Testing a Wellness App for First Responders, Military Personnel and Veterans

NCT06336967
Date: 4/11/2024

Protocol Details

Basic Info

Confirmation Number:	**eaicdefj**
Protocol Number:	**855282**
Created By:	**DUNPHY, MORGAN K**
Principal Investigator:	**NUSKE, HEATHER J**
Protocol Title:	**A Randomized Controlled Trial of a Wellness App for First Responders, Military Personnel and Veterans**
Short Title:	**The GUIDE App RCT**
Protocol Description:	**The purpose of the research study is to trial a smart phone application, the GUIDE App, to better understand its impact on social connectedness, personal growth and mental health/wellness among first responders, soldiers, and veterans. The research team will also investigate workplace metrics (e.g., engagement and burnout), implementation outcomes and technical merit. We plan to run a three-armed randomized waitlist pilot feasibility trial with up to 150 participants.**
Submission Type:	**Social and Biological Sciences**
Application Type:	**FULL**

Resubmission*
Yes

Hospital Sites
Will any research activities and/or services be conducted at a Penn Medicine affiliated hospital site?
No

Study Personnel

Principal Investigator

Name:	**NUSKE, HEATHER J**
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HS Training Completed:	**Yes**
Training Expiration Date:	
Name of course completed :	**CITI Protection of Human Subjects Research Training - ORA**
GCP Training Completed:	**No**
Training Expiration Date:	
Name of course completed :	

Study Contacts

Name:	**DUNPHY, MORGAN K**
Dept / School / Div:	**4423 - PS-Mental Health Services**
Campus Address Mail Code	
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HS Training Completed:	**Yes**
Training Expiration Date:	
Name of course completed :	**CITI Protection of Human Subjects Research Training - ORA**
GCP Training Completed:	**No**
Training Expiration Date:	
Name of course completed :	

Other Investigator

None

Responsible Org (Department/School/Division):

4412 - PS-Psychiatry

Key Study Personnel

Name:	**KAMEL, RIMA A**
Department/School/Division:	**PS-Mental Health Services**
HS Training Completed:	**Yes**
Training Expiration Date:	
Name of course completed:	**CITI Protection of Human Subjects Research Training - ORA**
GCP Training Completed:	**No**
Training Expiration Date:	
Name of course completed:	

Penn Intellectual Property*

To the best of the Principal Investigator's knowledge, does this protocol involve the testing, development or evaluation of a drug, device, product, or other type of intellectual property (IP) that is owned by or assigned to the University of Pennsylvania? Please refer to the Patent and Tangible Research Property Policies and Procedures.

No

Certification

I have reviewed the *Financial Disclosure and Presumptively Prohibited Conflicts for Faculty Participating in Clinical Trials* and the *Financial Disclosure Policy for Research and Sponsored Projects* with all persons who are responsible for the design, conduct, or reporting of this research; and all required Disclosures have been attached to this application.

Yes

Social and Biological Sciences

Study Instruments

Discuss the particulars of the research instruments, questionnaires and other evaluation instruments in detail. Provide validation documentation and or procedures to be used to validate instruments. For well know and generally accepted test instruments the detail here can be brief. More detail may be required for a novel or new instrument. For ethnographic studies identify any study instruments to be used (i.e. for deception studies) and describe in detail where, when and how the study will be conducted and who or what are the subjects of study. Note: For more information on how to conduct ethical and valid ethnographic research, follow the link For oral histories or interviews provide the general framework for questioning and means of data collection. If interviews or groups settings are to be audio taped or video taped describe in detail the conditions under which it will take place. Include a copy of any novel or new test instruments with the IRB submission.

The purpose of this study is to measure how the GUIDE App impacts social connectedness, personal growth, mental health/wellness, workplace engagement and burnout, among first responders, soldiers, and veterans. Participants assigned to the immediate and immediate with incentives groups will use the GUIDE App for their 4-week trial period. Participants in the waitlist group will be offered access at the end of the trial. The GUIDE App is a wellbeing app designed with first responders and veterans in mind. Because there is a stigma associated with seeking help and getting connected with resources, the GUIDE mobile app uses small group support, a learning management system, drivers of behavior change, and an anonymous member experience safeguarded by a leader in identity and login privacy, Okta (okta.com). It 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 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. While using the app, participants will be given the opportunity to complete assessments that screen for depression (PHQ-9), PTSD (PC-PTSD-5), insomnia (ICD-10), anxiety (GAD-7), alcoholism (AUDIT), and suicide (ASQ) in their Courses. 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. The SOS button on the app is highlighted for the first several seconds to remind them that there are resources available. The following crises numbers are built into the SOS button: Suicide and Crisis Lifeline, Veteran Crisis Line, Substance Abuse and Mental Health Services Administration, Disaster Distress Hotline, Red Nacional de Prevencion del Suicido, COPLINE, Firefights Union for PTSD & Mental Health, Frontline Helpline, Fire/EMS Helpline, Safe Call Now, and the All Clear Foundation. The research team will use baseline and post-trial assessments, administered via REDCap survey, to measure how app access impacts the primary and secondary proximal outcomes, as well as secondary distal outcomes, as proposed by our Theory of Change Model (attached), e.g., that by engaging with the GUIDE App, first responders/soldiers/veterans who commonly feel isolated, seek opportunities for personal growth, and have mental health challenges will build resilience using the Community, Wisdom, and Daily Practice features, influencing the primary proximal outcome of mental health/wellness, as well as the secondary proximal outcomes of social connectedness and personal growth. We propose that these proximal outcomes will then positively influence the secondary distal outcomes, including worker engagement and burnout. To measure App Engagement, we will use app metrics collected by GUIDE, including lessons completed, courses completed, small group posts, small group comments, journal entries, wellness check-ins, and usage streaks. To measure Mental Health/Wellbeing, we rely on a number of well-known and robust instruments including: the Patient Heath Questionnaire for depression symptoms (PHQ-8); the Generalized Anxiety Disorder-7 (GAD-7), the 5-Item World Health Organization Well-Being Index (WHO-5), the Difficulties in Emotion Regulation Scale Short Form (DERS-SF), the overall score and Positive Emotion sub-scale from the PERMA-Profiler, and the Personal Wellbeing Score (PWS). To measure Social Connectedness, we will use the Engagement and Relationships sub-scales from the PERMA-profiler. We will also use metrics collected by GUIDE, including the number of comments and

posts the participant creates in the app (1st vs. last week). To measure Personal Growth, we will use the Meaning and Accomplishment sub-scales from the PERMA-Profiler. We will also use metrics collected by GUIDE, including the number of lessons/courses completed. To measure Workplace Engagement, we will use Utrecht Work Engagement Scale (UWES) and the Maslach Burnout Inventory (MBI), both highly reliable and well-established measures in use for decades. In addition to the above measures, we will also be asking participants to answer questions about the app in the post-trial assessment survey. To measure Implementation and Technical Merit of the app, we will use the Feasibility of Intervention Measure (FIM), the Acceptability of Intervention Measure (AIM), the Intervention Appropriateness Measure (IAM) and the System Usability Scale (SUS). During the post-trial meeting, we will review a brief Adverse Event Checklist with participants. This checklist contains four questions and is attached to this application.

Group Modifications

Describe necessary changes that will or have been made to the study instruments for different groups.

For the "immediate" and "immediate with incentives" groups, the post-trial assessment will include measures about the Implementation and Technical Merit of the app (FIM, AIM, IAM, SUS listed above). These items will not appear on the "waitlist" group survey because those participants will not have used the app. Those who served in the armed forces will be asked to answer additional demographic questions (attached) related to their time in service.

