

PROTOCOL FOR:

BEHAVIORAL HEALTH & RESILIENCE TRAINING FOR MILITARY LEADERS

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1. Protocol Title

Behavioral Health & Resilience Training for Military Leaders

2. Objectives

Current training on resilience in the military focuses on the individual. Thus, leaders are trained in how to improve their own resilience but not necessarily how to support resilience within their troops. The proposed study adapts the researchers' existing evidence-based supportive leadership training for Veterans and the National Guard to an active duty population. The ultimate aim of our intervention is to train supervisors to be more supportive toward their subordinate soldiers leading to improved readiness, resilience, health and well-being of subordinates. The multi-component intervention uses accelerated-learning techniques, such as breaking information into small units and using various modalities of delivery. While being piloted with an Army population at Joint Base Lewis-McChord (JBLM) in Washington, the end training product will be translated and applicable for all branches and first-responders, enhancing resilience in the face of stressful and hazardous workplace situations in a myriad of contexts.

The overarching goals of this proposed study are to:

- 1) *customize* our existing evidence-based intervention on supportive supervision to active duty leaders in the U.S. Army with a focus on resilience and readiness, which we are calling the Resilience Supportive Leader Training (RESULT),**
- 2) *evaluate* RESULT and its effect on psychological health, unit cohesion, resilience and readiness of subordinates, and**
- 3) *translate* RESULT to leaders in all branches of the military, as well as civilian first-responders.**

Specific Aims of the study (listed in our Statement of Work in our funded grant):

Specific Aim 1: Customize and adapt current evidence-based leadership support training intervention to develop a multi-component training intervention, Readiness Supportive Leadership Training (RESULT), using accelerated learning strategies aimed at improving Service Member resilience and readiness in the military.

Specific Aim 2: To assess the impact of RESULT intervention components using reports of leaders' reactions to the training program in terms of satisfaction, utility, and learning outcomes (Hypothesis 1).

Specific Aim 3: To test the effects of the RESULT training compared to the control group on perceptions of increased leadership resilience-supportive behaviors from the perspective of the service members, following the training (Hypothesis 2).

Specific Aim 4: To test the effects of the RESULT training compared to the control group on behavioral health measures such as emotion regulation, connectedness, team cohesion, psychological health, and physical health following the training (Hypotheses 3 & 4).

Specific Aim 5: Translate the tenets of the RESULT to other branches of services, and other employee populations who would benefit, such as first responders.

Study Hypotheses

- 1) Leaders in the intervention group will report positive reactions to the training and will demonstrate increased knowledge from pre-test to post-test.
- 2) Service Members in the intervention group will report improved perceptions of resilience-supportive leadership behaviors compared to those in the control group.
- 3) Service Members in the intervention group will report higher levels of resilience-related factors such as adaptive emotion regulation strategies, resilience, social connectedness and belongingness, and team cohesion, compared to those in the control group.
- 4) Service Members in the intervention group will report higher levels of resilience-related outcomes such as psychological and physical health and well-being, compared to those in the control group.

3. Background

The Department of Defense (DoD) has prioritized programs to optimize readiness by enhancing resilience of its service members. Psychological resilience refers to the process of coping with or overcoming exposure to adversity or stress (Meredith, et al., 2011). Resilience enables individuals to persevere in challenging times, and is comprised of trainable skills as opposed to stable traits (Reivich, Seligman, & McBride, 2011). Despite this focus, **a gap exists in the current military resilience training that teaches leaders to provide support to subordinate soldiers, thereby promoting their psychological health, resilience, and ultimately readiness.** Our own previous research has demonstrated the effectiveness of supervisor training to provide support at improving health and workplace outcomes for subordinates (Dimoff et al., 2016; Hammer et al., 2011; Hammer et al., 2016; Odle-Dusseau, Hammer, Crain, & Bodner, 2016), including supervisors of veterans reintegrating into the civilian workforce. (Hammer et al., 2018). As in our previous work, the ultimate aim of our intervention is to train supervisors to be more supportive, leading to improved psychological health and well-being of subordinates.

Review of Resilience Definitions and Resilience Training Programs in the Military

The DoD and military services have embraced the idea of fostering resilience to maintain a healthy fighting force; however, there are no standard definitions and measures of resilience or outcomes used across DoD resiliency programs (Meredith et al., 2011). The Army has referred to resilience as the “ability to bounce back” (Reivich et al., 2011), suggesting an individual can maintain or return to previous levels of well-being and functioning in response to adversity (Bowels & Bates, 2010). A more recent perspective from the Air Force Resilience Training program suggests that resilience changes day-to-day; it is in a constant state of fluctuation where resilience resources and stressors can come and go (Meadows, Miller, & Robson, 2016). Additionally, others (e.g., Carver, 1989) have argued that beyond returning to a status quo, adversity can lead some to thrive or be stronger in the face of stress than before.

