Institutional Review Board
3600 Civic Center Blvd., 9th Floor
Philadelphia, PA 19104
Phone: 215-573-2540
(Federalwide Assurance # 00004028)

DATE: 17-Apr-2024
TO: Heather J Nuske
CC: Dunphy, Morgan K

RE:
IRB PROTOCOL#: 855282
PROTOCOL TITLE: A Randomized Controlled Trial of a Wellness App for First Responders, Military Personnel and Veterans

SPONSOR: Nlyten Corp
REVIEW BOARD: IRB #8

IRB AMENDMENT: NOTICE OF APPROVAL

Dear Dr. Nuske,

The documents noted below, for the above-referenced protocol, were reviewed by the Institutional Review Board using the expedited procedure set forth in 45 CFR 46.110 and approved on 16-Apr-2024.

Consistent with the regulations set forth in 45 CFR 46.109(f), continuing review of this research is not required. IRB approval of this protocol will not expire and continuing review applications should not be submitted. However, you are still required to submit modifications and reportable events to the IRB for review.

The documents included with the application noted below are approved:
-HSERA Application, confirmation code: eaicdehi, submitted on 4/10/2024
ONGOING REQUIREMENTS:

- You must obtain IRB review and approval under 45 CFR 46 if you make any changes to the protocol, consent form, or any other study documents subject to IRB review requirements. Implementation of any changes cannot occur until IRB approval has been given.
- Reportable event, such as serious adverse events, deviations, potential unanticipated problems, and reports of non-compliance must be reported to the IRB in accordance with Penn IRB SOP RR 404.
- When enrolling subjects at a site covered by the University of Pennsylvania's IRB, a copy of the IRB approved informed consent form with the IRB approved from/to stamp must be used unless a waiver of written documentation of consent has been granted.

COMMITTEE APPROVALS: You are responsible for assuring and maintaining other relevant committee approvals. This human subjects research protocol should not commence until all relevant committee approvals have been obtained.

If your study is funded by an external agency, please retain this letter as documentation of the IRB's determination regarding your proposal.

If you have any questions about the information in this letter, please contact the IRB

administrative staff. A full listing of staff members and contact information can be found on our website: http://www.irb.upenn.edu

***This letter constitutes official University of Pennsylvania IRB correspondence. ***

University of Pennsylvania
Informed Consent Form and HIPAA Authorization Form
The Guide App RCT
A Randomized Controlled Trial of a Wellness App for
First Responders, Military Personnel and Veterans

Protocol Title: The Guide App RCT
Principal Investigator: Heather J. Nuske, PhD, 3535 Market St, 3rd Fl., Philadelphia PA 19104, (215) 746-6041, heather.nuske@pennmedicine.upenn.edu.
Emergency Contact: Heather J. Nuske, PhD, 3535 Market St, 3rd Fl., Philadelphia PA 19104, (215) 746-6041, heather.nuske@pennmedicine.upenn.edu.
Sponsor: The GUIDE App

Research Study Summary for Potential Subjects

You are being invited to participate in a 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 research 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 research study is being conducted to trial the smart phone application, the GUIDE App, with first responders, military personnel and veterans to understand its impact on mental health/wellness, social connectedness (e.g., feeling supported and valued by others), and personal growth (e.g., sense of purpose; pursuit of competence/success). The research team will also investigate workplace metrics, including retention, job satisfaction and burnout; and report on implementation outcomes (e.g., the feasibility of using the app) and technical merit (e.g., how user-friendly the app is).

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

If you agree to join the study, you will be asked to: 1) be ok with being randomized into either using the app straight away ("immediate group"), using the app straight away with incentives ("immediate group with incentives") or using the app after a 4-week delay ("waitlist group"); 2) attend an intake meeting over Zoom that will include an overview of the app before commencing use of it; 3) use the app during your 4-week app access period to support your wellness; 4) attend a post-trial meeting, also on Zoom; 5) complete surveys at intake and at the end of the trial (if randomized to the waitlist group, this will be before using the app), to assess changes in your

wellness and related factors; and 6) complete a survey at the end of your app access period, to document your experience using the app and feedback.

Regardless of whether you are randomized to the immediate group, the immediate group with incentives, or to the waitlist group, your participation in the trial will last for 4 weeks, not including the time it takes to complete the surveys at the beginning and end of the trial, and for the waitlist group, after the app access period.

