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TITLE: Evaluating the Impact of a High-Intensity Cognitive Agility Optimization Intervention in Special Operations Forces: A Randomized Comparative Effectiveness Trial

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14. ABSTRACT <p>Complex and unpredictable operational demands require U.S. Special Operations Forces members to be <i>cognitively agile</i>, to have the ability to deliberately adapt cognitive processing strategies in accordance with the dynamic shifts in situational and environmental demands. The broad objective of this study is to conduct a cluster randomized controlled trial (C-RCT) to compare the efficacy of the Special Operations Cognitive Agility Training (SOCAT) program compared with routine DoD "training as usual" (TAU) on cognitive flexibility, cognitive agility, social problem-solving, and overall functioning (primary outcomes) as well as measures of focus, openness, interpersonal efficacy, psychological well-being, cognitive distortions (including suicide-related cognitions), grit, and resilience (secondary outcomes). Relative to participants in the TAU condition, participants allocated to the SOCAT condition are expected to report greater improvements on primary and secondary outcome measures at 3- and 6-month follow-ups. Using block, stratified random assignment, groups of SOF members will be allocated to either (1) SOCAT + TAU or (2) TAU. A highly trained sports or cognitive-behavior-oriented psychologist with SOF-relevant experience will deliver the 4-hour SOCAT program. Participants in the TAU condition will receive routine DoD training. Primary and secondary outcomes will be assessed online at baseline, 3, and 6 months. A subset of participants in the SOCAT + TAU condition will complete 30-minute telephone interviews to explore factors contributing to increases, stagnation, and reductions in cognitive agility scores. SOCAT emphasizes optimal and stable cognitive performance across different contexts – as well as across various stages of the military lifecycle – to serve as a buffer against biopsychosocial vulnerabilities, environmental stressors, military operational demands, and mental health problems, including suicide.</p>					
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1. INTRODUCTION:

Members of the United States (U.S.) Special Operations Forces (SOF) face frequent deployments, changes in station, and relocation for training duties, and they must often make decisions under pressure and uncertainty. Increasingly complex and unpredictable operational demands require SOF members to be flexible and adaptable in the midst of ever-changing circumstances, both operationally and in the home environment. The overarching goal of this study is to assess whether an intervention designed to improve cognitive agility and dynamic decision making, called Special Operations Cognitive Agility Training (SOCAT), does, in fact, positively affect SOF members' cognitive agility, cognitive flexibility, social problem-solving, and overall functioning. The SOCAT program is a 4-hour interactive, culturally relevant, and evidence-informed training curriculum designed to enhance the three domains of cognitive agility: (1) focused attention, the capacity to zoom in and to avoid distraction; (2) openness, the ability to zoom out, search for, and process new information; and (3) cognitive flexibility, the capacity to switch from focus to openness depending upon which attentional strategy is more adaptive. SOCAT has been commissioned by the United States Special Operations Command (USSOCOM), and desired outcomes are in psychological, spiritual, social, and human performance functional domains in accordance with the Preservation of the Force and Family (POTFF) mission.

Specific Aims: (1) To assess the efficacy of SOCAT + TAU compared with TAU on cognitive flexibility, cognitive agility, social problem-solving, and overall functioning (primary outcomes) at 3- and 6-month follow ups; (2) To examine the efficacy of SOCAT + TAU compared with TAU on focus, openness, interpersonal efficacy, psychological well-being, cognitive distortions (including suicide-related cognitions), grit, and resilience (secondary outcomes) at 3- and 6-month follow-ups; (3) To qualitatively explore factors contributing to increases, stagnation, and reductions in cognitive agility scores among participants in the SOCAT + TAU condition.

Impact: This study directly addresses the Focus Area of Cognitive Performance Optimization. This funding mechanism provides a timely opportunity to evaluate the efficacy of SOCAT in advance of widespread dissemination across USSOCOM. SOCAT emphasizes optimal and stable cognitive performance across different contexts – as well as across various stages of the military lifecycle – to serve as a buffer against biopsychosocial vulnerabilities, environmental stressors, military operational demands, and mental health problems, including suicide.

2. KEYWORDS:

Cognitive Performance Optimization, Cognitive Agility, Special Operations Forces, Randomized Trial

3. KEY RESEARCH ACCOMPLISHMENTS:

What were the major goals of the project?

As instructed, in the section below, the major tasks and goals are listed. For each, we have indicated estimated percent completion.