The Army Comprehensive Soldier Fitness Program (CSF) was created to prevent adverse mental health outcomes associated with trauma exposure by implementing resilience-enhancing interventions before deployment (Denning, Meisner, & Warner, 2014). The CSF includes five dimensions of health (physical, social, emotional, spiritual, and family) and is able to conform to each individual’s resilience level. Army Regulation 350-53 (i.e., CSF) defines resilience as “the mental, physical, emotional, and behavioral ability to face and cope with adversity, adapt to change, recover, learn, and grow from setbacks. A resilient and fit individual is better able to leverage intellectual and emotional skills and behaviors that promote enhanced performance and optimize their long-term health.” (Department of the Army [DA], 2014). The program is carried out through multiple avenues and includes resilience assessment tools, Master

Resilience Training (MRT), and online, self-help modules (Casey, 2011). The MRT curriculum consists of three components: Preparation, Sustainment, and Enhancement. The segments teach resilience fundamentals based on findings within the field of positive psychology, deployment cycle training, and personal skill-sets which enhance individual performance (Reivich et al., 2011). The MRT program is delivered through a 10-day, train-the-trainer model wherein unit leaders learn how to educate soldiers on respective resilience. These skills include improving awareness of individual assumptions and thought patterns in order to improve effectiveness and also are geared toward building mental toughness and strengthening relationships.

Another resilience program to note is the Airman Resilience Training Program (ART). ART was implemented to help airmen cope with deployment-related stress and improve well-being (Gonzalez, Singh, Schell, & Weinick, 2014). Similar to MRT, this training is also administered via PowerPoint by trained “briefers” and is a one-size-fits-all approach, as all airmen receive the same training. The training includes components named the “four C’s” of coping with stressful deployment situations, which include: check, control, connect, and confidence (Gonzalez et al., 2014). Check refers to self-awareness and checking on others around you. Control is related to self-control and the self-awareness of how one tends to respond in stressful situations. The third component, connect, is related to social connectedness with one’s friends and family. Finally, the last “C” is confidence, which is related to developing trust and leadership skills.

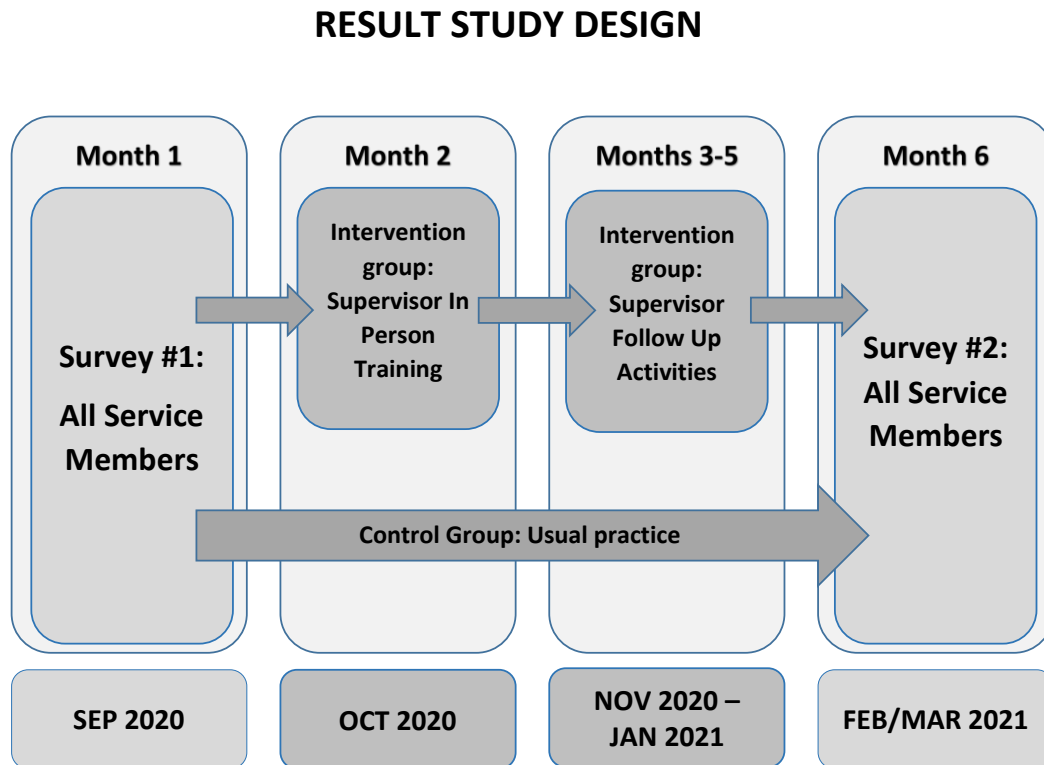
In their assessment of resilience programs being conducted within military populations, Morgan and Bibb (2011) suggested that subsequent resilience programs be founded on evidence-based interventions and include measures that capture intervention effectiveness. The authors emphasized the need for providing resilience resources that are applicable across military branches, occupations, and ranks in order to increase warfighter consistency. In terms of improving current programs, it was recommended that the ART program modify its formatting and incorporate more specific information on topic areas that were considered important but were not initially included, such as sleep, health, and relationship building (Gonzalez et al., 2014). Although contemporary resilience programs have demonstrated efficacy (Harms et al., 2013; Lester et al., 2011), and have been perceived by service members to be helpful in their military jobs and civilian life (Griffith & West, 2013), they have the potential to be strengthened. The MRT and ART programs focus largely on improving leader’s own resilience with little attention to providing support to subordinates to improve their resilience. Thus, a gap exists in the current training in terms of offering strategies and tools for leaders to use when intervening to provide support to subordinate service members and thereby promoting their resilience.

