

## **CONSENT TO TAKE PART IN RESEARCH**

Dartmouth College

*Study title:* : CREST - Creating Resilience and Emotional Stability through Technology

*Principal Investigator:* Thomas Thesen, Ph.D.

**You are being asked to take part in a research study. Taking part in research is voluntary.**

### Study Summary:

As a medical student, you are invited to participate in the CREST Study, a research study designed to use of wearable devices and technology-assisted coaching sessions for wellness self-management.

If you choose to participate, you will learn how to interpret the physiological information provided by a smartwatch and how you can leverage this information to improve your overall health and well-being during medical school. You will also receive one-on-one coaching sessions to help you along the way.

The study aims to understand how wearable devices and technology-assisted coaching can improve wellness and self-management among medical students. We are particularly interested in stress management, sleep quality, physical activity, and overall wellbeing.

If you choose to participate, you will be asked to complete an initial survey and brief follow-up surveys throughout the year through a mobile app. You will also be asked to share some of your anonymous smartwatch data, such as number of steps, heart rate and sleep quality. If you do not own a compatible smartwatch, we will give you a Fitbit device that you can use for the duration of the study.

### Study Group

After you agree to participate, you will be randomly assigned to either the immediate treatment group or the wait-list control group. Both groups will receive the same intervention - the difference is the timing of when the intervention is received.

Your decision whether to take part will have no effect on academic standing. Please ask questions if there is anything about this study that you do not understand. Taking part in this study is completely **voluntary**. You do not have to participate if you don't want

to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you.

Your privacy will be protected. Please read further below for the privacy protection measures of this study that have been developed in collaboration with Geisel medical students.

**What is the purpose of this study?**

The purpose of the study is to assess the effects of digital health education and technology-assisted coaching on lifestyle behaviors in medical students.

**Will you benefit from taking part in this study?**

The benefits for you may include increased knowledge about digital health, lifestyle medicine, potentially improved well-being, and the opportunity to contribute to research that may benefit future medical students.

**What does this study involve?**

Your participation in this study may last up to 6 months. If you agree to participate, we will ask you to complete an initial confidential survey and to install a secure app on your phone. If you do not own a compatible device, you will receive a FitBit Inspire 3 device for the duration of the study. You will be asked to sync the device with your phone daily, keep it charged, and wear it throughout the duration of the study (including when you sleep). This allows you to gain objective data related to your daily physical and physiological activity, such as steps, sleep, and heart rate. You will learn how to interpret these data to improve your well-being.

*Surveys.* Every three months you will be asked to fill out a survey with questions pertaining to your health beliefs. Participation will require approximately 3 minutes to complete the survey.

If you are a participant in the Wearable Wellness Study at Geisel, we ask your permission to link your data between the two studies.

Please indicate your preference here:

- ☐ I DO give permission to link my data from the CREST study and my data from the Wearable Wellness study
- ☐ I DO NOT give permission to link my data from the CREST study and my data from the Wearable Wellness study

#### Wearable Device:

You will be asked to wear a wearable sensor that tracks your daily activity levels, heart rate, and sleep patterns. If you already own a compatible device (FitBit, Garmin, or Apple), you can use your own. If not, we will provide you with a Fitbit Inspire 3™.

#### Smartphone App:

You will be asked to install the proprietary device app on your smartphone. This will allow the wearable device to sync data to your smartphone and enable you to view graphs of your physical activity, sleep, heart rate, and other metrics collected by the wearable device.

#### Education Session:

You will participate in an educational session, lasting about 50 minutes, on the use of wearable devices. Here, you'll learn how to track and interpret longitudinal physiological data relevant to your well-being.

#### Coaching Sessions:

Following the educational session, you will have 4 technology-assisted coaching session over three months. The first meeting will be 50 minutes long and includes setting up the device and orientating you to the process. Subsequent sessions will last 30 min. These sessions are designed to assist you in understanding your personal health data and creating a lifestyle management plan.

#### Data Collection:

During each coaching session, we will ask you to fill out a form asking for summary data from your wearable device over the prior period, including your physical activity levels, sleep patterns, and stress markers. Your lifestyle management plan developed with the coach will also be recorded. At the end of the three-month period, we'll conduct an interview to gather your feedback on your experience with the wearable device and the coaching sessions. All these information will be de-identified.

#### Time Commitment

The study will run for 6 months.

#### Confidentiality

The coaching sessions will be in-person and the coach will know your name. Your recorded data will be associated with a unique ID number, and not your name, to

ensure anonymity of your data for research purposes. Only a non-Geisel individual, without any access to other participant-related data, will be able to link the ID number to your name. Research personnel will not be able to associate the data collected as part of this study with your identity. The coach will not have access to the anonymized research data records.

**What are the options if you do not want to take part in this study?**

Your participation is completely voluntary. The alternative is not to participate in the study, in which case there will be no penalty.