Method for Assigning Subjects to Groups

Describe how subjects will be randomized to groups.

The research team will use block randomization to assign participants into one of three groups. Randomization will occur after a participant submits their Informed Consent through REDCap. Their name will be added to a blocked randomization spreadsheet, and they will be assigned to one of the three treatment groups.

Administration of Surveys and/or Process

Describe the approximate time and frequency for administering surveys and/or evaluations. For surveys, questionnaires and evaluations presented to groups and in settings such as high schools, focus group sessions or community treatment centers explain how the process will be administered and who will oversee the process. For instance, discuss the potential issues of having teachers and other school personnel administer instruments to minors who are students especially if the content is sensitive in nature. Describe the procedure for audio and videotaping individual interviews and/or focus groups and the storage of the tapes. For instance, if audio tape recording is to be used in a classroom setting, describe how this will be managed if individuals in the class are not participating in the study. Explain if the research involves the review of records (including public databases or registries) with identifiable private information. If so, describe the type of information gathered from the records and if identifiers will be collected and retained with the data after it is retrieved. Describe the kinds of identifiers to be obtained, (i.e. names, social security numbers) and how long the identifiers will be retained and justification for use.

First responders, soldiers and veterans will be invited to take a brief screener survey on REDCap to determine whether they are eligible to participate in the trial. If they meet our inclusion criteria, they will be prompted with an Informed Consent. The Informed Consent, like the screener, will be administered through REDCap. After giving consent, participants will fill out a baseline survey on REDCap. The baseline assessment will contain between 123 - 135 questions, depending on whether the participant served in the military and was deployed, and will take participants approximately 20-30 minutes to complete. Participant demographics will be collected during this assessment and stored in REDCap. Data will be de-identified for the purposes of later analysis. No identifiers will be stored after the study is completed. Participants will receive $50 in compensation for completing this survey, remitted through a Greenphire ClinCard®. Consented participants will receive an email additional from the research team asking them to schedule a virtual Intake meeting. They will be furnished with a link to a calendar management software, such as Microsoft Bookings to select a date and time that works best with their schedule. Intake meetings will be held one-on-one over Zoom and conducted by the Clinical Research Coordinator. They will be brief, about 20-30 minutes, and will not be recorded. Participants will be briefed on the GUIDE App and will have the opportunity to ask any questions they have about the trial. The baseline assessment should be completed prior to this intake meeting, but if it is not, participants will be given time to do so. Those in the immediate and immediate with incentives groups will also be walked through account creation and general app training. A standardized training protocol will be used so that the app is introduced to participants in a uniform and accurate manner.

During GUIDE account creation, participants will be required to provide their phone number and/or email address. This personal data will be secured by Okta, a third-party authentication provider, and stored separately from app data. Screenshots of this process can be found in the GUIDE Account Creation document attached to this application. When the meeting is over, all participants will receive an email from the research team with a link to a calendar management software, such as Microsoft Bookings, requesting that they schedule their post-trial meeting for 4-5 weeks out from the intake meeting. During the trial period of 4 weeks, participants in the immediate and immediate with incentives groups will have full access to the GUIDE App. To get started, the app will prompt participants to answer a series of onboarding questions about themselves, including their goals, wellness experience and demographic information (see attached GUIDE Onboarding Process). Based on their responses, participants will be assigned Courses and Daily Practices; as well as a personalized small group chat, where they can post and comment with likeminded others, anonymously, with the option to share app progress. Courses are composed of lessons, and include topics like Forgiveness, Gratitude, and Self-Awareness. The lessons contain a mix of media including videos, assessments, readings and exercises. Courses and lessons take varying amounts of time to complete, which the participant can see before adding it to their profile. The app also includes three types of Daily Practices including Meditation Practice (a simple timer to help keep participants focused while they meditate), Journal Practice (where participants can catalog their thoughts and reactions to lessons), and a Mood Tracker that participants can view over time (How are you feeling? 1 = Very Sad to 5 = Very Happy). On the home page, participants are invited to track their Wellness Score, based on the Personal Wellbeing Score (PWS), over time to see trends. Screenshots of GUIDE app content, and information about how it works, can be found in the GUIDE App Content document attached. The GUIDE App invites participants to complete assessments that screen for PTSD (PC-PTSD-5), insomnia (ICD-10), anxiety (GAD-7), and alcoholism (AUDIT) in their Courses. 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. For people needing a higher level of care, the following crises numbers are provided in the app: Suicide and Crisis Lifeline, Veteran Crisis Line, Substance Abuse and Mental Health Services Administration, Disaster Distress Hotline, Red Nacional de Prevencion del Suicido, COPLINE, Firefights Union for PTSD & Mental Health, Frontline Helpline, Fire/EMS Helpline, Safe Call Now, and the All Clear Foundation. Participants assigned to the immediate with incentives group will be asked to complete certain weekly tasks in the app order to receive an Amazon gift card for their participation. Required tasks include visiting the GUIDE App at least four times, completing at least one lesson, posting at least one time, commenting at least one time, and completing at least one wellness check-in. When the four-week trial period is over, participants will receive an email from REDCap with a link to their post-trial assessment survey. The survey for participants in the waitlist will contain 100 questions and take about 20 minutes to complete. The survey for participants in the immediate and immediate with incentives groups will contain 123 questions, including questions about app implementation and technical merit, and will take approximately 20-30 minutes to complete. Participants who have not yet scheduled their post-trial meeting will receive an additional email reminder from the research team, along with a link to a calendar management software, such as Microsoft Bookings. During the post-trial Zoom meeting, participants who have not yet completed their post-trial assessment will be given time to do so. They will get the opportunity to give feedback about the GUIDE App and the trial. The meeting will be brief, about 15 minutes, and will not be recorded. Participants will receive $50 in compensation for completing this survey, remitted through a Greenphire ClinCard®. The research team will also review a brief Adverse Event Checklist with these participants and record their responses. This checklist contains four questions and is attached to this application. Participants in the immediate and immediate with incentives groups will be told they may delete their account associated with GUIDE and remove the app from their phones. Participants in the waitlist group will get the opportunity access to the GUIDE App at this meeting if they are interested.

Data Management

Describe how and who manages confidential data, including how and where it will be stored and analyzed. For instance, describe if paper or electronic report forms will be used, how corrections to the report form will be made, how data will be entered into any database, and the person(s) responsible for creating and maintaining the research database. Describe the use of pseudonyms, code numbers and how listing of such identifiers will be kept separate from the research data.

