Award Number: W81XWH-09-2-0077

TITLE: A Randomized Effectiveness Trial of a Systems-Level Approach to Stepped Care for War-Related PTSD

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REPORT DATE: May 2016

TYPE OF REPORT: Final Report

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

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. REPORT DATE	2. REPORT TYPE	3. DATES COVERED
May 2016	Final Report	1 Sep 2009 – 28 Feb 2016

4. TITLE AND SUBTITLE
A Randomized Effectiveness Trial of a Systems-Level Approach to Stepped Care for War-Related PTSD

5a. CONTRACT NUMBER
W81XWH-09-2-0077

5b. GRANT NUMBER
DR080409

5c. PROGRAM ELEMENT NUMBER

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5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) **Henry M. Jackson Foundation for the Advancement of Military Medicine Bethesda, MD 20817**

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8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)
U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

10. SPONSOR/MONITOR'S ACRONYM(S)

11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION / AVAILABILITY STATEMENT
Approved for Public Release; Distribution Unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT

During the 6.5 year study period, investigators developed the STEPS UP intervention for treatment of service members with PTSD and/or depression; conducted a randomized controlled trial evaluating the effectiveness of STEPS UP as compared to optimized usual care (OUC) in Army primary care clinics; and created an effective research infrastructure to implement the project, per the SOW. Compared to OUC, STEPS UP participants reported significantly greater reductions in PTSD and depression symptoms over 12-months of follow-up (primary outcomes). Differences in effects were statistically significant at 12-months for PTSD and at 6- and 12-months for depression STEPS UP was associated with clinically significant improvements. STEPS UP was also significantly associated with decreased physical symptom burden and improved mental health functioning; no changes for alcohol consumption, physical health function, or pain were observed (secondary aims). STEPS UP appears to be a cost-effective strategy for managing PTSD and depression in the MHS. Results from the qualitative portion of the trial reveal that stakeholders within the MHS perceive significant barriers to mental health care and recognize the value of collaborative care in overcoming barriers to care, yet perspectives about the value and utility of different tools varied in this study. Investigators are currently completing multiple manuscripts to disseminate study findings.

15. SUBJECT TERMS
Collaborative care; PTSD; military; depression; primary care; care management; preference-based stepped care

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			USAMRMC
U	U	U	UU	182	19b. TELEPHONE NUMBER *(include area code)*

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INTRODUCTION:

The purpose of the STEPS UP (**ST**epped **E**nhancement of **P**TSD **S**ervices **U**sing **P**rimary Care) trial was to compare centralized telephonic care management with preference-based stepped PTSD and depression care to optimized usual care. We hypothesized that the STEPS UP intervention would lead to improvements in (1) PTSD and depression symptom severity (primary hypothesis); (2) anxiety and somatic symptom severity, alcohol use, mental health functioning, work functioning; (3) costs and cost-effectiveness. We further hypothesized that qualitative data would show (4) patients, their family members, and participating clinicians found the STEPS UP intervention to be an acceptable, effective, and satisfying approach to deliver and receive PTSD and depression care.

STEPS UP was a six-site, two–parallel arm (N = 666) randomized controlled effectiveness trial with 3-month, 6-month, and 12-month follow-up comparing centralized telephonic stepped- care management to optimized usual PTSD and depression care. In addition to the existing PTSD and depression treatment options, STEPS UP included web-based cognitive behavioral self- management, telephone cognitive-behavioral therapy, continuous RN nurse care management, and computer-automated care management support. Both arms could refer patients for mental health specialty care as needed, preferred and available. The study used sites running RESPECT-Mil, the existing military primary care-mental health services practice network, to access site health care leaders and potential study participants at the 6 study sites.

If eventually implemented, given our findings we expect that STEPS UP will increase the likelihood that military personnel with unmet PTSD- and depression-related health care needs will get timely, effective, and efficient PTSD and depression care. The real world utility and feasibility of the STEPS-UP intervention can improve on what the Institute of Medicine has

described as a 15 year science to service gap. STEPS UP is available to roll out immediately, reinforcing and facilitating pathways to PTSD and depression recovery within the Military Health System.

BODY:

Activities over the 6.5 year funding period included the following three key efforts and task activities:

1. Intervention development (including protocol, manual and intervention tool development; hiring and training staff; and conducting expert interviews),
2. Conduct of a randomized effectiveness trial (including developing the protocol and instruments; obtaining institutional review board (IRB) and other regulatory approvals; recruiting and consenting participants; collecting data from participants and acquiring administrative data; and conducting data cleaning, analyses, and writing manuscripts, presenting briefings to military leadership, and presenting findings at meetings of professional associations to disseminate findings, and
3. Ongoing project management (including holding regular team meetings; implementing QA/QC procedures; and submitting reports).

The project was accomplished in a timely manner, despite a number of administrative delays. Below we discuss each task activity in turn.

