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TITLE: **"**A Randomized Clinical Trial of the Collaborative Assessment and Management of Suicidality vs. Enhanced Care as Usual for Suicidal Soldiers"

PRINCIPAL INVESTIGATOR: David A. Jobes, Ph.D., ABPP

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14. ABSTRACT

This Randomized Clinical Trial (RCT) compares the effectiveness of CAMS versus Enhanced Care As Usual (E-CAU) in a sample of n = 148 active-duty Army Soldiers who are experiencing suicidal ideation and/or behaviors. Research clinicians for both treatment conditions were recruited from the Army Research Site (ARS), Fort Stewart, GA, and were trained and monitored for fidelity and adherence to their respective treatment condition by the study staff. Participants were recruited from a number of sources at the ARS including the outpatient behavioral health clinic and the inpatient unit. Approvals from all IRB committees involved in the study have been obtained. Participant recruitment began in MAY 2012 for the training phase of the study; intent-to-treat phase of the study began in FEB 2013; recruitment of all participants was completed in DEC 2014; follow-up 12 assessments after start of treatment are on-going.

15. SUBJECT TERMS
Suicide Risk Assessment, Suicide Risk Management, and Suicide-Specific Treatment

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INTRODUCTION: Narrative that briefly (one paragraph) describes the subject, purpose and scope of the research.

This study is designed to investigate the effectiveness of a novel clinical intervention developed by the PI called the Collaborative Assessment and Management of Suicidality (CAMS). CAMS is not a new psychotherapy. Rather, CAMS is a therapeutic clinical framework with a distinct clinical philosophy and a set of structured procedures that enhance the therapeutic alliance and increase treatment motivation in the patient. This Randomized Controlled Trial (RCT) is comparing the effectiveness of CAMS versus Enhanced Care As Usual (E-CAU) in a sample of n = 148 active-duty US Army Soldiers who are experiencing suicidal ideation and/or behaviors. Research clinicians for both treatment conditions were recruited from the Army Research Site (ARS), Fort Stewart, GA, and have be trained and monitored for fidelity and adherence to their respective treatment condition by the study staff. Participants were recruited from a number of sources at the ARS to include the behavioral health clinic and the inpatient unit. The goal of this study is to determine if CAMS is more effective than E-CAU in reducing suicidal ideation and behaviors (and various secondary variables such as overall symptom distress, Emergency Department utilization, etc.) in comparison to Soldiers who receive E-CAU at this ARS.

BODY: This section of the report shall describe the research accomplishments associated with each task outlined in the approved Statement of Work. Data presentation shall be comprehensive in providing a complete record of the research findings for the period of the report. Provide data explaining the relationship of the most recent findings with that of previously reported findings. Appended publications and/or presentations may be substituted for detailed descriptions of methodology but must be referenced in the body of the report. If applicable, for each task outlined in the Statement of Work, reference appended publications and/or presentations for details of result findings and tables and/or figures. The report shall include negative as well as positive findings. Include problems in accomplishing any of the tasks. Statistical tests of significance shall be applied to all data whenever possible. Figures and graphs referenced in the text may be embedded in the text or appended. Figures and graphs can also be referenced in the text and appended to a publication. Recommended changes or future work to better address the research topic may also be included, although changes to the original Statement of Work must be approved by the Army Contracting Officer Representative. This approval must be obtained prior to initiating any change to the original Statement of Work.

In the course of Year 1, the research team was primarily engaged in gaining IRB approvals from each of the IRB committees involved in this study: the Dwight D. Eisenhower Army Medical Center (DDEAMC), the Department of Veterans Affairs Veterans Integrated Service Network 19 Mental Illness Reseach, Education, and Clinical Center (VA VISN 19 MIRECC), the University of Washington (UW), and The Catholic University of America (CUA). The research team was successful in obtaining approval from all of the IRB committees, but this process took much longer than anticipated and pushed back the hiring and training of staff and therapists, as well as the recruitment of participants, approximately one year later than initially proposed in the Statement of Work (SOW). Since initial approval was gained form all involved IRB's during Year 1 of the study, we have subsequently applied for and maintained

continuous approval from all IRB's in Years 2, 3, 4, and during the current no cost extension (NCE) year.

Given this delay in the initial execution of the RCT, at the conclusion of Year 4 of the study team applied for, and was approved by MOMRP/TATRC to extend the study for a 12-month NCE period. The 12-month NCE period has been approved from 15 MAR 2015 through 14 MAR 2016. The study team anticipates completion of all study tasks and deliverables no later than the end date of the NCE on 14 MAR 2016. This includes analysis of all data, and preparation and submission of findings from the RCT to appropriate scholarly journals for publication.

The initially proposed timeline of activities is included below:

Timeline of Study Activities Over Four Years																
	Year 1				Year 2				Year 3				Year 4			
	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
Hiring and training of staff and therapists	X				X				X							
Training of therapists		X														
Recruitment of training cases		X	X													
Supervision of therapists adherence		X	X	X	X	X	X	X	X	X	X	X	X			
Recruitment of clinical trial cases			X	X	X	X	X	X	X	X	X	X				
Baseline assessments			X	X	X	X	X	X	X	X	X	X				
Clinical trial treatment conducted			X	X	X	X	X	X	X	X	X	X	X			
Follow-up assessments			X	X	X	X	X	X	X	X	X	X	X	X	X	X
Data entry and cleaning			X	X	X	X	X	X	X	X	X	X	X	X	X	X
Data analysis					X	X	X	X	X	X	X	X	X	X	X	X
Dissemination of results									X	X	X	X	X	X	X	X

The following table is a current updated timeline of the project. Due to the delays in gaining IRB approvals discussed above, initial difficulties with in-processing the study staff onto the ARS, administrative and practical challenges at the ARS, and difficulties

with retention among the clinical research therapists due to the high turnover rate of staff at the ARS, the table below is an updated timeline of study activities that reflects the impact of these challenges to conducting the study as per the original proposed timeline:

Timeline of Study Activities Over Four Years (Plus 12-Month No Cost Extension [NCE])																				
	Year 1				Year 2				Year 3				Year 4				NCE Year			
	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
Hiring and training of staff and therapists	X				X				X				X							
Training of therapists					X	X														
Recruitment of training cases					X	X	X													
Supervision of therapists' adherence					X	X	X	X	X	X	X	X	X	X	X	X	X			
Recruitment of clinical trial cases					X	X	X	X	X	X	X	X	X	X	X	X				
Baseline assessments					X	X	X	X	X	X	X	X	X	X	X	X				
Clinical trial treatment conducted					X	X	X	X	X	X	X	X	X	X	X	X	X			
Follow-up assessments						X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Data entry and cleaning					X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Data analysis									X	X	X	X	X	X	X	X	X	X	X	X
Dissemination of results													X	X	X	X	X	X	X	X

Participant recruitment for the study was completed in December 2014. After participant recruitment was completed, and the data were cleansed and checked for any errors, study staff noted that the total number of participants recruited was n = 148 rather than the original planned sample size of n = 150. This was due to an error in the database transposing two participants from the pilot phase of the RCT in Year 1, into the actual intent-to-treat (ITT) sample. The study team conducted power analyses with the sample size of 148 participants and compared that to the original power analyses conducted for an expected sample size of 150 participants. The team found negligible

differences in power between the sample sizes and determined that a final sample size of n = 148 participants provided more than sufficient power for subsequent statistical analyses of the data.

Please see the study's CONSORT chart listed in the Appendix for further, specific information on participant recruitment, randomization, treatment retention, and assessment follow-up.

At the time of this report, all study treatments for both experimental and control condition participants has concluded. While research clinicians were still actively providing treatment to participants, Dr. Katherine Comtois, the Co-PI from the University of Washington, and the on-site Participant Coordinator, Ms. Gretchen Ruhe, provided regular consultation to and have regular interactions with the E-CAU therapists to ensure that the study team provided needed resources for them to successfully participate in the study. The CUA team viewed 10% of all E-CAU therapy sessions to ensure fidelity to treatment condition and make sure that research clinicians are in fact providing E-CAU to study participants as outlined in the project's statement of work (SOW). Throughout the study, the E-CAU clinicians did in fact provide E-CAU, and at no time did they provide the experimental treatment (CAMS).

The CUA team did not need to conduct further CAMS trainings for the CAMS research clinicians during the current project year. The CUA team and the on-site Participant Coordinator provided regular consultation to and had regular interaction with the CAMS therapists to ensure that the study team provided needed resources for them

to successfully participate in the study. Each week the CUA team viewed the CAMS therapy sessions to further ensure fidelity and satisfactory adherence to the CAMS intervention that is being provided to the study participants.

Throughout Year 4, the entire study team held bi-monthly conference calls to coordinate and evaluate study progress. Once participant recruitment was completed in DEC 2014, the study team determined that a monthly conference call was appropriate to maintain focus on follow-up assessments and data analyses. These team consultation calls focused on further refining the procedures for administering the baseline and follow-up assessments with research participants, refining and making the implementation of the treatment protocols and the CAMS training manual more user-friendly, as well as problem-solving general administrative and site-specific difficulties that have arisen at different points in the project year. A monthly recruitment call was also conducted by a sub-set of study personnel through first few quarters of Year 4 to more closely monitor recruitment of study participants (and clinicians) and problem-solve ways to enhance existing recruitment procedures. This call was discontinued in the final quarter as the research team successfully recruited its total intent-to-treat sample size of 148 participants in December 2014.

During the project year, as the team neared recruitment of the final participants, the need for the clinician offsets (FTEs hired and paid through the study to work in the ARS and offset research clinician study-related efforts) was reduced. Contracts for the study clinician offsets ended in January 2015. Currently, only the participant

coordinator remains as a contract employee of the study, remaining on-site at the ARS to conduct follow-up assessments with participants and to conduct study close-out activities. The Participant Coordinator conducted intensive training with the UW team and continues to conduct daily conference calls with the project's recruitment and assessment team at UW. Additionally, the Participant Coordinator has regular contact with the study PI that includes regular phone calls to monitor the study's progress and problem-solve any issues or pending concerns pertaining to the study.

The PI made a site visit to the ARS during the project year to provide 6 hours of continuing education training in clinical ethics (not related to study content) to all study clinicians in an effort to further reinforce their participation in the study. During this visit, the PI was also able to further evaluate progress at the study site and provide consultation and support to the on-site study team. In addition, the UW Co-PI made a site visit to the ARS to further evaluate and aid in coordination and recruitment of Soldier participants and study clinicians. In addition she met with on-site Army leadership at the ARS to further problem-solve friction points seen at various clinics from which the study was recruiting. There had been a plan to add Hunter Army Airfield (HAAF) as a potential research study site, but space constraints, turnover in leadership, and lack of personnel engagement delayed this prospect.

The task list from the project's SOW is listed below in an effort to provide a task by task status update on progress made in the study, as well as to provide updated

revisions to the anticipated timeline of various tasks. Status updates and revised timelines are included in italics following the original task from the SOW.

Task 1: Prepare study manuals for CAMS and Enhanced Care as Usual (E-CAU) Groups. (Year 1, Months 1-6).

Completed. Following the initial trial implementation, minor revisions to these manuals have been made in accordance with feedback from the research clinicians and from the CUA fidelity and adherence team who have been evaluating all sessions in accordance with the SOW. These minor revisions have included obtaining IRB approval to have family members engaged in treatment if the provider determines that this is clinical indicated and to update the CAMS Rating Scale to better capture some aspects of the experimental treatment in the manner that the research clinicians are being evaluated for adherence to the treatment.

1a: Review existing written materials regarding CAMS. (Year 1 Months 1-3)

Completed.

1b: Review existing Usual Care Model at **"*Army Research Site" (hereafter referred to as ARS)*** (Year 1 Months 1-3)

Completed.