- Major Task 1: Develop Cluster Randomized Controlled Trial (C-RCT) Study Protocol
 - Subtask 1: Prepare Regulatory Documents
 - Schedule monthly conference calls for key study collaborators (100%)
 - Finalize consent form and human subjects' protocol (50%)
 - Develop study forms, semi-structured interview script, database, randomization procedures, risk management guide, and regulatory binders (25%)
 - Coordinate with sites for appropriate Institutional Review Board (IRB) submissions (25%)
 - Submit amendments, adverse events, and protocol deviations as needed (0%)
 - Prepare and submit all applicable quarterly and annual reports (100%)
 - Coordinate with sites for annual IRB report for continuing review (0%)
 - **Milestone:** Local IRB approval at USUHS and study sites (0%)
 - **Milestone:** Hold regular meetings for study collaborators (100%)
 - Subtask 2: Hire and Train Study Staff for C-RCT
 - Interview, select, and hire SOCAT trainer and research assistant (50%)
 - Conduct training and competency and fidelity checks for SOCAT trainer and research assistant (50%)
 - **Milestone:** Study staff hired and trained (50%)
- Major Task 2: Conduct C-RCT
 - Coordinate with study staff for creation and maintenance of Consolidated Standards of Reporting Trials (CONSORT) flow diagram (0%)
 - Coordinate with sites for monitoring data collection and data quality (0%)
 - Screen potential participants at study sites and consent (0%)
 - Conduct online baseline assessments and randomize groups of participants to one of two conditions (0%)
 - **Milestone:** 1st group of participants consented, screened, and enrolled in C-RCT (0%)
 - Participants completed assigned condition (0%)
 - Conduct competency and fidelity ratings (0%)
 - Conduct supervision of SOCAT instructor and research assistant (0%)
 - Conduct blind follow-up assessments online at 3- and 6-months post-baseline (0%)

- **Milestone:** Enroll all participants (0%)
 - **Milestone:** Complete all 3- and 6-month follow-up assessments (0%)
- Major Task 3: Conduct Data Analysis
 - Subtask 1: Coordinate with sites for monitoring data collection and data quality
 - Collect data (0%)
 - Extract and clean data (0%)
 - Subtask 2: Determine efficacy of SOCAT+TAU relative to TAU on primary and secondary outcome measures
 - Perform all data analysis according to specifications, share output and findings with all study collaborators (0%)
 - Disseminate findings (abstracts, presentations, publications, DoD reports) (5%)
 - **Milestone:** Report findings from 3-month follow-up assessments (0%)
 - **Milestone:** Report findings from 6-month follow-up assessments (0%)
- Major Task 4: Conduct Semi-Structured Interviews with a Subset of SOCAT Participants Who Received SOCAT
 - Analyze pre-post data for participants who received SOCAT to identify participants for interviews (0%)
 - Conduct interviews with a subset of participants who received SOCAT (0%)
 - Analyze qualitative data to identify themes associated with receipt of SOCAT (0%)
 - **Milestone:** Report findings from semi-structured interviews (0%)

What was accomplished under these goals?

To make progress on meeting our major goals, we have completed the following activities in Year 1. First, we have had multiple conference calls and meetings with key study collaborators to discuss site selection, recruitment, and methodological considerations. We have worked with U.S. Special Operations Command (USSOCOM) and Preservation of Force and Family (POTFF) to identify study sites, and we sent a formal, written request to POTFF to identify sites in Quarter 2, at which time POTFF began distributing the request to USSOCOM commands.

Thus far, two study sites have been selected and approved by USSOCOM and POTFF: (1) Marine Forces Special Operations Command at Camp Pendleton in San Diego, CA (MARSOC West), and (2) Naval Postgraduate School (NPS) in Monterey, CA. Initial phone calls were conducted between the study team and site personnel during Quarters

2 and 3. In Quarter 3, Dr. Sarah Carter, our new study Co-Principal Investigator, visited both sites to meet with study collaborators and members of command. Study procedures including recruitment, randomization, and data collection considerations were reviewed and finalized. Modifications to the SOCAT curriculum and Training Guide based on feedback received from study sites were also completed. Overall, as a result of these site visits, formal letters of support from MASROC West and NPS were secured in Quarter 4. We are continuing to work with our USSOCOM and POTFF collaborators to identify additional study sites.