To ensure the privacy and confidentiality of data for this project we will only store and use the identifiable data at the following locations: 1) Password-protected PCs in locked offices at the University of Pennsylvania. The desktop computer(s) that will access the data will be part of the Center for Mental Health (CMH) domain, with Windows Active Directory group policies in place to distribute and enforce best-practice desktop security policies. Security and software updates are pushed to the system in a timely manner using desktop management tools (Tivoli/BigFix and Windows Automated Update Service). The data on the desktop computer(s) can be encrypted with Bitlocker, PGP Whole Disk Encryption with PGP Virtual Disk which will provide an added layer of data security, or FileVault; 2) On Penn Box, a HIPAA-compliant server used for project file sharing in the context of the teams remote work on the project; and 3) A server at the University of Pennsylvania within the facilities managed room in the data center. A Senior LAN Consultant will upload the data onto the secure production servers (environment and security practices described above). Physical media that are received from the distributer or any physical copies of the data will be encrypted while at rest and will be held in a locked cabinet within the CMH office. Additionally, all PHI data hosted on the server will be accessed over an encrypted VPN connection. Individually identifiable or deducible data will not be transmitted by unsecured telecommunications, which include the Internet, email, and electronic File Transfer Protocol (FTP). Further, the data will not be physically moved or transmitted in any way from the CMH servers or secured desktop(s) without written approval. Physical Security Servers are hosted in dedicated virtual machines running on Dell SAN hardware in the In-formation Systems and Computing facilities managed computer room. The hosting environment SAN and Host Bus Adapters are in a locked Dell rack housed in the Computer Room with restricted door card access to authorized personnel only. There is 24-hours camera surveillance. Business Continuity Server environments get redundant power from independent power feeds. In addition, each of the power sources is UPS protected. There is a Halon fire suppression system, with alarm points below the raised floor and in the ceiling. The virtual machines are hosted in VMWare ESX environments connected to a Dell SAN for shared storage. All virtual machines are stored on the SAN. To minimize downtime caused by hardware failure, the environment is configured for redundancy with multiple ESX hosts, multiple Host Bus Adapters, multiple SAN Switch ports, multiple storage processors, and RAID 5 storage. The server environments are replicated to a secondary site at 3650 Chestnut Street, which has equivalent physical security and also employs all of the security best practices outlined below. The servers are administered by a team of four full-time professional IT staff. The team has over 50 years of combined experience configuring and supporting Windows servers, and all of the staff attend technical training regularly to stay current in best practices for configuring and securing Windows and VMWare environments. Server Security Best Practices In keeping with SANS and Microsoft best practices, all software services and corresponding ports on the servers that are known to be substantial security risks and which are not used by CMH resources are disabled including telnet, and ftp. Security patches are applied promptly and there are standard processes in place for preventive maintenance and monitoring of the servers. Hardware Firewalls - All servers reside behind a cluster of Juniper SSG520 firewalls. A Juniper SSG520 appliance configured in high availability mode acts as a secure gateway between PennNet/Internet (Untrusted Zone) and server resources behind the firewall. A custom firewall policy is developed for each resource hosted on each of the virtual machines. All policies are developed based on service port and PennNet-only IP addresses. VLAN - A Foundry Switch in the TSS managed rack is configured for 4 VLANs to support traffic segmentation behind the SSG520. LTS has access to each VLAN, giving us the ability to place each virtual machine in the appropriate VLAN for another layer of security. SSL Encryption for Web Services - When hosting web servers we only support the use of HTTPS with an SSL certificate to minimize vulnerabilities and exploits common on the standard HTTP port. All port 80 traffic is re- directed to port 443. SSL VPN An SSL VPN supports encryption of traffic between servers and client desktops and laptops. Password Policy - A complex password policy, meeting Microsoft complex password requirements, is in effective in the CMH domain. The password policy requires all CMH domain users to change their domain password every 180 days. 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). Additional details about data security can be found in the GUIDE Privacy Policy and GUIDE Terms & Conditions attached to this application. Point members of the research team (henceforth Research Specialists) will be responsible for data entry and database management. The Principal Investigator and Research Specialists will ensure that all study personnel are familiar with standardized data entry practices. The Research Specialists will also complete random audits of study files to ensure forms are completed in their entirety and stored in IRB- approved methods. Access to any PHI data will be limited to CMH

staff and authorized Research Assistants as well as to the small team of full-time professional IT staff that support the CMH servers and desktops. In order to be added to the protocol and receive PHI access, CMH staff will demonstrate completion of HIPAA training and will abide by the security procedures enforced within the Windows Active Director domain. At the conclusion of this study, a CMS Certification of Destruction certifying the proper destruction of all data obtained will be completed if destruction is warranted. Lastly, all output containing individual identifiable information is treated as confidential data. This information is never transferred electronically via email or other protocols. Shredders are used on any printed material containing individual identifiers. The PI, Heather Nuske who holds a PhD in Psychology will oversee all phases of the project and supervision of any staff on the research team.

Radiation Exposure*
Are research subjects receiving any radiation exposure solely because they are enrolled in this protocol? (e.g. X-rays, CT, Fluoroscopy, DEXA, pQCT, FDG, Tc-99m, etc.)?IF YES, the protocol must be approved by the RRSC (Radiation Research Safety Committee). Consult EHRS web site: www.ehrs.upenn.edu/protocols/radiohuman.html for more information.If you have questions, email jjesik@ehrs.upenn.edu or kavyap@upenn.eduIf your protocol includes Nuclear Medicine Procedures, the protocol must be reviewed by the Nuclear Med Operations Committee: https://redcap.link/NMOPS
No

Human Source Material*
Does this research include collection or use of human source material (i.e., human blood, blood products, tissues or body fluids)? IF YES, consult the EHRS web site: www.ehrs.upenn.edu/programs/bio/bbpathogens.html for information on OSHA Bloodborne Pathogens requirements (training, vaccination, work practices and Exposure Control Plan). If you have questions, call 215-898-4453.
No

Image Guided Biopsies*
Does the research involve imaging guided biopsy? IF YES, please contact the Clinical Imaging Core. See https://www.med.upenn.edu/cbi for more details. Any questions should be directed to the Director of Research Operations, Dept of Radiology, Kathleen Thomas.
No

Computerized Tomography (CT) Studies*
Does the protocol involve CT scans that are not considered standard of care and are being performed for research purposes?IF YES, complete the CACTIS Committee Application: https://is.gd/CACTIS and consult CACTIS website: http://www.uphs.upenn.edu/radiology/research/labs/cactis/ for application requirements.
No

CAMRIS and MRI Studies*
Is an MRI scan being performed for research only and NOT considered standard of care (example: specific scanner, parameters or solely for the purposes of research)?NOTE: Research/non-standard use of MRI may include but is not limited to any of the following: Situations in which MRI results may impact subjects current clinical care plan or treatment decisions, such as:The study requires a customized report with specifics regarding the study protocol (i.e., specific measurements or details); Introduction of a device of any kind during the MRI that is not used during a 'standard of care' type scan.Your MRI is not consistent with standard care time points for MRI imaging.Your MRI is not paid for by insurance.IF YES, consult CAMRIS website: https://www.med.upenn.edu/camris/application-and-faq.html for application requirements and required institutional consent form language.
No

Cancer Related research not being conducted by an NCI cooperative group*
Does this protocol involve cancer-related studies in any of the following categories? Therapeutic, Prevention, Supportive Care, Screening, Early Detection, or Diagnostic, Epidemiologic, Observational, Outcome, Ancillary or Correlative. For a description of these categories, see http://www.ctsrmc.org/submitting_a_protocol.php NCI Cooperative Groups are as follows:Alliance for Clinical Trials in OncologyNCI Clinical Trials Group (Canadian Cancer Society) (NCCTG)Children's Oncology Group (COG)NRG Oncology GroupECOG-ACRIN Cancer Research GroupSouthwest Oncology Group (SWOG) IF YES, the protocol must be submitted to the Cancer Center's Clinical Trials Scientific Review Committee for scientific review and approval prior to obtaining IRB approval. Consult the

CTSRMC website: www.ctsrmc.org for application requirements
No

HIPAA / Protected Health Information
Does the research proposal involve accessing (viewing / using), collecting, or disclosing of protected health information (PHI) directly from participants or their medical or dental record for research purposes?
Yes

CHPS Resources*
Does the research involve CHPS resources?
No

HUP Inpatient Nursing Resources
Does this research include an inpatient admission at HUP?
No

If the answer is YES, indicate which items is is provided with this submission:

Modified research informed consent document that incorporates HIPAA requirements

Use of UPHS services*
Does your study require the use of University of Pennsylvania Health System (UPHS) services, tests or procedures , whether considered routine care or strictly for research purposes? (UPHS includes all Penn hospitals and clinical practices, including the Clinical Care Associates network of community practices). Examples of UPHS services/tests/procedures includes the Clinical Translational Research Center (CTRC), laboratory tests, use of the pathology lab, cardiovascular imaging tests or radiology imaging tests (whether being billed via the Service Center or through UPHS), other diagnostic tests & procedures and associated professional services, etc.
No

Veteran's Affairs (VA) Patients or Subjects
Does your study involve data from Veteran's Affairs (VA) patients or subjects?
No

If yes, was this approved by the Philadelphia VA?

