86808

Adverse Childhood Experiences are associated with a higher prevalence of asthma among adolescents with sickle cell disease

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ABSTRACT IMPACT: This research highlights Adverse Childhood Experiences as a potential risk factor and intervention target contributing to the disproportionate number of individuals with sickle cell disease affected by asthma, a well-established catalyst to the increased morbidity and mortality impacting this high-risk population. OBJECTIVES/GOALS: Adverse Childhood Experiences (ACEs) are strongly associated with asthma. A disproportionate number of individuals with sickle cell disease (SCD) also have asthma. Asthma is strongly associated with increased SCD morbidity and mortality. This study compared the prevalence of asthma among children and adolescents with SCD with and without ACEs. METHODS/STUDY POPULATION: This retrospective cohort study involved 45 children and 30 adolescents with SCD. ACEs were captured using the Center for Youth Wellness Adverse Childhood Experiences Child and Teen Questionnaires, which encompass the original 10 ACEs as well as 7 (child) and 9 (teen) expert-recommended ('expanded') ACEs. ACE exposures were categorized as: Original 0-1 vs. ≥2; Original + Expanded 0-1 vs. ≥2. Asthma prevalence was compared among ≥2 and 0-1 ACE groups using the chi-square (or Fisher's exact) test. A binary logistic regression was performed to predict the likelihood of asthma while adjusting for characteristics (age, household income and gender) that were statistically different among ACE comparison groups at baseline. RESULTS/ANTICIPATED RESULTS: Among the 45 child participants, 64% had a history of asthma; whereas 50% of teens had a history of asthma. Asthma prevalence was higher among teens with ≥2 vs. 0-1 Original ACEs (89% v. 33%, p=0.014). A history of ≥2 ACEs remained significant (p=0.024) among teens after adjusting for age, household income and gender. There was no significance in asthma prevalence among child ACE comparison groups. DISCUSSION/SIGNIFICANCE OF FINDINGS: Adolescents with ≥2 ACEs had a higher prevalence of asthma compared to subjects with 0-1 ACE. This study, coupled with the cumulative nature of ACEs and the graded-dose response relationship between ACEs and poor health outcomes, highlight the need for larger, longitudinal studies examining the relationship between ACEs, asthma and SCD outcomes.

Clinical Trial

Clinical Epidemiology

41502

Does dietary fat composition predict short-term elevations in lipid levels in adults on a modified Atkins diet?

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ABSTRACT IMPACT: Our work provides guidance on whether dietary fat intake influences serum cholesterol levels in response to ketogenic diet therapy in adults with epilepsy. OBJECTIVES/GOALS: The modified Atkins diet (MAD) is used in the management of drug-resistant epilepsy in adults. Some patients on MAD show an increase in serum levels of total cholesterol and low-density lipoprotein (LDL) cholesterol. We explored whether dietary fat composition predicts short-term elevations in serum lipid levels in diet-naive adults who begin MAD. METHODS/STUDY POPULATION: Participants self-reported their diet intake with 3-day food records at baseline, 1 month and 2 months. Food records were analyzed using Nutrition Data System for Research software. Fasting serum levels of total cholesterol (TC), high-density lipoprotein (HDL) cholesterol, and triglycerides were also collected and LDL level calculated at baseline, 1 month, and 2 months. RESULTS/ANTICIPATED RESULTS: 38 patients submitted complete food records at each study visit (baseline, 1 month, and 2 month). Compared to baseline diet intake, there was a significant reduction in daily carbohydrate intake at 1 and 2 months ($p<0.001$) and a significant increase in daily fat intake at 1 and 2 months ($p<0.001$). There was also a significant increase in daily saturated fatty acid (SFA) intake at 1 and 2 months ($p<0.001$), daily mono-unsaturated fatty acid (MUFA) intake at 1 and 2 months ($p<0.001$), and daily cholesterol intake at 1 month ($p<0.05$) and 2 months ($p<0.001$), but no change in daily poly-unsaturated fatty acid (PUFA) intake over time. Compared to baseline, there was a significant increase in serum LDL at 1 month ($p<0.001$) and 2 months ($p<0.01$) and an increase in serum TC at 1 month ($p<0.01$) but not 2 months. DISCUSSION/SIGNIFICANCE OF FINDINGS: Despite a significant increase in total fat, saturated fat and mono-unsaturated fat intake as well as an increase in total cholesterol and LDL levels following MAD initiation, dietary fat composition appears to minimally predict serum lipid values in the short term.

79885

Self-Weighing in Adolescents with Obesity: Attitudes of Teens and their Parents.

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ABSTRACT IMPACT: Obesity is a quickly growing pandemic that negatively impacts health, and clinicians and clinics must employ all evidence-based tools (such as self-monitoring) to help patients control their weight. OBJECTIVES/GOALS: The objective of this study was to understand patient and parent perspectives on using daily self-weighing for adolescents with obesity who are seeking obesity treatment. The secondary objective was to understand perspectives on connecting smart-scales to the electronic medical record for messaging, feedback, and reminders between visits. METHODS/STUDY POPULATION: Thirty adolescents with obesity who were seeking obesity treatment at a tertiary pediatric weight management clinic were recruited into a single-arm feasibility study to create and assess a connection between blue-tooth scales and the electronic medical record. These adolescents and their parents were then approached about conducting exit interviews about their experience in the feasibility study – their perspectives on connecting bluetooth scales connected to the electronic health record and using daily self-weighing at home to help them reach their healthy weight goals. The interviews were conducted by a trained interviewer who was not a PI or Co-I on the feasibility study, recorded, and transcribed. The interviews were organized on themes including technical challenges, mood, stress, clinic feedback. RESULTS/ANTICIPATED RESULTS: The main theme expressed by participants and parents was related to past experiences of their weight loss journey. Sub-themes included:

