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ARENA LABS - IMPROVING CLINICIAN WELL BEING

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Atrium Health | Arena Labs Research Protocol

Project Title

The effect of an asynchronous coaching platform on measures of physiological resilience, professional fulfillment, burnout, self-valuation, and overall satisfaction in Atrium Health Sanger Heart and Vascular Institute Surgery, Emergency Department, and Pulmonary Critical Care Physicians and Advanced Practice Providers.

Principal Investigator and Co-Investigator Information

Principle Investigator: Dr. Kevin Lobdell

Research Question/Hypothesis

What is the effect of educational content; data feedback and monitoring; and tailored coaching touchpoints provided through an asynchronous coaching platform on measures of physiological resilience, professional fulfillment, burnout, self-valuation, and overall satisfaction in full time clinical providers?

Objectives

The primary objective of this study will be to determine the efficacy of the asynchronous performance coaching platform, Arena Strive at changing measures of physiological resilience, professional fulfillment, burnout, and self-valuation in full time clinicians. The anticipated **primary outcome** will be an improvement in measures related to clinician resilience including self-reported professional fulfillment and self-valuation; factors measured by the WHOOP biometric device: Heart rate variability (HRV), resting heart rate (RHR), time spent in bed, sleep quality, sleep consistency, reduction in "sleep debt"; and a reduction in burnout. Expected **secondary outcomes** include an overall high level of self-reported acceptance, satisfaction, and feasibility of the Arena Strive Platform.

- Primary outcome: Increases in physiological and self-reported measures of resilience / decreases in burnout measures.
- Secondary outcome: Feasibility, acceptance, satisfaction of Arena Strive platform

Background to Research Questions

Recent literature has found that burnout is highly prevalent among healthcare professionals, affecting between 40-60% of physicians. [1] The added stressors of the COVID-19 pandemic have also been associated with high rates of multidisciplinary healthcare professional burnout, depression and anxiety, especially among women, nurses, and those working in hospital environments.[2-3] Mental health disorders are also prevalent among health care workers. In a study of 4833 physicians, 41.7% screened positive for depressive symptoms and 6.9% reported having suicidal ideation in the previous year, of whom 27% reported that they would probably or definitely not seek help.[4] The healthcare professionals most in need of care and burnout prevention modalities are those least likely to seek support, with a perceived stigma associated with seeking help.[5] These findings contribute to the mounting body of evidence suggesting there is a significant unmet gap in this vulnerable population.

Healthcare clinicians work in a high-stress environment that requires quick decision making and high levels of both mental and physical acuity. Like other performance careers, a clinician's own mental and physical states are key to their ability to take optimal care of their patients. However, despite the

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similarities shared with these other performance careers, performance coaching, well-being interventions, and other burnout prevention initiatives are commonly perceived as either ineffective, or out of reach to the health professional workforce due to time restraints, lack of knowledge, or pre-existing stigmas around help seeking. Arena Strive and WHOOP aim to address these barriers by democratizing performance coaching with a seamless asynchronous coaching experience at the clinicians fingertips.

METHODOLOGY

Study design

This study is a prospective randomized controlled longitudinal crossover design with a per protocol analysis integrating one sensor (WHOOP, inc Platform) and one educational intervention (Arena Strive Platform). The **WHOOP** sensor collects **data** on heart rate (HR), heart rate variability (HRV), and sleep data, and will be worn by all participants in the experimental intervention. Participants will be asked to wear the biometric sensor for 12 weeks but will have optional access to the device for a total of 24 weeks.

Throughout the 12 week intervention period, **participant engagement** within the Arena Strive app will be collected including data points relating to videos/audio watched or listened to, content favorited, or user activities completed. Modifiable activities collected via the Arena Strive Platform include light exposure, light restriction, sleep hygiene, meal timing, and activation and deactivation techniques (yoga nidra, physiological sigh, super O2 breathing).

Self-reported data will also be collected relating to the participants ability to adapt to stress, rest and recover from stress, and self-awareness around these two constructs. WHOOP data, engagement within the Arena Strive app, and self-reported stress adaptability, rest and recovery, and self-awareness will be collected continually throughout the intervention period. The additional self-reported outcomes: professional fulfillment, burnout, self-valuation, and overall satisfaction will be collected by means of an in-app survey at key benchmark moments throughout the intervention period: once at intervention start, again at week 6 following the first phase of the Arena Strive intervention, then again at week 12 following the completion of the experimental intervention period. Participants in the control cohort will follow this same time frame with respect to self-reported surveys. All self-reported data within the control cohort will be collected via identical surveys hosted on Typeform, the web-based surveying platform.