No

Out of State Research
Will any Penn personnel conduct any research activities outside of the State of Pennsylvania?
No

Research involving Virtua Health
Will any Penn personnel conduct any research activities at a Virtua Health site location, OR in collaboration with Virtua Health System personnel, OR using any Virtua Health System resources (e.g., medical records)?
No

Primary Focus*
Sociobehavioral (i.e. observational or interventional)

Protocol Interventions

x	**Sociobehavioral (i.e. cognitive or behavioral therapy)**
	Drug
x	**Device - therapeutic**
	Device - diagnostic (assessing a device for sensitivity or specificity in disease diagnosis)
	Surgical
	Diagnostic test/procedure (research-related diagnostic test or procedure)
	Obtaining human tissue for basic research or biospecimen bank
x	**Survey instrument**
	None of the above

The following documents are currently attached to this item:

There are no documents attached for this item.

Sponsors

Business Administrator

Name:	**ENGLISH, LATONA**
Dept / School / Div:	**4423 - PS-Mental Health Services**
Phone:	**215-573-7063**
Fax:	**215-349-8715**
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Email:	**latona.english@pennmedicine.upenn.edu**

Department budget code

400 - 400 - 4 - 589297 - 3000 - 2810 - 4657

Funding Sponsors

Name:	**NLYTEN CORP**
Type:	**UPENN Commercial/Industrial**

Funding sponsors billing address
If you have selected a commercial or industry sponsor, please provide the appropriate address and contact information for the Sponsor for the purposes of billing for IRB review fees (initial review, continuing review and convened modification fees apply here). If the Sponsor is not industry/ commercial, this information is not necessary to provide with your application.
Patrick Sandone psandone@theguideapp.com Nlyten Corp ATTN: Patrick Sandone 201 Lackawanna Ave, Scranton, PA 18503

Funding sponsors gift
Is this research being funded by a philanthropic gift?
No

Regulatory Sponsor

IND/IDE Sponsor

none

400 - 400 - 4 - 589297 - 3000 - 2810 - 4657

Industry Sponsor

None

Project Funding*
Is this project funded by or associated with a grant or contract?
Yes

Selected Proposals

Proposal No	Title
10096293	**The Guide App RCT**

Sponsor Funding
Is this study funded by an industry sponsor?
Yes

Status of contract

Complete

The following documents are currently attached to this item:

Grant Application (contract_docusign_upenn-nlyten_investig.pdf)

Multi-Center Research

Penn as lead
1. Is this a multi-center study where Penn is serving as the Lead Site or the Penn PI is serving as the Lead Investigator?
No

Management of Information for Multi-Center Research

Penn irb of record
2. Is this a multi-center study where the Penn IRB will be asked to serve as the IRB of Record for other external study sites?
No

Other Sites

No other sites

Protocol

Abstract
The purpose of the research study is to trial the smart phone application, the GUIDE App, to understand its impact on mental health/wellness, social connectedness and personal growth, as well as on workplace metrics including retention, work engagement and burnout, among first responders, soldiers

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). To test the effectiveness of GUIDE, we plan to conduct a three-armed randomized waitlist pilot feasibility trial with up to 150 participants (50 in GUIDE with incentives group [immediate access to GUIDE with incentives], 50 in GUIDE without incentives group [immediate access to GUIDE without incentives], 50 in waitlist group [waitlisted with delayed access to GUIDE without incentives]).

Objectives

Overall objectives

The primary goal of this project is to test whether the GUIDE App promotes wellness and builds resilience in first responders, soldiers and veterans. Using a randomized three-arm pilot feasibility trial (immediate app access, immediate app access with incentives, waitlist), we will investigate whether the GUIDE App impacts mental health/wellness, social connectedness and personal growth; how app engagement relates to secondary outcomes, including work engagement and burnout; the extent to which participants engage in the app; as well as whether the GUIDE App is feasible, acceptable, appropriate, and usable. In our Theory of Change Model (attached), we propose that engagement with the Community, Wisdom, and Daily Practice features in GUIDE app will lead to improved proximal outcomes of mental health/wellbeing, social connectedness, and personal growth, and that these improvements will in turn will improve distal outcomes by increasing work engagement and reducing burnout.

Primary outcome variable(s)

The primary proximal outcome for this trial is mental health/wellbeing. This will be tested using: the overall score and Positive emotion subscale of the PERMA-Profiler, the Patient Health Questionnaire for depression symptoms (PHQ-8), the Generalized Anxiety Disorder-7 (GAD-7), the World Health Organization Five Well-Being Index (WHO-5), the Personal Wellbeing Score (PWS), and the Difficulties in Emotion Regulation Scale Short Form (DERS-SF). The primary outcome variable will be the overall wellbeing score of the PERMA-Profiler.

Secondary outcome variable(s)

The secondary proximal outcome variables for this trial include social connectedness and personal growth. Social connectedness will be measured using the Engagement and Relationship subscales of the PERMA-Profiler, as well as the number of posts/comments in the app (1st week vs. last week). Personal growth will be measured using the Meaning and Accomplishment subscales of the PERMA-Profiler, as well as lessons/courses completed in the app. The secondary distal outcome variables for this trial include work engagement, burnout, and retention. Work engagement will be measured using the Utrecht Work Engagement Scale (UWES-17); burnout will be measured using the Maslach Burnout Inventory (MBI); and retention will be reported based on whether the participant is still employed at the end of the trial. We will also report on app engagement metrics and their effects on secondary outcomes (total and per feature) for the immediate and immediate with incentives groups, including small group posts and comments, lessons/courses completed, wellness check-ins, daily practices completed, badges earned, and other usage statistics collected by GUIDE. Implementation and Technical Merit of the app will be measured using the Feasibility of Intervention Measure (FIM), the Acceptability of Intervention Measure (AIM), Intervention Appropriateness Measure (IAM), and the System Usability Scale (SUS). Protocol feasibility will be measured by recruitment and retention, sensitivity of the measures and intervention operations.

