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TITLE: Eating Disorders in Veterans: Prevalence, Comorbidity, Risk, and Healthcare Use

PRINCIPAL INVESTIGATOR: Zafra Cooper

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5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

Yale University
105 Wall Street
New Haven CT 06511-8917

8. PERFORMING ORGANIZATION REPORT

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U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

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13. SUPPLEMENTARY NOTES

14. ABSTRACT

This application focuses on eating disorders (EDs) and addresses several FY17 PRMRP Areas for Encouragement, including prevalence of diagnosable EDs and other clinically significant disordered eating, associations between ED symptoms and military-unique behaviors and conditions, and treatment patterns of individuals with EDs. We will establish a cohort of post-9/11 Veterans who were separated from service within the past year in order to: (1a) Examine the prevalence of full/subthreshold EDs among male and female Veterans. (1b) Examine the proportion of full/subthreshold EDs among vulnerable subgroups of Veterans. (1c) Examine temporal associations among EDs and comorbid disorders, including PTSD, depression, anxiety, and alcohol and substance use disorders. (2a) Document treatment patterns and healthcare preferences among male and female Veterans with probable full/subthreshold ED diagnoses. (2b) Compare treatment patterns for Veterans with probable full/subthreshold ED diagnoses to Veterans without ED diagnoses. (2c) Identify barriers to care for Veterans seeking mental health treatment in general and for EDs specifically. (3) Identify the impact of general and military/Veteran-specific risk/maintenance factors for ED symptoms and investigate gender differences. (4) Validate and compare two existing, scalable, screening measures of EDs in a Veteran sample.

Data collection began in January 2020.

15. SUBJECT TERMS

Eating disorder in Veterans; risk factor assessments; comorbid disorders; health care use; survey assessments; interview assessments

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
					USAMRMC
a. REPORT	b. ABSTRACT	c. THIS PAGE	UU	16	19b. TELEPHONE NUMBER *(include area code)*
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1. **INTRODUCTION:** *Narrative that briefly (one paragraph) describes the subject, purpose and scope of the research.*

The specific aims of the project are to recruit a nationally representative cohort of post-9/11 veterans in order to (1a) Examine the prevalence of full and subthreshold eating disorders (EDs) among male and female Veterans. (1b) Examine the proportion of full and subthreshold EDs among vulnerable subgroups of Veterans. (1c) Compare temporal associations among EDs and comorbid disorders, including PTSD, depression, anxiety, and alcohol and substance use disorders. (2a) Document treatment patterns and healthcare needs/preferences among male and female Veterans with probable full or subthreshold ED diagnoses. (2b) Compare treatment patterns for Veterans with probable full and subthreshold ED diagnoses to Veterans without ED diagnoses. (2c) Identify barriers to care for Veterans seeking mental health treatment in general and for EDs specifically. (3) Identify the impact of general and military/Veteran-specific risk factors for ED symptoms. (4) Validate and compare two existing screening measures of EDs in Veterans.

2. **KEYWORDS:** *Provide a brief list of keywords (limit to 20 words).*

Eating disorders, veterans, military stressors, comorbid disorders, risk factors

3. **ACCOMPLISHMENTS:** *The PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency grants official whenever there are significant changes in the project or its direction.*

What were the major goals of the project?

List the major goals of the project as stated in the approved SOW. If the application listed milestones/target dates for important activities or phases of the project, identify these dates and show actual completion dates or the percentage of completion.

Major Task 1: Prepare Research Protocol	**Target date**	**Completion date or %**
Milestone Achieved: Local IRB approval at VABHS, Yale	10/30/18	10/29/18
Major Task 2: Hiring and Training of Study Staff	**Target date**	**Completion date**
Milestone Achieved: Research staff trained	3/30/19	100%
Major Task 3: Participant Recruitment and Survey Mailing	**Target date**	**Completion date**
Milestone Achieved: 1st participant returns completed survey	3/30/19	2/3/20
Milestone Achieved: Survey mailing completed	6/30/20	4/5/20
Milestone Achieved: Survey database will be cleaned, finalized, and provided to the Initiating PI	9/30/20	7/30/20
Major Task 4: Interview Assessments	**Target date**	**Completion date or %**
Milestone Achieved: all interviews completed.	9/30/20	20%
Milestone Achieved: data collection completed.	9/30/20	20%
Major Task 5: Data Analysis	**Target date**	**Completion date**
Milestone achieved: report prevalence of EDs.	12/30/20	25%
Milestone achieved: report treatment patterns of Veterans with EDs and barriers to care.	12/30/20	0%
Milestone: report military-specific risk/maintenance factors for EDs in Veterans.	3/30/21	0%

Milestone: report validity of screening measures for EDs.	6/30/21	0%
Milestone Achieved: Report results from data analyses	9/30/21	0%

What was accomplished under these goals?