The experimental intervention, 'Arena Strive', will be conducted through the Arena Strive app, self-described as "Healthcare's First Performance Coach". This second-generation platform provides frontline clinicians with a comprehensive journey to access the tools, training, and technology used by other high-pressure fields to increase performance and enhance resilience. Strive uses a dynamic, interactive content platform to bring frontline clinicians the lessons learned, tools, and tailored instruction of world-class performers from elite military, professional athletes, and creative performers. The design will test the effect on measures of professional fulfillment and burnout; self-valuation; satisfaction; and feasibility in full-time NHS clinicians.

Intervention

The experimental intervention employed in this study will be a 12-week, multi-phased approach involving asynchronous learning and coaching experience (6 weeks), and exploration phase (6 weeks).



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Phase 1: Enrollment period and participant recruitment, obtain informed consent, complete WHOOP device setup & download Arena Strive app. During the study kickoff, intervention participants can choose to attend coaching workshops with an Arena labs performance coach to learn more about the principles of high-performance medicine, biometric data, and the Arena Strive platform.

Phase 2: In the second phase, a performance coaching platform comprising educational content; data feedback and monitoring; and tailored coaching touchpoints will then be administered via the smartphone application, Arena Strive for a duration of 6 weeks (Arena Strive :: Foundations). Arena Labs performance coaches can be accessed via the app. Arena Labs performance coaches provide personalized coaching tailored to the individual clinician and his/ her unique set of needs. The intervention will also include a wearable biometric device provided by WHOOP to collect physiological data relating to measures of resilience and autonomic function. The accompanying WHOOP app will be available in this phase of the intervention. Data from the wearable device will be passed directly into the Arena Strive app to be summarized and delivered to participants through the app interface for self-monitoring, feedback, and coaching touchpoints.

Phase 3: After 6 weeks of asynchronous guidance through the Arena Strive app, users will then continue the intervention (Arena Strive :: Explorations) with an additional 6 week experience of data feedback.

As a behavioral intervention, Arena Strive follows the COM-B framework of behavior change, which targets participants' capabilities (C), opportunities (O), and motivations (M) to integrate performance practices into their routines. The first phase of the intervention will involve 6 weeks of micro-learning audio and video content targeting clinicians' capabilities and opportunities to learn and train 17 foundational performance practices. Targeted behavior change techniques (BCTs) help participants overcome barriers, monitor progress, and build intrinsic motivation toward the integration of these 17 practices. These practices leverage techniques and physiological processes that aim to influence the three main foundations of High Performance Medicine: self-awareness, rest & recovery, and stress adaptability. Techniques include but are not limited to autonomic regulation, self-reflection, environmental restructuring, task-based coping, emotion-based coping, guided attention control, and shaping behavior around physiological triggers.

Control Cohort: Participants randomized into the control cohort will receive no intervention for the duration of the experimental intervention. At the conclusion of the full 12 week baseline and intervention period, participants in the control cohort will be given the option to participate in the intervention.

Setting

The study will take place within the Atrium Health Sanger Heart and Vascular Institute, Emergency Department, Surgery and Pulmonary Critical Care.. All data collection, intervention, and participant interaction will take place asynchronously through the Arena Strive smartphone application, and the WHOOP wearable biometric device.

Expected Start Date

The expected enrollment will begin on January 2023 for both cohorts.

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Duration of Study

The total length of this study will be 24 weeks from participant recruitment to conclusion of data analysis.

- 6 weeks = Phase 1 Enrollment period and participant recruitment, obtain informed consent, complete WHOOP device setup & download Arena Strive app.
- 6 weeks = Phase 2: Arena Strive Intervention period (Arena Strive :: Foundations)
- 6 weeks = Phase 3 Continue WHOOP device & Arena Strive Intervention (Arena Strive :: Explorations)
- 6 weeks = Data analysis

Study Participants

Participants sought for this study will include full time Physicians and Advanced Practice Providers employed by Atrium Health Sanger Heart and Vascular Institute, Surgery, Emergency Department, and Pulmonary Critical Care. Investigating this special subject population will allow the study team to address with the greatest accuracy the effects of the proposed intervention on the unique workforce at Atrium Health. The maximum number of subjects sought for this study is 100; with a 2:1 randomization ratio with 2/3 receiving the experimental intervention, and 1/3 receiving no intervention to act as an inactive control.

