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

PRINCIPAL INVESTIGATOR: Karen Mitchell (Initiating PI)

CONTRACTING ORGANIZATION: Boston VA Research Institute, Boston, MA

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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.		

15. SUBJECT TERMS Eating disorder in Veterans; risk factor assessments; comorbid disorders; health care use; survey assessments; interview assessments			
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1. INTRODUCTION:

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:

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

3. ACCOMPLISHMENTS:

What were the major goals of the project?

Major Task 1: Prepare Research Protocol	Target date	Completion date or %
<i>Milestone Achieved: Local IRB approval at VABHS, Yale</i>	10/30/18	10/29/18
Major Task 2: Hiring and Training of Study Staff	Target date	Completion date
<i>Milestone Achieved: Research staff trained</i>	3/30/19	100%
Major Task 3: Participant Recruitment and Survey Mailing	Target date	Completion date
<i>Milestone Achieved: 1st participant returns completed survey</i>	3/30/19	2/3/20
<i>Milestone Achieved: Survey mailing completed</i>	6/30/20	5/4/20
<i>Milestone Achieved: Survey database will be cleaned, finalized, and provided to the Initiating PI</i>	9/30/20	7/30/20
Major Task 4: Interview Assessments	Target date	Completion date
<i>Milestone Achieved: all interviews completed.</i>	9/30/20	16%
<i>Milestone Achieved: data collection completed.</i>	9/30/20	16%
Major Task 5: Data Analysis	Target date	Completion date
<i>Milestone achieved: report prevalence of EDs.</i>	12/30/20	25%
<i>Milestone achieved: report treatment patterns of Veterans with EDs and barriers to care.</i>	12/30/20	0%
<i>Milestone: report military-specific risk/maintenance factors for EDs in Veterans.</i>	3/30/21	0%

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

What was accomplished under these goals?

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 IRB approved on July 23.
- *Refine and edit interview assessment protocol:* All interview assessments were finalized and piloted by May 2020. However due to the time lag between the original survey and interview, initially because the survey was done more quickly online than anticipated, which was and then 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.

Nothing to report

How were the results disseminated to communities of interest?

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:

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:

Nothing to report

Actual or anticipated problems or delays 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 towards the end of February and Erin Healey started in mid-March (remotely from the start).

However, in early March, due to the looming COVID-19 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 and some design level 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 further problems and delays:

While the numbers of participants both male and female identified 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, 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 it takes 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

The delay in beginning the interviews, detailed above, has had an impact on expenditure. Staff were employed for longer than anticipated prior to beginning interviews. This was due to the unanticipated shut-down at Yale due to COVID and the need to make study changes. So, although staff time was used productively to make all the necessary changes and adjustments, staff will need to be employed for longer than planned to complete the interviews. In addition, there were some extra equipment costs (e.g., monitors, 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 not requesting an additional 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

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. Modifications described above and approved (5/20/20, 7/23/20)
4. Continuing Review and HRPO review (6/29/20, 7/13/20, 7/15/20)

Significant changes in use of biohazards and/or select agents

Nothing to report

6. PRODUCTS:

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

Journal publications.

Nothing to report

Books or other non-periodical, one-time publications.

Nothing to report

Other publications, conference papers and presentations.

Nothing to report

- **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: Karen Mitchell
Project role: Initiating PI
Researcher Identifier: 0000-0002-1516-7239
Nearest person month worked: 3.0
Contribution to the project: Dr. Mitchell has been working with the survey research firm and VA Information Security to plan the data collection.

Name: Megan Sienkiewicz
Project role: Research Assistant
Nearest person month worked: 12
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 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 amendments. She has completed practice interviews and received feedback as part of the training plan. She currently recruits and interview participants and especially 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: Mx. 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?

Nothing to report

What other organizations were involved as partners?

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

Contribution: facilities and collaboration

VA Connecticut Research and Education Foundation/ VA Connecticut Healthcare System
 Campbell Avenue
 West Haven CT 06516

Contribution: collaboration and advice in assessing Veterans from Dr. Robin Masheb

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS:

QUAD CHARTS:

9. APPENDICES: