIC AIMS: Familial partial lipodystrophy (FPLD) is an inherited, rare syndrome characterized by selective absence of adipose tissue from extremities which is associated with severe insulin resistance, and metabolic dyslipidemia (with hypertriglyceridemia, and low HDL) Typically, 30%–50% of patients with FPLD demonstrate a pathogenic variant in Lamin A (LMNA) gene that is associated with inherited cardiomyopathy and arrhythmia syndromes. We inquired the prevalence of having abnormal ECGs and echocardiograms in FPLD and whether there is a difference in evaluated parameters with respect to genotype. METHODS/STUDY POPULATION: We conducted a retrospective review of an established a cohort of 58 patients (age range: 12–71, M/F 8/50) with FPLD. Demographic characteristics, genotype, fasting triglyceride, hemoglobin

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A1c, LDL, and HDL levels were collected; ECGs and echocardiograms were also interrogated. RESULTS/ANTICIPATED RESULTS: Out of 58 patients, 22 (38 %) displayed a pathogenic variant in the LMNA gene. In total, 71% of patients (41/58) had an abnormal ECG and echocardiogram; 40% (23/58) of the patients displayed an arrhythmia on the ECGs (13 in the patients with LMNA variants and 10 in the non-LMNA group). The likelihood of having an arrhythmia was significantly higher in the patients with LMNA variants versus those without (odds ratio of 3.4, CI: 1.1–10.6). DISCUSSION/SIGNIFICANCE OF IMPACT: The overall prevalence of abnormal ECHO and/or ECG is high at 45/58 (78 %) in FPLD. Patients with LMNA variants have a 3.4 times increased risk of developing cardiac arrhythmias compared to those without. We recommend vigilant, monitoring for cardiac disease in FPLD and for arrhythmias in patients with FPLD and LMNA variants.

2034

Effect of balanced crystalloids on renal outcomes among critically ill adults does not differ from 0.9% saline across baseline risk of renal outcomes

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OBJECTIVES/SPECIFIC AIMS: Traditional clinical trials typically enroll a homogenous population to test the efficacy of an intervention. Pragmatic trials deliberately enroll a more diverse population to enhance generalizability, but doing so may increase heterogeneity of treatment effect among subpopulations. For example, the effect of a treatment on an outcome may vary based on patients' sex, comorbidities, or baseline risk of experiencing the outcome. We hypothesized that heterogeneity of treatment effect by baseline risk for the outcome could be demonstrated in a large pragmatic clinical trial. METHODS/STUDY POPULATION: We performed a prespecified secondary analysis of a recent pragmatic trial comparing balanced crystalloids Versus 0.9% saline among critically ill adults. The primary endpoint of the trial was major adverse kidney events within 30 days of ICU admission, censored at hospital discharge (MAKE30). MAKE30 is a composite outcome of all-cause mortality, new renal replacement therapy, or persistent renal dysfunction. Using a previously published model with high predictive accuracy for MAKE30 (area under the curve = 0.903), we calculated the baseline risk of MAKE30 for all trial participants. We then developed a logistic regression model for MAKE30 with independent covariates of fluid group assignment, baseline risk of MAKE30 as a nonlinear continuous variable, and the interaction between group assignment and MAKE30 baseline risk. RESULTS/ANTICIPATED RESULTS: Among 15,802 patients from 5 intensive care units enrolled in the original trial, 126 had missing variables for predicted risk of MAKE30. Mean predicted risk of MAKE30 among all patients was 15.4%; median was 4.4% (interquartile range 2.2%–17.1%). Predicted risk of MAKE30 did not significantly differ between groups ($p = 0.61$ by Mann-Whitney *U*-test). The incidence of MAKE30 in the trial was 14.9%, and the prediction model was well-calibrated overall (AUC = 0.891). In a logistic regression model examining the interaction between group assignment and predicted risk of MAKE30, group assignment significantly affected MAKE30 (odds ratio saline: balanced 1.13, 95% CI: 1.02–1.27, $p = 0.02$), but we observed no interaction between the effect of group assignment on MAKE30 and patients' predicted risk of MAKE30 at baseline ($p = 0.66$ for interaction term). DISCUSSION/SIGNIFICANCE OF IMPACT: In a large pragmatic trial demonstrating a significant difference in the primary outcome of MAKE30 between balanced crystalloids and saline, a previously published model accurately predicted MAKE30 using baseline factors. However, contrary to our hypothesis, the baseline risk of MAKE30 did not modify the effect of fluid group on the observed incidence of MAKE30. Our analysis could not account for unmeasured confounders and may be underpowered to detect a significant interaction. Our findings suggest that the impact of balanced crystalloids versus normal saline on renal outcomes in critically patients is consistent across all levels of risk.