1c: Regular (e.g., 2 per month) group meetings regarding key manual components (Year 1 Months 1-5)

Completed.

1d: Condense key components and write text of first drafts (Year 1 Months 2-3)

Completed.

1e: Review of drafts by senior research team members, outside experts, and study clinicians for 1) readability, 2) comprehensiveness, and 3) feasibility (Year 1 Months 3-4)

Completed.

1f: Manual revision based upon feedback to produce final version (Year 1 Months 5-6)

Completed.

Task 2: Hire and train study staff; modifications with training cases. (Year 1 Months 1-6)

On-going. The 1.0 FTE Participant Coordinator, the 1.0 FTE Backfill Clinician, and the 0.8 FTE Backfill Clinician were all hired, in-processed at the ARS, became fully credentialed at the ARS, and received all necessary training during Year 2. The final study hire, the 1.0 FTE Research Assistant was hired in the final quarter of Year 2 and it was fully in-processed and credentialed at the ARS, as well as fully trained in her duties and responsibilities in Year 3.

2a: Select or hire Participant Coordinator (PC), and study therapist FTE to supplement existing *ARS* staffing for study. University of Washington (UW) Co-PI and Research Coordinator (RC) hire research assistant (RA) for follow-up assessments. (Year 1 Month 1-3)

Participant Coordinator, Research Assistant, and study therapists (1.0 and 0.8 FTE Backfill Clinicians) have been hired and trained. The 1.0 FTE Research Assistant, 1.0 FTE Backfill Clinician, and 0.8 Backfill Clinician completed their contracts in Year 4, Month 9, and are no longer working at the ARS because the study team successfully completed all participant recruitment.

2b: UW CO-PI and RC train PC and RA in human subjects and other research protections, study policies and procedures, and administering study assessments. (Year 1 Month 2-3)

Completed.

2c: UW Co-PI and RC train ***ARS*** PC in recruiting procedures and develop adaptations to fit *ARS* context and environment (Year 1 Months 1-6)

Completed.

2d: Study therapists are matched to treatment condition and PI and CUA staff train CAMS therapists in CAMS as well as human subjects and other research protection and study policies and procedures (Year 1 Month 3)

Completed.

2e: PC begins recruitment and assessment procedures for training cases in CAMS. UW staff work with PC on effectiveness of recruitment procedures in ***ARS*** context and develop adaptations as needed prior to RCT intent to treat cases. (Year 1 Month 3-6)

Completed.

2f. CAMS and E-CAU clinicians receive training with draft version of manuals and provide feedback to senior research team members (Year 1 Month 3)

Completed.

2f: CAMS study therapists see training cases with supervision and adherence ratings from PI and CUA staff. Modifications to CAMS appropriate to ***ARS*** context are identified, implemented, and codified in supplementary manual for clinical trial (Year 1 Month 3-6)

Completed.

2g: Enhanced Care as Usual (E-CAU) study therapists see training cases to pilot the intervention. Modifications to E-CAU appropriate to ***ARS*** context are identified, implemented, and codified into E-CAU treatment manual. (Year 1 Month 3-6)

Completed.

2h: UW RA begins follow-up assessments with training cases and UW Co-PI, and RC (with consultation from PI, co-PIs, and statistical consultant) develop any modifications to the tracking and assessment procedures, if needed. (Year 1 Month 4-6)

Completed. Follow-up assessments are on-going as the follow-up period is 12 months following recruitment.

2i: UW Co-PI and Denver VA MIRECC Co-PIs (with consultation from PI, ***ARS*** Co-PIs, RC, PC, and statistical consultant) evaluate feasibility and value of assessment battery as implemented with training cases and make needed changes in format, length, etc. to assure a viable assessment battery is established (Year 1 Month 3-6)

Completed.

2k: Final versions of CAMS and E-CAU manuals reviewed with study clinicians (Year 1 Months 5 -6)

Completed. The study team modified the adherence scale (CAMS Rating Scale) for the CAMS condition and submitted a revision for IRB approval which occurred in the second quarter of Year 3. The CAMS Rating Scale-3 is now fully implemented.

Task 3: Implementation of clinical trial and follow-up of Soldiers of Concern (SOC) (Year 1 Month 7 through Year 4 Month 12)

All 148 intent-to-treat participants have been recruited and treated to completion.

3a: PC recruits study participants and assures fast and efficient randomization and matching to study therapists for first session (Year 1 Month 7 through Year 4 Month 12)

Completed.

3b: CAMS and E-CAU therapists follow their respective manuals to treat randomized participants (Year 1 Month 7 through Year 4 Month 12)

Completed.

3c: UW team conducts follow-up assessments ***using the University of Washington Risk Assessment Protocol (UWRAP) to address suicide risk during follow-up*** *(*Year 1 Month 8 through Year 4 Month 12).

On-going.

3d: ***PI and CUA staff will*** conduct ongoing adherence evaluation of CAMS study therapists and provide feedback and supervision to assure CAMS therapists remain adherent—***consultation by MIRECC Co-PI's will be used on complex cases (e.g., TBI and PTSD)*** (Year 1 Month 7 through Year 4 Month 3).

Completed.

3e: With consultation from statistical consultant, ***the UW site*** establishes final database systems and data entry and cleansing procedures appropriate to data collected. ***All pre-treatment and adherence data will be transported by HIPAA secure means to UW site to be entered and maintained.*** Data entry occurs in an ongoing basis (Year 1 Month 7 through Year 4 Month 12).

On-going.

3f: With assistance of the PC and *ARS* co-PIs establish and implement procedures for reviewing Army records for study participants and extracting this data ***which will be transported by HIPAA secure means to UW site. This data will be matched to study collected data in consultation with UW PI and statistical consultant.*** With consultation of PI, Co-PIs, and statistical consultant, the data and procedures used to extract medical records will be reviewed and modifications made, if needed, to assure viable data extraction access and procedures are established (Year 2 Month 1-12).

This process is on-going and the policies and procedures that have been established in coordination with the Army personnel at the ARS will be updated as required during the implementation of the study.

