Evaluating the Effectiveness of an Enhanced Digital Mental Health Care Delivery System

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UNIVERSITY OF PENNSYLVANIA
RESEARCH SUBJECT
INFORMED CONSENT AND HIPAA AUTHORIZATION FORM

Protocol Title:	Evaluating the Effectiveness of an Enhanced Digital Mental Health Care Delivery System
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Sponsor	National of Institutes of Health (NIH)

Research Study Summary for Potential Subjects
You are being invited to participate in a randomized control clinical trial research study. Your participation is voluntary, and you should only participate if you completely understand what the study requires and what the risks of participation are. You should ask the study team any questions you have related to participating before agreeing to join the study. If you have any questions about your rights as a human research participant at any time before, during or after participation, please contact the Institutional Review Board (IRB) at (215) 898-2614 for assistance.

The randomized control clinical trial research study is being conducted to test the effect of tailored mental health support for health care workers during the response and recovery phases of the COVID-19 pandemic.

The support platform being tested is Penn COBALT, a web-based Penn Medicine well-being and mental health platform. COBALT offers resources that individuals may use on their own time, access to individual or group sessions, and appointments with trained mental health experts. This trial will test the effect of how participants engage and access COBALT in a passive or active way.

If you agree to join this randomized controlled clinical trial you will be asked to complete the following research procedures:

1. Complete an online survey asking about your background and health and well-being
2. Complete an online survey on health and well-being at 6 months
3. Complete an online survey on health and well-being at 9 months

Regardless of your randomization, you will be asked questions about your well-being and emotional state, such as those that ask about depression, anxiety, and suicide ideation.

Your participation will last for 9 months. A subset of participants will receive an email (up to 4) or text message (up to 3) invitation(s) after the 9-month study period to participate in voluntary a debriefing interview (approximately 20-30 minute interview). The purpose of the interview is to learn about your experience in the study. This is completely voluntary and the decision to participate will not affect participation in the COBALT trial. If you are contacted for an interview, you will be asked to read and sign a separate informed consent document at that time.

Your participation will help better understand how to support health care workers at Penn Medicine during the response and recovery phases of the COVID-19 pandemic. This study has minimal risks, but the most common risks of participation include the disclosure of sensitive information like your mental health information and potential discomfort in answering questions about depression, anxiety, and suicidal ideation. Another potential risk in permitting your data to be stored in our research database is the potential risk of loss of confidentiality.

Your Penn Medicine director, supervisor, or co-worker may be an investigator in this research study. Investigators on this study will only have access to de-identified data at the group level, such as gender, race-ethnicity, and type of role. Investigators on this study include: Raina Merchant, Anish Agarwal, Lisa Bellini, Noelle Ciara, Nandita Mitra, Courtney Wolk, Rachel Kishton, Mohan Balachandran, Judy Shea, David Asch, and Emily Becker-Haimes. Research staff: Rachel Gonzales and Lauren Southwick.

Names are also found in this Appendix.

Only the Principal Investigator (Merchant) and Co-Investigator (Agarwal) will receive a de-identified notification when a study participant expresses suicide ideation. This notification only includes a randomly generated study ID number. The purpose of this notification is to ensure that these participants are appropriately connected to the Penn Employee Assistance Program. Only the research staff (Southwick and Gonzales) will have access to information about suicidality and information about attended/missed appointments.

You do not have to participate in any research study offered by your director, supervisor, or co-worker. If you choose not to participate, there will be no loss of benefits to which you are otherwise entitled. Your employment is not in jeopardy should you decide not to participate

You may also decide to discuss the study with your family, friends, or family doctor. Being in a research study is different from being a patient. As an investigator, your director, supervisor, or co-worker is interested both in your clinical welfare and in the conduct of this study.

Please note that there are other factors to consider before agreeing to participate such as additional procedures, use of your personal information, costs, and other possible risks not discussed here. A research team member is readily available to discuss the informed consent form with you and answer questions via email or telephone communications. Please text back the Way to Health number or email digitalhealth@uphs.upenn.edu.

The University of Pennsylvania has a significant financial interest in the Penn Medicine COBALT resources and delivery system used as a part of this protocol. It was developed by inventors at Penn Medicine, and if it were to be successful, the University of Pennsylvania will likely receive significant financial benefit.

