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ARENA LABS - IMPROVING CLINICIAN WELL BEING

Informed Consent Form to Participate in Research
Kevin Lobdell MD, Principal Investigator

SUMMARY

You are invited to take part in a research study. The purpose of this research is to evaluate the effect of an asynchronous coaching platform on measures of physiological resilience, professional fulfillment, burnout, self-valuation, and overall professional satisfaction. You are invited to be in this study because you are from the Sanger Heart and Vascular Institute, and Atrium Health Pulmonary Critical Care department. Your participation in this research will involve a baseline period with enrollment period and participant recruitment, obtain informed consent, complete WHOOP device setup & download Arena Strive app. An Intervention period with Arena Strive: Foundations access, followed by an Explorations period with WHOOP app & Arena Strive Interventions.

This study will be enrolling employees from the Sanger Heart and Vascular Institute, Emergency Department, Surgery, and Atrium Health Pulmonary Critical Care department. In addition to your rights as a research participant noted in the earlier section, as an employee, you are under no obligation to take part in this study. You may refuse to take part or withdraw from the study at any time and for any reason without affecting your employment status, performance evaluations, or salary. You will not be pressured into taking part in this research study by any statements or implied statements that your employment status will be affected by your willingness to enroll in the study. Your medical records/information will not be used by the faculty, administration, or study staff to make decisions regarding the status of your medical benefits. If you have questions about your enrollment in the study and your status as an employee, please contact the research subject advocate for more information.

The rest of this form holds a more complete description of this study. Please read this description carefully. You can ask any questions if you need help deciding whether to join the study. If you have questions, suggestions, or concerns about this study or you want to withdraw from the study please contact the Principal Investigator at [redacted].

If you have any questions, suggestions, or concerns about your rights as a volunteer in this research, contact the Institutional Review Board at [redacted] or the Wake Forest University Health Sciences Research Subject Advocate at [redacted].

INTRODUCTION

You are invited to be in a research study. You are being asked to be in this study because you are a Sanger Heart and Vascular Institute Physicians, SHVI Advanced Practice Provider, Emergency Department Physician, Atrium Health Surgeon, Atrium Health Pulmonary Critical Care Physician, or AH Advanced Practice Provider. Your participation is voluntary. You do not have to be a part of this study if you do not want to. Please take your time in making your decision if you would like to join. Ask your study doctor or the study staff to explain any words or

information contained in this informed consent document that you do not understand. You may also discuss the study with your friends and family.

WHY IS THIS STUDY BEING DONE?

The purpose of this research study is 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.

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 making up 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. 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 with an added 6-week experience of data feedback

Participants will also be asked to complete four surveys at three points during the study (onboarding, midpoint, and exit of the study). The three surveys are: Standard Professional Fulfilment Index (PFI). and Maslach Burnout Inventory (MBI) and Stanford Self Valuation Scale. You will also be asked to complete the client satisfaction questionnaire-8 (CSQ-8) at the exit of the study. You will also be as to self-report using the In-ap survey & app engagement.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

100 people at will take part in this study.

WHAT IS INVOLVED IN THE STUDY?

You will be randomized into one of the study groups described below. Randomization means that you are put into a group by chance. It is like flipping a coin.

Participants randomized into the experimental intervention cohort will be taking part in a 12-week, multi-phased study. This will include intervention phase of asynchronous learning and coaching experience (6 weeks), and exploration phase (6 weeks).

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 choice to take part in the intervention.

If you take part in this study, you may have the following tests and procedures: wear the WHOOP device, complete four surveys, and in app self-monitoring, feedback, and coaching touchpoints.

How Long Will I Be in the Study?

You will be in the study for about 12 weeks. You will have the choice to access to the device and applications for a total of 24 weeks.

You can stop taking part at any time. If you decide to stop taking part in the study, we encourage you to talk to the investigators or study staff first.

What Are the Risks of the Study?

Being in this study involves some risk to you. You should discuss the risk of being in this study with the study staff. Risks and side effects related to the study include:

Risk of the Study

Confidentiality and privacy	Taking part in this research study may involve supplying information that you consider confidential or private. Efforts, such as coding research records, keeping research records secure and allowing only authorized people to have access to research records, will be made to keep your information safe.
interview questions related to depression, suicidal ideations, abuse, illegal behavior, or other information that may require reporting to authorities outside of the study	As part of this study, you will be asked questions about Professional Fulfillment & Burnout and Stanford Self-Valuation Scale. If we learn that you or someone else is in danger of harm, the study team must report that information to the proper authorities.

There also may be other risks that we cannot predict. You should tell the research staff about all the medications, vitamins and supplements you take and any medical conditions you have. This may help avoid side effects, interactions, and other risks to your health.

Are There Benefits to Taking Part in the Study?

If you agree to take part in this study, there may or may not be direct benefit to you. We hope the information learned from this study will help other people in the future.

Because individuals respond differently to therapy, no one can know in advance if it will be helpful in your case.

What Other Choices Are There?

You do not have to be in this study. You should talk to the researchers about all the choices you have. Instead of being in this study, you have these options:

This is not a treatment study. Your alternative is to not take part in this study.

WHAT ARE THE COSTS?

All study costs, including any study products related directly to the study, will be paid for by the study.

WILL YOUR RESEARCH RECORDS BE CONFIDENTIAL?

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed unless it is authorized by you, needed, or allowed by law, or necessary to protect the safety of yourself or others.