Task 4: Hiring and training of additional or replacement staff, if needed (Years 2-4)

4a: PI provides CAMS training to any additional or replacement CAMS study therapists, if needed, to assure sufficient flow through clinical trial (Year 2 Month 1 and Year 3 Month 1). Supervision of CAMS therapists will continue. (Year 2 Month 1 through Year 4 Month 3).

Completed. Throughout the course of the study, supervision and consultation with CAMS therapists was on-going, with the CUA team providing 1-hour long, weekly conference calls to the CAMS therapists.

Task 5: Data analysis and dissemination of results (Years 3 and 4)

On-going.

5a: Aim I: In consultation with PI, Co-PIs, and statistical consultant, Denver VA MIRECC Co-PIs will analyze data from ongoing follow-up of suicidal individuals enrolled in trial to establish a recommended assessment battery from the briefest possible screening tools through an expanded assessment. Data will be compared with that collected in Army record to evaluate the reliability and validity of Army measures as compared to full research battery. (Years 3 and 4)

On-going. Initial data baseline analyses are on-going and will be presented at the upcoming 2015 American Association of Suicidology conference in Atlanta, GA. Several journal articles using data from this study are also planned for an upcoming

issue of Military Behavioral Health at the invitation of the journal editors. Please see the Appendix for the current list of planned presentations and scholarly journal articles that will report and disseminate findings from this study. These presentations and publications are still being developed, and the data are still being analyzed, so only brief, tentative summaries of each of these projects is presented in this annual report.

5b: Presentations, reports, publications prepared reflecting analyses of Aim 1 (Years 3 and 4)

On-going. Please refer to Appendix.

5c: Aim II: In consultation with PI, co-PIs, and statistical consultant, Denver VA MIRECC Co-PIs will analyze clinical trial data to evaluate effectiveness of CAMS from hypotheses (Year 4)

On-going.

5d: Presentations, reports, and publications will be prepared reflecting the clinical trial results of Aim II hypotheses. (Year 4)

On-going. Please refer to Appendix.

KEY RESEARCH ACCOMPLISHMENTS: Bulleted list of key research accomplishments emanating from this research.

- The research team finalized a new version of the “Suicide Status Form” (SSF) to be used in this study, the SSF-IV. The SSF is the primary clinical tool used in CAMS for assessing, managing, treating, and tracking suicidal risk in patients.

- The research team developed a revised manual for conducting CAMS with patients who are suicidal (tailored to a military population).

- The research team has developed a revised version of the “CAMS Rating Scale” (CRS-3) which is the key adherence tool used by the study team to ensure fidelity in the research design and adherence to CAMS in the experimental condition. On-going psychometric research on the CRS-3 is underway with the goal of publishing data on the validity and reliability of the tool.

REPORTABLE OUTCOMES: Provide a list of reportable outcomes that have resulted from this research to include: manuscripts, abstracts, presentations; patents and licenses applied for and/or issued; degrees obtained that are supported by this award; development of cell lines, tissue or serum repositories; infomatics such as databases and animal models, etc.; funding applied for based on work supported by this award; employment or research opportunities applied for and/or received based on experience/training supported by this award

There are not yet major reportable outcomes associated with this study as the intent-to-treat phase of this project began in the 4th quarter of the previous project Year 2 (FEB 2013) and full study recruitment was just completed in the previous quarter. However, in the coming year it is anticipated that a preliminary baseline cross-sectional study will be conducted with a subset of combined pilot and intent-to-treat cases to provide a dataset for a CUA study team member's doctoral dissertation. This preliminary investigation will be the first to directly use data from the RCT and will provide a helpful means to further establish and refine our baseline research methodology and provide some initial cross-sectional findings related to a sub-set of the entire study sample.

Along these lines, various other baseline and cross-sectional studies are now being developed from the study data. For example, at last year's annual conference of the American Association of Suicidology (9-12 April 2014) the UW Co-PI led a Research Symposium entitled "Predictors of Suicidality Among Help-Seeking Active Duty Military and OEF/OIF Veterans: Analysis of Baseline Data from Current Clinical Trials" wherein the PI and another Co-PI presented. To our knowledge this collaborative research effort is unique in the history of suicide research in that PI's across six DOD-funded studies have collaboratively "pooled" their de-identified subsets of their respective data into a larger

dataset in an effort to better understand suicidal risk among cross section of active duty service members (across branches, including reserve components) and veterans (this collaborative research activity was approved by respective IRB's involved in with these studies). By pooling shared data a total sample of n=1465 was created that will be further analyzed in relation to various quasi-independent variables developed by the PI's of these studies. For example this research can investigate suicide ideation and behaviors in relation to gender effects, the role of suicide attempt behaviors (prior to and subsequent to enlistment and deployments), pre-enlistment behavioral health histories, and the potential impact of combat, trauma, and traumatic brain injuries. This collaborative baseline research should yield critical information to further inform our research efforts. But beyond research, this kind of pooled investigation will provide vital data relevant to clinical practices, systems of care, and may provide invaluable guidance to DOD and VA leadership as to how to best respond to the myriad challenges of preventing active duty service member and veteran suicides.

CONCLUSION: Summarize the results to include the importance and/or implications of the completed research and when necessary, recommend changes on future work to better address the problem. A "so what section" which evaluates the knowledge as a scientific or medical product shall also be included in the conclusion of the report.