There are no direct benefits to you for participating in this study. However, this study is expected to improve our understanding of the potential of a digital mental health application to improve the wellness of first responders, military personnel and veterans. We do not anticipate any significant risks of participation. Possible risks of participation are experiencing discomfort in talking about your experiences and emotions during the post-trial interview or in filling out the surveys.

Your alternative to participation is not participating in the study at all. The decision is yours to make and will not affect your relationship with your employer, the University of Pennsylvania, the GUIDE App team, or the research team.

Please note that there are other factors to consider before agreeing to participate such as additional procedures, use of your personal information, and other possible risks not discussed here. If you are interested in participating, you may read on to the full information with you. You are free to decline or stop participation at any time during or after the initial consenting process.

Would you like to continue? [Yes] [No]

Why am I being asked to be a volunteer?

You are being asked to take part in a research study. Your participation is voluntary which means you can choose whether or not to participate. If you decide to participate or not to participate there will be no loss of benefits to which you are otherwise entitled. Before you make a decision, you will need to know the purpose of the study, the possible risks and benefits of being in the study and what you will have to do if you decide to participate. The research team is going to talk with you about the study and give you this consent document to read. You do not have to make a decision now; you can take the consent document home and share it with friends and family.

If you do not understand what you are reading, do not sign it. Please ask the researcher to explain anything you do not understand, including any language contained in this form. If you decide to participate, you will be asked to sign this form and you will be able to download a copy, or it can be emailed or mailed to you. Keep this form, in it you will find contact information and answers to questions about the study.

You may ask to have this form read to you.

_____

What is the purpose of the study?

As mentioned above, the purpose of the research study is to trial the smart phone application, the GUIDE App, to understand it's impact on social connectedness, personal growth, mental health/wellness, as well as on workplace metrics, including retention, job satisfaction and burnout among first responders, military personnel and veterans. The research team will also investigate implementation outcomes (e.g., the feasibility of using the app) and technical merit (e.g., how user-friendly the app is).

What is the GUIDE App?

The GUIDE App is a wellbeing smartphone application designed with first responders and veterans in mind. It delivers small group support, a learning management system, drivers of behavior change, and an anonymous member experience safeguarded by the leader in identity and login privacy, Okta (Privacy Policy).

The app includes three main features: 1) Community, 2) Wisdom, and 3) Daily Practice. The Community feature connects app users with an online community of like folks, allowing for human support, encouragement, accountability and coaching. Online communities are anonymous and moderated by GUIDE employees. The Wisdom feature includes tools and interactive media for personal growth. The Daily Practice feature includes simple, daily routines to maintain mental and emotional wellness.

Why was I asked to participate in this study?

You are being asked to join this study because you are either a first responder, military personnel or a veteran.

How long will I be in the study? How many other people will be in the study?

We will recruit up to ~110 participants in total. The teams will be randomized into one of three groups:

- Group 1 will use the app immediately for 4 consecutive weeks,
- Group 2 will use the app immediately for 4 consecutive weeks with incentives, and
- Group 3 will be placed on the waitlist to use the app following the first group's completion of their trial (i.e., after 4 weeks)

Therefore, each individual participant will participate in the testing of the app for 4 consecutive weeks and people in the Group 3 will commence this after a 4-week waiting period.

Where will the study take place?

The research will take place virtually through use of the app, online surveys and via video conference meetings.

What will I be asked to do?

To participate in this study, you must complete the consent process. The consent process requires you to review and virtually sign this consent form. If you decide to participate, we will ask you to:

1) Be ok with being randomized into either using the app straight away ("immediate group"), using the app straight away with incentives ("immediate group with incentives"), or using the app after a 4-week delay ("waitlist group").

2) Complete demographic and baseline assessment surveys on REDCap to assess for mental health, wellness and related factors.

3) Attend an intake meeting held virtually that will include an overview of the app before commencing use of it. During this meeting, participants will be individually briefed on the GUIDE App, and will have the opportunity to ask any questions they have about the research study. Baseline surveys will be completed prior to/at this meeting.

4) Use the app during your app access period of 4 weeks to support your wellness.

5) Complete a post-trial survey after 4 weeks to assess changes in your wellness, mental health and related factors; as well as to document your experience using the app and feedback.

6) Attend a post-trial meeting held virtually that will provide an opportunity to give feedback on study participation. Post-trial surveys will be completed prior to/at this meeting.

What are the risks of participating in the study?

In previous pilot work on the GUIDE App, no one has ever reported any negative experiences as a consequence of using the app.