Background

There is an urgent need to address mental wellbeing, isolation, and burnout among first responders, military personnel and veterans. Research shows that these groups are at a greater risk for suicide, depression, and post-traumatic stress disorder (PTSD) than the general civilian population (Walker at al., 2016; Hymen at al., 2018; Sher et al., 2012); and that their occupations make them more likely to feel isolation and burnout, which go on to create problems with occupational functioning, retention and home life (Boland et al., 2019; Smith et al., 2017; Hendrickson et al., 2022). Despite these risks, first responders, soldiers and veterans tend not to seek help due to stigma, time burden and other barriers to entry (Jones et al., 2020; Haugen et al., 2017; Botero et al., 2020; True et al., 2015). The GUIDE App was designed with these findings in mind. The lessons and exercises take only minutes to complete, and the group chats are anonymous, so users can share their thoughts with likeminded peers, without the stigma. In a 4-week pilot study with 16 participants from the Wilkes Barre Police Department, the

GUIDE App showed promising results in promoting wellbeing, reducing anxiety and encouraging personal growth (Stewart & Merron, 2022). Our clinical trial builds off this pilot study. We will use a three-armed randomized waitlist pilot feasibility trial with 150 participants (first responders, soldiers, veterans) to test whether use of the GUIDE App will lead to increased social connectedness, personal growth, and mental health/wellbeing, and whether these outcomes will in turn increase work engagement and reduce burnout according to our Theory of Change Model (attached). References: 1. Walker, A., McKune, A., Ferguson, S., Pyne, D. B., & Rattray, B. (2016). Chronic occupational exposures can influence the rate of PTSD and depressive disorders in first responders and military personnel. Extreme physiology & medicine, 5(1), 1-12. 2. Heyman, M.; Dill, J.; Douglas, R. The Ruderman White Paper on Mental Health and Suicide of First Responders; Ruderman Family Foundation: Newton, MA, USA, 2018. 3. Sher, L., Braquehais, M. D., & Casas, M. (2012). Posttraumatic stress disorder, depression, and suicide in veterans. Cleveland Clinic journal of medicine, 79(2), 92. 4. Boland, L. L., Mink, P. J., Kamrud, J. W., Jeruzal, J. N., & Stevens, A. C. (2019). Social support outside the workplace, coping styles, and burnout in a cohort of EMS providers from Minnesota. Workplace health & safety, 67(8), 414-422. 5. Smith, B. N., Taverna, E. C., Fox, A. B., Schnurr, P. P., Matteo, R. A., & Vogt, D. (2017). The role of PTSD, depression, and alcohol misuse symptom severity in linking deployment stressor exposure and post-military work and family outcomes in male and female veterans. Clinical Psychological Science, 5(4), 664-682. 6. Hendrickson, R. C., Slevin, R. A., Hoerster, K. D., Chang, B. P., Sano, E., McCall, C. A., ... & Raskind, M. A. (2022). The impact of the COVID-19 pandemic on mental health, occupational functioning, and professional retention among health care workers and first responders. Journal of general internal medicine, 37(2), 397-408. 7. Jones, S., Agud, K., & McSweeney, J. (2020). Barriers and facilitators to seeking mental health care among first responders: removing the darkness. Journal of the American Psychiatric Nurses Association, 26(1), 43-54. 8. Haugen, P. T., McCrillis, A. M., Smid, G. E., & Nijdam, M. J. (2017). Mental health stigma and barriers to mental health care for first responders: A systematic review and meta-analysis. Journal of psychiatric research, 94, 218-229. 9. Botero Jr, G., Rivera, N. I., Calloway, S. C., Ortiz, P. L., Edwards, E., Chae, J., & Geraci, J. C. (2020). A lifeline in the dark: Breaking through the stigma of veteran mental health and treating America's combat veterans. Journal of clinical psychology, 76(5), 831-840. 10. True, G., Rigg, K. K., & Butler, A. (2015). Understanding barriers to mental health care for recent war veterans through photovoice. Qualitative Health Research, 25(10), 1443-1455. 11. Stewart, V., & Merron, K. (2022). (working paper). The GUIDE Pilot Study White Paper (pp. 111). Scranton, PA: GUIDE.

Study Design

Phase*
Not applicable

Design
The study is a three-armed randomized waitlist pilot feasibility trial with up to 150 participants (50 in GUIDE with incentives group [immediate access to GUIDE with incentives], 50 in GUIDE without incentives group [immediate access to GUIDE without incentives], 50 in waitlist group [waitlisted with delayed access to GUIDE without incentives]).

Study duration
The project will last approximately two years, through January 2026.

Resources necessary for human research protection
Describe research staff and justify that the staff are adequate in number and qualifications to conduct the research. Describe how you will ensure that all staff assisting with the research are adequately informed about the protocol and their research related duties. Please allow adequate time for the researchers to conduct and complete the research. Please confirm that there are adequate facilities for the research.
The research team includes the Principal Investigator, Heather Nuske, PhD, a Research Assistant Professor in the Penn Center for Mental Health, University of Pennsylvania and Director of the Digital Mental Health @ Penn Working Group. She will direct all research activities on the proposed project. There will also be a dedicated Clinical Research Coordinator, Morgan Dunphy, who has a BA in Psychology and prior research experience. She will be responsible for all organizational tasks of the proposed study, including recruitment and scheduling, as well as many routine administrative tasks and data entry. Rima Kamel, a Senior Research Assistant, will also assist with administrative tasks. All

research staff completed human subjects training and will undergo training on the study protocol with the PI of the study before contact with any human subject data. The Center for Mental Health, UPenn has adequate facilities for the research. The GUIDE App team will assist the research team with the recruitment of first responders, soldiers and veterans, as advised by our research team. The research team will be responsible for enrollment, app training, intake and post-trial meetings with participants, data collection, analysis, and documentation. The research team will also be responsible for participant compensation to all groups, while the GUIDE team will be responsible for providing additional compensation to the immediate with incentives group.

Characteristics of the Study Population

Target population
The target population will be comprised of first responders, soldiers, and veterans. Participants must be employed full-time. They also must have a compatible smartphone and be willing to download the GUIDE app on their personal device. The research team will assure all participants that their employment status will not be affected by their participation or non-participation in this study.

Subjects enrolled by Penn Researchers
150

Subjects enrolled by Collaborating Researchers
0

Accrual
This proposal involves the recruitment of 150 participants, including about 75 first responders/ corrections officers and 75 soldiers/veterans. Participation will be capped for each group using REDCap. To recruit these participants, the research team will rely on the GUIDE teams agency connections, existing partnerships, customers, and advisers. We do not anticipate difficulty meeting the recruitment and retention goals for this project because we have the GUIDE apps recruitment support, as well as the participant compensation at pre- and post-trial.

Key inclusion criteria
This project will recruit first responders, soldiers, and veterans employed full-time who have access to a smart phone and are willing to download the GUIDE App on their personal device.

Key exclusion criteria
Exclusion criteria includes: 1) individuals who are not first responders, soldiers or veterans; 2) first responders, soldiers or veterans without full-time employment; and 3) first responders, soldiers and veterans who do not have a compatible smart phone or are unwilling to download the app on their device; 4) first responders, soldiers and veterans who have used the GUIDE app before, 5) first responders, soldiers and veterans who receive financial compensation from the GUIDE app/Nylten Corp.

Vulnerable Populations

	Children Form
	Pregnant women (if the study procedures may affect the condition of the pregnant woman or fetus) Form
	Fetuses and/or Neonates Form
	Prisoners Form
	Other
x	**None of the above populations are included in the research study**

The following documents are currently attached to this item:

There are no documents attached for this item.

Populations vulnerable to undue influence or coercion
We will emphasize that participation in the study is completely voluntary and will not affect their relationship with their employer, the University of Pennsylvania, the GUIDE app team, or the research team. We will emphasize that they can end their participation at any time.