In conclusion, this study—referred to as the “Operation Worth Living” (OWL) project—is poised to make valuable contribution to the scientific knowledge-base about the potential *causal* effectiveness of a relatively new suicide-specific intervention for treating suicidal Soldiers. The OWL study got off to a slow start due to considerable IRB-related concerns and various administrative and practical challenges of setting up the study infrastructure and all the related study procedures. Having worked through these challenges, we became fully engaged and operational and have now completed the recruitment of all intent-to-treat study participants who were enrolled, randomized, and treated in both arms of this randomized controlled trial (n = 148). Currently, we are conducting follow-up assessments (out to 12 months following the start of treatment) of the remaining participants in our intent-to-treat sample. We are currently in the first quarter of a 12-month no cost extension (NCE) year. Careful and prudent management of our budget will provide sufficient funding support to meet all study objectives stated in the SOW within the final NCE year of research. Beyond the potential effectiveness of CAMS as a suicide-specific intervention, this study is among the first to recruit and train on-site clinicians in a new approach where adherence to the new intervention was routinely achieved by their site provider with their first CAMS patient in four sessions. While other evidence-based interventions show great promise for treating suicidal risk at military treatment facilities, none have the flexibility or ease of training to adherence that CAMS appears to have. Finally, beyond studying the potential effectiveness of CAMS, the

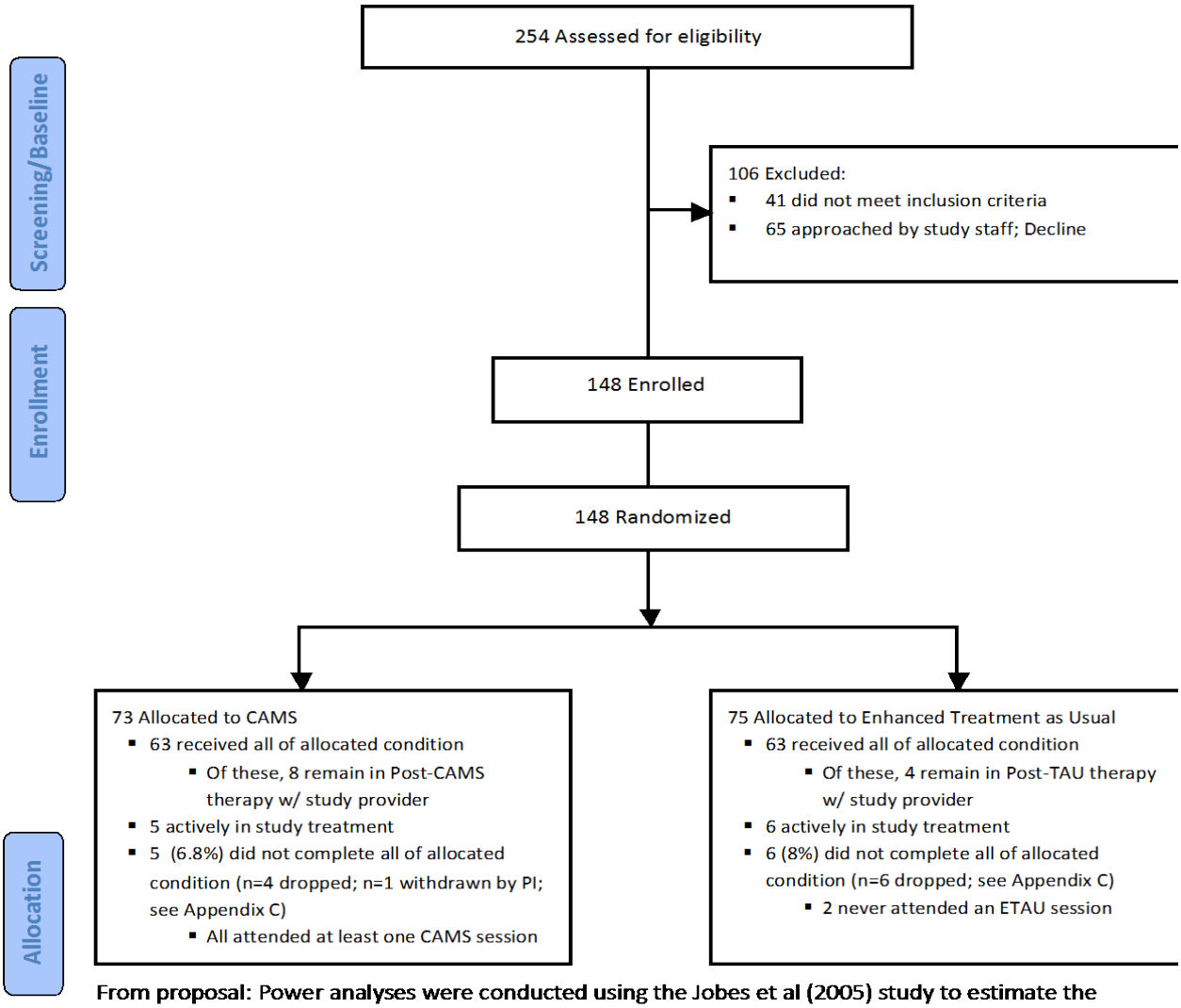
promise of using our data in collaborative pooled research across other DOD-supported studies represents a potentially seminal contribution to the field of suicide prevention with significant implications for impacting suicide deaths among those who have served the nation as members of the United States military.

REFERENCES: List all references pertinent to the report using a standard journal format (i.e. format used in *Science, Military Medicine*, etc.).

None at this time.

APPENDICES: Attach all appendices that contain information that supplements, clarifies or supports the text. Examples include original copies of journal articles, reprints of manuscripts and abstracts, a curriculum vitae, patent applications, study questionnaires, and surveys, etc.

CONSORT Flow Diagram for Operation Worth Living (OWL) *Intent-to-Treat Phase*



From proposal: Power analyses were conducted using the Jobes et al (2005) study to estimate the effect size for detecting a difference on our primary analysis related to the number of sessions required to reach resolution of suicidality between the control and experimental conditions. Calculations relying on the reported means and standard deviations yielded a critical effect size of .33 (Kraemer & Thiemann, 1987). Since the variance of the two samples was known, the current study requires 68 subjects to have 80% power of detecting a difference using a one-tailed two independent sample *t-test* with an alpha level of .05. A total intent-to-treat sample of 150 will give us 99% power to detect a mean difference of 4 weeks (*SD* = 2) in time to resolution. Assuming a 25% drop-out rate, which is consistent with previous studies of CAMS, a final sample of 112 would give us 95% power to detect this same difference.