Table 1. Milestones by Task	Year 1				Year 2				Year 3				Year 4				Year 5				Year 6			
	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
	Sept 09	Dec 09	Mar 10	June 10	Sept 10	Dec 10	Mar 11	June 11	Sept 11	Dec 11	Mar 12	June 12	Sept 12	Dec 12	Mar 13	June 13	Sept 13	Dec 13	Mar 14	June 14	Sept 14	Dec 14	Mar 15	June 15
Task 1: Develop Intervention																								
Develop protocol, tools, manuals	x	x	x	x	x	x	x	x	x															
Hire staff and conduct training							x	x	x	x	x													
Provider Interviews & Expert Panel		x	x																					
Task 2: Conduct Randomized Effectiveness Trial																								
Develop protocol/instruments	x	x	x	x	x	x	x	x																
Obtain IRB approval	x	x	x	x	x	x	x	x	x	x	x	x												
Conduct pilot test									x	x														
Recruit & consent participants*									x	x	x	x	x	x	x	x								
Conduct data collection										x	x	x	x	x	x	x	x	x	x	x				
Analysis and Writing													x	x	x	x	x	x	x	x	x	x	x	x
Task 3: Create an Effective Research Structure																								
Hold research team meetings	x	x	x	x	x		x		x		x		x		x		x		x		x		x	
Implement QA/QC procedures	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Submit reports	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x

In terms of <u>development of the protocol and intervention tools and manuals</u>, the study team developed and refined the STEPS UP intervention during Year 1 – Year 3, Quarter 1 of the project period. This included a web-based care management support tool (FIRST STEPS), nurse-assisted web-based cognitive behavioral self-management options (DESTRESS-PC for PTSD and "Beating the Blues" for depression), a structured telephonic cognitive-behavioral therapy approach, and a preference-based stepped care approach to primary care PTSD and depression treatment sequencing. During Year 2, a contract between the Henry M. Jackson Foundation (HJF) and Ultrasis, the developer of "Beating the Blues," was developed; this contract was finalized in Year 3.

In terms of <u>conducting expert interviews</u>, RAND obtained feedback on the STEPS UP intervention protocol from experts during the third quarter of Year 1, and revisions were made to the protocol as necessary.

In terms of <u>hiring staff and conducting training</u>, site study staff were hired and trained as sites obtained IRB approval and prepared for recruitment, from Year 2, Quarter 3

through Year 3, Quarter 3. From Years 2-4, RTI recruited, hired, and trained study site coordinators at each study site. These site coordinators assisted with local study site recruitment, enrollment, and logistics. In Year 3, HJF hired one full-time centralized care manager, two part-time centralized psychologists to deliver the phone therapy intervention and serve as on-call clinicians for our emergency protocol, and one part-time centralized psychiatrist to provide telephonic consultation and treatment plan recommendations to nurse care managers and serve as an on-call clinician for our emergency protocol.

In Year 3, all seven care managers (six site care managers, one centralized care manager) were trained to use "Beating the Blues," the web-based therapy for depression used in the STEPS UP trial. Also in Year 3 (April 2012), the STEPS UP team held a two-day training event for the seven study care managers at the Deployment Health Clinical Center (DHCC) location in Silver Spring, MD. The training included care manager skills training and discussions about study recruitment and enrollment. In Year 4, HJF hired and trained a new STEPS UP study care manager at the Ft. Stewart site.

The study team also conducted site visits in preparation for study launch prior to beginning recruitment at each site. The purpose of the site visits was to initiate intervention awareness and training for primary care and behavioral health providers, clinic nurses and clerical staff, and RESPECT-Mil personnel at each site. In Year 2, site visits to Joint Base Lewis-McChord (JBLM; formerly Ft. Lewis), Ft. Bliss, and Ft. Carson were conducted. In Year 3, investigators conducted initial site visits at Forts Campbell, Bragg, and Stewart. Additionally, the STEPS UP team conducted "kick off" site visits to JBLM and Ft. Bliss in Year 3, prior to starting recruitment. In Year 4, investigators conducted a "kick off" site visit at Ft. Carson. Also in Year 4, the team conducted a series of site visits to all six study sites in

order to discuss study progress with site personnel and local providers.

In terms of development of the protocol/instruments, the study team refined our recruitment strategy, finalized measures, refined final study methods, developed data collection procedures and forms, produced key materials (manuals, training materials, forms), and clarified safety procedures including inclusion criteria, consent procedures, and confidentiality protections during Years 1-2 of the study period. In Year 3, RTI, along with the other STEPS UP investigators, developed telephone interview and paper and pencil versions of the follow-up instruments to maximize data collection.

In terms of obtaining IRB approval, the study team coordinated regularly with the Human Research Protection Office (HRPO) to streamline the regulatory submission and approval process during Year 1. Also during Year 1, the study protocol and consent form were submitted HRPO for preliminary review and to the Walter Reed Army Medical Center (WRAMC) Department of Clinical Investigation (DCI) for official review as the lead IRB. RAND and RTI obtained IRB approval from their respective IRBs during Year 1, and the University of Washington and Boston VA Research Institute (BVARI) subawards also obtained preliminary IRB approval from their respective IRBs to begin work on the project. Additionally, per the guidance of HRPO and WRAMC DCI, the study team began to initiate an omnibus IRB agreement with each study site IRB beginning in Year 1.