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technical challenges with apps, parental involvement in weighing, being told by clinicians to weigh, and intervention impact. Most parents desired more directions and help with setting up the app connection to the EHR. Most parents did not ask their child daily about their weight status as they did not want to cause stress. Some adolescents found it stressful when parents asked about daily weight status; others found it helpful or at least not stressful. Most participants had never been advised by their clinician to regularly self-weigh. Most found it helpful to monitor their weight regularly. Most asked for reminders from clinic to weight and for feedback on weight between visits. DISCUSSION/SIGNIFICANCE OF FINDINGS: Overall, adolescents with obesity reported self-weighing as being helpful and most wanted some, but not daily, involvement from parents. Most parents wanted additional technological support to create the scale set-up. Nearly all parents and adolescents wanted the weights to be connected to clinic, and for there to be feedback from clinic on weight.

Commercialization/Entrepreneurship

92090

Novel use of REDCap to develop a Crisis Management Decision-Support Portal at an Academic Medical Center

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ABSTRACT IMPACT: Implementation of digital and mobile applications in clinical research crisis response protocols can mitigate their impact on clinical research. OBJECTIVES/GOALS: Crisis management is fundamental to ensuring the protection of human subjects during a clinical trial. Mobile apps have the capacity to allow for quick access to crisis response plans and can serve to mitigate their impact on clinical research. Electronic data capture tools can be used to create digital applications for such a response. METHODS/STUDY POPULATION: The Clinical Research Center at Rutgers University transferred a paper-based crisis management response plan to a digital mobile application format using Vanderbuilt's Research Electronic Data Capture Tool (REDCap). REDCap's branching logic allowed for programming a decision support functionality to guide users through 3 specific crises. (1) threatening or aggressive study subject behavior; (2) clinical research center break in or theft; and (3) adverse event observed for ongoing or closed clinical research study. Applicable U.S. Code of Federal Regulations, IRB guidelines, institutional policies and procedures were also used as a component of the mobile development. RESULTS/ANTICIPATED RESULTS: The Crisis Management Decision-Support Portal within the Clinical Research Center has an interactive structure. The use of branching logic demonstrates the ability for users to answer each question and be guided to appropriate responses specific to selected criteria related to each event. The tool contains a self-correct function by providing a reset option after answering each section. The portal itself can be accessed using any computer or cellphone with an internet connection. It provides the users with appropriate criteria to determine to exact communication and management protocols for reporting for the crisis event they are witnessing. As users access the portal, usage data can be collected, tracked, and stored. DISCUSSION/SIGNIFICANCE OF FINDINGS: The REDCap platform offers the opportunity to digitize crisis management protocols that ensure professionals have easy access to appropriate responses to crises at the center. The use a digital application rather than paper allows for a CTSA sponsored hub to mitigate damage, simply build new protocols, modify existing protocols, and track usage.

Evaluation

62610

Effects of electronic verses paper based data capture in large multinational trials on time to complete, time to publication, participation and collaboration.

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ABSTRACT IMPACT: My work evaluates the impact of electronic data capture/eSource on several aspects of clinical trial efficiency and scale, aiming to demonstrate how eSource can be used to improve the way we run clinical trials. OBJECTIVES/GOALS: Using eSource may increase the efficiency of data collection in clinical trials. However, adoption of eSource has been slow. We reviewed over 100 large multinational clinical trials to analyze how eSource use correlated with trial size, sponsor collaborations, time to complete, and time to publication. METHODS/STUDY POPULATION: We searched ClinicalTrials.gov for completed, interventional, Stage II-IV clinical trials with posted results and an uploaded study protocol document. This produced 3,962 trials. We identified all studies with over 1,200 participants and sites in multiple countries (or at least 100 sites in one country). After eliminating ten studies with duplicate protocols, we had a database of 123 trials. From the ClinicalTrials.gov listing, the study protocol, and any published papers, we determined the start, end, and publication dates, data collection protocol, sponsors and collaborators, and any reasons given for delays for each trial. We performed statistical tests comparing trial delay, participant and country count, and collaboration status (yes or no) between the two groups (eSource users and non-eSource users). RESULTS/ANTICIPATED RESULTS: Of our 123 trials, 60 (48.7%) used eSource, 48 (39.1%) used paper source documentation, and 15 (12.2%) used some combination. We found no statistically significant difference between eSource and non-eSource trials in terms of trial delay ($p=0.43$), time to publish ($p=0.33$), collaboration status ($p=0.54$), number of participants ($p=0.36$), or number of countries ($p=0.12$). However, our analysis was limited by what data was publically available. To investigate the effects of eSource on site efficiency, data accuracy, and data security, which are three major factors behind the FDA's 2013 eSource recommendation, we would need access to proprietary information from trial sponsors. DISCUSSION/SIGNIFICANCE OF FINDINGS: The use of eSource in large multinational clinical trials is not correlated with a change in time to completion or publication nor a higher number of participants or countries. We aim to acquire proprietary data to further analyze the impacts of eSource on trial efficiency, data accuracy, and data security.

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