**If you take part in this study, what activities will be done only for research purposes?**

If you take part in this study, the following activities will be done only for research purposes:

1. Surveys (active, requiring you to answer questions)
2. Participate in 50 min of digital health education
3. Participate in 4 x 30 min coaching sessions over 3 months.

**What are the risks involved with being enrolled in this study?**

Discussions about your wellness may trigger emotions in you. If you experience distress at any point during the study or feel you require medical, psychiatric, or other forms of assistance, we strongly urge you to obtain it through the Dartmouth Counseling Center at 603-646-9442 or the Uhelp Crisis Line at 833-646-1526. You will be provided with a comprehensive list of resources for mental health counseling and treatment on campus upon enrollment.

During this study, we may ask you questions related to suicidal thoughts. Should you select any response that indicates suicidal thoughts, an immediate automated message will be sent to you. This message provides guidance and comprehensive information on crisis management resources. This message is automated without human interaction, and your privacy will not be compromised.

Our protocol has been designed in consultation with the on-campus counseling center to prioritize your privacy while providing appropriate supportive resources. We are aware that medical students may be hesitant to openly disclose mental health concerns and may not provide truthful responses if their privacy is perceived to be at risk. By ensuring your privacy, we aim to create an environment where you can comfortably respond honestly to sensitive questions. This enables us to promptly provide effective information on resources should a crisis arise.

Our protocol is designed to both protect your mental well-being and maintain the integrity of our study. Your participation is highly valued and your privacy and safety are of utmost importance to us.

In rare cases, minor skin irritation may occur on the wrist because of wearing a Fitbit or smartwatch. There are no other known or expected risks from smartwatch/Fitbit use.

Additionally, there may be a risk of loss to confidentiality or privacy. However, the study is explicitly designed to protect your confidentiality and privacy (see below).

As with any research study, there may be additional risks that are unknown or unexpected.

### **Will my data be de-identified and used in the future for other purposes?**

Your data will be stripped of identifiers and may be used for future research. Any future research that uses your data will be reviewed by the Committee for the Protection of Human Subjects at Dartmouth College and an independent Student Monitor, who will determine if the research requires your permission or may be properly done without further permission from you. Your de-identified data will be kept indefinitely.

### **Other important items you should know:**

- **Leaving the study:** You may choose to stop taking part in this study at any time. If you decide to stop taking part, it will have no effect on your academic standing.
- **Number of people in this study:** We expect (92) people to enroll in this study.
- **Funding:** Funding is provided by the International Association of Medical Science Educators and the McDonnell Fund.

### **How will your privacy be protected?**

The information collected as data for this study includes self-reported data from wearable fitness devices. During your meetings with your coach, you will be asked to fill out a form with your summary scores (heart rate, steps, sleep, etc.) since your last meeting. This information will be coded with a unique non-decodable identifier so that all information provided by you will remain confidential. These data will be stored in a secure and HIPAA compliant environment. All identifying information, such as your name and contact information will be stored in encrypted format and secured separately from your other data. Identifying information will only be accessible to a

dedicated Dartmouth person who is a faculty member at Thayer School of Engineering. Other study personnel, including the Principal Investigator, will not have access to your identifying information at any time.

Anonymous data collected for this study will be maintained indefinitely.

We are careful to protect the identities of the participants in this study. We also keep the information collected for this study secure and confidential.

#### Student Monitor

To ensure transparency in data handling, the study includes a dedicated medical student representative, who acts as a "Student Monitor" who has complete knowledge about the data privacy protections of the study. The independent Student Monitor is not a participant in the study or part of the research team but helps oversee the data use and privacy procedures. The role of the Student Monitor is to act in the interest of study participants and to ensure that strong data protection and privacy procedures are followed in a transparent manner. The Student Monitor can veto any data access and/or analysis that they deem to violate subject privacy protection and/or interest.

#### **What about the costs of this study?**

There are no costs for you if you decide to participate in this study besides electrical costs to charge your wearable device.

#### **Will you be paid to take part in this study?**

You will not be paid as part of this study.

#### **Whom should you call with questions about this study?**

If you have questions about this study or concerns about a research-related problem or injury, you can call the research director Dr. Thomas Thesen for this study: 347-668-7432 or email: [thomas.thesen@dartmouth.edu](mailto:thomas.thesen@dartmouth.edu)

If you have questions, concerns, complaints, or suggestions about human research at Dartmouth, you may call the Office of the Committee for the Protection of Human Subjects at Dartmouth College (603) 646-6482 during normal business hours.

**CONSENT**

I have read the above information about the Wearable Wellness Study and have been given time to ask questions. I agree to take part in this study, and I will be given a copy of this signed consent form.

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Participant's Signature and Date

PRINTED NAME

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Researcher or Designee Signature and Date

PRINTED NAME