In Year 2, WRAMC DCI, HRPO, and USUHS IRB approved the core protocol, consent form, and related study materials (20 appendices including data collection materials, manuals, impact statements, advertisements, and study personnel scripts). RAND and RTI had the protocol reviewed and approved and were pending final approval at the end of Year 2, after submission of revisions requested by HRPO. Additionally, the University of

Washington and BVARI received approval of the updated protocol package from their IRBs. As previously mentioned, investigators began to initiate Institutional Agreements (IAs) with each study site's IRB in order to streamline regulatory approvals. By the end of Year 2, all six site IRBs verbally agreed to cooperate with applicable IAs, and two site IAs (JBLM and Ft. Bliss) were under review.

Obtaining site IRB approvals to begin recruitment at each of the six study sites was time consuming and variable. As this was a relatively novel experience for most sites involved, the approval process varied across sites. Repeated inquiries to IRB staff were made to request information about approval procedures and obtain estimated timelines from IRB staff. Based on conservative estimates, it took approximately six months to receive site approval to begin recruitment for each site, from time of site-specific package submission, to issuance of a start letter. Due to these administrative delays and in order to begin recruiting as early as possible, we staggered start dates of each of the sites so recruitment could begin at each site as soon as IRB approval was received. In Year 3, the study team received final IRB approval at five of the six study sites: JBLM (February 2012), Ft. Bliss (March 2012), Ft. Campbell (April 2012), Ft. Carson (August 2012), and Ft. Stewart (August 2012). Final IRB approval for the sixth site, Ft. Bragg, was received in Year 4 (February 2013).

In terms of recruiting and consenting participants, the study team began recruiting participants at five of the six study sites in Year 3. Table 2 and Figure 1 below display final enrollment counts and timeline of the recruitment period. In Year 4, we examined the existing baseline data to determine variability in our main outcome measures, and conducted a power analysis based on these data. Results of this analysis showed that we would have adequate power for the study to test the main outcomes with around 625 enrolled

participants. We presented this work to the DSMB and they concurred that this plan appeared to be adequate, and our Science Office was also informed of our plan to reduce the projected number of participants and stop enrollment. In Year 4, active recruitment stopped at five study sites at the end of June 2013 (JBLM, Ft. Bliss, Ft. Carson, Ft. Stewart, and Ft. Bragg), and active recruitment stopped at Ft. Campbell at the end of July 2013. In Table 2 below, participants were enrolled in July and August 2013 based on availability to schedule appointments with the site research coordinators to provide informed consent, complete the eligibility assessment, and be randomized to a study arm.

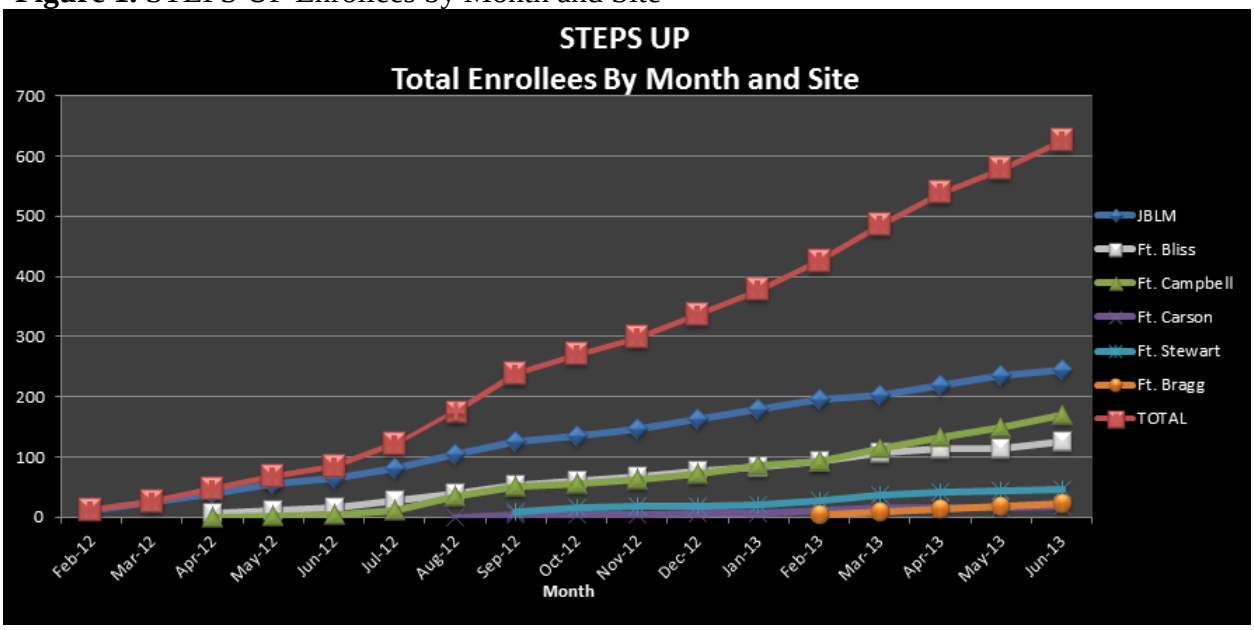
Table 2. STEPS UP Final Enrollment Counts and Timeline

