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

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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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FEASIBILITY OF RAPID MEASUREMENT OF BRAIN METABOLITES IN OBSTRUCTIVE SLEEP APNEA

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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):

0090

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

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

sleep-wake patterns at home and in the laboratory. Additional sensors and more complex scoring algorithms may improve the ability of wearables to assess sleep health.

Methods: Thirty-six healthy adults completed assessment while wearing the experimental device (Happy Ring), as well as Philips Actiwatch, Fitbit, Oura, and Whoop devices. Evaluations occurred in the laboratory (Alice 6 polysomnogram). The Happy Ring includes sensors for accelerometry, photoplethysmography, electrodermal activity, and skin temperature. Epoch-by-epoch analyses compared the Happy Ring to lab polysomnography, as well as other sleep-tracking devices. Scoring was accomplished using two machine-learning-derived algorithms: a "generalized" algorithm which was static and applied to all users (like those used for other devices) and a "personalized" algorithm where parameters are personalized, dynamic, and change based on data collected across different parts of the night of sleep.

Results: Compared to in-lab polysomnography, the generalized algorithm using data from the Happy Ring demonstrated good sensitivity (94%) and specificity (70%). The personalized algorithm also performed well with good sensitivity (93%) and specificity (83%). Other devices also demonstrated good sensitivity, ranging from 89% (Fitbit) to 94% (Actiwatch); specificity however, was more variable, ranging from 19% (Actiwatch) to 54% (Whoop). Overall accuracy was 91% for generalized and 92% for personalized, compared to 88% for Oura, 86% for Whoop, 84% for Fitbit, and 85% for Actiwatch. Measurement of sleep stage accuracy was 67%, 85%, and 85% for light, deep, and REM sleep, respectively, for the Happy generalized algorithm. For the Happy personalized algorithm, accuracy for sleep stages were 81%, 95%, and 92%, for light, deep and REM sleep, respectively. Post-hoc analyses showed that the Happy personalized algorithm demonstrated better specificity than all other modalities ($p<0.001$). Kappa scores were 0.45 for generalized and 0.68 for personalized, compared to 0.32 for the Oura Ring, 0.32 for Whoop Strap, and 0.37 for Fitbit wristband.

Conclusion: The multisensory Happy ring demonstrated good sensitivity and specificity for the detection of sleep in the laboratory. The personalized approach outperformed all others, representing a potential innovation for improving detection accuracy.

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THE PRACTICALITY OF IMPLEMENTING NIGHTLY REMOTE PATIENT MONITORING (RPM) OF OSA PATIENTS IN CLINICAL PRACTICE

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Introduction: If Remote Patient Monitoring (RPM) is to become integrated into sleep medicine practices, patient compliance and reliability of data acquisition needs to be determined. We developed the REST Tracker platform to monitor OSA patients nightly, using an oximeter ring with data analyzed by a recognized method (1) to render a sAHI that has been FDA approved (FDA reference number K182618) providing an equivalent to the AHI. The REST Tracker tracks the sAHI along with multiple other parameters, providing the clinician nightly physiologic data to assist in OSA management decisions. Here we present patient compliance and system reliability data.

Methods: Data obtained from a ring pulse oximeter worn nightly is transmitted by Bluetooth to a cellular device at the bedside. Nightly data from bedtime to final morning awakening is transmitted to the cloud and retrieved by the REST Tracker system which tabulates and displays the data in a format that assists the clinician in OSA management decisions. Compliance and reliability performance criteria used to assess the REST Tracker system were as follows: Patient Retention Rate (patients were considered a Drop Out if there was no usage within 15 days prior study termination on Dec 15th), Data Acquisition Reliability = percentage of nights with > 3 hours of data on those nights the ring was used. Successful Monitoring Achieved if a patient had over 70% of nights containing > 3 hours of data. Data acquisition was initiated on 1/1/21 and ended 12/15/21 with a minimum of 6 weeks of monitoring.

Results: A total 38 patients (28 M / 10 F) Ave age 60 (SD +/-13) enrolled from 1/1/21 to 10/31/21, and acquisition ended 12/15/21. Monitoring ranged from 6 to 50 weeks. 10 patients dropped out, rendering a 74% Patient Retention Rate. Data was collected for a total 4072 nights from all patients, of which 3441 nights had > 3 hrs of data, rendering an overall Data Acquisition Reliability of 84.5%. There were 33 patients that achieved Successful Monitoring (87%) as defined above.

Conclusion: In our practice RPM has been well accepted with 74% Patient Retention Rate and 87% achieving Successful Monitoring. This study demonstrated the feasibility of this approach. We are currently implementing methods to achieve higher retention successful monitoring rates. The REST Tracker has been used in our practice for the management of OSA patients undergoing a variety of treatments approaches ranging from PAP, dental appliances and Inspire (HGNS). The REST Tracker has enhanced our ability to assess these patients on an ongoing basis, decreased the need for in lab sleep testing and expedited management decisions. Clinical cases are currently being accumulated and will be presented to demonstrate the utility of the REST Tracker RPM approach.

Support (If Any): Reference: (1) Al Ashry HS, Hilmisson H, Ni Y, Thoms RJ, Investigators A. Automated Apnea-Hypopnea Index from Oximetry and Spectral Analysis of Cardiopulmonary Coupling. Ann Am Thorac Soc. 2021;18(5):876-83.

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THE EFFECTS OF SLOW-OSCILLATORY GALVANIC VESTIBULAR STIMULATION ON SLEEP PHYSIOLOGY IN HEALTHY HUMANS

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Introduction: Recent studies have demonstrated that rocking promotes sleep in animals and humans. The application of an alternating current galvanic vestibular stimulation (GVS) can elicit body sway like rocking sensation. Here, we examined the effects of slow-oscillatory GVS, which can evoke the virtual rocking sensation in the brain, on objective and subjective sleep quality in healthy young adults.

Methods: We studied 14 healthy subjects (age: 22.7 p/m 1.4 years) who underwent 3 nap conditions (adaptation, sham [SHAM], and stimulation [STIM]), where SHAM and STIM were randomly allocated with a 1-week interval in general. The polysomnographic recordings were started at 2 pm and time in bed was restricted to 90 min for all subjects. In both conditions, electrodes were placed on both mastoids for GVS; in STIM condition, the slow-oscillatory (0.25 Hz sinusoidal) GVS was applied