Participant recruitment
Please describe the plan to equitably identify and recruit a diverse group of participants that is reflective of the population under study. If this is a multicenter protocol, the recruitment plan should describe the local (Penn) site's plan. Describe:how potential participants may be identified (review of medical records, Slicer Dicer, DAC reports including referrals from physician offices and clinics);who may approach potential participants;methods to achieve sample diversity and inclusiveness;what information may be presented to or discussed with them; andthe context and setting in which recruitment will happen.
The research team anticipates recruiting primarily from the GUIDE Apps existing network of agencies, partnerships, advisers and customers. We will create all recruitment materials, including study flyers (attached), email communications (attached), a video (attached), and all other media. There are multiple versions of the flyers and an assortment of occupations referenced in the video to target a mix of law enforcement, corrections officers, soldiers, and/or veterans and achieve greater sample diversity. The research team will rely on the GUIDE app team to disseminate these materials to existing customers, advisers, internal teams, partner agencies, and other contacts using established communication channels (via LinkedIn, Facebook, Instagram and email).

Recruitment Materials
Is the research team using any recruitment materials? These may include but are not limited to: phone call scripts, radio/video scripts, flyers/brochures, internet postings, email, letters to potential participants, letters to patient physicians, My Penn Medicine (MPM), other direct messaging, etc. For guidance regarding recruitment materials, please review the IRB's guidance on Participant Recruitment Materials online:https://irb.upenn.edu/recruitment
Yes

Use of Penn Media & Social Media Services
Will the recruitment plan propose to use any Penn media services (communications, marketing, etc.) for outreach via social media avenues (examples include: Facebook, Twitter, blogging, texting, etc.) or does the study team plan to directly use social media to recruit for the research?
Yes

Please identify which method(s) of social media you will utilize, the content of the text to be used, and the method(s) for posting this information (i.e., using Penn supported communication services). When proposing the text to utilize, please be aware of any social media limitations (i.e., number of characters allowed in a tweet) and any appropriate confidentiality practices necessary to be compliant with posting research recruitment text.NOTE: Penn Medicine must utilize one of the centralized PM Facebook Pages:ClinicalResearch@Penn Facebook pagePenn Medicine Facebook page@PennCancer Facebook pageAll clinical research paid Facebook ads must be listed on Clinical Research @ Penn Facebook page,www.facebook.com/ClinicalTrialsAtPenn. Exceptions to the above must get approval from the Penn Medicine Social Media Committee: pennmedicinesocialmediacommittee@uphs.upenn.edu.
We will use GUIDEs LinkedIn, Facebook and Instagram channels for recruitment. Posts will include the recruitment video (attached) and/or the flyers (attached). The social media posts from the GUIDE accounts will be worded as follows: Are you a first responder, soldier or veteran? We are looking for you. Help us build resilience in your community. Penn Medicine (UPenns Medical School) is conducting a clinical trial of GUIDE, the smartphone application we designed to promote wellness and build resilience among warriors, and they are recruiting participants to test it. To sign up: Click Here [LINK TO REDCAP SURVEY] To learn more: Watch this video/Check out this flyer, Or email the research team at GUIDEapptrial@pennmedicine.upenn.edu

The following documents are currently attached to this item:

There are no documents attached for this item.

Subject compensation*
Will subjects be financially compensated for their participation?
Yes

The following documents are currently attached to this item:

There are no documents attached for this item.

If there is subject compensation, provide the schedule for compensation per study visit or session and total amount for entire participation, either as text or separate document

All participants will receive $100 for completing the trial, in two disbursements: $50 after completion of the baseline assessment, and $50 after completion of the post-treatment assessment. Payments will be sent via Greenphire ClinCard®, from an account managed by the research team. Participants randomly assigned to the immediate group with incentives will have the opportunity to earn an additional $100 from the GUIDE team. Payments will be remitted on a weekly basis in increasing increments according to the following payment schedule: $10 for week one, $20 for week two, $30 for week three, and $40 for week four. In order to qualify for each weekly disbursement, participants in the immediate group with incentives must complete specific tasks each week, including: completing at least three lessons, posting at least three times, commenting at least three times, completing three How I Am Feeling exercises, and liking three peer posts. Compensation will be provided in Amazon gift cards emailed directly to the participant from the GUIDE team.

Study Procedures

Suicidal Ideation and Behavior
Does this research qualify as a clinical investigation that will utilize a test article (ie- drug or biological) which may carry a potential for central nervous system (CNS) effect(s)? Centeral nervous system(CNS) effect: the ability of a test article to enter into and potentially interact with the central nervoous system (brain and spinal cord). Clinical Investigation: Any experiment that involves a test article and one or more human subjects that either is subject to requirements for prior submission to the Food and Drug Adminstration (FDA) under section 505(i) or 520(g) of the Federal Food, Drug, and Cosmetic Act, or is not subject to the requirements for prior submission to the FDA under these sections of the act, but, the results of which are intended to be submitted later to, or held for inspection by, the FDA as part of an application for a research or marketing permit.
No

Procedures
We plan to conduct a three-armed randomized waitlist pilot feasibility trial with up to 150 participants. 50 will receive immediate GUIDE access (immediate group), 50 will receive immediate GUIDE access with incentives (immediate with incentives group), and 50 will be waitlisted with delayed access to GUIDE (waitlist group). Participants will be recruited from GUIDEs network of contacts including customers, advisers, and agency partners. We plan to recruit approximately 75 participants who are first responders/corrections officers, and 75 participants who are veterans/soldiers. Recruitment will be capped to 75 for each group using REDCap. Though we intend to recruit veterans, we will not be recruiting this population directly through the VA. All participants will be screened for eligibility via a brief REDCap eligibility screener (attached), based on our selected inclusion criteria (i.e., must be a first responder/veteran/soldier, must be employed, must own a compatible smartphone, must not be paid by GUIDE/Nlyten, must not have used GUIDE before). If eligible, REDCap will direct them to a copy of the Informed Consent. Participants will have the option to download this document for their personal files and can contact the research team if they have any questions. After participants give their consent, REDCap will email them with a link to their baseline assessment survey. This assessment is intended to capture a baseline of their wellness and other related factors, as well as their demographic information. The following measures will be included (all attached): demographic questionnaire, the PERMA-Profiler (overall score and all subscales, including Positive emotion, Engagement, Relationships, Meaning, Accomplishment), the Patient Health Questionnaire (PHQ-8) for depression symptoms, the Generalized Anxiety Disorder-7 (GAD-7), World Health Organization Five Well-Being Index