Also in support of our major goals, we have prepared the USUHS Institutional Review Board (IRB) protocol and supporting documents including study forms, semi-structured interview script, and randomization procedures. During Quarter 4, we consulted with NPS IRB and confirmed that a Department of Defense (DoD) Institutional Agreement for IRB Review (IAIR) is in place and that there will not be a secondary review required. We also confirmed that because USSOCOM does not have their own IRB, they will defer to the USUHS IRB. A consultation with USUHS IRB administrators indicated that DoD Instruction 3216.02 aims to “reduce redundancy with respect to reviews of studies by DoD” IRB and therefore, “it is the position of [Research Regulatory Oversight Office] that duplicate reviews of studies that have been approved by another DoD IRB are not permitted within [Office of the Under Secretary of Defense for Personnel and Readiness] institutions.” Thus, following USUHS IRB approval, the protocol will be sent for HRPO review and will we will not need to secure site-specific IRB approval to begin recruitment. Amendments will be made to the USUHS IRB protocol to add future study sites once additional letters of support are received.

Finally, during Year 1, we interviewed, selected, hired, and trained several study staff members. We are spending very conservatively and will hire additional staff members as the needs of this project advance.

What opportunities for training and professional development has the project provided?

Nothing to report

How were the results disseminated to communities of interest?

During Year 1 Quarter 2, Dr. LaCroix and two of our USSOCOM and POTFF collaborators, Colonel (Dr.) Mark Baggett and Staci Vileta, presented on Special Operations Cognitive Agility Training (SOCAT) at the DoD/VA Suicide Prevention Conference in Nashville, TN. The study team also submitted an overview of this project as part of a larger review paper in response to a call for submissions to support a special, public health issue of *Suicide and Life-Threatening Behavior*.

What do you plan to do during the next reporting period to accomplish the goals?

During Year 2, Quarter 1, we plan to submit the study IRB protocol to USUHS and HRPO and receive approvals. We will continue to work with key personnel and collaborators within USSOCOM and POTFF to identify additional study sites. Having said that, we may also decide that 2 study sites will provide us with the desired sample size in which case we will ask the sponsor for approval on this change. If additional study sites are identified, a member of the research team will conduct a site visit to meet with study collaborators and members of command. Study procedures including recruitment, randomization, and data collection considerations, will be reviewed and finalized for each site. If travel is not possible due to the coronavirus pandemic, these meetings will take place via virtual teleconferencing so that study procedures can be finalized and sites may be submitted as amendments to the USUHS IRB protocol. During the next quarter, we will also finalize the minor revisions to the SOCAT curriculum and Training Guide based on feedback received from study sites and begin to conduct training and competency and fidelity checks for SOCAT facilitators. In anticipation of recruitment beginning in summer 2020, study staff will continue to be trained in recruitment, consenting, randomization, and data collection procedures.

4. IMPACT:

What was the impact on the development of the principal discipline(s) of the project?

Nothing to report

What was the impact on other disciplines?

Nothing to report

What was the impact on technology transfer?

Nothing to report

What was the impact on society beyond science and technology?

Nothing to report

5. CHANGES & PROBLEMS:

Changes in approach and reasons for change

The following changes in approach have been made to meet the overall goals of the project while navigating methodological challenges:

- (1) Possible change in facilitation approach. We have considered that instead of using one SOCAT facilitator for all sites, we could use facilitators embedded within the sites, ideally two facilitators per site who will co-facilitate the program. The reasons for this include: (a) facilitators at MARSOC West have already been trained and observed delivering the program to fidelity during pilot-testing; (b) facilitators embedded within SOF will not require study funds to train or maintain; (c) facilitators chosen from within each site will have an established relationship with site personnel, including commanders and SOCAT learners; (d) a co-facilitation model, rather than a single-facilitator model, allows for one facilitator (e.g., a psychologist) to provide didactic instruction on cognitive performance-related content, and the other facilitator (e.g., a senior enlisted noncommissioned officer) to provide real-life, “boots-on-the ground” examples of application.
- (2) Change in selected sites. Originally we had proposed four sites: MARSOC East at Camp Lejeune, NC; United States Army Special Operations Command (USASOC) at Fort Bragg, NC; Naval Amphibious Base (NAB) at Coronado, CA; and 1st Special Operations Wing at Hurlburt Field, FL. However, after ongoing consultation with USSOCOM and POTFF, these sites have yet to agree to serve as study sites. Thus, the first two study sites that have been identified, approved by USSOCOM, and that have provided letters of support are MARSOC West at Camp Pendleton and NPS in Monterey, CA. We are continuing to work with USSOCOM and POTFF to secure additional sites but this may not be necessary if the two existing sites can meet our study’s recruitment goals.
- (3) Change in collecting identifiable data. In our project narrative, we had proposed to qualitatively explore factors contributing to increases, stagnation, and reductions in cognitive agility scores by identifying subgroups of participants who met those criteria based on quantitative data. However, after consultation with study sites, we have decided to collect quantitative data anonymously (but using answers to non-identifiable questions to link longitudinal responses). Thus, we will not know the personally identifiable information of participants who increased, stagnated, or reduced their cognitive agility scores over time. However, we have included a section on the consent form where participants can indicate whether or not they agree to be contacted in 6 months to provide feedback on the program. We will elicit information learners perceive as contributing to, or not contributing to, improved cognitive agility via qualitative interviews.