4. Study Design

The study design is a cluster-randomized controlled trial randomized by battalion. There are 11 battalions in the population we are targeting at Joint Base Lewis-McChord (JBLM) in Lacey, Washington. Soldiers in each battalion will be randomly assigned to the RESULT intervention or usual practice control condition, ideally after baseline data collection, if possible. The intervention targets mid-level military leadership, namely the Platoon Leadership Team (PLT), usually consisting of a platoon leader (i.e., a junior-level officer) and a platoon sergeant.

Figure 1 depicts the overall study design. To test the effectiveness of the intervention, we will collect data pre- and post- intervention from all soldiers, as well as platoon leaders. The control group will be usual practice, as we have done in most of our prior clinical trials. There are an estimated 5200 soldiers in the Battalions included in the study; we anticipate about 30% will participate with a target sample size of $n = 1560$).

Figure 1. Study Design



The surveys will take approximately 30 minutes to complete and will be completed electronically, using REDCap survey software. Survey participation is voluntary and leadership training is mandatory per the senior command at JBLM. However, any data collected from the leaders during training will be consented or if consent is not given, will not be analyzed.

Baseline data collection with all Soldiers will be conducted within a 2-3 week period, with a follow-up survey 4 months later. The leadership training intervention will begin approximately 3 weeks after the baseline survey is completed, with scheduling occurring over a 3 week period.

A research unit at JBLM, the West coast arm of the Walter Reed Army Institute of Research (aka WRAIR-W) and with whom we have been working for several years, will provide advice in the form of consultation and coordination with unit leaders at JBLM. The WRAIR-W team located at JBLM has extensive experience working with operational partners for the development and execution of studies assessing novel interventions for optimizing psychological health and soldier readiness. Lieutenant Colonel Oscar Cabrera, Director of WRAIR-W, will serve as the primary consultant, with additional support from Major Mike Dretsch, Deputy Director. We are also currently working with WRAIR-W on our DoD-funded Military Employee Sleep and Health (MESH; Study #00016555) study that is taking place in the Oregon National Guard and have made numerous trips to JBLM to discuss current and future research. Based on this relationship, we have developed a greater sense of the context and culture of the workings at JBLM and our proposal has benefitted from the experiences of the WRAIR-W staff conducting studies at that installation. We have been discussing issues surrounding study design for over a year now with LTC Cabrera. While we are working with the Army specifically, we anticipate this training will be easily translatable to other branches, as well as to segments of the public sector, such as first responders. We have also developed a successful and supportive working relationship with the Division Behavioral Health leader, Major Connie Thomas, who has been critical to the

development of this study, particularly in the COVID-19 era. The majority of the changes to this protocol are under her guidance.

Randomization

Based on advice received from our partners at JBLM, we determined that it is best to randomize at the battalion level because of the likelihood of contamination effects between intervention and control groups if randomization was conducted at a lower level (e.g., platoon or company). Furthermore, randomizing at the battalion level will provide protection from intervention selection effects that occur in traditional non-equivalent control group quasi-experimental designs. Along with the collection and use of baseline, pre-intervention soldier data for the targeted study outcomes, our proposed approach can go a long way in reducing concerns related to biases that undermine internal validity when it is not feasible to randomize more units by balancing potentially confounding covariates across study conditions (Shadish, Cook & Campbell, 2002).

Timeline

Start date: 15 SEP 2019, anticipated end date: 14 SEP 2022

| Activity | YEAR 1 | | | | YEAR 2 | | | | YEAR 3 | | | |
|--|--------|---|---|---|--------|---|---|---|--------|---|---|---|
| | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| IRB and HRPO approval | | | | | | | | | | | | |
| Formative Information Gathering | | | | | | | | | | | | |
| Survey Development | | | | | | | | | | | | |
| Coordination/Timeline | | | | | | | | | | | | |
| Customization of Intervention | | | | | | | | | | | | |
| Baseline survey | | | | | | | | | | | | |
| Implement Intervention | | | | | | | | | | | | |
| 6-month Survey | | | | | | | | | | | | |
| Cleaning & Analyzing Data | | | | | | | | | | | | |
| Report Findings | | | | | | | | | | | | |
| Write Papers/Translation/Dissemination | | | | | | | | | | | | |

Note: Lighter color cells are for contingency planning

The first three quarters will focus on hiring personnel, formative information gathering, regulatory review, protocol creation, and refining our schedule. Coordination and refining the timeline for participant recruitment will occur during the first nine months; however, actual participant recruitment will not happen until after we receive HRPO approval. Intervention activities begin about 3-weeks (intervention group only) after the baseline survey so they co-occur in the same quarter. The follow up survey is 4-months post-baseline. Contingency periods are built in for both the intervention and 6-month survey. Data cleaning begins shortly after the first surveys are administered. The last year of the grant is reserved for translating the intervention to other branches of the military, analysis, writing and dissemination of findings.