(WHO-5), Personal Wellbeing Score (PWS), Difficulties in Emotion Regulation Scale Short Form (DERS-SF), the Utrecht Work Engagement Scale (UWES), and the Maslach Burnout Inventory (MBI). Consented participants will receive an additional email from the research team asking them to schedule a virtual Intake meeting. They will be furnished with a Calendly link to select a date and time that works best with their schedule. Intake meetings will be held one-on-one over Zoom and conducted by the Clinical Research Coordinator. They will be brief, about 20-30 minutes, and will not be recorded. Participants will be briefed on the GUIDE App and will have the opportunity to ask any questions they have about the trial. The baseline assessment should be completed prior to this intake meeting, but if it is not, participants will be given time to do so. Those in the immediate and immediate with incentives groups will also be walked through account training and general app training. A standardized training protocol will be used so that the app is introduced to participants in a uniform and accurate manner. During GUIDE account creation, participants will be required to provide their phone number and/or email address. This personal data will be secured by Okta, a third-party authentication provider, and stored separately from app data. Screenshots of this process can be found in the GUIDE Account Creation document attached to this application. The participant will provide their randomly assigned username to the research team during their Intake meeting. The research team will keep a separate spreadsheet, locked and encrypted on Box, to match participant usernames with Study IDs. The participant will schedule their Post-Trial Meeting during the Intake Meeting through a calendar management software, such as Microsoft Bookings. During the trial period of 4 weeks, participants in the immediate and immediate with incentives groups will have full access to the GUIDE App. To get started, the app will prompt participants to answer a series of onboarding questions about themselves, including their goals, wellness experience and demographic information (see attached GUIDE Onboarding Process). Based on their responses, participants will be assigned Courses and Daily Practices; as well as a personalized small group chat, where they can post and comment with likeminded others, anonymously, with the option to share app progress. Courses are composed of lessons on topics such as Forgiveness, Gratitude, and Self-Awareness. The lessons contain a mix of media including videos, assessments, readings and exercises. Courses and lessons take varying amounts of time to complete, which the participant can see before adding it to their profile. The app includes three types of Daily Practices including Meditation Practice (a simple timer to help keep participants focused while they meditate), Journal Practice (where participants can catalog their thoughts and reactions to lessons), and a Mood Tracker that participants can view over time (How are you feeling? 1 = Very Sad to 5 = Very Happy). On the home page, participants are also invited to track their Wellness Score through a wellness check-in, which uses the Personal Wellbeing Score (PWS) administered repeatedly over time to track trends. Screenshots of GUIDE app content described above, and information about how it works, can be found in the GUIDE App Content document attached. The GUIDE App gives participants the option to complete assessments that screen PTSD (PC-PTSD-5), insomnia (ICD-10), anxiety (GAD-7), and alcoholism (AUDIT) in their Courses. Study participants are not required to complete these assessments for the trial. 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. For people needing a higher level of care, the following crises numbers are provided in the app: Suicide and Crisis Lifeline, Veteran Crisis Line, Substance Abuse and Mental Health Services Administration, Disaster Distress Hotline, Red Nacional de Prevencion del Suicido, COPLINE, Firefights Union for PTSD & Mental Health, Frontline Helpline, Fire/EMS Helpline, Safe Call Now, and the All Clear Foundation. These resources are available through the SOS button, which is highlighted after an assessment is completed. Small group chats are monitored by GUIDE moderators. GUIDE moderators work part-time and possess the following qualifications: Crisis Intervention Training Instructor & Coordinator, Peer Support/Critical Incident Stress Management Counselor, Certified Life Coach, Somatic Practitioner Certification, Trauma Informed Certification. If/when participants post comments and/or assessment results about suicide, moderators will escalate to the Research Team within 24 hours by email. The email will contain the participant's username (no PHI) and details about the escalation. PI Nuske, a psychologist, will investigate the escalation within 12 hours of receipt and contact the participant by phone and/or email to ensure they are connected to appropriate resources. App engagement will be captured by GUIDE using small group posts, small group comments, lessons completed, courses completed, wellness check-ins and other usage metrics and will be used for analysis by the research team. Data will be encrypted, password protected, and transferred securely from GUIDE to the research team using Box. Participants assigned to the immediate with incentives group will have the opportunity to earn additional

compensation for their participation. If they complete certain weekly tasks, they will be emailed Amazon gift cards by the GUIDE team. These tasks include completing at least three lessons, posting at least three times, commenting at least three times, liking three peer posts, and completing three How I Am Feeling exercises. When the four-week trial period is over, participants will receive an email from REDCap with a link to their post-trial assessment survey. The survey will include the same measures from the baseline assessment, but without demographic questions. We will also include a question about whether they are still employed, to report on retention. The survey will include four additional measures that assess the feasibility and usability of the app for participants in the immediate and immediate with incentives groups, including: the System Usability Scale (SUS), the Acceptability of Intervention Measure (AIM), the Intervention Appropriateness Measure (IAM), and the Feasibility of Intervention Measure (FIM). When the trial is over, participants who have not yet scheduled their post-trial meeting will receive an email reminder from the research team and a link to a calendar management software, such as Microsoft Bookings. The post-trial meeting will be brief, about 15-30 minutes, and held over Zoom. It will not be recorded. During the post-trial meeting, participants who have not yet completed their post-trial assessment will be given time to do so. They will also get the opportunity to give feedback about the GUIDE App and the trial. Participants in the immediate and immediate with incentives groups will be told that they may delete their GUIDE account and remove the app from their phones; while participants in the waitlist group will get the opportunity access to the GUIDE App at this meeting if they are interested. Participant feedback and suggestions about the app will be consolidated and discussed with the GUIDE team.

The following documents are currently attached to this item:

There are no documents attached for this item.

Deception
Does your project use deception? Deception could be considered any direct misinformation presented to the subject or omission of key information pertaining to the design or nature of the project.
No

International Research
Are you conducting research outside of the United States?
No

Analysis Plan
To analyze GUIDEs impact on the proximal and distal outcomes as detailed in our Theory of Change model (i.e., mental health/wellbeing, social connectedness and personal growth; work engagement and burnout) (attached), secondary outcomes from the trial (pre-post) will be analyzed either using linear mixed models or repeated-measures ANOVA, depending on whether there are clustering variables (e.g., workplace, first responder/veteran). Key measures used for this analysis will be the: PERMA-Profiler overall wellbeing score and subscales (Positive emotion, Engagement, Relationships, Meaning, Accomplishment), PHQ-8 (depression), GAD-7 (anxiety), WHO-5 (wellbeing), the Personal Wellbeing Score (PWS), DERS-SF (emotional regulation), UWES (work engagement), and MBI (burnout). We predict that participants with access to the GUIDE App during the trial will show improved positive emotion, engagement, relationships, meaning, accomplishment, wellbeing, work engagement and emotional regulation; as well as reduced burnout and symptoms of depression and anxiety, when compared to the waitlist group. We do not predict significant differences between the immediate and immediate with incentives groups. To assess how GUIDE app engagement relates to secondary outcomes, we will use exploratory analyses to examine the relationships between app engagement (total and by feature) to all secondary outcomes (delta between pre-post) using Pearson correlation coefficients. We will also report on the extent to which participants engage in the GUIDE App, total and per feature, for lessons completed, courses completed, small group posts, small group comments, wellness check-ins, journal entries, meditation sessions, badges earned and other usage metrics. The feasibility, acceptability, appropriateness and usability of the app will also be reported on with descriptive statistics to assess implementation and technical merit.

The following documents are currently attached to this item:

There are no documents attached for this item.

Data confidentiality

- x **Paper-based records will be kept in a secure location and only be accessible to personnel involved in the study.**
- x **Computer-based files will only be made available to personnel involved in the study through the use of access privileges and passwords.**
- x **Prior to access to any study-related information, personnel will be required to sign statements agreeing to protect the security and confidentiality of identifiable information.**
- x **Wherever feasible, identifiers will be removed from study-related information.**

A Certificate of Confidentiality will be obtained, because the research could place the subject at risk of criminal or civil liability or cause damage to the subject's financial standing, employability, or liability.

A waiver of documentation of consent is being requested, because the only link between the subject and the study would be the consent document and the primary risk is a breach of confidentiality. (This is not an option for FDA-regulated research.)

- x **Precautions are in place to ensure the data is secure by using passwords and encryption, because the research involves web-based surveys.**

Audio and/or video recordings will be transcribed and then destroyed to eliminate audible identification of subjects.