The following are abstracts submitted for presentation at the 2015 American Association of Suicidology (AAS) Conference in Atlanta, GA. This conference will take place in April 2015.

1. Presentation Title: *Feeling trapped inside and outside: Entrapment levels and suicide risk in military, incarcerated, and college student populations*

Authors: Josephine Au, BS and David A. Jobes, PhD

Abstract: People experience a sense of entrapment when they want to change or flee from a situation but lack the capacity to do so (Taylor, Gooding, Wood, & Tarrier, 2011). Additionally, Shneidman (1996) and Baumeister (1990) conceptualize the desire to escape as being a major impetus of suicide. This is a natural experimental study that draws data from three settings that vary inherently in escape potential, which is a modulating factor to one's perceived level of entrapment (Williams, 1997). Based on the suggestion of Gilbert and Allan (1998), we divide entrapment into two subcategories: external entrapment (i.e., by external circumstances) and internal entrapment (i.e., by inner thoughts and feelings). Level of external entrapment is determined by the escape potential from an institution, with prison representing the highest degree of inescapability, followed by the military, and then college. As for internal entrapment, qualitative data of suicidal patients from the three samples regarding various reasons for dying (RFD) as recorded on the Suicide Status Form (SSF; Jobes, Kahn-Greene, Greene, Goeke-Morey, 2009) will each be manually coded as related or not related to desire to escape. We hypothesize that people with higher levels of external entrapment will also experience higher levels of internal entrapment, and that these two levels of entrapment will together predict the subject's overall suicide risk indicated in the SSF.

Research Aims: To understand the role that entrapment plays in predicting suicide risk based on three populations that vary in degree of escape potential.

Methods**:** Qualitative data of RFD among suicidal patients in prison, in the military (N = 75), and in college (N = 180) will be drawn and manually coded into four categories based on a coding manual developed by Jobes (2006): escape from the past, the pain, the subject's responsibilities, and a general category. The data will be analyzed as a 3x2 factorial ANOVA, with the first independent variable being the institution and the second one being the presence of an escape-related RFD. A post-hoc analysis will also be conducted to clarify the specific reasons for escape.

Results: The results of this study will elucidate whether external entrapment and entrapment in internal states predicts risks for suicide.

Conclusions**:** The knowledge gained from this study will shed light on the differentiated risk for suicide among various populations and the underlying mechanisms for suicide.

What the work adds to our knowledge on the topic: Little is known regarding how entrapment relates to suicide risk. The present study examines how various populations may experience various levels of external and internal entrapment.

Learning Objective**:** After the presentation, the audience will be able to identify external and internal factors that contribute to one's feelings of entrapment, and describe how these perceptions are related to suicide risk.

How learning objective will be met**:** The presentation will describe how people in different institutions vary in levels of external and internal entrapment, and how these factors relate to suicide.

2. Presentation Title: *The Relationship Between Dimensions of Suicidality and "Drivers" in Treatment Planning*

Authors: Asher Siegelman, BA and David A. Jobes, PhD

Abstract: Military suicide has exceeded the rates of the general population (Kuehn, 2009). To address this issue, researchers are developing methods to identify, assess, and treat Soldiers at risk. One such method is the Collaborative Assessment and Management of Suicidality (CAMS) which employs a unique approach to helping a suicidal patient by using a collaborative assessment (Suicide Status Form (SSF)) with both qualitative and quantitative measures to understand their suicidality in its idiosyncratic aspects and to build a treatment plan that caters to his/her struggle. Within the SSF is a tool based on the "internal struggle hypothesis" that measures patient ratings of Wish to Live (WTL) vs. Wish to Die (WTD). Researchers have found that suicidality based on this concept of internal struggle can be used to create three distinct suicidal typologies—those attached to living, vs. being ambivalent, vs. being attached to dying (O'Connor et al., 2012). More recently, researchers found that these dimensions are significantly related to treatment course, outcome and unique patterns of symptom severity – WTL clients, less severe; WTD clients, more severe (Lento et al., 2013). Finally, central to CAMS care is treatment planning that centers on two patient-defined

problems conceptualized as “suicidal drivers” that must be targeted and treated for successful clinical suicide prevention.

Research Aims: Considering that WTL, AMB, WTD, index ratings have been shown to uniquely relate to treatment course/outcome they may be potentially relevant to suicidal “drivers” that are the focus of CAMS-oriented treatment.

Methods: 1) Organize the three types of suicidal risk as a quasi-independent variable from an archival data set (n=75) of suicidal soldiers from a South East military base. 2) Examine their potential differential relationship to respective suicidal problems/drivers that appear on CAMS treatment plans using a cross-sectional approach. 3) Code and analyze Soldiers’ suicidal treatment plans/drivers using the Modified Consensual Validation (Jobes, 2004) to organize reliable themes of treatment problems/drivers.

Results: Analyses will be conducted to determine the relationship between the three suicidal types and reliably coded suicidal drivers obtained from CAMS treatment plans.

Conclusions: Discuss findings in relation to clinical utility and future research.

What the work adds to our knowledge on the topic: Describing the relationship between suicidal typologies and drivers of suicide will help inform clinicians of what treatment course to choose and what possible symptomology to expect.

Learning Objective: Describe how soldiers’ self-report ratings of their internal struggle with suicide relates to their drivers for suicide.

How learning objective will be met: 1) Discuss research on suicide typologies in relation to treatment planning, course, and outcome. 2) Describe conceptualization and coding of drivers and their role in treatment planning. 3) Present correlational analyses between suicide typologies and drivers. 4) Discuss results in conjunction with their relevance to treatment planning, course, and outcome.