5. Study Population

a. Number of Subjects

For the intervention, approximately 102 Platoon Leadership Teams (PLTs) from 7-8 battalions will be targeted for leadership training and testing of Hypothesis 1. For Service Member participation, based on communications with our JBLM partners, we expect about 30% of the total population ($N=5200$) to participate ($n=1560$) at baseline. In addition, based on both our own experience and on those same communications, we expect about 20% attrition at the second data collection, owing largely to individual change in duty stations, remote training, deployments, etc. Thus, we anticipate 1245 soldiers to participate in the study data collection at baseline and at the 6-month follow-up for Hypotheses 2, 3 and 4.

We will work with command teams to avoid data collection, when possible, that would be timed during large deployments or other similar anticipated events. Participation in the training is mandatory, though allowing our researchers to use data collected in association with the training (e.g., test scores, reaction) will be consented. However, the increased sample size will allow our team greater flexibility in dealing with these issues should they arise.

b. Inclusion and Exclusion Criteria

The inclusion criteria for soldiers is to be currently serving Active Duty in one of the targeted battalions, and in positions of platoon leader or below. For the leader training, we will target the platoon leaders and platoon sergeants. We will work with senior leadership to identify these individuals.

c. Vulnerable Populations

No individuals who are known to be members of a vulnerable population will be enrolled. We will not identify subjects on whether they are members of a vulnerable population. In other words, we will not collect any information about subjects' status as part of any vulnerable populations, including prisoners, pregnant woman, children, neonates, and/or adults lacking capacity.

d. Setting

Survey data collection will occur online using REDCap survey software. Currently, training delivery will all take place on site at Join Base Lewis-McChord (JBLM) near Tacoma, WA. For the training, class size will be limited to 10 people, including the training, wearing masks. If COVID-19 conditions worsen, training will be conducted remotely using Webex or Microsoft Teams. Data collection (i.e., recruitment, consenting, data analysis) will be performed primarily by OHSU personnel, with some Portland State University (PSU) personnel assisting. PSU personnel will work under the direction of OHSU personnel to ensure all procedures are followed. PSU has ceded oversight to the OHSU IRB. We will also inform the IRB at JBLM of our study and provide study materials for their review.

e. Recruitment Methods, Consent & Data Collection Procedure

Baseline Survey Data Collections with Service Members

Data from the surveys, completed by soldiers, will be used to evaluate the Resilience Supportive Leader Training (RESULT). Recruitment will occur at the company level; each Brigade is comprised of approximately 20-25 companies of about 40-70 soldiers each.

Several months prior to data collection and based on our timeline, our Study Coordinator will work with our staff at JBLM to have an Operations Order issued, directing a company to click or copy the provided link to the online survey. These orders are standard operating procedure for studies conducted with the military and assures time is set aside for participation during duty hours. Our contacts at WRAIR-W have used this procedure in previous studies. We will provide a recruitment flyer, included with IRB application. Soldiers will be required to access the survey, provide their name, rank and unit and then opt in or out by consenting or not. It will be made clear that they do not HAVE to complete the survey, but have to at least go through the opt in/out process. Names of the soldiers who have opted in/out will be provided to Battalion POCs, but not whether the soldier has completed the survey.

Soldiers will be consented online and select “I consent to participate” if they would like to participate and then immediately be launched into the survey. If they select “I do not consent”, we will confirm their declination, and then the survey will end.

The survey will be open for two weeks and our team will communicate several times with Battalion POCs to communicate who has accessed the survey (but not whether or not they completed the survey). At the conclusion of the two week period, the project manager will download the data from REDCap, deidentify and clean the responses, then store them on a restricted folder on Box.

4-Month Follow-Up Survey

The 4-month survey will mirror the baseline data collection, where another Operation Order will be issued with the survey link and a brief explanation for the study.

We will duplicate the consent procedure at 4 months to cover those who did not participate at baseline (i.e., were not in the unit at that time, not present, or changed their mind about participating). The surveys will be identical except we will ask if they participated in the survey at baseline in order to facilitate matching of responses.

Survey Incentives. Financial incentives will not be provided for participation, as service members are completing the surveys while on duty and compensation is not allowed while on duty hours per DoD regulations. However, to help increase the response rate we will offer pizza for platoons with 50% response rate or higher.

Platoon Leader Recruitment: Training

After randomization occurs, our Training Coordinator (i.e., separate from Study Coordinator responsible for survey data collection) will work with Brigade command on scheduling for specific units, dates and times for the face-to-face training. Command will inform leaders when and where to report for training and that participation in the training is being mandated by Command (Note – we will consent for use of any training data; see below). Typically, two members of each Platoon Leadership Team will participate in the training, the Platoon Leader (i.e., officer) and Platoon Sergeant (i.e., enlisted, non-commissioned officer, who is subordinate to the officer). An Operations Order will be issued for the leadership team to be at the training at a designated date, time, and location.

