0088

REMOTE CLINICAL RESEARCH OPERATIONS DURING COVID-19: LESSONS LEARNED AND RECOMMENDATIONS

Julianna Adornetti[1], Christine Wade[1], Maura Deeley[2], Hannah Eldringhoff[3], Rachell Jones[3], Janna Mantua[3], Jacob Collen[4], Emerson Wickwire[5]

Sleep Disorders Center, Division of Pulmonary and Critical Care, Department of Medicine, University of Maryland School of Medicine, Baltimore, MD [1] University of Maryland Baltimore [2] Center for Military Psychiatry and Neuroscience, Behavioral Biology Branch, Walter Reed Army Institute of Research [3] Department of Medicine, Uniformed Services University of the Health Sciences Program Director, Sleep Medicine Fellowship [4] Department of Psychiatry, University of Maryland School of Medicine, Baltimore, MD Sleep Disorders Center, Division of Pulmonary and Critical Care, Department of Medicine, University of Maryland School of Medicine, Baltimore, MD [5]

Introduction: As a result of the global COVID-19 pandemic, there have been significant challenges conducting clinical sleep research. Participant recruitment has been a particular challenge due to federal safety guidelines and institutional directives. The purpose of this project is to describe the adaptation of an in-person study protocol (of sleep problems among military service members and their families) to an entirely remote approach.

Methods: Prior to COVID-19, planned research methods included in-person recruitment, enrollment, and study support; approved by the Institutional Review Board (IRB) of Walter Reed National Military Medical Center (WRNMMC), Fort Belvoir Community Hospital (FBCH), and the University of Maryland, Baltimore (UMB). As COVID-19 restrictions increased, the research team adapted to a fully remote approach (via phone/email) and developed a "research call center" to replace in-clinic recruitment/enrollment. Detailed operating procedures were standardized, including shipping study materials (wearable device) via FedEx. Following enrollment, participants completed multiple assessments, sleep diaries 2x/day over 10 days, and a post-monitoring satisfaction survey.

Results: Thirty-five participants between the ages of 18-75 years (M= 46 years, SD= 15.8) were successfully recruited from the Internal Medicine clinic and Sleep Disorders Center at WRNMMC. Following data collection, the research team debriefed and developed recommendations to execute a successful remote study protocol. Three key operational domains were identified: research team, remote procedures, and data management. Recommendations included 1) prioritizing consistent communication, mutual support, and personal wellbeing among the research team, 2) advancing recruitment by establishing and refining preferred recruitment pathways, and 3) providing critical attention to remote data management—allocating responsibilities to regulate the evolving changes of multiple data sources. In addition, partnering closely with IRB personnel was invaluable to refine procedures and maintain regulatory compliance.

Conclusion: Despite challenges associated with the on-going pandemic, researchers can conduct high-quality clinical research by transitioning to a fully remote study approach. These recommendations can help guide investigative teams to transition from in-person protocols to remote approaches, thus advancing the perpetuation of research activities through a pandemic.

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0089

FEASIBILITY OF RAPID MEASUREMENT OF BRAIN METABOLITES IN OBSTRUCTIVE SLEEP APNEA

Andres Saucedo[1], Ravi Aysola[2], Paul Macey[3], Michael Thomas[1]

Department of Radiological Sciences, David Geffen School of Medicine, University of California, Los Angeles, Los Angeles, CA, United States [1] Division of Pulmonary and Critical Care, David Geffen School of Medicine, University of California, Los Angeles, Los Angeles, CA, United States [2] School of Nursing, University of California, Los Angeles, Los Angeles, CA, United States [3]

Introduction: Obstructive Sleep Apnea (OSA) affects over 15% of the adult population and is associated with brain dysfunction. Although the dysfunction is well-identified and presents brain morphological changes as shown with structural imaging, it is unclear what pathology underlies these neural alterations. Magnetic resonance spectroscopic imaging (MRSI) can non-invasively measure several metabolites from multiple brain regions in vivo. However, the clinical practicality of the standard MRSI techniques (Cartesian phase-encoding or echo-planar [EP]) is hindered by long scan times. In order to assess clinical populations, our group developed an alternative MRSI technique, "radial" EP-MRSI. To assess the feasibility and calculate effect sizes we did a pilot study of brain metabolites in OSA using radial EP-MRSI.

Methods: Radial EP-MRSI data with a speed-up (undersampling) factor of 2.5 (compared to a fully-sampled Cartesian MRSI scan) were acquired in 5 OSA patients (3 males, 37±11 yrs., Apnea Hypopnea Index (AHI): 8.2±5.5) and 10 healthy controls (5 males, 28±7 yrs.). Spectra from twelve brain regions were selected from each subject and five metabolites–total choline, myo-inositol (mI), total N-acetylaspartate, glutamine+glutamate (Glx) and lactate (Lac)–were quantified as ratios with respect to creatine (Cr), using "LC Model" software. The brain regions include left/right of: basal ganglia, insula, and gray/white of the frontal and occipital regions. Mean group differences were calculated and compared with independent samples t-tests.

Results: Glx/Cr was significantly decreased (27%; $p<0.05$) in OSA vs. control in the left posterior insula. Other metabolites did not show significant differences. mI/Cr trends were consistent with previous findings (higher in OSA) and Lac/Cr trended higher OSA.

Conclusion: This feasibility study showed that it is possible to measure multiple metabolites in multiple regions and detect effects of OSA. The accelerated technique enabled measurements to be completed in under 4 minutes.

Support (If Any):

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PERFORMANCE OF A MULTISENSOR RING TO EVALUATE SLEEP: IN-LAB EVALUATION RELATIVE TO PSG AND ACTIGRAPHY: IMPORTANCE OF GENERALIZED VERSUS PERSONALIZED SCORING

Michael Grandner[1], Stephen Hutchison[1], Zohar Bromberg[2], Zoe Morrell[2], Arnulf Graf[3], Dustin Freckleton[2]

University of Arizona [1] Happy Health [2]

Introduction: Multisensor sleep wearable devices have demonstrated utility for research and relative accuracy for discerning