analytic tool to identify regions in the US where preterm birth interventions would be most beneficial.

4575

Implementing a Workflow Management Tool for Clinical Trials

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OBJECTIVES/GOALS: A workflow management tool is essential in order to help support consistent processes with transparency in next steps of the study process. Prior to this tool, staff has relied upon extensive training and coaching on the study process. While resources and guidelines exist, it requires additional time for staff to identify these resources and allows for confusion and rework. Implementation of a systematic workflow management tool was identified as a critical need in order to support streamlined processes, improve transparency and support business continuity, and to accelerate the study process. METHODS/STUDY POPULATION: This effort was undertaken as part of the Protocol Lifecycle Management effort to implement a comprehensive clinical trial management system for clinical research studies. Mayo Clinic has designed a workflow management tool within the Velos eResearch system. The workflow manager is dynamic and will present specific activities based on the study design and responses to data entered on the ad hoc forms. A Workflow Build group contributed to the design of the workflow in order to reflect appropriate, current operational processes. The workflow was vetted and validated with research teams. In addition to designing activities, planned dates and target timelines were established for relevant workflows to help promote transparency in the study start-up timelines and allow study staff to identify overdue activities. Study status controls were designed in the workflow to protect study staff from inadvertently changing the status until appropriate activities are complete. RESULTS/ANTICIPATED RESULTS: A dynamic workflow has been designed and implemented in the Velos eResearch system to support Mayo Clinic research sites. This system will be implemented February 24, 2020 to all consenting studies. DISCUSSION/SIGNIFICANCE OF IMPACT: The implementation of this workflow management tool is critical to help support research operations in a large, academic medical center. Benefits to implementation are expected to include improved transparency in the study status and next steps, reductions in rework due to confusion in next steps, better understanding from new staff in the appropriate study process, and improved timelines for study start-up. As we prepare for the implementation of the Velos eResearch system at Mayo Clinic, the workflow management tool has been identified in training sessions as a positive benefit.

4211

Longitudinal cohort study of the association between atopic dermatitis and depression/anxiety throughout childhood

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OBJECTIVES/GOALS: Atopic dermatitis is one of the most common chronic childhood conditions worldwide and is associated with poor mental health outcomes. Our aim is to determine whether childhood atopic dermatitis is associated with symptoms of depression throughout childhood and adolescence, and whether this association is mediated by serum inflammatory markers. METHODS/STUDY POPULATION: We will perform a longitudinal analysis of over 7000 children from an existing prospective cohort. The primary exposure is atopic dermatitis (AD) annual period prevalence measured by a standardized questionnaire at 12 time points between age 6 months and 16 years. Depression is measured using self-reported responses to the Short Moods and Feelings Questionnaire at 6 time points between 10 and 18 years of age. Cross-sectional regression analyses will be performed to compare depressive signs between children with and without AD and test for dose-response effects with AD and depression. Longitudinal analyses will be conducted using mixed-effects models to estimate the average effect across childhood. We will complete a mediation analysis to determine the extent to which IL-6 and CRP mediate this association. RESULTS/ANTICIPATED RESULTS: We anticipate that atopic dermatitis will be associated with SMFQ scores in a dose response relationship, and that inflammatory markers CRP and IL-6 will partly mediate this association. DISCUSSION/SIGNIFICANCE OF IMPACT: Childhood is a critical time for mental health. Understanding the longitudinal relationship between atopic dermatitis, depression, and inflammatory mediators is crucial as new biologic treatments targeting inflammatory cascades are approved for atopic dermatitis and have the potential to prevent mental health conditions.

4448

Mental Stress Induced Myocardial Ischemia as a Marker for Adverse Cardiovascular Events After MI†

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OBJECTIVES/GOALS: Young and middle-aged adults with a myocardial infarction (MI) represent an understudied group potentially with unique risk indicators such as emotional stress. We sought to investigate if mental stress-induced myocardial ischemia (MSIMI), a marker of cardiovascular vulnerability to psychological stress, is associated with poor outcomes among this population. METHODS/STUDY POPULATION: We studied 306 patients (150 women and 156 men) ≤61 years of age who were hospitalized for MI in the previous 8 months. Clinical, behavioral and psychosocial factors were assessed with standardized measures. Patients underwent myocardial perfusion imaging with mental stress (public speaking) and conventional stress (exercise or pharmacological testing). MSIMI and conventional stress-induced ischemia were defined as a new or worsening perfusion defect. Patients were followed for 3 years for adverse events, which were independently adjudicated. Cox proportional hazard models were used to estimate the association of MSIMI and CSIMI with a composite endpoint of recurrent MI or cardiovascular (CV) death with adjustment for demographic, clinical and psychosocial risk factors. RESULTS/ANTICIPATED RESULTS: The mean age of the sample was 50 years (range, 22-61). MSIMI occurred in 16% of the patients, and conventional ischemia in 35%. Over a 3-year follow-up, 28 individuals had a recurrent MI and 2 died due to cardiovascular causes. The incidence of the composite endpoint of MI or CV death was more than doubled in patients with MSIMI (20%) than those without MSIMI (8%), HR 2.6, 95%CI, 1.2-5.6. Further adjustment for demographic and clinical risk factors and depressive symptoms did not substantially change the relationship. In contrast, conventional stress ischemia was not significantly

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related to the outcome (HR 1.4, 95%CI, 0.6-3.0). DISCUSSION/SIGNIFICANCE OF IMPACT: Young and middle-aged individuals with MSIMI after MI have a >2-fold higher likelihood of recurrent MI and CV mortality compared with those without MSIMI. In this patient group, MSIMI is a better risk indicator than ischemia with a conventional stress. These findings point to psychological stress as an important determinant of risk in this patient population. Ischemia induced by mental stress is a potent risk indicator in young post-MI patients. Stress-reduction interventions may be especially beneficial in patients who show this abnormal response.