Prior to beginning the training, we will inform the leaders of our interest in including data associated with the training (e.g., test scores, reactions) as part of our research to evaluate the training but emphasize that allowing use of those data is voluntary and declining will not affect them in any way. We will clarify the while the training is mandated, the use of any training-

related data is not. We will provide them an opportunity to complete the informed consent confidentially before beginning the training. We will have physical copies of the consent forms (included in the IRB submission) for them to sign and provide them a copy as well. In accordance with DoD regulation, if any senior-ranking officers are present, particularly if they command the platoon leaders, they will be asked to leave the room during the consent portion of the session.

If they do not sign the consent form to use their training data, any individual data collected as a result of the training will not be used in the study. Blanks will be considered as non-consent.

The leader intervention involves an initial in-person training with the PI of the study, including a computer-based training, an evaluation of a case study, group discussions and more related to providing resilience support for their subordinates. The content will be based on previous training developed by the PI and consultants on the project, all which were part of previous IRB-approved protocols. The content will be adapted to focus on resilience and readiness in the military. Some examples of the types of information the training will include based on the Hammer's (PI) prior validated trainings include: 1) the benefits of reducing stress and increasing resilience for one's soldier; 2) why it is important to focus on resilience, making the case that it is important to support soldiers' resilience so that it will make the team more autonomous and efficient in the field; 3) reducing suppression of emotion and increased reappraisal of negative situations (adaptive emotion regulation), leading to leaders facilitating stronger resilience behaviors in soldiers; 4) how to enact resilience supportive behaviors such as providing emotional and instrumental support and modeling effective resilience behaviors. Topics to be covered based on the Dimoff mental health awareness training: 1) facts about the prevalence of mental health; 2) warning signs of deteriorating mental health; and 3) what leaders can do to promote resilience. The intervention also includes several 'micro-learning' activities over the following two months to reinforce learning and assist leaders to enact supportive behaviors they learned in the training. These activities include watching videos with testimonials about supportive leadership, podcasts, team activities, and quizzes. More detailed information can be provided to the IRB once it becomes available.

Following current base regulations, class size will be limited to 10 individuals including the trainer with masks on. If conditions change, the training will change to comply with the current recommendations.

f. Consent Process

The consent process is described in detail above, but summarizing/highlighting salient points:

- Consent will take place online, just before survey data collection and/or just before training implementation.
- Participants will be re-consented at the 4 month follow up survey.
- We will have contact information available if Soldiers have questions.

6. Procedures Involved

Data collection procedures are described in #5 above, but summarizing/highlighting salient points:

- Data collection is online using REDCap survey software. The link is available through an Operations Order issued by leadership at JBLM. The survey will be repeated 4 months later. We estimate 30 minutes for completion.
- For those leaders in the training condition, we will collect data about their learning, participation and reaction to the training. Training participation is mandated by the base leadership at Ft. Lewis; participants can choose whether they consent to their data being used.

- Participants will be provided contact information for staff if they chose to withdraw from the study.

7. Data and Specimens

a. Handling of Data and Specimens

Once downloaded from REDCap, data will be saved to a secure Box folder with very limited access (i.e., only study staff who need to access raw data based on their job description) and then imported into SPSS.

De-identified data will be kept indefinitely on the secure servers at OHSU; data with identifiers will be deleted at the conclusion of the study.

We will act as our own Repository for the survey and training data. We will keep it on the OHSU secure servers (X: drive) with access limited to only a few key research staff (i.e., PI, project manager, data manager). We will provide information on our study website (<https://www.resultstudy.org/>) at the completion of the study and once results are published on the potential availability of the survey data. Potential researchers will be provided with a form to complete, similar to what we use for our internal paper development purposes. Researchers will need to state the purpose of data use (e.g., specific hypotheses), provide a background rationale for those hypotheses, specify which variables are requested, and where the data will be published (e.g., the conference and/or journal). We will also provide acknowledgement language required in any papers or presentations. Once approved by the PI and the co-PIs, this information will be drafted into a formal Data Use Agreement signed by all parties. The Project Manager (currently Dr. Krista Brockwood) will be the repository guardian.

All study staff dealing with both participants and/or data will have completed sanctioned Human Subject Research training. The PI and Project Manager both have experience with DoD-regulated research and reviewed these regulations with the DoD Science Officer after the grant was awarded. They will both be responsible for training any new study staff with regard to these specific DoD regulations.

b. Survey Measures

We will collect sociodemographic data and military experience, including military work history, combat exposure and deployment history. Our survey outcome measures will map on to our hypotheses to ensure we can evaluate between- and within-group effects. We will also ask which specific unit to which they are currently assigned so we can nest data within units and account for unit-level similarities (see Statistical Analysis below). Some of the hypotheses include data that are not from the surveys, such as training data (pre- and post-tests) (see Hypothesis 1), but we will track that information as well and merge with survey data. Table 1 includes a summary of proposed measures, sources, and when and from whom they will be collected. All proposed measures have been used in previous research and are psychometrically sound. A list of individual surveys items are included in our submission.

Hypothesis 2 will be evaluated with a measure assessing the leader's support for resilience within their unit. This measure, commensurate with previous work we have done (e.g., Family-Supportive Supervisor Behaviors and Sleep Leadership), will be developed based on tenets of the intervention. It will be measured from the perspective of the subordinates (e.g., "My platoon leadership team supports resilience in our unit"). Before reporting any

findings on Hypothesis 2, we will examine the psychometric properties of the adapted measure to ensure reliability and validity.