Through participating in the research, you may experience discomfort in talking about your experiences and emotions. If you experience discomfort, you may contact the Principal Investigator or the emergency contact name on the first page of this form throughout the duration of this study. For immediate access to mental health resources while using the GUIDE App, you can click the SOS button, which will direct you to crisis hotlines designed specifically for first responders and veterans. If you disclose suicidal ideations while using the GUIDE App, the research team will be notified by GUIDE moderators within 24 hours. Dr. Heather Nuske, a psychologist, will contact you within 12 hours by phone and/or email to ensure that you are connected to the appropriate resources.

Please note that participation is completely voluntary, and that commanding officers, managers, and/or supervisors will not know who enrolls in the study and will not have access to any study-related information.

How will I benefit from the study?

There are no direct benefits to you for participating in this study. However, this study is expected to improve our understanding of the potential of a digital mental health application to improve the wellness of first responders, military personnel and veterans.

What other choices do I have?

Your alternative to participation is not participating in the study at all. The decision is yours to make and will not affect your relationship with your employer, the University of Pennsylvania, the GUIDE App team, or the research team.

What happens if I choose not to join the research study?

You may choose to join the study, or you may choose not to join the study. If after beginning the study, you decide not to continue your participation, you may choose to stop participating at any time. Your participation is voluntary.

Your decision on whether or not to participate in this research will not affect your relationship with your employer, the University of Pennsylvania, the GUIDE App team, or the research team. You can end your participation at any time.

When is the study over? Can I leave the study before it ends?

The study is expected to end in 2025, though your participation will end after your app access period and completing all measures and virtual meetings with the research team. The study may be stopped without your consent for the following reasons:

- The Principal Investigator feels it is best for your safety or the safety of the student. You will be informed of the reasons why.
- The Principal Investigator, the sponsor, or the Office of Regulatory Affairs at the University of Pennsylvania can stop the study anytime.

You may drop out of the study at any time. Study participants will only receive compensation for study procedures they complete. Other than ceasing to receive financial incentives for participation, there is no penalty or loss of benefits to which you are otherwise entitled if you decide to do so. Withdrawal will have no bearing on your relationship with your employer, the University of Pennsylvania, the GUIDE App team, or the research team. You can end your participation at any time.

There is no set time for destroying the information that will be collected for this study. Your permission to use and share the information and data from this study will continue until the research study ends and will not expire. Researchers continue to analyze data for many years, and it is not possible to know when they will be completely finished. Saved data will not identify participants and will be labeled with a unique numerical code.

If you no longer wish to be in the research study, please contact the Principal Investigator, Heather Nuske, PhD, at (215) 746-6041. You can withdraw from the study by verbally stating that you do not wish to participate in the Guide App RCT. Clearly state your name and address and a written verification of your removal from the study will be sent to you within 30 calendar days. Alternatively, if you would prefer to provide written notification of withdrawal you may send this information to:

Dr. Heather Nuske
Penn Center for Mental Health
Department of Psychiatry
Perelman School of Medicine
3535 Market Street, Floor 3
Philadelphia
PA 19104

Return written verification of your removal from the study will be sent to you within 30 calendar days.

How will my personal information be protected during the study?

All information you provide will be kept confidential, except as required by law. Confidentiality will have to be broken if you express a current plan to harm yourself or others, or if you report that you have committed child abuse or neglect. Therefore, we will do our best to make sure that the personal information obtained during this research study will be kept private. The Institutional Review Board (IRB) at the University of Pennsylvania is responsible for protecting the rights and welfare of research volunteers like you. The IRB has access to study information. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. Confidentiality will be maintained through deidentifying any personal information obtained during the study, and only allowing access to such information to the research team. HIPAA guidelines will be followed for storage of research data (see more detail below).

What may happen to any identifiable information collected in this study?

As part of the study, you will complete demographic surveys and surveys relating to your social connectedness, personal growth, mental health/wellness, as well as on workplace metrics, including retention, job satisfaction and burnout.

The only identifiable information entered in the GUIDE App by participants will be your email or phone number, in order to set up your account. All other information you provide including information provided in the GUIDE App will be de-identified by the research team. De-identified means that all identifiers have been removed. The information could be stored and shared for future research in this de-identified fashion. The information may be shared with other researchers within the University of Pennsylvania, 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.

Will I receive the results of research testing that may be relevant to my health?

As part of the survey measures completed you will complete two short screening measures, one for anxiety and one for depression. If you would like to know whether you report symptoms that meet the clinical threshold, please let the research team know during your Intake meeting.