I give permission to Atrium Health, Wake Forest University Health Sciences, and their respective affiliated entities and representatives (including third-party agents if applicable) to contact me by text message at the number I provided to send information, reminders, and to communicate with me about the research study. I understand that I am responsible for the standard text message rate of my carrier. I also understand that text messaging is not a secure form of communication and I accept the risk that individuals not involved in the research study may be able to access the text messages. I also understand that texting is not to be used for emergency situations.

By supplying my email address, I give permission for Atrium Health, Wake Forest University Health Sciences, and their respective affiliated entities and representatives (including third-party agents if applicable) to send me information, reminders, and messages about the research study by email. I understand that these email messages may not be encrypted, and I understand and accept the risks that individuals not involved in the research study may be able to access unencrypted email messages. I also understand that email is not to be used for emergency situations.

WILL YOU BE PAID FOR PARTICIPATING?

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

The findings from this research may result in the future development of products that are of commercial value. There are no plans to provide you with financial compensation or for you to share in any profits if this should occur.

WHO IS SPONSORING THIS STUDY?

This study is being sponsored by Sanger Heart and Vascular Institute. The sponsor is supplying money or other support to the researchers to help conduct this study. The researchers do not, however, hold a direct financial interest in the sponsor or the product being studied.

WHAT ABOUT MY HEALTH INFORMATION?

In this research study, about your health or behaviors is considered Protected Health Information.
. The information we will collect for this research study includes: biometrics, and surveys.

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.

If this research study involves the diagnosis or treatment of a medical condition, then Protected Health Information collected from you during this study may be placed in your medical record, and may be used to help treat you, arrange payment for your care, or assist with the health care operations of Atrium Health, Wake Forest University Health Sciences, and their respective affiliated entities.

We will take steps to keep your Protected Health Information private. We will store records of your Protected Health Information in a cabinet in a locked office or on a password protected computer.

Your personal health information and information that identifies you ("your health information") may be given to others during and after the study. This is for reasons such as to carry out the study, to determine the results of the study, to make sure the study is being done correctly, to provide required reports and to get approval for new products.

Some of the people, agencies and businesses that may receive and use your health information are the research sponsor; representatives of the sponsor assisting with the research; investigators at other sites who are assisting with the research; central laboratories, reading centers or analysis centers; the Institutional Review Board; representatives of Wake Forest University Health Sciences and Atrium Health Facilities; representatives from government agencies such as the

Food and Drug Administration (FDA) or the Office of Human Research Protections (OHRP), the Department of Health and Human Services (DHHS) and similar agencies in other countries.

Some of these people, agencies and businesses may further disclose your health information. If disclosed by them, your health information may no longer be covered by federal or state privacy regulations. Your health information may be disclosed if required by law. Your health information may be used to create information that does not directly identify you. This information may be used by other researchers. You will not be directly identified in any publication or presentation that may result from this study unless there are photographs, videotapes, audiotapes or other recorded media which are identify you unless we you're your written authorization.

Monitors, auditors, IRB or other regulatory agencies will be granted direct access to your medical record for verification of clinical trial procedures or data to the extent permitted by other applicable laws. These monitors, auditors, and other individuals are also required to maintain the confidentiality of your protected health information.

If required by law or court order, we might also have to share your Protected Health Information with a judge, law enforcement officer, government agencies, or others. If your Protected Health Information is shared with any of these groups it may no longer be protected by federal or state privacy rules.

Any Protected Health Information collected from you in this study that is maintained in the research records. You can tell Kevin Lobdell, MD that you want to take away your permission to use and share your Protected Health Information at any time by sending a letter to this address:

Kevin Lobdell
[redacted]

However, if you take away permission to use your Protected Health Information you will not be able to be in the study any longer. We will stop collecting any more information about you, but any information we have already collected can still be used for the purposes of the research study.

By signing this form you give us permission to use your Protected Health Information for this study.

If you choose to participate in this study, your medical record at Atrium Health, Wake Forest University Health Sciences, or their respective affiliated entities will indicate that you are enrolled in a clinical trial. Information about the research and any medications or devices you are being given as a participant may also be included in your medical record. Authorization to access this part of the medical record will only be available to people who have a need to know this information in order to perform their job-related duties. If you are not a patient of these health care facilities, a medical record will be created for you anyway to provide access to this important information to providers in case of an emergency.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this Web site at any time

WHAT ARE MY RIGHTS AS A RESEARCH STUDY PARTICIPANT?

Taking part in this study is voluntary. You may choose not to take part, or you may leave the study at any time. Refusing to take part or leaving the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to stop taking part in the study, we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences. The investigators also have the right to stop your participation in the study at any

time. Information that identifies you may be removed from the data that are collected as part of this study and could be used for future research or shared with others without added consent.

You will be given the latest information we become aware of that would affect your willingness to continue to participate in the study.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or in case of a research-related injury, contact the study investigator, *Kevin Lobdell MD at* [redacted]

The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, or you would like to discuss problems or concerns, have questions, or want to offer input, or you want to obtain additional information, you should contact the Chairman of the IRB at [redacted] or the Research Subject Advocate at [redacted]

You will be given a copy of this signed consent form.

SIGNATURES

I agree to take part in this study. I authorize the use and disclosure of my health information as described in this consent and authorization form. If I have not already received a copy of the Privacy Notice, I may request one or one will be made available to me. I have had a chance to ask questions about being in this study and have those questions answered. By signing this consent and authorization form, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Subject Name (Printed): _____

Subject Signature: _____ Date: _____Time: _____ am pm

Person Obtaining Consent (Printed): _____

Person Obtaining Consent: _____ Date: _____ Time: _____ am pm