Finally, we have reached the conclusion that the original Statement of Work (SOW) provided at the time of the grant submission needs to be updated, particularly in light of the PI's maternity leave and the COVID-19 pandemic. We will provide a modified and more detailed SOW to the sponsor along with a request for a No Cost Extension within the next 90 days.

Actual or anticipated problems or delays and actions or plans to resolve them

Please note that the study faced three major challenges during Year 1:

- (1) Spending on this project was significantly delayed due to administrative procedures. The Notice of Fund Approval (NOFA) was approved by the USUHS Budget Office on May 4, 2019, and the approved NOFA was sent to the Principal Investigator on May 10, 2019. The cooperative agreement was approved and funds were received by HJF on August 25, 2019. The Principal Investigator was notified that funds were available on September 9, 2019. Thus, spending on this project was not able to begin until Quarter 3.
- (2) The Principal Investigator went on maternity leave in Quarter 2 and did not return until the end of Quarter 3. Dr. Su Yeon Lee-Tauler, originally a Co-Principal Investigator, also went on maternity leave in Quarter 4.
- (3) There have been a series of unexpected challenges relating to the coronavirus pandemic during Quarter 4, including school closings and staff reorganization to accommodate full-time telework. Our progress on this project along with other duties have been significantly impacted.

To mitigate these challenges, we have taken the following steps:

First, with the delay in funding, we moved forward with the hiring process so that candidates were ready to be hired as soon as the cooperative agreement was established and funds were available at HJF to hire personnel in Quarter 3. This allowed us to reach the milestone of hiring and training study staff in Year 1. We anticipate our spending to be on track with overall study projections, particularly as the study progresses to the data collection phase.

Second, we have continued to have regular communication with our study collaborators despite the above challenges, and we have worked with POTFF and USSOCOM to identify and secure letters of support from two study sites. Upon receipt of those letters in Quarter 4, we were able to complete a full draft of the study IRB protocol. We have recently formed a Risk Management working group within our program and we plan to solidify this section of the proposal during the next month. Upon the Principal Investigator's final review and approval, the protocol will be ready for submission to USUHS during the coming quarter. We are also continuing to work with our USSOCOM and POTFF collaborators to identify additional study sites but may decide to exclusively focus on our existing two sites.

Third, the USUHS study team has continually made progress toward major goals during the Principal Investigator's maternity leave through regular phone and email consultation. The Principal Investigator formally returned from maternity leave in Quarter 4 and has fully re-engaged in study-related activities. During her absence, two key study team members provided leadership – Dr. Jessica LaCroix and Dr. Sarah Carter. Given the significant role of Dr. Carter and her contributions, she has been asked to serve as the study Co-Principal Investigator along with Dr. Jessica LaCroix. Dr. Su Yeon Lee-Tauler, previously a Co-Principal Investigator, has been functioning as a Co-Investigator given her other commitments as well as her maternity leave beginning in Quarter 4. As a qualitative expert, Dr. Lee-Tauler is expected to significantly contribute to the success of this project at a later stage.

Finally, with regard to the challenges presented by the coronavirus pandemic, including school closures and mandatory telework guidance provided by USUHS, all study staff have completed HJF telework agreements and have moved off-site to perform full-time telework. The two Co-Principal Investigators have continued to discuss this project regularly via telephone and email, and the study team has been meeting regularly via virtual teleconferencing to discuss IRB-related considerations.

Changes that had a significant impact on expenditures

Spending was delayed due to administrative processes and did not begin until Year 1, Quarter 3. Thus, we are behind on projected spending, but we anticipate our spending to be on track with overall project projections.

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

Significant changes in use or care of human subjects

Nothing to report

Significant changes in use or care of vertebrate animals

Nothing to report

Significant changes in use of biohazards and/or select agents

Nothing to report

6. PRODUCTS:

- **Publications, conference papers, and presentations**

Journal publications

LaCroix, J. M., Walsh, A., Baggett, M. A., the Suicide Care, Prevention, and Research Initiative (Suicide CPR Initiative) Team, & Ghahramanlou-Holloway. (Under Review). Three Department of Defense-funded public health approaches to reduce military suicide. *Suicide and Life-Threatening Behavior*.