As a reminder, all Penn Medicine employees have access to COBALT for resources regardless of if they participate in the study. *You are free to decline or stop participation at any time during or after the initial consenting process.* To decline or stop participation, please email digitalhealth@uphs.upenn.edu or text in 'Bye" to the Way to Health number.

Why am I being asked to volunteer?
You are being invited to participate in a research study because you are 1) age 18 years or older; 2) regular, daily access to a smartphone; 3) able to communicate fluently in English; 4) work at least 4 hours per week in either a Penn Medicine or UPHS hospital or outpatient-based setting.

If you decide to participate, you will be asked to sign this form.

What is the purpose of this research study?
The purpose of this randomized controlled trial is to test with and without an intervention - the effect of tailored mental health support on self-reported health care worker mental health and well-being, during the response and recovery phases of the COVID-19 pandemic.

How long will I be in the study?
The study will last 9 months. If you are enrolled in the study, you will complete regular surveys, each survey takes about 5-10 minutes to complete. You will complete all surveys online through Way to Health, a HIPAA compliant Penn Medicine research platform.

What am I being asked to do?
You will be asked to create an account on Way to Health. Once you're enrolled on Way to Health, you will complete a survey; the survey will ask questions about your health status, basic demographic information, and contact information including your email address, home mailing address, phone number, and PennKey. Your PennKey is used to observe your use of Penn COBALT during the trial. It will not be used to track any information or personal health information within the health record. It will not be used to

inform the University of Pennsylvania, University of Pennsylvania Health System, or your supervisor of your participation. Over the course of 9 months will be asked to complete 2 more short online surveys on Way to Health. Do not disclose personal health information (PHI) on the Way to Health texting platform and only respond to the survey questions or text message prompts.

If you participate in the study, there is a 50% chance (similar to flipping a coin), that you just complete surveys and a 50% chance that you receive monthly text messages or email reminders and links to Penn COBALT resources and additional short surveys at month 2 and 4. If you receive text message reminders and two additional surveys, you will receive tailored well-being resources delivered via texting-messaging with links to Penn COBALT. When you log onto Penn COBALT, you will be prompted to sign in using your Penn Key credentials. Please note, every time you log onto Penn COBALT during the study period, you are expected to use your Penn Key credentials. Your PennKey is used to observe your use of COBALT during the trial.

Regardless of your randomization, you will be asked questions about your well-being and emotional state, such as those that ask about depression, anxiety, and suicide ideation. If your answers are above a certain threshold, you will receive an appointment with a psychiatrist or other mental health care professional through the Penn COBALT platform. If you express suicide ideation, you will be contacted by Penn Behavioral Health Corporate Services / EAP for a self-harm risk assessment, a no-cost, confidential, professional service, within 24-48 hours. They will attempt to call the phone number you list in Way to Health at most 3 times during a 3 day period. You may also be contacted by a research team member.

One month after the study concludes, you may receive an email (up to 4) or text message (up to 3) invitation(s) to participate in a debriefing interview (approximately 20-30 minute interview). The purpose of the interview is to learn about your experience in the study. This is completely voluntary and the decision to participate will not affect participation in the COBALT trial. If you are contacted for an interview, you will be asked to read and sign a separate informed consent document at that time.

What are the possible risks or discomforts?
The study has minimal risks. Possible risks include the disclosure of potentially sensitive information like mental health information (i.e., questions on depression, anxiety, suicidal ideation and other well-being measures). Permitting your data to be stored in our research database is the potential risk of loss of confidentiality. There is the risk that you may find some of the questions to be sensitive and/or that some questions may cause emotional discomfort since survey questions ask about depression, anxiety, suicidal ideation and other well-being measures. These may be distressing to you as you think about your experiences. Unintentional disclosure of mental health information may be stigmatizing, embarrassing, or emotionally sensitive.

What if new information becomes available about the study?
During the course of this study, we may find more information that could be important to you. This includes information that, once learned, might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

What are the possible benefits of the study?
Information learned from this study could help our understanding of employee health and well-being benefit programs like COBALT. This can be used to better connect with health care workers, collect regular information about mental health and put people in touch with mental health care and resources. Additionally, through this randomized controlled trial research study you may connect to COBALT resources or services related to your mental health and well-being which may improve those areas of your personal health.