For this reporting period describe: 1) major activities; 2) specific objectives; 3) significant results or key outcomes, including major findings, developments, or conclusions (both positive and negative); and/or 4) other achievements. Include a discussion of stated goals not met. Description shall include pertinent data and graphs in sufficient detail to explain any significant results achieved. A succinct description of the methodology used shall be provided. As the project progresses to completion, the emphasis in reporting in this section should shift from reporting activities to reporting accomplishments.

Major Task 1: Prepare Research Protocol

- *Refine assessment battery:* The survey was finalized in preparation for data collection, which was complete in May 2020. Interview assessment was finalized in January 2020 in preparation for beginning interviews. Interviews were programmed for use and automatic data entry in preparation for receiving participant roster from survey firm at the end of March 2020. Newly appointed staff (only appointed in February and March respectively -please see details re staff appointments below) commenced training in anticipation of piloting (see below for further staff details and further pandemic related changes and piloting).
- *Pilot test survey and diagnostic interview*: The survey at VA Boston was piloted and subsequently completed in May 2020. Interviews were fully piloted and research staff at Yale were trained for interviews to begin in July. Multiple mock interviews were completed by all the three research staff at Yale. The Yale PI listened to all these recordings, provided individual feedback and ratings were agreed. Interviews began in late July once further IRB permission was obtained, with some further telecommunication problems due to all staff working at home (see below) As of August 2020 interviews are proceeding with all staff working at home according to Yale requirements.
- *Finalize consent form and human subjects protocol:* Given the current ongoing health crisis and directives at Yale to initially pause all research and have all non-essential staff work from home it was necessary to modify the consent process and human subjects protocol so as to carry the study out by fully remote means. This involved adapting methods of contacting participants and the consent process, as well as repeating some self -report measures (please see details about time lag below). These changes were finalized and piloted and received IRB approval July 23.
- *Refine and edit interview assessment protocol:* All interview assessments were finalized and piloted by May. However due to the time lag between the original survey and interview, initially because the survey was done more quickly online rather than in waves as originally planned and then further exacerbated by the stay at home directives, some screening instruments are being repeated prior to interview

Major Task 2: Hiring and Training of Study Staff

- Dr Sursatie Frazier who was hired as a post-doctoral assistant and started in October 2019 resigned in January. She primarily wished to have supervised clinical work for licensure purposes and although the study and role was clearly explained at the outset, she only subsequently decided that it did not fit her needs. Perhaps, because of this mismatch, her work was unsatisfactory from the outset and, had she not resigned, lengthy dismissal proceedings would have had to be instituted.
- Andrea Gould, an internal Yale candidate started 11/1/19 and Julianne Dorset another internal candidate started 2/18/20 (replacing Dr Frazier). After obtaining permission for a further post, Erin Healey was appointed and began 3/16/20. All staff are fully trained and conducting interviews as of August 2020. (further details below)

Major Task 3: Participant Recruitment and Survey Mailing

- *Coordinate with sites and survey research firm for all study steps and data collection methods:* Survey data collection was complete in May 2020, and the survey research firm provided a clean dataset to Dr. Mitchell in July 2020. Interview data collection has begun and is likely to take at least another 8-10 months.

Major Task 4: Interview Assessments

- These are underway as of August 2020 and likely to require another 8-10 months to complete (please see anticipated delays below)

Major Task 5: Data Analysis

- Survey dataset checking and scoring the measures has begun.

If the project was not intended to provide training and professional development opportunities or there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe opportunities for training and professional development provided to anyone who worked on the project or anyone who was involved in the activities supported by the project. "Training" activities are those in which individuals with advanced professional skills and experience assist others in attaining greater proficiency. Training activities may include, for example, courses or one-on-one work with a mentor. "Professional development" activities result in increased knowledge or skill in one's area of expertise and may include workshops, conferences, seminars, study groups, and individual study. Include participation in conferences, workshops, and seminars not listed under major activities.

Nothing to report

How were the results disseminated to communities of interest?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how the results were disseminated to communities of interest. Include any outreach activities that were undertaken to reach members of communities who are not usually aware of these project activities, for the purpose of enhancing public understanding and increasing interest in learning and careers in science, technology, and the humanities.

Nothing to report

What do you plan to do during the next reporting period to accomplish the goals?
If this is the final report, state "Nothing to Report."

Describe briefly what you plan to do during the next reporting period to accomplish the goals and objectives.