Note: The employees who volunteer for participation but are assigned to the control condition will be given the opportunity to participate in the exact same program at the completion of the trial with the experimental group. Those employees who take this opportunity can then serve as an internal replication of the findings with the experimental group.

All Participants must meet the following Inclusion/ Exclusion Criteria. Criteria points will be self-reported and acknowledged by the participant.

Key Inclusion Criteria:

- Employed full time by an Atrium Health affiliated entity
- Age 18+
- Willing and able to give written informed consent for study participation.
- Healthcare workers working ≥ 36 hours of clinical duties/week.
- Willingness to wear WHOOP and keep it charged for the entire duration of study.
- Have a smart phone for pairing with WHOOP and the Arena Strive platform.

Key Exclusion Criteria:

- Current diagnosis of a sleep-related breathing disorder including obstructive sleep apnea not being treated (with or without continuous positive airway pressure (CPAP) treatment)
- Circadian rhythm sleep-wake disorders
- Narcolepsy
- Recurrent isolated sleep paralysis
- Restless legs syndrome
- Periodic Leg Movement Disorder
- Comorbid nocturia or other conditions (eg. benign prostatic hyperplasia) resulting in frequent need to get out of bed to use the bathroom during the night (≥ 3 times per night average)
- Atrial Fibrillation
- COPD other than mild, pulmonary fibrosis or severe chronic lung disease
- Sleep apnea or undergoing treatment for a sleep related illness

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- Lack of availability of iPhone or Android device
- Part-time clinical duties

Participant Consent: All participants involved in this study will be required to provide written consent to participate. Participants will be asked to consent to the collection of self-reported data provided through in-app and digital surveys as well as biometric data collected through the WHOOP device. A copy of the written consent form is included in the appendix. Spanish language consents will be made available upon request.

Equipment/Supplies/Services

All equipment, services, and supplies related to the study intervention will be provided by Arena Labs, and WHOOP. All equipment, services, and supplies related to the recruitment of study participants will be provided by the Atrium Health team.

Data Collection

All study data will be collected via an in-app or online survey, through app interactions, or through the WHOOP wearable biometric device. Data collection for the control cohort will mirror that of the experimental group in both frequency and content with a select few exceptions. Control cohort participants will not receive questions relating to feasibility and satisfaction, and self-reported data will be collected via online surveys hosted on Typeform. A breakdown of the primary and secondary outcome variables are summarized below.

		Outcome Variable	Instrument	Collection Method
<u>Primary Outcomes</u>	Self Reported	Professional Fulfillment & Burnout	Stanford Professional Fulfillment Index (PFI)	Onboard, midpoint, and exit Survey
		"Gold standard" for measuring burnout	Maslach Burnout Inventory (MBI)	Onboard, midpoint, and exit Survey
		Self Valuation	Stanford Self Valuation Scale	Onboard, midpoint, and exit Survey
	Biometric Data	HRV	WHOOP Strap	Continuous
		SWS %	WHOOP Strap	Continuous
		REM %	WHOOP Strap	Continuous
		RHR	WHOOP Strap	Continuous
		Awake Time	WHOOP Strap	Continuous
		Light Sleep Duration (%)	WHOOP Strap	Continuous

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		Sleep Disturbances	WHOOOP Strap	Continuous
		Sleep Debt	WHOOOP Strap	Continuous
		Sleep Consistency	WHOOOP Strap	Continuous
<u>Secondary Outcomes</u>	Self-reported	Satisfaction	Client Satisfaction Questionnaire-8 (CSQ-8)	Exit Survey
		Feasibility/Adherence	NA	In-app Survey & app engagement

Data Analysis

- We will use t-tests in SPSS to compare the primary outcome measures across the experimental and control groups.
- We will also test for dose effects in the experimental condition via a series of correlational analyses that estimate whether the extent of engagement with the Arena Strive platform predicts better outcomes on the primary measures.
- We will use multilevel-modeling (MLM) in R (using the lme4 package) to compare the various indicators of sleep duration and quality, as well as HRV and RHR, across time as a function of participation in the experimental vs. control conditions. We will allow random intercepts and slopes to model the possibility that some individuals will show different baselines and/or larger effects of participation in the experimental condition than others.
- We will also test for dose effects in the experimental condition via a series of MLMs that estimate whether extent of engagement with the Arena Strive platform predicts better sleep performance and recovery.
- Finally, we will estimate a series of regression-based mediational models that test whether the Arena Strive manipulation enhances sleep and recovery, which in turn enhance the primary outcome measures.