3. Presentation Title: *The Use of Clinical Risk Assessment Coding Systems with Suicidal Soldiers*

Authors: Katherine A. Brazaitis, MA and David A. Jobes, PhD

ABSTRACT**:** Each year hundreds of thousands of Americans attempt to take their lives and some 38,000 die by suicide (Kung et al., 2008; McIntosh, 2009). Understanding the unique factors that contribute to an individual’s suicidal ideation is essential for suicide-

focused clinical assessment and treatment (Jobes, 2006). The “Suicide Status Form” (SSF; Jobes, 2006; Jobes et al., 1997)—used in the “Collaborative Assessment and Management of Suicide” approach (CAMS; Jobes, 2006)—is a valuable tool for collecting qualitative and quantitative data pertaining to different suicidal states. The psychometrics of the SSF are strong (Jobes et al., 1997; Conrad et al., 2009). Three different SSF-based coding systems (Jobes, 2012) have been developed for identifying suicidal typologies and include the SSF-based “Suicide Index Score” (SIS), “Suicide Motivation,” and “Suicide Orientation.” The following presentation will outline the study design, methodology, and findings of a study applying these coding systems to the baseline data collected as part of a large randomized control trial of CAMS. The sample (n=75) consists of suicidal active duty US Army Soldiers who are being seen in a military treatment facility who have consented to participated in the RCT and have been randomized to receive CAMS. Baseline assessments include Lifetime Suicide Attempt Self-Injury Count; Scale for Suicide Ideation-Current; Outcome Questionnaire-45; Connor-Davidson Resilience Scale; and Structured Clinical Interview for DSM Disorders I and II. SSFs completed during the first session of CAMS will be coded for SSF based SIS, Suicide Motivation, and Suicide Orientation.

The following hypothesizes will be applied: **H1:** Participants quantitatively categorized by the SSF-based SIS coding system as “Wish To Live,” “Ambivalent,” and “Wish to Die” will demonstrate significant between-group differences on measures of lifetime suicide attempts, current suicidal ideation, psychological distress, hope, and psychological resiliency. **H2:** Participants’ qualitatively-generated data that is categorized by the Suicide Motivation coding system as “Life-Motivated,” “Ambivalently-Motivated,” and “Death-Motivated” will demonstrate significant between-group differences on the measures identified in H1. **H3:** Participants qualitatively-generated data that is categorized by the Suicide Orientation coding system as “Self-Oriented” or “Relationally-Oriented” will demonstrate significant between-group differences on the measures identified in H1. **Post-Hoc:** Post-hoc exploratory analyses will identify the potential relationship between the three SSF-based coding systems and major psychiatric disorders coded using the SCID-I and SCID-II.

This study represents the first simultaneous application of three SSF coding systems to a relatively large sample of suicidal Soldiers. The findings of this study are critical to on-going development and understanding of suicide risk typologies with clear implications for clinical risk assessment and treatment which may help to clinically prevent suicidal patient deaths.

4. Presentation Title: *Characterizing Pre-Enlistment Risk Factors in Help-Seeking Suicidal Soldiers*

Authors: Gretchen R. Ruhe, BS, Kate Comtois, PhD, MPH, Amanda H. Kerbrat, MSW, LICSW, Anthony D. Greenman, BA, and David A. Jobes, PhD

Data from this RCT is included in a conference presentation that pools data from multiple DoD and VA studies to examine predictors of suicidal behavior using baseline (pre-randomization) data from six studies. Excerpts of this pooled data are included for reference in the supporting data section, Table 1. Analyses of this data are on-going.

The following are tentative titles and summaries of in-progress manuscripts for an upcoming special issue of *Military Behavioral Health*.

1. Tentative Title: *Timing of first suicide attempt: characteristics of active duty Service Members with no history of attempt, 1st attempt pre-enlistment, and 1st attempt post-enlistment (during active duty service)*

First Author: Katherine A. Comtois, PhD, MPH, University of Washington

2. Tentative Title: *Military, demographic, and clinical predictors of severity of suicidal ideation among active duty Service Members*

First Author: Lindsey Zimmerman, PhD, University of Washington

3. Tentative Title: *Differences in Risk Factors and Characteristics of Suicide Attempts between Active Duty Military Personnel and Veterans*

First Author: Jennifer Villatte, PhD, University of Washington

4. Tentative Title: *Differentiators of Military Personnel with a History of One versus Multiple Suicide Attempts*

First Author: Craig Bryan, PsyD, University of Utah

SUPPORTING DATA: All figures and/or tables shall include legends and be clearly marked with figure/table numbers.

Figure 1. Demographic Characteristics of DOD/VA pooled study data.