Site	**Feb 12**	**Mar 12**	**Apr 12**	**May 12**	**June 12**	**July 12**	**Aug 12**	**Sept 12**	**Oct 12**	**Nov 12**	**Dec 12**	**Jan 13**	**Feb 13**	**Mar 13**	**Apr 13**	**May 13**	**June 13**	**July 13**	**Aug 13**
JBLM	12	26	40	56	65	82	104	125	134	146	162	180	196	203	219	235	244	250	250
Ft. Bliss			7	10	16	28	39	52	61	67	77	83	93	108	115	115	125	126	126
Ft. Campbell				2	3	11	34	50	56	62	73	86	93	114	133	150	169	190	200
Ft. Carson								3	4	5	7	7	12	15	16	16	18	18	18
Ft. Stewart								9	15	18	18	21	27	37	42	44	46	46	46
Ft. Bragg													4	9	14	18	23	26	26
TOTAL	12	26	47	68	84	121	177	239	270	298	337	377	425	486	539	578	625	656	666

Notes on Table 2:

- Numbers in cells are cumulative totals, not monthly totals
- Totals and timeline are for enrollment in the study; follow up data collection continued for 12 months following end of enrollment.

Figure 1. STEPS UP Enrollees by Month and Site



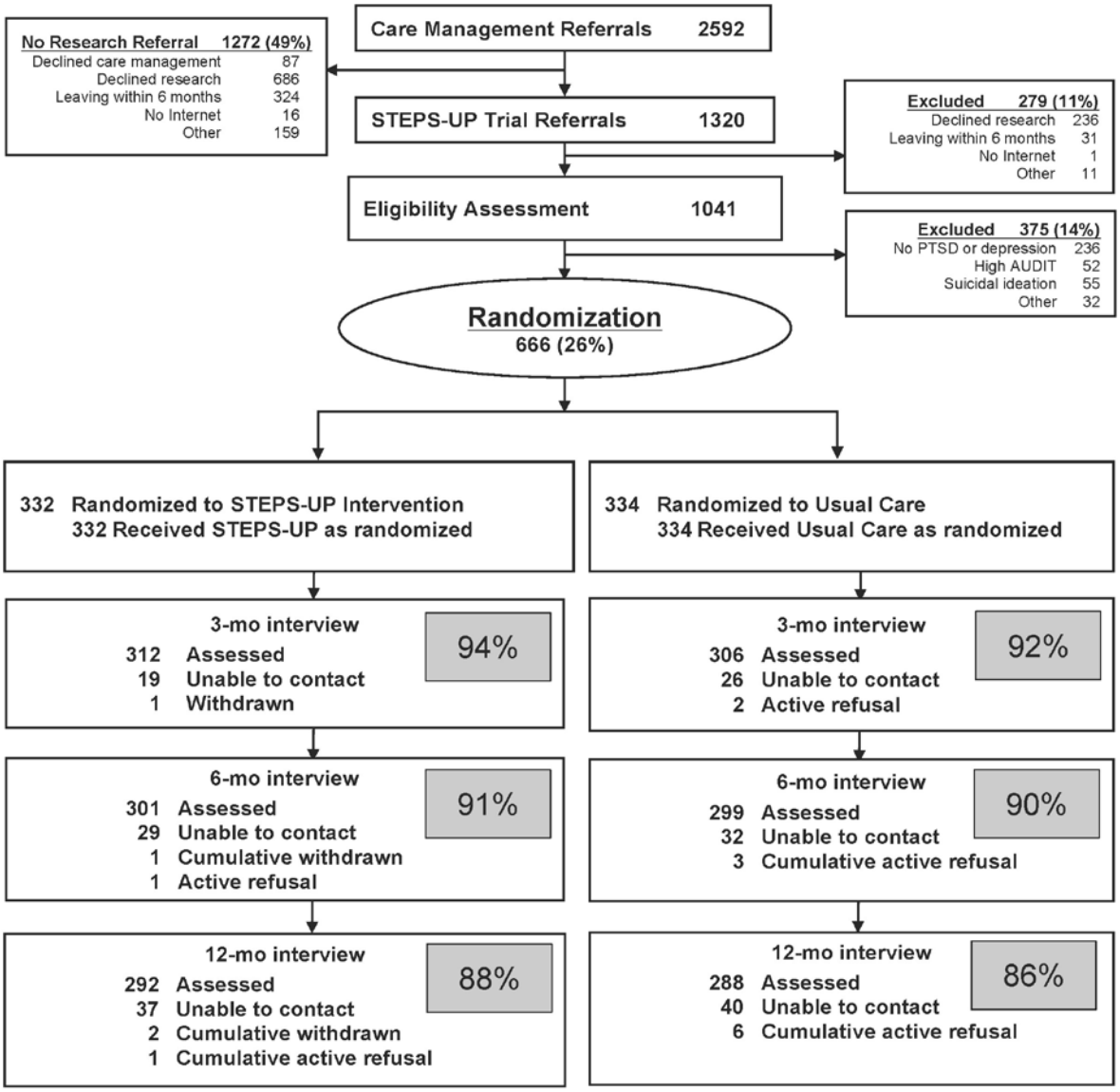
In October 2012 (Year 4, Quarter 1), investigators uncovered programming issues with the survey that resulted in some misclassification of cases within the project. We consulted with the IRBs and DSMB over specific plans for informing participants and for data analysis. The DSMB and all appropriate IRBs concurred with the proposed plans, and the study team implemented manual and automated checks of eligibility determinations for the remainder of the recruitment period to ensure the error was fully resolved.