What other choices do I have if I do not participate?
Penn COBALT is available to all employees regardless of their participation. You do not have to participate in the study to use Penn COBALT. Your alternative to being in the study is to not be in the study. Individuals can access COBALT without being enrolled in the study. The use of COBALT outside the study will not affect employment or care received at Penn Medicine.

As a reminder, your employment will not be impacted should you decide not to participate, and your supervisor will have no knowledge of your participation. If your Penn Medicine director, supervisor, or co-worker is an Investigator on this research study (please reference Page 1 of this document or the Appendix), they may review de-identified data, such as gender, race-ethnicity, type of role at the group-level. They will never review or have access to individual-level or potentially identifiable data. Only the Principal Investigator (Merchant) and Co-Investigator (Agarwal) will receive a de-identified notification when a study participant expresses suicide ideation. This notification only includes a randomly generated study ID number. The purpose of this notification is to ensure that these participants are appropriately connected to the Penn Employee Assistance Program.

Will I be paid for being in this study?
You can receive up to $200 upon survey completion ($50 at enrollment, $75 at 6 months and $75 at 9 months). All study compensation will be paid via Greenphire ClinCard. You will receive the same compensation regardless of which group you are randomized to. If you participate in the debriefing interview after this study concludes at the 9-month mark, you will receive a $50 payment added to your ClinCard.

Will I have to pay for anything?
Depending on your use of Penn COBALT for a therapy session, payment options vary by insurance provider. Use of COBALT resources (e.g., group sessions, session with a resilience coach, peer-to-peer support, EAP intake coordinator, therapist, psychologist,

psychiatrist, or psychiatrist Nurse Practitioner, or Emotional or Spiritual Support like a Penn Medicine Chaplain) may be free of charge, covered by insurance, or self-pay.

You may choose to filter for a session appointment based on your specific payment preferences. PennCare PPO and insurance plans through Penn cover most services with Penn providers. Copays and deductibles may apply.

You are still responsible for any deductibles or applicable co-pays for visits through the Penn COBALT website.

Please talk to the study team about putting you in touch with a financial counselor to determine exactly what the deductible and co-pay will be for you; this is highly variable depending on your type of insurance.

If your survey responses are above a certain threshold, you will receive a text message with Penn COBALT provider availability. If you express suicide ideation, your phone number will be shared with Penn Behavioral Health Corporate Services / Employee Assistance Program (EAP) and you will be contacted via telephone by Penn Behavioral Health Corporate Services / EAP for a self-harm risk assessment, an included Penn Medicine supplied, confidential, professional service, within 24-48 hours. Please note, they may contact you up to 3 times to conduct a self-harm risk assessment.

What happens if I am injured from being in the study?
There are no plans for the University of Pennsylvania to pay you or give you other compensation for the injury. If you feel this injury was caused by medical error on the part of the study doctors or others involved in the study, you have the legal right to seek payment, even though you are in a study. You do not give up your legal rights by signing this form.

If you think you have been injured as a result of taking part in this research study, tell the person in charge of the research study as soon as possible. The researcher's name and phone number are listed in the consent form.

When is the Study over? Can I leave the Study before it ends?
This study is expected to end after all participants have completed all visits, and all information has been collected. This study may also be stopped at any time by your physician, the study Sponsor, Data and Safety Monitoring Board, or the IRB without your consent because:

- The Primary Investigator feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.
- You have not followed study instructions.
- The Sponsor or the study Principal Investigator has decided to stop the study.

If you decide to participate, you are free to leave the study at anytime. To decline or stop participation, please email digitalhealth@uphs.upenn.edu or text in 'Bye" to the

Way to Health number. ***Withdrawal will not interfere with your future care or employment.***

How will my personal information be protected during the study?
We will do our best to make sure that the personal information obtained during the course of this research study will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. The Institutional Review Board (IRB) at the University of Pennsylvania will have access to your records.

If your survey responses are above a certain threshold, you will receive a text message with Penn COBALT provider availability. If you express suicide ideation, your name and phone number will be shared with Penn Behavioral Health Corporate Services / EAP and you will be contacted via telephone by Penn Behavioral Health Corporate Services / EAP. for a self-harm risk assessment, an included Penn Medicine, confidential, professional service.

Will information about this study be available to the public?
A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you.

What may happen to my information collected on this study?
All identifiable data will be kept in a secure, password protected database behind a firewall. The sample is assigned a unique random identifier that is separately linked to subject identifiers. Re-identification is possible.

Data from this study will be submitted to the National Institute of Mental Health Data Archive (NDA) at the National Institutes of Health (NIH). NDA is a large database where deidentified study data from many NIH studies are stored and managed. Sharing your deidentified study data helps researchers learn new and important things about brain science more quickly than before. If you have questions about the storage of your information, you can contact the Principal Investigator, Dr. Raina Merchant.

De-identified study data means that all personal information about you (such as name, address, birthdate and phone number) is removed and replaced with a code number. The study researchers will have to collect your personal information from you in order to make that code number. The code number cannot be used to identify you. The study researchers will never send your personal information to NDA. It is possible that you will participate in more than one study that sends data to NDA. NDA can connect your data from different studies by matching the code number on your deidentified data from each study. This data matching helps researchers who use NDA data to count you only one time. It also helps researchers who use NDA to better understand your health and behavior without knowing who you are.

Future Use of Data

Your information will be de-identified. De-identified study data means that all personal information about you (such as name, address, birthdate and phone number) is removed and replaced with a code number. The information could be stored and shared for future research in this de-identified fashion. The information may be shared with other researchers within Penn, or other research institutions, as well as pharmaceutical, device, or biotechnology companies. It would not be possible for future researchers to identify you as we would not share any identifiable information about you with future researchers. This can be done without again seeking your consent in the future, as permitted by law. The future use of your information only applies to the information collected on this study.

There is a risk of breach of confidentiality (unintentional release of your information). We will do our best to make sure that this doesn't happen. However, we cannot guarantee total privacy. We will protect your confidentiality during storage and sharing by keeping all information behind Penn Medicine firewalls.

You will likely not directly benefit from future research with your information. Research with your identifiable information may help others by improving our understanding of health and disease, improving healthcare and making safer or more effective medical therapies, and developing new scientific knowledge.

During and after the study, the study researchers will send de-identified study data about your health and behavior to the NDA. Other researchers across the world can then request your deidentified study data for different research projects. Every researcher (and the institution to which they belong) who requests your deidentified study data must promise to keep your data safe and promise not to try to learn your identity. Experts at the NIH who know how to keep your data safe will review each request carefully to reduce risks to your privacy. Sharing your study data does have some risks, although these risks are rare. Your study data could be accidentally shared with an unauthorized person who may attempt to learn your identity. The study researchers will make every attempt to protect your identity.

You may decide now or later that you do not want your study data to be added to NDA. You can still participate in this research study even if you decide that you do not want your data to be added to NDA. If you know now that you do not want your data in NDA, please email the study researcher. If you decide any time after today that you do not want your data to be added to NDA, email the study staff who conducted this study, and they will tell NDA to stop sharing your study data. Once your data is part of NDA, the study researchers cannot take back the study data that was shared before they were notified that you changed your mind.

If you would like more information about NDA, it is available on-line at http://nda.nih.gov.

If you change your mind, we will permanently delete all records related to your participation.

What information about me may be collected, used or shared with others?
Information about your health/health conditions, mental health, well-being, satisfaction with access to mental health care, employment absence, work productivity, experience using the COBALT platform and services will be collected over the course of 9 months via survey. You will be asked questions about symptoms of depression, anxiety, suicidal ideation, difficulties due to health conditions, and mental health conditions. We will also collect PHI identifiers such as name, mailing address, cell phone number, date of birth, personal medical history, IP address, email addresses (e.g., work and personal), results from survey responses, and usage metrics, such as if appointments are fulfilled or cancelled/skipped from Penn COBALT support services.

If you express suicide ideation, your phone number will be shared with Penn Behavioral Health Corporate Services / EAP and you will be contacted via telephone by Penn Behavioral Health Corporate Services / EAP for a self-harm risk assessment. You may also be contacted by a research team member via telephone. The research team will receive usage metrics such as date, time of phone call and outcome (e.g., contacted or assessed).