The bulk of the survey will be comprised of measures that assess Hypotheses 3 and 4. Hypothesis 3 is specific to perceptions around resilience factors such as social connectedness, resilience, and emotional regulation, whereas Hypothesis 4 is specific to perceptions around resilience-related outcomes including psychological, physical health, and well-being.

Table 1. Summary of Survey Measures

| Concept | Measure | Reference | # of Items | When collected* | Who* | Hyp. |
|---------------------------------|---|---|------------|-----------------|------|------|
| Leader Training Data | Leader reactions to training | Adapted from Hammer et al. (2011) | 3 | T | PLT | 1 |
| | Knowledge of resilience leadership | Adapted from Hammer et al. (2011) | 3 | T | PLT | 1 |
| Resilience-supportive Behaviors | RSLB measure adapted from VSSB and FSSB (Service Member's Ratings of Leaders) | Adapted from Perry et al. (2018) and Hammer et al. (2009, 2013) | 3-5 | S | SM | 2 |
| | Perceived Leader Effectiveness | Adapted from Ragins 1989 by WRAIR | 5 | S | SM | 2 |
| | General Supervisor Support | Yoon & Lim (1999) | 3 | S | SM | 2 |
| Emotion Regulation | Reappraisal and Emotion Suppression | Gross & John (2003) | 10 | S | SM | 3 |
| Resilience | Brief Resilience Scale | Smith et al. (2008) | 6 | S | SM | 3 |
| | CD-RISC (Brief Connor-Davidson Resilience) | Campbell-Sills & Stein (2007) | 10 | S | SM | 3 |
| Social Connectedness | Thwarted Belongingness Subscale | Hill et al. (2015). | 5 | S | SM | 3 |
| | Brief Loneliness Scale | Hughes, et al. (2004) | 3 | S | SM | 3 |

| | | | | | | |
|----------------------|--|-------------------------|----|--------|---------|---|
| Psychological Health | K6 Psychological Distress | Kessler et al. (2002) | 6 | S | SM | 4 |
| | Functional Impairment (WRAIR) | Herrell et al. (2014) | 13 | S | SM | 4 |
| | Perceived Stress Scale (PSS) | Cohen et al. (1983) | 4 | S | SM | 4 |
| | PTSD (PCL-5) | Price et al. (2016) | 4 | S | SM | 4 |
| | Dimensions of Anger (DAR-5) | Forbes et al. (2014) | 5 | S | SM | 4 |
| Physical Health | Sleep Problems | Jenkins et al. (1988) | 4 | S | SM | 4 |
| | General Perceived Health | Hobfoll et al. (2012) | 4 | S | SM | 4 |
| | Chronic Pain | Mattacola et al. (1997) | 1 | S | SM | 4 |
| | Alcohol misuse (AUDIT-C) | Bush et al. (1998) | 3 | S | SM | 4 |
| Unit Cohesion | Unit Cohesion | Williams et al. (2016) | 8 | S | SM | 4 |
| Demographics | Brief Combat Exposure | WRAIR | | T S | PLT, SM | |
| | Unit info, age, rank, gender, Relationship Status, # of Children, Years in military, deployment history, Months in platoon | | | T S | PLT, SM | |

**NOTE: T = Training; S = Survey; PLT = Platoon Leadership Team; SM = Service Member*

c. Sharing of Results with Subjects

We currently do not have plans to share results with participants participating in the survey. Leaders in the treatment group will receive the results of their pre- and post-test on the training. Results of the study will be shared with the leadership at JBLM, but only at an aggregate level.

8. Data Analysis

a. Statistical Plan and Data Analysis

The data for this study will be generated from a randomized controlled trial with all participating leaders and soldiers (in non-support units) within the participating units randomly assigned (by battalion) to either an intervention or usual practice control condition. Standard general linear and generalized linear mixed model approaches for clustered designs (i.e., hierarchical linear models, multilevel models; Murray, 1998; Murray, Varnell, & Blitstein, 2004) will be used for data analysis for Hypotheses 2-4 to account for the clustered nature of the data. As these models are now widely used and understood and are available in numerous statistical software packages, our discussion here on the specifics of these analyses will be brief. For each hypothesis, link functions for these models will be determined by the scaling of each outcome variable. As study implementation (i.e., intervention-related and data collection activities) will occur at the level of the platoon within brigades, platoon-level random effects will be included in these statistical models. The evaluation of Hypothesis 1 will focus on leaders in the intervention condition providing a point estimate and confidence interval for the usefulness of the training and the change in training-related knowledge from pre- to post-training. Hypotheses 2-4 will focus on differences in the key study outcomes between the intervention and usual practice conditions for soldiers. For these latter models, we will use the outcome variable at baseline as a predictor in the model to adjust for unexpected imbalance across conditions and to increase the statistical power for and precision of parameter estimates (cf. Bodner & Bliese, 2018). Finally based on planned preliminary data analyses, the recruitment wave (i.e., block), rank, gender, unit type, marital status, and mental health symptoms of soldiers may be used as predictors in the statistical models to further increase statistical power or eliminate potential intervention effect bias. Of interest in these latter models is the direction, magnitude, and statistical significance of the parameter corresponding to the intervention condition indicator. As needed, depending on attrition and missing data, this basic generalized linear mixed model will be extended in the analysis of the study hypotheses as mentioned below (e.g., multiple imputation for missing predictor variable values, FIML estimation for missing outcome variable values).

b. Power Analyses

This section documents the power analyses we conducted for the planned analyses for Hypotheses 1-4.