Variable	Jobes Fort Stewart (N=154)	Comtois Fort Bragg (N=143)	Comtois NC Marines (N=23)	Comtois 29 Palms (N=25)	Luxton Madigan Army MC (N=185)	Luxton VA Palo Alto (N=317)	Luxton Navy MC San Diego (N=184)	Luxton Tripler Army MC (N=107)	Luxton West NY VA N=153)	Luxton Landstuhl Army MC (N=130)	Gutierrez Denver VA (N=261)	Johnson Louisville VA (N=140)	Bryan Fort Carson (N=54)
Age - Mean (SD)	26.8 (5.9)	27.1 (6.2)	22.4 (5.4)	24.0 (4.7)	24.0 (4.4)	43.7 (12.5)	23.7 (6.0)	26.3 (7.0)	45.7 (13.4)	27.0 (7.1)	54.5 (10.3)	47.9 (11.6)	25.5 (4.9)
Female (%)	18.0%	21.0%	21.7%	12.0%	36.8%	10.1%	31.0%	33.6%	10.5%	29.2%	13%	12%	16.7%
Ethnicity													
% African-American	22.1%	10.0%	4.3%	4.2%	9.2%	8.9%	14.2%	8.4%	23.5%	16.3%	%	20.9%	9.8%
% Hispanic/Latino/a	8.4%	15.7%	4.3%	0%	14.7%	17.1%	25.7%	18.7%	6.6%	20.2%	%	2.2%	7.8%
% AI/AN	0%	2.1%	0%	0%	0%	1.9%	0.5%	0%	1.5%	2.3%	%	1.4%	3.9%
% Asian/Pacific Islander	2.6%	1.4%	0%	20.8%	4.3%	8.2%	4.9%	9.3%	0%	1.6%	%	3.6%	0%
% Mixed or other	10.4%	10.0%	30.4%	29.2%	5.4%	5.7%	7.7%	11.2%	9.6%	7.0%	%	0%	2.0%
% Caucasian	56.5%	60.7%	60.9%	45.8%	66.3%	58.2%	47.0%	52.3%	58.8%	52.7%	%	71.9%	76.5%
Education													
% some HS; no GED	0.6%	4.3%	4.3%	0%	0.5%	2.2%	0%	0%	0.7%	0%	8%	2.9%	-
% GED	8.2%	24.8%	73.9%	70.8%	41.1%	23.7%	46.4%	35.8%	29.0%	33.1%	29.9%	13.7%	-
% High school diploma	32.7%	12.8%	0%	8.3%								20.9%	-
% Business or tech train	3.1%	27.7%	21.7%	12.5%	52.4%	57.9%	49.7%	50.9%	51.7%	54.6%	42.1%	1.4%	-
% Some college/AA or tech degree	47.8%	28.4%	0%	8.3%								46%	-
% BA or graduate degree	7.5%	2.1%	0%	0%	5.9%	16.1%	3.8%	13.2%	18.6%	12.3%	19.9	14.3%	-
Current Marital Status													
% Never married	27.2%	32.4%	69.6%	56.0%	44.8%	29.0%	62.4%	46.2%	31.6%	36.2%	26.1%	25.2%	?
% Married	49.4%	45.3%	13.0%	32.0%	45.9%	23.3%	24.9%	41.5%	21.3%	47.7%	23.0%	26.6%	?
% Separated or divorced	22.8%	22.3%	17.4%	12.0%	9.3%	44.2%	12.7%	12.3%	42.6%	16.2%	47.1%	46.0%	?
% Widowed	0.6%	0%	0%	0%	0%	3.5%	0%	0%	4.4%	0%	3.9%	2.2%	?
Has children (%)	60.3%	46.6%	22.2%	25.0%	25.4%	60.9%	21.7%	31.8%	69.1%	39.2%	-	-	37.0%
Military Status													
% Active Duty	100%	100%	100%	100%	98.9%	0.9%	98.4%	94.4%	0%	96.2%	0%	0%	100%
% Veteran	0%	0%	0%	0%	0%	95.3%	0.5%	1.9%	98.0%	1.5%	100%	100%	0%
% Other (Reserve, Guard, Dependent)	0%	0%	0%	0%	1.1%	3.8%	1.1%	3.7%	2.0%	2.3%	0%	0%	0%
Branch													
% Army	100%	0%	0%	0%	64.7%	48.3%	1.6%	57.9%	55.6%	71.5%	55.6%	64.7%	100%
% Marine Corps	0%	100%	100%	100%	0.5%	17.7%	48.9%	14.0%	15.7%	0.8%	12.1%	11.5%	0%
% Navy	0%	0%	0%	0%	28.8%	18.6%	49.6%	25.2%	19.6%	3.8%	18.8%	16.5%	0%
% Air Force	0%	0%	0%	0%	3.8%	14.8%	0%	1.9%	7.2%	23.8%	11.7%	10.1%	0%
% Other	0%	0%	0%	0%	2.2%	0.6%	0%	0.9%	2.0%	0%	.8%	0%	0%
Enlistment Year – Mean (SD)	2008 (4.7)	2007 (5.6)	2010 (5.3)	2009 (4.9)	2009 (2.8)	1990	2009 (4.5)	2008 (4.7)	1986	2007 (5.5)	1978 (11.4)	1985 (13.0)	-

Variable	Jobes Fort Stewart (N=154)	Comtois Fort Bragg (N=143)	Comtois NC Marines (N=23)	Comtois 29 Palms (N=25)	Luxton Madigan Army MC (N=185)	Luxton VA Palo Alto (N=317)	Luxton Navy MC San Diego (N=184)	Luxton Tripler Army MC (N=107)	Luxton West NY VA N=153)	Luxton Landstuhl Army MC (N=130)	Gutierrez Denver VA (N=261)	Johnson Louisville VA (N=140)	Bryan Fort Carson (N=54)
						(13.0)			(13.8)				
Years of Service – Median (IQR)	4 (2-7)	4 (3-8)	2 (1-3)	3 (1.5-5.5)	3 (2-5)	4 (3-6)	3 (1-5)	4 (2-7)	4 (3-7)	4 (2-9)			4.9 (3.9)
1st four years of enlistment (%)	56.0%	50.3%	78.3%	72.0%	72.5%	0%	73.9%	59.2%	N/A	56.7%	N/A	N/A	55.6%
Rank													
% Junior Enlisted	69.6%	56.6%	69.6%	60.0%							61.0%	-	?
% NCO	20.5%	19.6%	21.7%	32.0%							34.3%	-	?
% Senior Enlisted	6.8%	20.3%	8.7%	8.0%							1.9%	-	?
% Officer	3.1%	3.5%	0%	0%							2.7%	-	?
Any combat deployment (%)	59.0%	57.3%	34.8%	36.0%	45.4%	44.3%	29.0%	42.5%	48.0%	51.9%	28.7%	41.0%	?
Number of combat deployments													
Mean (SD)	1.2 (1.2)	1.3 (1.6)	0.6 (0.9)	0.8 (1.8)	0.7 (0.9)	0.7 (1.1)	0.3 (0.6)	0.7 (1.1)	0.7 (1.0)	0.7 (1.0)	.4 (.8)	-	%
Median (IQR)	1 (0-2)	1 (0-2)	0 (0-1)	0 (0-1)	0 (0-1)	0 (0-1)	0 (0-1)	0 (0-1)	0 (0-1)	0 (0-1)	0 (0-1)	-	%
Combat Site													
% OEF/OIF/OND ever	59.0%	55.9%	26.1%	29.2%							-	-	100%
% Other conflict only	0 %	1.4%	8.7%	4.2%							-	-	?
Era of Active Duty Service													
% OEF/OIF/OND	100%	100%	100%	100%							12.3%	29.5%	100%