In terms of data collection, participants began providing data at five of the six study sites in Year 3, and at the remaining site in Year 4. In Year 4, the study team began holding monthly calls with all of the study Site PI's, as well as regular calls every other week with all of the STEPS UP and regular RESPECT-Mil care facilitators at the six study sites. The purpose of these calls was to discuss any potential barriers to recruitment and retention of participants in the study, and brainstorm solutions to address these barriers. These regular calls were also useful so investigators could better understand local issues occurring at the sites that may have an impact on study participation. The regular calls with study Site PI's

continued in Year 5.

The study team completed follow-up data collection in Year 6, Quarter 1 (October 2014), keeping the data collection window open slightly longer than planned to capture the final assessments on a few patients. Final follow-up rates for the 666 participants in the study are as follows and are considered to be excellent (see Figure 2): 93% overall 3-month follow-up rate (94% in STEPS UP intervention arm; 92% in OUC arm); 90% overall 6-month follow-up rate (91% in STEPS UP intervention arm; 90% in OUC arm); and 87% overall 12-month follow-up rate (88% in STEPS UP intervention arm; 86% in OUC arm). Final administrative datasets were received in May 2015; by Year 6, Quarter 3, all institutions had access to the eligibility, baseline, 3-month, 6-month, and 12-month survey datasets, as well as FIRST STEPS, M2, and MDR administrative service use datasets.

Figure 2. Study flow diagram. Percentage in gray box is response rate by follow-up assessment and treatment arm.



In terms of analysis and writing, the study team prepared numerous publications, briefings, and presentations throughout the study period. In November 2014, a manuscript describing the overall design and methods of the STEPS UP study was published in

Contemporary Clinical Trials (see Appendix A). The primary outcomes manuscript was accepted for publication by the journal *JAMA Internal Medicine* in March 2016 and is in press (see Appendix B). A qualitative study manuscript describing barriers to engagement was accepted for publication by the journal *Psychiatric Services* for online publication in March 2016 and print publication in July 2016 (see Appendix C). Also, a manuscript describing mental health care service utilization in the study was accepted for publication by the journal *Medical Care* in February 2016 and was published in April 2016 (see Appendix D). A manuscript modeling trajectories of PTSD symptoms and predictors of one-year prognosis was accepted for publication by the *Journal of Traumatic* Stress in April 2016 and is in press (see Appendix E). A second qualitative study manuscript describing stakeholder experiences with stepped collaborative care (Appendix F) is under review for publication. Several other planned manuscripts are in the analysis and writing phases. The intervention materials are also in preparation. The study team also presented multiple study-related presentations and posters at various conferences throughout the study period. A full list of study publications and presentations is presented below in the "Reportable Outcomes" section of this report.

In terms of research team meetings, investigators held a kick-off conference call in the beginning of Year 1. We also convened a 1-day meeting in Washington, DC, in May 2010 to work on study measures. Over the course of the 6.5 year study period, study investigators participated in multiple routine weekly conference calls and other communications as necessary to ensure timely completion of all tasks.

In terms of ongoing QA/QC procedures, multiple amendments and regulatory documents were submitted to and approved by the lead WRAMC/WRNMMC, local site, RAND, RTI, BVARI, University of Washington, and HRPO IRBs throughout the study

period. In Year 2, amendments adding a WRAMC Medical Monitor and updating core protocol documents based on HRPO revisions were approved. In Year 3, amendments approved included revising the data collection section of the protocol and Appendix B (Data Collection Forms), adding new Site Principal Investigators at four study sites (JBLM, Ft. Campbell, Ft. Carson, and Ft. Bragg), revising eligibility criteria and updating data collection forms, and adding new site personnel (RTI-hired site coordinators, care managers, Medical Monitors, and Co-Investigators) at Ft. Bliss and Ft. Campbell.

In Year 4, an amendment allowing for reimbursement for off-duty participation in the trial via online Amazon.com gift cards was approved. Additionally, an amendment containing telephone interview and paper/pencil versions of the follow-up assessments, increasing the number of qualitative study interview participants, revising SAE reporting language in the core WRNMMC protocol, and updating site and centralized personnel was approved. After the web portal misclassification error was discovered, an amendment allowing investigators to manually check the study web portal automated eligibility determinations to ensure potential participants were correctly classified as eligible or ineligible for study participation was approved. After five months of manual checks where no errors were found, an amendment ceasing the manual checks and continuing a weekly automated check of all eligibility determinations was approved. Also, amendments making changes to the qualitative study (shortening and simplifying the primary care provider qualitative interview and conducting the chart-assisted recall portion of the qualitative interviews with the nurse care facilitators rather than the primary care providers) and modifying the study recruitment pamphlet were approved by the WRNMMC IRB in Year 4. Site-specific amendments updating personnel at all six study sites throughout Year 4 were

also submitted and approved by the each local site IRB and the lead WRNMMC IRB. An amendment increasing the number of allowed enrollees from the JBLM site from 250 participants to 350 participants was also approved in Year 4.