The GUIDE App includes a feature that gives participants the option to complete assessments that screen for PTSD (PC-PTSD-5), insomnia (ICD-10), anxiety (GAD-7), and alcoholism (AUDIT) in their Courses. There is no requirement to fill out any of these measures in the app as part of the study. Before the assessment is administered, participants must watch a 2-minute video about the selected measure and its effectiveness, why it is used and by whom, and how it is a screener (i.e., not a diagnostic tool) that should be used to determine whether further testing or treatment should be solicited. Scores from these measures are not tabulated or collected by GUIDE. When participants finish filling out the assessment, they are brought to a screen that shows them how to score their own responses.

What happens if I am injured from being in the study?

If you are injured or feel emotional discomfort while participating in the study, you may contact the Principal Investigator or the emergency contact name on the first page of this form. They can go over things with you, let you know of resources that may be available and give you information on what you need to do. In case of injury resulting from this study, you will not lose any legal rights by signing this form. Also, you may contact your own doctor, counselor or seek treatment outside of the University of Pennsylvania. Bring this document and tell your doctor/counselor or his/her staff that you are in a research study being conducted at the University of Pennsylvania. Ask them to call the numbers on the first page of this form for information.

If you are injured or feel emotional discomfort from being in the study, the appropriate care will be provided without cost to you through the University of Pennsylvania, but financial compensation is not otherwise available from the University of Pennsylvania. If you are injured or feel emotional discomfort while in the study but it is not related to the study, you and your insurance company will be responsible for the costs of that care.

Will I have to pay for anything?

There are no costs associated with participating in this study, beyond your time to complete the consent process, app-testing, meetings, and surveys.

Will I be compensated for participating in the study?

You will be compensated a total of $100 for participating in all study activities, $50 at each measurement timepoint (before and after the trial period). Participants assigned to the immediate group with incentives will have the opportunity to earn additional compensation.

The following section relates to your personal health information collected as part of the study

What personal health information about me may be collected, used, or shared with others?

When creating a new GUIDE account within the mobile app, we will ask for your phone number or your email address. As part of your participation in the study through online surveys or in meetings we will ask your name, address, telephone number, date of birth, Social Security number (for compensation purposes), and personal and medical history (the latter as it relates to your responses on mental health and wellness surveys we administer as part of the study only).

Why is my personal health 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:

- use the app
- 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 HIPAA-compliant software used at the Penn Medicine, REDCap and a clinical trial management system (CTMS). REDCap and CTMS are used to register your information as a participant in a study and track your completion of tasks within the study (e.g., completion of surveys). 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 REDCap and/or CTMS your information may be accessible to other authorized personnel at Penn Medicine that support research operations. Your information will be stored in other HIPAA-compliant databases and servers. Data entered into the GUIDE App for account creation (phone number or email address) will be stored in Auth0 by Okta (a third-party authentication provider) and all other user activity in the app, such as taking courses and lessons, will be stored in a database hosted in Amazon Web Services. All user data is encrypted in transit (via HTTPS SSL TLS v1.2 ECDHE-RSA-AES128-GCM-SHA256) and at rest (via AES-256).

Who may use and share health information about me?

- The Principal Investigator of the study, Dr. Nuske, and the research team
- Members of the GUIDE App team
- 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 personal health information?

- Those working under the direction of the Principal Investigator for the study, Dr. Nuske, including the app development team
- The funding sponsor, the GUIDE App

Oversight organizations

- The U. S. Office of Human Research Protections (OHRP)

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 as described above. 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 personal health information?

Then you will not be able to be in this research study.

You will be given a copy of this Informed Consent Form and HIPAA Authorization Form describing your confidentiality and privacy rights for this 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 participant?

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 participant, 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 Office of Regulatory Affairs with any questions, concerns, or complaints at the University of Pennsylvania by calling (215) 898-2614.

When you sign this form, you are agreeing to take part in this research study. If you have any questions or there is something you do not understand, please ask. You will receive a copy of this consent document.

By signing this form, you are indicating that you have had your questions answered and you agree to take part in this research study. You are also agreeing to let the University of Pennsylvania use and share your health information, as explained above. If you don't agree to the data collection, use and sharing of your health information, you child cannot participate in this study.

Please sign below if you agree to participate in the study:

First name: _____

Last name: _____

Date: _____ / _____ / _____

Signature: _____

☐ I am interested in being contacted about other studies at the University of Pennsylvania

[Administered via REDCap]