We will complete interview assessments and conduct analyses for all study aims.

4. **IMPACT:** D*escribe distinctive contributions, major accomplishments, innovations, successes, or any change in practice or behavior that has come about as a result of the project relative to:*

What was the impact on the development of the principal discipline(s) of the project?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how findings, results, techniques that were developed or extended, or other products from the project made an impact or are likely to make an impact on the base of knowledge, theory, and research in the principal disciplinary field(s) of the project. Summarize using language that an intelligent lay audience can understand (Scientific American style).

Nothing to report

What was the impact on other disciplines?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how the findings, results, or techniques that were developed or improved, or other products from the project made an impact or are likely to make an impact on other disciplines.

Nothing to report

What was the impact on technology transfer?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe ways in which the project made an impact, or is likely to make an impact, on commercial technology or public use, including:

- *transfer of results to entities in government or industry;*
- *instances where the research has led to the initiation of a start-up company; or*
- *adoption of new practices.*

Nothing to report

What was the impact on society beyond science and technology?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how results from the project made an impact, or are likely to make an impact, beyond the bounds of science, engineering, and the academic world on areas such as:

- *improving public knowledge, attitudes, skills, and abilities;*
- *changing behavior, practices, decision making, policies (including regulatory policies), or social actions; or*
- *improving social, economic, civic, or environmental conditions.*

Nothing to report

5. CHANGES/PROBLEMS: *The PD/PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency grants official whenever there are significant changes in the project or its direction. If not previously reported in writing, provide the following additional information or state, "Nothing to Report," if applicable:*

Nothing to report

Actual or anticipated problems or delays and actions or plans to resolve them
Describe problems or delays encountered during the reporting period and actions or plans to resolve them.

Actual problems and delays: As previously reported there were delays in obtaining the survey data. Hence Yale staff were not appointed until the end of the first year of the study in order to conserve salary costs. These initial delays were partly mitigated by a revised timeline for collecting survey data, as data was collected primarily online, rather than by paper-and-pencil mailed surveys. We had hoped that, although delayed, interviews would be able to be completed in a timely manner within 9 months to a year from the end of March 2020 with the addition of a further research assistant/interviewer to the team. Further funding for this was agreed 1/31/20 and the post was advertised immediately at the same time as recruiting to replace Dr Frazier whose resignation took effect from the end of January. Julianne Dorset was in post and had begun training close to the end of February and Erin Healey started in mid -March (remotely from the start).

However, in early March, due to the looming health crisis, Yale paused all non-urgent research until the end of April and directed all non-essential staff to work at home. The stay at home guidance was then extended until the end of July and, to date, non-essential workers are still being directed to work from home. Although it was already possible for many aspects of the present study to be completed remotely- indeed interviews were planned to be remote- a number of other aspects of the study have required modification so as to be completed by staff who are currently still completely confined to working at home. The circumstances detailed above required further planning at administrative, regulatory level and some design changes (repeating some self-report assessments). A further delay involved the continuing review process. Despite submitting the details for this at the end of April 2020, it was only conditionally approved by Yale to go to HRPO on 6/30/20. HRPO approval was obtained on 7/13/20 and final Yale confirmation on 7/15/20. We were advised by Yale to delay until this was approved. All IRB permissions from Yale were obtained (7/23/20) and, after some further problems with remote telecommunications in late July, participants are now being interviewed.

Potential/anticipated problems and delays: While the numbers of identified participants both male and female who potentially have an eating disorder are as planned in the original protocol, the number of potential female control group participants identified were fewer than anticipated and marginally fewer than the number of participants with an eating disorder.

In many respects recruiting participants is going very well and approximately 90% of those with whom we make contact are agreeing to participate. However, we are having difficulty, despite numerous attempts via phone and text messaging, in making any contact with approximately 15% of those whom we try to contact. So overall, at present, we are managing to recruit approximately 75% of the sample, slightly lower than the originally planned 80%. Failure to contact participants is sometimes accounted for by incorrect contact details and may also be due to extra pressures as a result of the current health crisis. We have certainly been in contact with people who have initially not got back to us and then have told us that the delay was due to their having had COVID. We will try to overcome some of the problems of contacting participants by also writing to them. Further delays may result because of the time taken and the difficulties involved in contacting people to arrange interviews, rather than our ability to complete the interviews once participants have agreed.

Changes that had a significant impact on expenditures

Describe changes during the reporting period that may have had a significant impact on expenditures, for example, delays in hiring staff or favorable developments that enable meeting objectives at less cost than anticipated.