Please review Penn COBALT's Privacy Statement https://www.penncobalt.com/privacy. If you do not agree to Penn COBALT's Privacy Statement, do not sign this informed consent.

If you book an appointment at the Penn Psychiatry Time Efficient, Accessible, Multidisciplinary (TEAM) Clinic, the research team will receive data from your PennChart such as if appointments are fulfilled or cancelled/skipped.

All PHI and other data will be not visible to a prospective participant's director, supervisor, or co-worker, who might be an Investigator on this study (please reference Page 1 of this document or the Appendix for a list of Investigators). Only the Principal Investigator (Merchant) and Co-Investigator (Agarwal) will receive a de-identified notification when a study participant expresses suicide ideation. This notification only includes a randomly generated study ID number. The purpose of this notification is to ensure that these participants are appropriately connected to the Penn Employee Assistance Program.

Why is my information being used?
Your information is used by the research team to contact you during the study. Your information and results of tests and procedures are used to:

- do the research
- oversee the research
- to see if the research was done right
- to evaluate and manage research functions.

Where may my information be stored?
Information related to your participation in clinical research will be contained in a clinical trial management system (CTMS). A clinical trial management system (CTMS) is used to register your information as a participant in a study. This allows for your research data to be entered and stored for the purposes of study operational and financial applications and other activities required as part of the conduct of the research. Once placed in the CTMS your information may be accessible to other authorized personnel at Penn Medicine that support research operations. Your information may be held in other research databases.

Who may use and share information about me?
The following individuals may use or share your information for this research study:

- The Investigators and members of the study team may include directors, supervisors, and co-workers
    - Please reference Page 1 of this document or the Appendix.
- Other authorized personnel at Penn Medicine and the University of Pennsylvania, including offices that support research operations
- Other research personnel with access to the databases for research and/or study coordination and as otherwise approved by the IRB

Who, outside of Penn Medicine, might receive my information?
Oversight organizations

- The U. S. Office of Human Research Protections (OHRP)
- The study data and safety monitoring board
- National Institutes of Health (NIH), specifically, the National Institute of Mental Health Data Archive (NDA)
    - NDA is a large database where deidentified study data from many NIH studies are stored and managed.
    - Sharing your deidentified study data helps researchers learn new and important things about brain science more quickly than before.

You may not benefit directly from allowing your study data to be shared with NDA. The study data provided to NDA may help researchers around the world learn more about brain science and how to help others who have problems with brain science.
NIMH will also report to Congress and on its website about the different studies using NDA data. You will not be contacted directly about the study data you contributed to NDA.

Once your personal health information is disclosed to others outside Penn Medicine, it may no longer be covered by federal privacy protection regulations.

The Principal Investigator or study staff will inform you if there are any additions to the list above during your active participation in the trial. Any additions will be subject to Penn Medicine procedures developed to protect your privacy.

How long may Penn Medicine use or disclose my personal health information?
Your authorization for use of your personal health information for this specific study does not expire.

However, Penn Medicine may not re-use or re-disclose information collected in this study for a purpose other than this study unless:

- You have given written authorization
- The University of Pennsylvania's Institutional Review Board grants permission
- As permitted by law

Can I change my mind about giving permission for use of my information?
Yes. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the investigator for the study. If you withdraw your permission, you will not be able to stay in this study.

What if I decide not to give permission to use and give out my health information?
Then you will not be able to be in this research study.

By signing this document, you are permitting Penn Medicine to use and disclose personal health information collected about you for research purposes as described above.

Who can I call with questions, complaints or if I'm concerned about my rights as a research subject?
If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on page one of this form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the IRB at the number on page one of this form.

When you sign this form, you are agreeing to take part in this research study. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer. Your signature also means that you are permitting the University of Pennsylvania to use your personal health information collected about you for research purposes within our institution. You are also allowing the University of Pennsylvania to disclose that personal health information to outside organizations or people involved with the operations of this study.

A copy of this consent form will be given to you.

_____ _____

Name of Subject (Please Print) Signature of Subject Date

_____	_____	
Name of Person Obtaining Consent (Please Print)	Signature	Date

Appendix

Protocol Title:	Evaluate the Effectiveness of a Cobalt+ on Health Care Worker Depression and Anxiety
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Sponsor	National of Institutes of Health (NIH)

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