Books or other non-periodical, one-time publications

Nothing to report

Other publications, conference papers and presentations

LaCroix, J.M., Lee-Tauler, S.Y., Grammer, J., Baggett, M., Vileta, S., Trieu, T., Fox, A. M., Darmour, C., Finton, B., Bottema, J., Bowling, E., Hosak, M., Walsh, A., & Ghahramanlou-Holloway, M. (2019, August). *Universal approaches for military suicide prevention*. Panel presented at the Department of Defense/Veterans Health Administration Suicide Prevention Conference, Nashville, TN.

- **Website(s) or other Internet site(s)**

Nothing to report

- **Technologies or techniques**

Nothing to report

- **Inventions, patent applications, and/or licenses**

Nothing to report

- **Other Products**

Nothing to report

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Name:	Marjan G. Holloway, Ph.D.
Project Role:	PI
Researcher Identifier (e.g. ORCID ID):	https://orcid.org/0000-0001-8377-3698
Nearest person month worked:	6
Contribution to Project:	Oversees all scientific and administrative aspects of project
Name:	Jessica M. LaCroix, Ph.D.
Project Role:	Co-PI
Researcher Identifier (e.g. ORCID ID):	https://orcid.org/0000-0002-4040-4275
Nearest person month worked:	6
Contribution to Project:	Oversees all scientific and administrative aspects of project with PI and Co-PI
Name:	Sarah Bricker-Carter, Ph.D.
Project Role:	Co-PI
Researcher Identifier (e.g. ORCID ID):	https://orcid.org/0000-0003-4598-7091
Nearest person month worked:	6
Contribution to Project:	Oversees all scientific and administrative aspects of projects with PI and Co-PI
Name:	Su Yeon Lee-Tauler, Ph.D.
Project Role:	Co-I
Researcher Identifier (e.g. ORCID ID):	N/A
Nearest person month worked:	6
Contribution to Project:	Contributes to methodology, study execution, and qualitative research
Name:	Ayan Elmi.
Project Role:	Research Support Staff
Researcher Identifier (e.g. ORCID ID):	N/A
Nearest person month worked:	3
Contribution to Project:	Contributes to administrative and regulatory aspects of project
Name:	Kanchan Perera
Project Role:	Research Support Staff
Researcher Identifier (e.g. ORCID ID):	N/A
Nearest person month worked:	2.4
Contribution to Project:	Creates study database, manages data cleanup, data analysis, and reporting

Name:	Robert Wheeler
Project Role:	Research Support Staff
Researcher Identifier (e.g. ORCID ID):	N/A
Nearest person month worked:	2.4
Contribution to Project:	Leads regulatory aspects of project
Name:	Nate Kerr
Project Role:	Research Support Staff
Researcher Identifier (e.g. ORCID ID):	N/A
Nearest person month worked:	3
Contribution to Project:	Contributes to intervention design and implementation practices
Name:	Erin Cobb
Project Role:	Research Support Staff
Researcher Identifier (e.g. ORCID ID):	N/A
Nearest person month worked:	2.4
Contribution to Project:	Contributes to intervention design and implementation practices
Name:	Joseph Grammer
Project Role:	Research Support Staff
Researcher Identifier (e.g. ORCID ID):	N/A
Nearest person month worked:	3
Contribution to Project:	Assists with writing and editing
Name:	Andrea Euribe-Arellano
Project Role:	Research Support Staff
Researcher Identifier (e.g. ORCID ID):	N/A
Nearest person month worked:	3.6
Contribution to Project:	Serves as a military subject matter expert given prior Marine Corps service
Name:	Eric Ekman
Project Role:	Research Support Staff
Researcher Identifier (e.g. ORCID ID):	N/A
Nearest person month worked:	3.6
Contribution to Project:	Assists with task management and literature searches

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

Nothing to report

What other organizations were involved as partners?

<i>Organization Name:</i>	HQ USSOCOM, POTFF
<i>Location of Organization:</i>	MacDill Air Force Base, Tampa, FL
<i>Partner's contribution to the project:</i>	Collaboration

<i>Organization Name:</i>	MARSOC West
<i>Location of Organization:</i>	Camp Pendleton, San Diego, CA
<i>Partner's contribution to the project:</i>	Collaboration, Study Site

<i>Organization Name:</i>	NPS
<i>Location of Organization:</i>	Monterey, CA
<i>Partner's contribution to the project:</i>	Collaboration, Study Site

8. SPECIAL REPORTING REQUIREMENTS

QUAD CHART: The study Quad Chart has been updated and is being submitted with this report.

9. APPENDICES

Not applicable