In Year 5, an amendment allowing investigators to digitize consent forms and store them centrally at RTI for the required six year time period rather than storing the hard copies at their respective posts was approved. Also, an amendment changing the study Initiating PI from COL Charles Engel to Dr. Michael Freed due to Dr. Engel's retirement from the military was approved. Amendments providing Data Safeguarding Plans for data sharing between RTI and the other partnering institutions (DHCC, RAND, University of Washington, and BVARI) to conduct data analyses were also approved by the IRB of each respective institution. One amendment submitted in Year 5 was to allow RTI to conduct batch tracing for lost-to-contact participants in order to get updated contact information to obtain follow-up data. The RTI IRB approved the amendment, but the WRNMMC did not approve the amendment, and batch tracing was not conducted. Site-specific amendments approved in Year 5 updated site personnel at all six study sites, including adding new Site PIs, Associate Investigators, Medical Monitors, and STEPS UP care facilitators. Also in Year 5, all partnering institutions (DHCC, RAND, University of Washington, and BVARI) finalized Data Transfer Agreements with RTI for the study datasets.

In Year 6, an amendment updating the core protocol and DHCC Data Safeguarding Plan to remove language regarding the "Safe Harbor method" and describing the administrative service use data being requested for analyses was approved by the WRNMMC IRB. Amendments changing the Initiating PI at HJF from Dr. Michael Freed to Dr. Bradley Belsher and updating the DHCC Data Safeguarding Plan with language about

long-term data storage at DHCC were also submitted to the WRNMMC IRB during the second EWOF period. Furthermore, amendments to update site personnel at the lead WRNMMC site, Ft. Bliss, Ft. Bragg, Ft. Carson, and JBLM (including adding a new Site PI at JBLM) were approved by the local site IRBs and core WRNMMC IRB in Year 6.

Continuing review packages for each institution, subaward, and study site were submitted on at least an annual basis to both the respective IRB and HRPO for approval to allow study continuation. After consultation with the local DDEAMC and lead WRNMMC IRBs, investigators submitted IRB closure report packages for the Ft. Campbell and Ft. Stewart sites in Year 6, Quarter 3 because study activities were no longer physically occurring at the study sites. Site closure packages for Ft. Bliss, Ft. Bragg, Ft. Carson, and JBLM were submitted to the local and WRNMMC IRBs in October 2015.

In Year 2, DSMB membership was finalized. In Year 4, two DSMB meetings were held to discuss study progress. A third meeting with the DSMB was held in Year 5, Quarter 2. The STEPS UP team held a final meeting with the DSMB in Year 6 to discuss and review study status.

In terms of submitting reports, investigators developed and submitted detailed study timelines for regulatory approval and recruitment projections to the Science Officer in Year 2 due to the administrative delays experienced in obtaining regulatory approvals. Investigators also revised the budget and SOW in Year 2 to reflect delays in obtaining regulatory approvals, anticipating that the study would take approximately 6.5 years to complete. In Year 3, investigators continued to update the regulatory approval and recruitment projection documents for the Science Officer to reflect current projections. Investigators also submitted updated SOWs in Years 3 and 4. In August 2013 (Year 4, Quarter 4), HJF submitted an

official request to USAMRAA to change the study Initiating PI from COL Charles Engel to Dr. Michael Freed. Dr. Engel transitioned to a Collaborator at RAND for the remainder of the study. This modification was issued by MRMC in January 2015. In November 2015, MRMC approved a request to change the Initiating PI from Dr. Michael Freed to Dr. Bradley Belsher due to Dr. Freed's job transition.

RAND and RTI submitted updated SOW's to USAMRAA in February 2014; HJF submitted an updated SOW in March 2014. At this time, HJF, RAND, and RTI also provided notice to MRMC that they would like to exercise the one-year extension without funds (EWOF) option, as it was clear early on that investigators would need an extension to conduct analyses and complete study deliverables, primarily due to extensive administrative delays in the beginning of the study period. All three organizations (HJF, RAND, and RTI) experienced administrative delays in negotiating the budget for the allowable one-year EWOF after Year 5 of the study period. There was an extended process in negotiating the extension officially from late February/early March 2014, until 23 January 2015. These administrative delays substantially slowed investigator capability to analyze data and initiate dissemination efforts. HJF, RAND, and RTI requested a second EWOF in order to complete approved analyses and reporting activities for the study. USAMRAA issued notification in August 2015 that an additional 6-month EWOF was granted which extended the award period of performance through 29 February 2016.

Specific Contributions of RTI

In addition to helping with the intervention development, execution of the randomized controlled trial, and ongoing project management activities detailed above, RTI designed, programmed, tested, and launched the study web portal, including secure web-based study

instrumentation, materials for site coordinators, and other study tools in Year 2. Part of this effort involved development and testing of an emergency alert system to address potential suicidal concerns that sometimes surfaced during patient enrollment screening. If patients screened positive for suicidal issues, the emergency system alerted the on-call mental health professional by a coded phone text message and a coded email that a potential respondent needed further evaluation. The patient was then contacted by the on-call mental health professional within a matter of a few minutes (often while still in the site coordinator's office completing screening and background information) and conducted a more formal assessment of the issue, determined whether further action was needed and, if so, set the help process in motion to address it. For the remainder of the study period, RTI continued ongoing routine maintenance and evaluation of the web portal and its functions. RTI collected data using the web-based portal in which participants were assessed about their PTSD, depression, and other issues at baseline, 3 months, 6 months and 12 months following enrollment. This took place from Year 3, Quarter 2 – Year 6, Quarter 1.