4451

On the loss of individual joint controllability and the organization of muscle synergies in the impaired arm following a stroke: A pilot study

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OBJECTIVES/GOALS: Damage to the sensorimotor cortex areas or/and motor/sensory pathways after a stroke could lead the motor system to a loss of controllability for joints. We investigate the loss of individual joint controllability called a loss of individualization during arm movement, which would provide an insight into abnormal motor coordination. METHODS/STUDY POPULATION: We recruit 12 chronic stroke survivors with Fugl-Meyer score between 26 and 50. A robotic exoskeleton with minimum mechanical resistance is equipped to measure the movements of the shoulder, elbow and wrist joints, respectively. Surface EMGs on muscles related to the joints are recorded using 11 wireless pre-amplified electrodes. Participants are asked to move the shoulder, elbow, or wrist joint individually throughout their range of motion, without moving the other joints voluntarily. RESULTS/ANTICIPATED RESULTS: It would be expected that participants show more difficulty in individualization of the distal joint in comparison with the proximal joint. A reduced joint range of motion would be observed in a descending order of the wrist, elbow and shoulder. These results are in line with the proximal-to-distal gradient of motor deficits after a stroke. Intention of moving the distal joint would induce a greater deviation in the position of the proximal joint than that of the distal joint when moving the proximal joint. A non-negative matrix factorization algorithm would reveal a decreased number of muscle synergies in the groups with a loss of individuation in comparison with the groups with no loss. DISCUSSION/SIGNIFICANCE OF IMPACT: We demonstrate that a stroke leads to a lack of individual joint controllability, with a greater deficits on the distal joint, and that it is related to a decreased number of muscle synergies across the corresponding joints. CONFLICT OF INTEREST DESCRIPTION: N/A.

4125

Plan for a Retrospective Evaluation of a Multi-Modal Weight-centric Prediabetes Intervention.

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OBJECTIVES/GOALS: To determine if a multi-modal, interdisciplinary intervention delivered to a group of prediabetic patients will result in reduced rates of diabetes progression. This project is a retrospective evaluation that will exam the feasibility and possibly efficacy of this intervention. METHODS/STUDY POPULATION: We will evaluate outcomes of 50 participants for the clinic, aged 21-60 inclusive. Patients will have a Body Mass Index >25kg/m^2 with a diagnosis of prediabetes. Patients must be non-pregnant, using approved contraception, and agree to not become pregnant for 1 year after enrollment. After enrollment, the initial treatment period is for 1 year and includes a 12 week low calorie diet plan, a 6-month intensive behavioral and lifestyle modification plan followed by a 6 month behavior reinforcement extension. Weight management medications may be used if appropriate for the patient from a clinical perspective during the 6-month intensive behavioral/lifestyle modification. RESULTS/ANTICIPATED RESULTS: It is anticipated that there will be decreased weight with a mean weight loss goal of approximately >10%. Furthermore, it is expect that there will be improvement of other markers of metabolic disease. These include improvement of lipid values (LDL-C, HDL-C, Triglycerides, Total Cholesterol) as well as blood pressure with expected blood pressures of below 130/80 in greater than 50% of participants. Finally, It is expected that 50% or greater participants will have improvement of glycemic control. It is anticipated that greater than 50% of participants will have improvement of glycemic control and achieve normoglycemia. These values will be determined based upon fasting glucose or A1c. DISCUSSION/SIGNIFICANCE OF IMPACT: The significance of this intervention is enormous. By demonstrating feasibility in this trial, we can work toward both assessing efficacy and possibly dissemination of this model program. If these interventions provide durable changes at scale, this could help slow the epidemic of obesity and obesity related comorbid conditions.

4036

POSITIVE EXPERIENCE OF INFORMED CONSENT UNDERSTANDING AT A METROPOLITAN MULTI-INSTITUTIONS CTSA HUB

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OBJECTIVES/GOALS: There is not much known on how to improve informed consent understanding and there are no effective interventions that have been identified to improve understanding rates of information. This study seeks to assess participants understanding of the informed consent. METHODS/STUDY POPULATION: We studied a non-probability sample of 245 participants, 57% female, with age range from 6 to 84, currently enrolled in clinical trials conducted at an urban city, multi CTSA institution. A self-administered questionnaire approved by IRB was utilized. Redcap database was utilized for data entry. The items in the questionnaire reflected understanding of the informed consent (e.g., purpose for the study, participants' rights, risks, benefits). Participants completed the survey during their first visit to the research centers or on a follow-up visit. Data were collected from July 2018 to November 2019. Data were analyzed descriptively by summary statistics. RESULTS/ANTICIPATED RESULTS: African Americans were 44%, Non-Hispanic Whites were 36%, Hispanic 6%. Others 13%. 52% married, 12% completed High school, 74.8% completed College, 13% less High school. 91% read the form themselves. 99% knew the purpose of the study; 99% knew they could quit the study at any time. While (113) 47% indicated knowledge of the potential risk, only (12)10.6% could not list any associated risk. 98% stated they had information on who to call with questions regarding the study. (204)86% knew of a potential benefit, only (11)5% could

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