2265

Effect of dietary approaches to stop hypertension (DASH) diet on hemodynamic markers in advanced heart failure patients

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OBJECTIVES/SPECIFIC AIMS: The central aim of the study is to examine the effect of a Dietary Approaches to Stop Hypertension (DASH) diet on hemodynamic, cardiometabolic, and inflammatory markers in advanced heart failure patients with implanted hemodynamic monitoring devices. METHODS/STUDY POPULATION: This pilot study will employ a clinical feeding trial using a 1-group pre-post test design with an anticipated sample size of n = 36 (n = 20 plus 44% expected attrition). Heart failure patients 18+ years of age with English language literacy, classified as NYHA functional stage III, regardless of ventricular ejection fraction, who have undergone CardioMEMS™ hemodynamic monitoring device (St. Jude Medical, Atlanta, GA, USA) implantation and have received optimized heart failure therapy for 3+ months will be recruited at Piedmont Athens Regional Hospital in Athens, GA. The study is divided in (a) a calibration (self-selected diet) and (b) a DASH feeding intervention phase (each 21 days in length). The DASH meals will strictly follow meal planning guidelines published by the National Heart, Lung, and Blood Institute of the National Institutes of Health, and be prepared under the supervision of a registered dietitian at the University Health Center in Athens, GA. The DASH diet is a heart-healthy eating pattern that is focused on adequate consumption of fruits, vegetables, whole grains, low-fat dairy, fish, poultry, beans, nuts, and vegetables oils while emphasizing limited intake of foods containing saturated fat, such as fatty red meats, full-fat dairy products, and tropical oils, such as coconut, palm kernel, and palm oils, as well as sugar-sweetened beverages and sweets. Participants will visit the University of Georgia Clinical and Translational Research Unit on 3 occasions at baseline, upon completion of the calibration phase, and following completion of the intervention phase for repeated collection of anthropometric (height, weight, waist and hip circumference, percent body fatness), cardiometabolic (blood pressure, blood glucose, HbA1C, lipid panel, basic metabolic panel, BNP, NT-proBNP, troponin I, MR-proADM, sST2), functional status (6-min walk test), inflammatory (IL-1a, IL-1b, IL-6, TNF-a), and self-reported measures (demographic and economic characteristics, health, chronic diseases, perceived stress, heart failure-related quality of life, social support, sleep quality, food insecurity, tobacco smoking status, healthcare utilization, medication adherence). Hemodynamic marker (pulmonary artery pressure, heart rate) and pharmacotherapy information (medication count, type, strength, and dosing) will be obtained from through retrospective assessment of EHR data. Descriptive statistics [percentage, mean (SD), median (IQR), mode, range] will be used to describe sample characteristics at each of the study visits, as well as characteristics of participants' self-selected diets during the calibration phase. To measure changes in hemodynamic, cardiometabolic, and inflammatory markers pre-post DASH diet intervention, we will use paired Student *t*-tests (normal distribution) or Wilcoxon rank-sum tests (non-normal distribution), as appropriate. Data collection will be carried out between February and November 2018. RESULTS/ANTICIPATED RESULTS: The study builds upon previous studies showing improvement of ventricular function, arterial stiffness, oxidative stress, and blood pressure after short-term consumption of a sodium-restricted DASH diet in heart failure patients with preserved ejection fraction, and will provide new information on the cumulative effect of short-term adherence with a DASH diet on indicators of heart failure complications, including hemodynamic, cardiometabolic, and inflammatory markers. In addition, it will give better insight on heart failure patients' habitual dietary intake in the context of other sociodemographic, economic, health, and social factors. DISCUSSION/SIGNIFICANCE OF IMPACT: Findings from the proposed study will provide key knowledge of dietary influences on ventricular function in order to define evidence-based diet therapy needed for the early prevention of HF complications in advanced heart failure patients.

2420

Examining characteristics of placebo effects on trauma-related insomnia in a suvorexant trial

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OBJECTIVES/SPECIFIC AIMS: The aims of this project are to: (1) examine placebo effects on subjective and objective outcome measures, (2) determine if an increase in the placebo is associated with changes in benefit, (3) evaluate if the trauma related insomnia placebo group in our study has different side effect reports compared with insomnia placebo participants in previous suvorexant trials, and (4) (Exploratory) examine associations between the placebo group's characteristics (e.g., trauma/PTSD severity, demographics) and placebo effects. METHODS/STUDY POPULATION: The parent study is a randomized double-blind placebo-controlled clinical trial (clinicaltrials.gov ID: NCT02704754) of suvorexant for treatment of adults (age 18–55) with insomnia that started or worsened after trauma exposure. Suvorexant is a first in class orexin antagonist and is approved by the FDA for the indication of insomnia. In this 6-week trial, all participants initially take 10 mg of suvorexant/placebo, and the dose will be increased to 20 mg if participants continue to experience clinically significant insomnia symptoms

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