The RTI team was unable to make expected work progress early in Year 6 due to work stoppage pending USAMRAA confirmation of the one-year EWOF, until its approval on 23 January 2015. After confirmation of the EWOF, RTI resumed work, engaging in data editing, cleaning, and preparation of data files and comprehensive codebooks for the eligibility, baseline, 3-month, 6-month and 12- month follow-up assessments, and the M2 and MDR administrative datasets.

RTI also played a lead role in statistical analyses of the study findings for the primary outcomes manuscript in consultation with study partners in Year 6, and contributed to the writing and preparation of the manuscript reporting the main outcomes of the trial.

Finally, RTI continued internal and team discussions, planning, and preparation for analyses and writing of several additional manuscripts. RTI investigators were involved in all aspects of project management and maintaining the SharePoint data system as the study repository for all aspects of the study data, instruments, and manuscripts. RTI had lead responsibility for several papers that have been published, are in press, under review, or in progress. RTI also took the lead on several presentations at scientific meetings.

Specific Contributions of RAND

In addition to involvement with the intervention development, execution of the randomized controlled trial, and ongoing project management activities described above, staff at RAND developed and refined the qualitative interview protocols and emergency procedures for the qualitative portion of the study during Years 1-2, and contributed to the final measures so that appropriate inputs for the costs and cost-effectiveness analyses were gathered. In Year 3, RAND initiated the early-phase patient and nurse care manager interviews for the qualitative study portion of the trial. In Year 4, RAND continued conducting qualitative study interviews. RAND completed all interviews with patients, care managers, and providers within the qualitative study in Year 5. In total, RAND recruited 39 patients for the qualitative study and completed a total of 97 interviews with them (27 of the 39 patients completed all three interviews). In addition, RAND completed early phase qualitative interviews with eight nurse care managers and 7 late phase chart-assisted recall nurse care manager interviews (one care facilitator left the study early). RAND also completed 31 semi structured interviews with health care providers across the six study sites.

In Year 6, RAND completed analyses of patient, nurse care manager, and health care provider interviews for the qualitative study portion of the trial. As described above, a

manuscript using qualitative study data describing barriers to engaging in mental health care within the MHS was accepted for publication by *Psychiatric Services*, was published online in March 2016, and will be published in print in July 2016 (see Appendix C). A second manuscript using qualitative study data to examine stakeholder experiences with the collaborative care model has been submitted for publication and is pending peer review (see Appendix F). Findings from the qualitative study were also presented at multiple conferences in Year 6.

Throughout the study, RAND was actively engaged in obtaining administrative data, working with HJF and RTI to develop procedures for data storage and transfer, preparing and cleaning datasets, and analyzing data. During Year 6, several iterations of FIRST STEPS, M2, and MDR datasets were received and cleaned for analysis. In addition, RAND led the cost-effectiveness analysis, including gathering information on typical time spent on aspects of the intervention that were not captured in the medical records (i.e., phone calls, documentation). A manuscript evaluating the cost-effectiveness of STEPS UP has been submitted for publication and is pending peer review (see Appendix E). RAND also developed variables with the MDR dataset for the cost effectiveness and service utilization papers. Also, RAND led the effort to impute missing data for use by the investigative team and developed 10 datasets that fill in missing items through imputation for use by the project.

Specific Contributions of BVARI

Throughout the trial, BVARI investigators provided group supervision and oversight of the telehealth approaches to care. In Year 1, BVARI investigators obtained IRB approval from the Boston VA IRB, began work on the development of treatment protocols for the web-based self-management intervention for PTSD (DESTRESS-PC) and the phone-based therapy,

and hired a web company (Boston Interactive) to develop and maintain the DESTRESS-PC website. In Year 2, BVARI developed an initial full draft of the phone-based treatment protocol and worked with the web company (Boston Interactive) to make revisions to the DESTRESS-PC self-management intervention.

In Year 3, BVARI investigators developed a broad-based ideographic modularized approach to telephone therapy, and trained and supervised the two centralized psychologists in its use. The telephone therapy entailed ten therapeutic modules disseminated to patients and therapists with the purpose of being used in conjunction with phone-based therapy. The modules consisted of materials taken from the original DESTRESS study and a PTSD-specific telephone therapy manual. Since these materials were found to be too narrow in scope for the soldiers first enrolled in this study, BVARI collaborated with other STEPS UP study investigators to develop the modularized approach to provide additional content that specifically targeted high probability mental and behavioral health problems that service members face. The aim of using this updated, modularized approach was to be able to flexibly address the pressing needs that patients presented with in addition to increasing the credibility and usefulness of the therapeutic services offered through the study. This was intended to enhance patient engagement in care, reduce the risk of attrition and increase the effectiveness of the phone-based therapy. The modules were distributed to and approved by the study team, and BVARI investigators initiated weekly conference calls with study clinicians to familiarize them with the modules and strategies for assigning the appropriate modules to each patient and provide on-going support.