Key factors for the power analysis are the likely size of the intervention effect and the degree of non-independence, quantified as an intra-class correlation, as leaders and soldiers are nested in platoons, given the expected number of platoons discussed above. Prior research with platoon-level implementation (e.g., Adler, et al., 2009; Adler, et al., 2015a; Adler, et al., 2015b) indicates platoon-level random effects are often considered small in size (e.g., ICCs < .04, except when the outcome involves a platoon-level construct such as cohesion). Although small, it is important to include these effects in the analysis models for the study hypotheses and to incorporate these random effects into the power analyses for the study hypotheses. In the power analyses, we assumed an ICC of .04 for the platoon-level random effects.

Hypothesis 1 assesses the perceived usefulness of the training as rated by the leaders that participate in the training. Our prior research involving similar leadership training (i.e., SERVe) indicated that 81% of the 928 trained leaders rated it as good or excellent and 95% rated it as useful to extremely useful for their work. Hypothesis 1 also assesses the increase in leader knowledge of the training material. Prior research indicates that these increases in knowledge are large [e.g., $d = 3.31$ in Anger, et al., unpublished; $d = 1.23$ in Hammer, et al. (2011)]. Using

the smaller of these effect size estimates for the power analysis for H1, we estimate power to be .99 in the current study.

Hypothesis 2 assesses the effect of the intervention on the soldiers' perceptions of their leaders on the targeted intervention behaviors. Estimates of the effect of similar leadership interventions on subordinate perceptions of targeted leadership behaviors indicate small positive effects [e.g., $d = .27$ in Crain, et al. (2018); $d = .39$ in Odle-Dusseau, et al. (2016)]. Using the smaller of these effect size estimates for the power analysis for H2, we estimate power to be .96 in the current study.

Hypothesis 3 assesses the effect of the intervention on the soldiers' resilience-related factors such as adaptive emotion regulation strategies, resilience, social connectedness and belongingness. Estimates of the effect of similar interventions on adaptive emotion regulation vary widely [e.g., $d = .26$ in Bentley, et al. (2018); $d = .30$ in Cameron, Carroll & Hamilton (2018); and $d = .90$ in Mahatmya, Thurston, & Lynch (2018)]. Estimates of the effect of similar interventions on prosocial connections tend to be small in size [e.g., $d = .205$ for organizational citizenship behaviors in Hammer, et al. (2016)]. Using the smallest of these effect size estimates for the power analysis for H3, we estimate power to be .80 in the current study.

Hypothesis 4 assesses the effect of the intervention on the soldiers' resilience-related outcomes such as psychological and physical health and well-being. Estimates of the effect of similar interventions on health outcomes tend to be small in size [e.g., $d = .26$ for physical health in Hammer, et al. (2011); $d = -.217$ for blood pressure in Hammer, et al. (2015)]. Using the smallest of these effect size estimates for the power analysis for H4, we estimate power to be .84 in the current study.

In summary, based on the expected sample sizes, participation and attrition rates, and effect sizes (i.e., from the research literature) we are adequately powered to test the 4 study hypotheses.

c. Missing Data and the Application of Intent-to-Treat

Missing data intermittently during the study and/or dropouts are inevitable and an issue faced by all longitudinal studies, although recent evidence indicates relatively low levels of attrition for randomized trials in a military context (Adler, Williams, et al., 2015). There is no consensus, however, on the optimal analytical strategy to analyze missing data. Using the standard missing data taxonomy (Rubin, 1987), we will follow the recommendations made by Nich and Carroll (1997, 2002) and conduct intent-to-treat analyses using three strategies. In the first strategy we will extend the multiple imputation method of Little and Yau (1996) to allow for non-monotone missing values, which could occur intermittently during the study period. Monotone missing patterns require subsequent variables to be missing once a variable is missing. We will impute unobserved outcomes based on study condition, observed subject-level covariates at baseline and observed follow-ups. Inferences will be made on imputed datasets using Rubin's method (Barnes, Lindborg, & Seaman, 2006; Rubin, 1996). Our second analytical strategy will consider selection models and pattern-mixture models (Michiels, Molenberghs, Bijns, Vangeneugden, & Thijs, 2002) based on different factorization of the joint distribution of the response variables and the missing patterns. As different strategies require different assumptions for the estimated treatment effects to be unbiased and some assumptions are not testable, comparisons of these strategies serve mainly as sensitivity analyses of their influence on the estimated key parameters of each Aim. A third strategy will consider the use of Full Information Maximum Likelihood methods in the analysis of incomplete data as implemented in several software programs (e.g., Mplus; Muthen & Muthen, 2007). As mentioned in the prior section, this study is adequately powered for an attrition rate of 20%.

9. Privacy, Confidentiality, and Data Security

Confidentiality:

- All devices that can link to OHSU or house OHSU data are required to have Symantec Whole Disk Encryption software installed. All data will be stored on secure, password protected servers.
- Methods of sharing data will NOT include the use of email or thumb drives, but rather by IRB approved methods, such as Box.com, which is sanctioned by OHSU's IRB.
- Any contact information, including mailing address, email and phone numbers for participants will be kept separate from any files containing survey data. We will only have this contact information from platoon leaders and unit POCs (not soldiers). Only a few key staff members will have access to these files with contact information, generally those who need to interact with participants for incentive payments or for reminders to complete a survey or training.
- If there is a reasonable expectation of harm to self or others, staff are expected to break confidentiality by reporting this to the proper authorities. This information is included in the Informed Consent.
- We have included a statement in the Informed Consent stating that representatives of USAMRMC (DoD) may review our study records to ensure we are compliant with our research protocols.

Disposition of Data:

- Electronic data will be stored primarily on the secure OHSU servers, which is encrypted and password protected.
- Any hard copies of data will be kept in a locked file cabinet in the project office, which is also locked when no one is present.
- De-identified data will be kept indefinitely on the secure servers at OHSU.
- Any contact information for participants will be destroyed at the end of the project.
- The project manager will be primarily responsible for ensuring data are secure and protocols are followed by all approved and trained staff.
 - We will have a data sharing agreement that details these protocols to ensure the confidentiality and integrity of the data. A signed copy stating they will comply with these protocols must be on file with the project manager before an individual is granted access to data, as well as a valid reason for having access (e.g., a paper proposal).
 - All individuals who will have contact with data and/or participants will have a copy of a record of Human Subjects training on file.

10. Provisions to Monitor the Data to Ensure the Safety of Subjects

We will prepare this if the study is deemed to be more than Minimal Risk.

11. Risks and Benefits

a. Risks to Subjects

Foreseeable risks:

Efforts will be made to minimize risks associated with this study. Minimal potential risks for participation include breaches of confidentiality associated with data collected for research purposes. In addition, there is a risk of psychological distress associated with the psychological distress survey measures. Additional potential, but not expected, risk is that a supervisor may be

upset about being contacted to participate in a study or may not like the training. Leaders can discuss these issues at any time with research staff.

Risk management and emergency response:

To mitigate potential distress related to the psychological well-being survey items, participants will be made aware that participation is completely voluntary and that they are welcome to not answer any questions participants find distressing or to withdraw involvement at any moment without consequence. On the information sheet, we will provide contact information for behavioral health resources at OHSU.

Confidentiality:

Several processes are put in place to mitigate against breach of confidentiality for survey and training data:

- All devices that can link to OHSU or house OHSU data are required to have Symantec Whole Disk Encryption software installed. All data will be stored on secure, password protected servers.
- Methods of sharing data will NOT include the use of email or thumb drives, but rather by IRB approved methods, such as OneDrive, which is sanctioned by OHSU's IRB.
- If we collect any contact information, including mailing address, email and phone numbers for participants will be kept separate from any files containing survey data. We will only have this contact information from department heads. Only a few key staff members will have access to these files with contact information.
- If there is a reasonable expectation of child abuse, staff are expected to break confidentiality by reporting this to the proper authorities. This information is included in the Informed Consent.
- In the event we have any hard copies of data, they will be kept in a locked file cabinet in the project office, which is also locked when no one is present.
- De-identified data will be kept indefinitely on the secure servers at OHSU.
- Any contact information for participants will be destroyed at the end of the project.
- The project manager will be primarily responsible for ensuring data are secure and protocols are followed by all approved and trained staff.
 - We will have a data sharing agreement that details these protocols to ensure the confidentiality and integrity of the data. A signed copy stating they will comply with these protocols must be on file with the project manager before an individual is granted access to data, as well as a valid reason for having access (e.g., a paper proposal).
 - All individuals who will have contact with data and/or participants will have a copy of a record of Human Subjects training on file.

The Study PI will also follow the University's guidelines for reporting any unanticipated events in a timely fashion and consult with compliance specialists at the university on appropriate responses or additional reporting as needed.

b. Potential Benefits to Subjects

For employees, there is no immediate, direct benefit. We expect that when we train leaders in mental health support, we also may enhance employees' psychological health and attenuate

traumatic situations that could lead to negative behavioral health outcomes. We anticipate that the training program serves as a primary prevention intervention that will have a positive impact on individual health behaviors, including psychological health, risky behaviors, and hazardous alcohol consumption. This training intervention will eventually have the opportunity of being extended and implemented more broadly. The study holds great promise for informing the implementation of evidence-based leadership training programs across workplace settings.

12. Multi-Site Coordination (delete if not applicable)

Portland State University is a co-investigation site on our grant; Dr. Leslie Hammer, PI for OHSU, also has a dual appointment at PSU and Dr. Cynthia Mohr is PI for PSU. All research activities will be overseen by OHSU staff, including recruitment, data collection, and training delivery. The PSU IRB is ceding oversight to OHSU's IRB. Any PSU research assistants will go through the same training as OHSU RAs. The PSU team will be working primarily in providing consultation and writing papers.

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