Subject Confidentiality
Paper-based records will be kept in a secure location and only be accessible to personnel involved in the study. Electronic files will only be made available to personnel involved in the study through the use of access privileges and passwords. Prior to access to any study-related information, personnel will be required to sign statements agreeing to protect the security and confidentiality of identifiable information. Whenever feasible, identifiers will be removed from study-related information. Precautions are in place to ensure the data is secure by using passwords and encryption, because the research involves web-based surveys. The GUIDE App uses phone numbers and emails for account creation. They are secured by Okta and stored separately from app data. This data is later de-identified for analysis, and participants may delete their account after the study has ended.

Sensitive Research Information*
Does this research involve collection of sensitive information about the subjects that should be excluded from the electronic medical record? [NOTE: This does not apply to: 1) research information that would not normally be included in the electronic medical record or 2) information that is in the electronic medical record as part of clinical care.]
No

Subject Privacy
Privacy refers to the person's desire to control access of others to themselves. Privacy concerns people, whereas confidentiality concerns data. Describe the strategies to protect privacy giving consideration to the following: The degree to which privacy can be expected in the proposed research and the safeguards that will be put into place to respect those boundaries. The methods used to identify and contact potential participants. The settings in which an individual will be interacting with an investigator. The privacy guidelines developed by relevant professions, professional associations and scholarly disciplines (e.g., psychiatry, genetic counseling, oral history, anthropology, psychology).
Data from the study will only be shared with personnel that work on the study. Data from the GUIDE App will only be seen by the research team and the GUIDE App development team. Professional conduct will be expected by each member of the research team and advised to the GUIDE App team, and will be overseen by the PI, Dr. Nuske, in accordance with the privacy guidelines developed by the discipline of psychology.

Disclosures
Will any data or specimens from Penn participants OR other research generated work product (e.g., intellectual property) be disclosed to any individuals, entities, or vendors, etc. outside of Penn?
No

Data Protection*

x	**Name**
x	**Street address, city, county, precinct, zip code, and equivalent geocodes**
	All elements of dates (except year) for dates directly related to an individual and all ages over 89
x	**Telephone and fax number**
x	**Electronic mail addresses**
x	**Social security numbers**
	Medical record numbers
	Health plan ID numbers
	Account numbers
	Certificate/license numbers
	Vehicle identifiers and serial numbers, including license plate numbers
	Device identifiers/serial numbers
	Web addresses (URLs)
	Internet IP addresses
	Biometric identifiers, incl. finger and voice prints
	Full face photographic images and any comparable images
	Any other unique identifying number, characteristic, or code
	None

Does your research request both a waiver of HIPAA authorization for collection of patient information and involve providing Protected Health Information ("PHI") that is classified as a "limited data set" (city/town/state/zip code, dates except year, ages less than 90 or aggregate report for over 90) to a recipient outside of the University of Pennsylvania covered entity?
No

Tissue Specimens Obtained as Part of Research*
Are Tissue Specimens being obtained for research?
No

Tissue Specimens - Collected during regular care*
Will tissue specimens be collected during regulator clinical care (for treatment or diagnosis)?
No

Tissue Specimens - otherwise discarded*
Would specimens otherwise be discarded?
No

Tissue Specimens - publicly available*
Will tissue specimens be publicly available?
No

Tissue Specimens - Collected as part of research protocol*
Will tissue specimens be collected as part of the research protocol?
No

Tissue Specimens - Banking of blood, tissue etc. for future use*
Does research involve banking of blood, tissue, etc. for future use?
No

Genetic testing
If genetic testing is involved, describe the nature of the tests, including if the testing is predicative or exploratory in nature. If predictive, please describe plan for disclosing results to subjects and provision

of genetic counseling. Describe how subject confidentiality will be protected Note: If no genetic testing is to be obtained, write: "Not applicable."
Not applicable.

Consent

1. Consent Process

Overview
Once participants are recruited and communication is established, interested invitees will be prompted to complete a brief screener on REDCap to determine eligibility based on inclusion criteria. After eligibility is established, they will be directed to review the Informed Consent Form and HIPAA Authorization Form via REDCap. These consent forms include a description of the study and expected roles and responsibilities of the participant, risks and benefits to participants, and confidentiality procedures (see attached). The consent forms also clearly state that participation in the study is completely voluntary, and participants can drop out of the study without penalty at any time. All consent forms follow the guidelines outlined by the University of Pennsylvania, and ethical guidelines set forth by the state and federal governments. Documentation of subject consent will be stored in a locked file in the PI or designees office at each study site or in one of the HIPAA-compliant servers described above.

Children and Adolescents
Not applicable.

Adult Subjects Not Competent to Give Consent
Yes. Not applicable.

2. Waiver of Consent

Waiver or Alteration of Informed Consent*
No Waiver Requested

Minimal Risk*

Impact on Subject Rights and Welfare*

Waiver Essential to Research*

Additional Information to Subjects

Written Statement of Research*
No

If no written statement will be provided, please provide justificiation

The following documents are currently attached to this item:

There are no documents attached for this item.

Risk / Benefit

Potential Study Risks
We do not anticipate any significant risks of participation. Possible risks for participants include experiencing discomfort in talking about their experiences and emotions during the post-trial interview or in filling out the surveys. There is a chance that participants with suicidal ideation join the trial, given the higher risk of suicide among veterans, soldiers and first responders. In the event that a participant is

in imminent danger to themselves or others, PI Nuske, a psychologist, will remain on-call to address all participant related risk concerns for the duration of the study. Our provisions for clinical management regarding suicide risk in participants include: 1) Flagging of any suicidal intentions, thoughts, or behaviors disclosed in the GUIDE App to the research team within 24 hours (via GUIDE moderators); 2) Offering the participants immediate access to mental health resources via the SOS button in the GUIDE app, including the 988 Suicide and Crisis Lifeline; 3) Reviewing the flagged message with PI Nuske within 12 hours of receipt of the escalation; 4) If PI Nuske determines that the message is indeed deemed to be indicative of suicidal risk, she will contact the participant within 12 hours by phone and/or email to ensure they are connected to the appropriate resources. PI Nuske will contact a local hospital if indicated (because the study will be conducted remotely, each participant is likely to be proximal to a different hospital or emergency room). In order to maintain sufficient safety and risk monitoring (including the ability to contact the participant directly in the case of potential imminent clinical risk), we must have access to personally-identifiable information (i.e., phone number, email address, and alternate contact information for the participant).

Potential Study Benefits
There are no direct benefits to 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.

Alternatives to Participation (optional)

Data and Safety Monitoring
The PI (Dr. Heather Nuske) will closely monitor safety, privacy, and data integrity throughout the project.

The following documents are currently attached to this item:

There are no documents attached for this item.

Risk / Benefit Assessment
There is minimal to no risk associated with this study.

General Attachments

The following documents are currently attached to this item:

Additional forms (citi_gcp_nuske.pdf)

Additional forms (citi_gcp_kamel.pdf)

Additional forms (citi_gcp_dunphy.pdf)

Informed consent form (informedconsentform_tracked_changes_04.05.2024.docx)

Informed consent form (informedconsentform_clean_04.05.2024.docx)

Questionnaires (supplementarydemographicquestions_modification1.docx)

Additional forms (updatestoprotocol_modification1.docx)

Cover Letter (coverletter_modification1.docx)

Questionnaires (adverseeventchecklist.docx)