Study Title: LA-CEAL 4.0: Wearable Sensor Project

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1. Study aim, background, and design

In August 2020, Louisiana (LA) ranked first in the US for COVID-19 cases by population with a case rate of 2,960 per 100,000 and fifth in deaths by population with a death rate of 97 per 100,000[1,2]. The added strain on the healthcare system was associated with high levels of burnout and among the healthcare workforces[3,4]. Biofeedback is a technique in which patients use data about their own physiology to improve their mental, physical, and emotional health [5]. Biofeedback is an effective method of treating mental health symptoms and managing chronic illness. More specifically heartrate biofeedback has been successful in treating depression, anxiety, and sleep disturbances in patient populations[6]. LA-CEAL will test the value of biofeedback delivered via wearable sensor in addressing stress, burnout, depression, and anxiety in healthcare populations to enhance resilience with the long-term aim of improving workforce retention.

OBJECTIVE: To develop and test approaches for strengthening the capacity and resilience of the primary care workforce to support their roles as Trusted Messengers for Long COVID, chronic disease, preventive healthcare and clinical research participation.

This approach will use a randomized two-group crossover design to test the hypothesis that using real-time biofeedback to present, interpret, and bring attention to information regarding stress levels will increase participants readiness to change in regard to addressing burnout. To test this hypothesis, we will recruit 80 providers/staff from FQHC partner sites to participate in a 6-week crossover design. All participants will be given a wrist worn sensor developed by Biostrap. The sensor links with a phone application (API) controlled by the research team. The research team can release forms, surveys, and summary information from the wearable sensory onto the phone application. The API can also push notifications to complete self-report surveys as needed. Biostrap collects biometrics such as the following: (1) sleep pattern/ quality; (2) steps, activity, calories; (3) heart rate; (4) oxygen saturation; and (5) respiratory rate. Participants will be randomly assigned to one of two groups. The first group will receive access to their biometric data in real-time via the Biostrap API (information received condition) while the second group will be given a summary of their biometrics at the end of their 14-day control period (information delayed condition). After 1 week “washout” the conditions will cross-over, and the second group will receive real-time access to their biometrics via the Biostrap API while the first group receive their biometric report at the end of the control period. Participants will complete a pre and posttest self-report survey using the measurements tool attached.

2. Subject Population

Up to 80 participants from staff members of partner federally qualified health centers (FQHCs):

Inclusion criteria: Age >=18 years; ability to understand and speak English; staff at FQHC; smartphone compatible with the Biostrap sensor and phone application; attending work during the six week study period.

Exclusion criteria: Unable or unwilling to give informed consent, disclosed pregnancy at the start of the study, pace maker or other device regulation heart rate/rhythm, previous diagnosis of atrial fibrillation.

3. Procedure

Enrolled participants will be asked to complete 2 brief surveys via REDCap, once at the start of the study and a second time at the end, approximately 6 weeks later. The survey should take about 20-25 minutes to complete. During the six-week period, participants will be given a wearable sensor made by Biostrap. Participants will be randomly assigned to one of two groups. Both groups will be asked to wear the sensor during the six-week period. Both groups will begin with 7 days to get used to wearing the sensor. Group 1 will receive access to their biofeedback information in real-time for the next 14 days via the Biostrap dashboard on the mobile app. Group 2 will not have access to this real-time data during the same 14 day period, but will receive a summary report at the end of the 14-day period. Both groups will then have a 7-day “washout” period before switching

conditions: Group 2 will see their biofeedback information in real-time on the mobile app while Group 1 will have all real-time biofeedback information hidden, instead receiving a summary report at the end of the 14-day period. During the time participants are wearing the sensor they will receive one notification a day prompting them to answer two questions via the Biostrap dashboard. During the time they are wearing the sensor it will be recording biometric information such as: (1) sleep pattern/ quality; (2) steps, activity, calories; (3) heart rate; (4) oxygen saturation; and (5) respiratory rate. All of this data is linked with a randomly generated Study ID.

4. Risks

The risk of physical, psychological, social, or legal harm associated with participation in all components of this study is minimal:

- Though not sensitive in nature and widely used in social science research, participants may feel uncomfortable responding to some of the survey, participants will be informed that they do not have to answer any question they do not want to answer and that they can stop participating at any time without penalty.
- Participants may find it inconvenient to take time to participate in the study. All study activities will be arranged at a time that is convenient for participants.
- There is a small risk of unauthorized disclosure of participants' responses, which will be prevented by following a strict protocol for data handling and rigorous training of study staff:
    - No identifying data (e.g., name, address) will be recorded on study forms. Identifying data used for participant recruitment will be kept separate from study data and no linkage will exist.
    - All electronic study records will be stored with password-protection. All paper study records will be locked in a secure study office. Data will be accessible only by study staff with approval from the PI.
    - The data will be retained without identifiers in a secure location for possible use in a future project, which will be consistent with the original research purpose.
    - Data may be shared with the NIH or other researchers upon request. Any data shared with the NIH or other researchers will not contain identifying information.

5. Benefits

Wearable sensor project: There may not be any direct benefit from participating in the study. We have found that talking about work related stress and burnout is helpful for people. In addition, wearing a sensor like Biostrap will provide participants with information about their sleep, heartrate, activity level, and pulse oxygenation which can also help form health habits. The knowledge gained from the study may provide evidence for a strategy to improve healthcare worker well-being.

6. Remuneration

Participants will receive the following payments for completing the following study activities $25 per week during the wearable sensor protocol (maximum of $150 per person, $25*6 weeks).

7. Costs

There will be no costs to the participant for participating in this research study.

8. Consent process and documentation

Eligible participants will view and sign the consent form (attached) via REDCap. Participants will review the consent form and be asked to verify their understanding of consent by Yes or No to the following statements:

- I have read this consent form, or it has been read to me.
- This study has been explained to me, including risks and possible benefits (if any) and other options besides study participation.
- I have had the opportunity to ask questions.
- I understand the information that has been provided to me.
- I have had enough time to think about participation in the study.

Participants will have the ability to click on "I consent" or "decline." Participants will also be given the opportunity to pause the consent process to speak with a study team member to answer any questions they have.

9. References

1. Centers for Disease Control and Prevention. CDC COVID Data Tracker. https://www.cdc.gov/covid-data-tracker/#cases. Published 2020. Updated Aug 19 2020. Accessed Aug 19 2020.
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6. Fournie, C., Chouchou, F., Dalleau,G., Caderby, T., Cabrera, Q., & Verkindt, C. (2021). Hreat rate variability biofeedback in chronic disease management: a systematic review. Complementary There Med, 60 102750 doi: 10.1016/j.ctim.2021.102750