The delay in beginning the interviews detailed above has had an impact on expenditure. Staff were employed for longer than anticipated while not completing interviews. This was due to the unanticipated shut down at Yale and the need to make study changes. So, although staff time was used productively to make all the necessary changes and adjustments, they will need to be employed for longer to complete the interviews. In addition, there were some extra equipment costs (such as further screens, a laptop, headphones, cell phone etc. for working remotely). However, the major contributor to extra costs is the salary costs. We were able to secure funds for an extra RA for a year and received these funds in the year 2019/2020 for 8 months ($80,000) and are now requesting a further 4 months for 2020/2021. Should this be granted, the potential shortfall would be greatly mitigated. The Yale PI has been working with the business office at Yale to pursue other possible ways of mitigating some of these unforeseen (and largely pandemic related) costs and has now secured a method to cover any relatively small remaining potential shortfall.

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

Describe significant deviations, unexpected outcomes, or changes in approved protocols for the use or care of human subjects, vertebrate animals, biohazards, and/or select agents during the reporting period. If required, were these changes approved by the applicable institution committee (or equivalent) and reported to the agency? Also specify the applicable Institutional Review Board/Institutional Animal Care and Use Committee approval dates.

Significant changes in use or care of human subjects

1. We made minor edits to the survey (amendment approved 12/23/19)
2. We made minor modifications to the postal communications for the survey (amendments approved 12/16/19 and 1/27/20)
3. Yale modifications described above and approved (5/20/20, 7/23/20)
4. Yale Continuing Review and HRPO review (6/29/20, 7/13/20, 7/15/20)

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: *List any products resulting from the project during the reporting period. If there is nothing to report under a particular item, state "Nothing to Report."*

- **Publications, conference papers, and presentations**
  Report only the major publication(s) resulting from the work under this award.

  Journal publications. *List peer-reviewed articles or papers appearing in scientific, technical, or professional journals. Identify for each publication: Author(s); title; journal; volume: year; page numbers; status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

Nothing to report

  Books or other non-periodical, one-time publications. *Report any book, monograph, dissertation, abstract, or the like published as or in a separate publication, rather than a periodical or series. Include any significant publication in the proceedings of a one-time conference or in the report of a one-time study, commission, or the like. Identify for each one-time publication: author(s); title; editor; title of collection, if applicable; bibliographic information; year; type of publication (e.g., book, thesis or dissertation); status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

Nothing to report

  Other publications, conference papers and presentations. *Identify any other publications, conference papers and/or presentations not reported above. Specify the status of the publication as noted above. List presentations made during the last year (international, national, local societies, military meetings, etc.). Use an asterisk (*) if presentation produced a manuscript.*

Nothing to report

- **Website(s) or other Internet site(s)**
  List the URL for any Internet site(s) that disseminates the results of the research activities. A short description of each site should be provided. It is not necessary to include the publications already specified above in this section.

Nothing to report

- **Technologies or techniques**
  Identify technologies or techniques that resulted from the research activities. Describe the technologies or techniques were shared.

Nothing to report

- **Inventions, patent applications, and/or licenses**
  Identify inventions, patent applications with date, and/or licenses that have resulted from the research. Submission of this information as part of an interim research performance progress report is not a substitute for any other invention reporting required under the terms and conditions of an award.

Nothing to report

- **Other Products**
  Identify any other reportable outcomes that were developed under this project. Reportable outcomes are defined as a research result that is or relates to a product, scientific advance, or research tool that makes a meaningful contribution toward the understanding, prevention, diagnosis, prognosis, treatment and /or rehabilitation of a disease, injury or condition, or to improve the quality of life. Examples include:
  - *data or databases;*
  - *physical collections;*
  - *audio or video products;*
  - *software;*
  - *models;*
  - *educational aids or curricula;*
  - *instruments or equipment;*
  - *research material (e.g., Germplasm; cell lines, DNA probes, animal models);*
  - *clinical interventions;*
  - *new business creation; and*
  - *other.*

Nothing to report

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Provide the following information for: (1) PDs/PIs; and (2) each person who has worked at least one person month per year on the project during the reporting period, regardless of the source of compensation (a person month equals approximately 160 hours of effort). If information is unchanged from a previous submission, provide the name only and indicate "no change".

Name: Karen Mitchell
Project role: Initiating PI
Researcher Identifier: 0000-0002-1516-7239
Nearest person month worked: .75
Contribution to the project: Dr. Mitchell has been working with survey research firms and VA Information Security to plan the data collection.

Name: Megan Sienkiewicz
Project role: Research Assistant
Nearest person month worked: 1.5
Contribution to the project: Ms. Sienkiwicz has assisted with survey refinement, IRB amendments, and literature searches.