Data Management

WHOOOP maintains a Member Data Retention & Disposal Policy to govern our data management practices.

All WHOOOP member data retained in any WHOOOP environment is subject to the WHOOOP's access control, information classification, and key management and cryptography policies. When a data subject requests access to their WHOOOP member data, WHOOOP takes measures to validate the identity of the requestor to ensure the security of the data being provided.

Disposal of WHOOOP member data will be carried out in accordance with the contractual agreement between WHOOOP and the member. In the absence of any contractual agreement with respect to Personal Data disposal, an automatic script or manual script (for ad-hoc requests) may be requested by a data subject and, after verifying the identity of the requestor, shall be initiated on the WHOOOP



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platform containing WHOOP member data. This activates a deletion of WHOOP member data on the platform, except for those data elements required to satisfy legal and financial retention requirements.

In connection with our research partnerships, WHOOP will only provide member data to our partners in an anonymized, de-identified manner.

Within the Arena Strive platform, individual-level data is only shared with the individual. Deidentified, aggregate data is shared with leaders with informed consent of participants. All data collected through Arena Strive including self-reported data and in-app engagement data is owned and stored by Arena Labs Inc. in line with the company's privacy principles below. Arena-Strive technology is HIPAA compliant. Per written privacy policy, Arena Strive does not sell any data and maintains the highest level of privacy standards for all data collected. In line with the Arena Strive data privacy policy, and in partnership with WHOOP, every volunteer participant user has the right to control their own data. Any user can choose to have their individual information deleted at any point.

Arena Labs Data Privacy Policy

- Compliance - Strive solution is deployed on AWS cloud services which are HIPAA, PCI-DSS, PA-DSS certified. We store no user PHI. The Strive solution is accessible to registered and verified users only. Their data is stored in AWS data sources housed in Amazon's US-East location data servers. The organization's IT infrastructure is deployed on AWS and accessed securely by the employees.
- Personal Device Use Only - Strive Platform does not need any computing equipment hosted in the organization's premises. The organization's network would not be accessed by any user/third party. Strive is a web based platform and does not require any on-premises deployment or network access.
- Security Framework - Arena Labs infrastructure and Strive platform is developed and deployed based on the security controls of NIST SP800-53 R4, HIPAA and HITRUST CSF. The underlying cloud technologies are NIST/HITRUST/ISO 27001/CIS certified.
- Data Storage - Strive anonymizes and encrypts PII data stored in durable AWS data sources-- including usernames, emails, cell-phone numbers, dates of birth, stress levels, heart rates, & respiratory metrics--to ensure it is secured against unauthorized access or use.

Identified Risks/Ethical Considerations

De-identified data from the applications (WHOOP, Arena-Strive) will be shared with the study coordinator and collaborators listed in the application. No identifiers will be shared with any third party persons or services. Should any participant find wearing any device uncomfortable they will be able to not participate in that part of the study. The other aspects of the study (i.e. Arena Strive educational content) will still be available for their use. Hospital employees are potentially vulnerable subjects and will be protected in two ways. First, all specific identifying information will be coded and assigned study number and device serial number. The data that are collected for analysis by the investigators will not necessitate access to any identifiable medical records. The study investigators will be the sole individuals with access to the identity of the specific assigned study numbers. Secondly, the recruitment material and informed consent will clarify that the decision to participate is voluntary and performance during the study is in no way tied to their employment or pay.



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Individual results will not be shared with any hospital leadership or administration, or with the participant's coworkers or supervisors unless those members are among the study investigators and with the explicit informed consent from the participant. Participants have access to their own personal physiological data via the Arena Strive and WHOOP apps and individual logins to the WHOOP website. Language will be included in the consent document to reflect the importance of provider well-being. Incidental findings may be identified throughout the study, such as identifying stressors that contribute to anxiety or depression. These will be handled appropriately, with recommendations and resources for professional help. At any point, the participant may choose not to answer a survey question for any reason.