Name: Zafra Cooper
Project role: Partnering PI
Researcher Identifier: 0000-0001-7963-656X
Nearest person month worked: 2.5
Contribution to the project: Dr. Cooper has continued to work to train two new staff members. She has worked remotely to train staff (all working at home), supervise the finalizing of interview drafts and their entry into REDCap for ease of administration and coding. She has worked with Yale IT to ensure all staff have Yale computers to work remotely and to set up a phone system to allow participants to be contacted through official Yale sources. Aspects of recruitment and consent procedures for interviewing participants have had to be revised as have methods of compensating participants. These modifications have been submitted for and obtained IRB approval so that the interview phase of the study may begin in changed circumstances. She has also recently submitted and obtained continuing review permission from Yale and HRPO. All interviewers have been trained to use the eating disorder diagnostic interview, the risk factor interview and the appropriate SCID modules. This has involved listening to recordings of each research assistant completing at least 4 mock interviews, providing individual feedback and agreeing ratings. She continues to supervise the research staff completing interviews and to listen to interview recordings for quality assurance purposes.

Name: Andrea Gould
Project role: Research Assistant
Nearest person month worked: 11
Contribution to the project: A Gould has assisted with finalizing interview assessments, programming and testing REDCap, arranging for remote subject compensation. getting the remote phone system working. They have started a database of relevant publications and completed mock practice interviews and received feedback as part of the training plan. They have started a database of relevant publications and completed mock practice interviews and received feedback as part of the training plan. They continue these administrative tasks, ensure participant compensation is timely and logged and recruit and interview participants.

Name: Julianne Dorset
Project role: Research Assistant
Nearest person month worked: 9
Contribution to the project: Julianne Dorset has assisted with finalizing interview assessments, programming and testing REDCap, devising alternative recruitment and consent processes and preparing IRB amendents. She has completed practice interviews and received feedback as part of the training plan. She currently recruits and interview participants and has a particular role in following up and recruiting participants who are difficult to contact and engage.

Name: Erin Healey
Project role: Research Assistant
Nearest person month worked: 6
Contribution to the project: Erin Healey has assisted with finalizing interview assessments, programming and testing REDCap, devising alternative recruitment and consent processes and programming additional screening. She has completed d practice interviews and received feedback as part of the training plan. She continues to make any programming changes and amendments required and maintains our detailed recruitment figures. She recruits and interviews participants.

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

If the active support has changed for the PD/PI(s) or senior/key personnel, then describe what the change has been. Changes may occur, for example, if a previously active grant has closed and/or if a previously pending grant is now active. Annotate this information so it is clear what has changed from the previous submission. Submission of other support information is not necessary for pending changes or for changes in the level of effort for active support reported previously. The awarding agency may require prior written approval if a change in active other support significantly impacts the effort on the project that is the subject of the project report.
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Assessing non-specialist health worker competence for treating depression in primary care
PI: Vikram Patel
CoI: Zafra Cooper
NIMH Administrative Supplement: "Assessing non-specialist health worker skills and competence for treating depression"
Project period: 07/03/18 -05/31/20.
Further support pending (delays due to health crisis)
.

Describe partner organizations – academic institutions, other nonprofits, industrial or commercial firms, state or local governments, schools or school systems, or other organizations (foreign or domestic) – that were involved with the project. Partner organizations may have provided financial or in-kind support,

supplied facilities or equipment, collaborated in the research, exchanged personnel, or otherwise contributed.

Provide the following information for each partnership:
Organization Name:
Location of Organization: (if foreign location list country)
Partner's contribution to the project (identify one or more)

- *Financial support;*
- *In-kind support (e.g., partner makes software, computers, equipment, etc., available to project staff);*
- *Facilities (e.g., project staff use the partner's facilities for project activities);*
- *Collaboration (e.g., partner's staff work with project staff on the project);*
- *Personnel exchanges (e.g., project staff and/or partner's staff use each other's facilities, work at each other's site); and*
- *Other.*

Minneapolis VA Healthcare System
1 Veterans Drive CCDOR(152)
Minneapolis, MN 55417

Contribution: facilities and collaboration

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS: *For collaborative awards, independent reports are required from BOTH the Initiating Principal Investigator (PI) and the Collaborating/Partnering PI. A duplicative report is acceptable; however, tasks shall be clearly marked with the responsible PI and research site. A report shall be submitted to* ***https://ers.amedd.army.mil*** *for each unique award.*

QUAD CHARTS: *If applicable, the Quad Chart (available on https://www.usamraa.army.mil) should be updated and submitted with attachments.*

Quad chart submitted with this report.

9. 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.*

None