Benefits of Proposed Research to the Subjects and Others (significance of your study)

Study participants will have real-time access to their personal biometric data which can be used to assess their own physiologic response throughout daily work, exercise and sleep. In prior studies conducted by WHOOP, after 4 months on the WHOOP platform, tactical athletes, medical professionals, and professional athletes on average improved time spent in deep sleep with improved sleep performance and reduced alcohol consumption within 2 hours of bedtime, as well as reduced pre-bedtime screen-time. These improved behaviors translated to statistically significant physiological advantages seen by increased heart rate variability and reduced resting heart rate. Participants across these cohorts also showed a positive downward trend in reported stress and sickness. Participants in both groups will have access to the Arena Strive targeted education platform where they will be shepherded through various techniques and tools to help manage and buffer stress.

The Arena Strive platform was built to bring a data-driven, scalable and cost-effective solution to the challenge of burnout in healthcare. Prior studies conducted have shown that after 4 months of real-time data access provided by the Whoop device, tactical athletes, medical professionals, and professional athletes on average improved time spent in deep sleep with improved sleep performance and reduced alcohol consumption within 2 hours of bedtime, as well as reduced pre-bedtime screen-time. These improved behaviors translated to statistically significant physiological advantages seen by increased heart rate variability (HRV) and reduced resting heart rate. Participants across these cohorts also showed a positive downward trend in reported stress and sickness. These results are mirrored in early adopters of the Arena Strive platform with increases in sleep efficiency and reductions in resting heart rate (RHR) across users of all engagement levels.

Arena Strive's targeted education platform provides an additional layer of context and benefit to subjects by shepherding users through various techniques and tools to help manage and buffer the metrics provided by the Whoop device. This additional layer of context in comparison to physiological data access alone has yielded greater increases in heart rate variability (HRV) and rapid eye movement sleep (REM) as shown in users who are highly engaged in the Arena Strive platform. Early benefits experienced by Arena Strive users extend beyond physiological markers of performance as well. Users of the Arena Strive platform have also reported a more than 12% increase in self-reported energy management, adaptability, and self-awareness.

The Arena Strive experience prioritizes health professionals and provides them with the same tools, science, and frameworks used in other high-pressure fields; however, the benefits of this first-of-its-kind platform extend beyond the individual users. Anticipated benefits to the involved NHS institutions will mirror those already seen in contracted institutions engaging with Arena Strive. While traditional approaches to reduce burnout and promote resilience in healthcare workforces require extensive time, resources, and involvement from the responsible healthcare institution, Arena Strive steps in to take the burden off of the institution by delivering a fully packaged intervention. The components comprising the Arena Strive platform aim to deliver a revolutionary tool that radically transforms the way hospitals



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think about performance in the healthcare setting by providing an experience that is embedded, proactive, data driven, accessible, and acceptable.

1. Embedded: While similar interventions demand the use of long blocks of discretionary time outside of work as well as hospital resources, the Arena Strive platform is designed to be embedded in the workday. In addition, while it is often the case that individuals access and learn resilience strategies in isolation, our team-based methodology leverages the wellbeing benefits of community-building and the benefits of social contagion in cementing behavior change.
2. Proactive: Resilience tools and resources are often deployed after an individual or team is already suffering from burnout. Our program is designed to function as a preventative measure upstream of burnout by engaging individuals proactively, though it is also beneficial for those who are already experiencing burnout.
3. Data-driven: The Arena Strive platform allows individuals and teams to assess their stress and burnout and evaluate the effectiveness of resilience techniques in real time. De-identified, summarized daily survey and physiologic data can inform organizational interventions and culture change to address drivers of stress and burnout.
4. Accessible: The Arena Strive platform is asynchronous and available 24/7 to users regardless of shift, maximizing accessibility to the NHS employees and reducing the barriers associated with accessing traditional resilience training.
5. Acceptable: Due to the stigma around help-seeking and mental health diagnoses and a professional culture that has traditionally associated self-care with weakness, healthcare professionals can be hesitant to engage with resilience modalities that are framed as “wellness” or “self-care.” Arena Strive is explicitly framed around the connection between resilience, endurance, and performance and is contextualized to appeal to healthcare professionals.

Participant reimbursement/compensation

Subjects will not receive money, incentives, payment, or reimbursement for participation in this study. Each participant will keep the Whoop device issued to them.

References

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5. Brower KJ. Professional Stigma of Mental Health Issues: Physicians Are Both the Cause and Solution. *Acad Med* 2021;96(5):635–40.



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ATTACHMENTS

Survey (if using a survey)

Data collection spreadsheet

Consent forms if needed