In Year 4, the BVARI study team began participating in the weekly staffing calls with study clinicians and each of the seven study care managers. BVARI's role in these calls was to

track study patients being staffed and write staffing notes that were then reviewed by study personnel and used to track the progress of patients in the centralized record system (FIRST STEPS). During this period, BVARI team members were also more generally available for as-needed telephonic consultation with nurse care managers, to provide additional clinical assistance for difficult clinical cases, and to provide one-on-one training in clinical strategies and techniques.

In Year 5, in addition to their continued role on the weekly staffing calls and providing telephonic consultation for care managers, the BVARI team provided consultation to the project team on strategies to increase usage of the DESTRESS-PC web-based self-management site, provided usage estimates of the site for internal reporting, and worked with the Boston-based contractor to restore an administrative feature of the site to full functionality. BVARI investigators presented on combat trauma types' relations with mental health as part of a symposium at the 30th Annual Meeting of the International Society for Traumatic Stress Studies (ISTSS) in November 2014. BVARI also secured local approvals for their Data Safeguarding Plan and Data Transfer Agreement.

BVARI investigators completed study deliverables and submitted a final report in January 2015 describing their responsibilities throughout the study period. In the final 1.5 years of the study, BVARI investigators continued to participate in weekly conference calls and contribute to the development of manuscripts and presentations as interest permitted.

Specific Contributions of University of Washington

Throughout the study period, University of Washington investigators contributed to care manager coaching, web-based therapy development, FIRST-STEPS enhancements, and general study implementation. In Year 1, University of Washington investigators refined and

developed training for the STEPS UP trial intervention and developed working drafts of the care management manual. Dr. Zatzick, in consultation with Drs. Unützer and Katon, initiated more intensive supervision related to care management practices in Year 2 - Year 6, Quarter 1, and Dr. Unützer provided expert consultation regarding information technologies development in support of the protocol in Years 2-4. University of Washington collaborators attended weekly telephone conferences with the study team and the regular University of Washington STEPS UP internal team meeting during the entire trial period.

During Years 5-6.5, University of Washington collaborators were involved in in-depth review and analysis of study data as well as planning and preparing manuscripts and presentations. Due to the passing of Dr. Wayne Katon in March 2015, Dr. Zatzick took over the role of Principal Investigator at the University of Washington for the study. Additionally, Joan Russo, PhD was added as a collaborator at the University of Washington in Year 6 to advise the University of Washington team on STEPS UP manuscript preparations and submissions. EWOFs were also approved for the University of Washington to continue work for the remainder of the project from September 2014 – January 2016. University of Washington investigators completed study deliverables and submitted a final report in February 2016.

KEY RESEARCH ACCOMPLISHMENTS:

The specific aims of this project were as follows:

Aim 1: To assess whether active duty primary care patients with PTSD and/or depression randomly assigned to 12 months of STEPS UP will report significantly reduced PTSD and depression symptoms (primary outcomes) compared to those randomly assigned to optimized usual care.

Aim 2: To evaluate whether active duty primary care patients with PTSD randomly assigned to 12 months of STEPS UP will report significantly reduced symptoms of anxiety and somatic symptom severity, alcohol use, mental health functioning, and work functioning (secondary outcomes) compared to those randomly assigned to 12 months of optimized usual care.

Aim 3: To examine whether active duty primary care patients with PTSD and/or depression randomly assigned to 12 months of STEPS UP have significantly lower direct and indirect costs of care and a more favorable cost-effectiveness ratio (tertiary outcomes) compared to those randomly assigned to 12 months of optimized usual care.

Aim 4: To use state-of-the-art qualitative methods to examine participant, clinician, care manager, and family member perceptions of STEPS UP as well as associated intervention outcomes.

Many findings are still undergoing peer review and are not yet published. Thus, they must be considered preliminary.

- Aim 1: We found that compared to usual care, participants in the STEPS UP intervention arm reported significantly greater reductions in PTSD and depression symptoms over 12-months of follow-up as shown in Table 3. Differences in effects were statistically significant at 12-months for PTSD and at 6- and 12-months for depression. The STEPS UP intervention was also associated with clinically significant improvements (for every 12 patients (with PTSD) or 11 patients (with depression), we see a 50% improvement in symptoms). Main outcomes are further described in Appendix B.

Table 3. PTSD and depression related outcomes among study patients.

Outcome	CACT (n=332)	Usual Care (n=334)	Measure (95% CI)	p-value
PTSD (PDS) Severity				
0 to 3 months	-2.95[1] (0.53)	-2.73 (0.54)	-0.23 (-1.72,1.26)	0.59
0 to 6 months	-4.86 (0.61)	-3.42 (0.60)	-1.43 (-3.11, 0.25)	**0.057**
0 to 12 months	-6.07 (0.68)	-3.54 (0.72)	-2.53 (-4.47,-0.59)	**0.0029**
Depression (SCL-20)				
0 to 3 months	-0.29[1] (0.04)	-0.20 (0.04)	-0.08 (-0.19, 0.03)	0.062
0 to 6 months	-0.44 (0.05)	-0.25 (0.05)	-0.19 (-0.32, -0.06)	**0.0007**
0 to 12 months	-0.56 (0.05)	-0.31 (0.05)	-0.26 (-0.41, -0.11)	**<0.0001**
≥50% Improvement, PTSD				**0.023**
0 to 3 months	11.5[2] (36)	9.5 (29)	1.25[3] (0.74, 2.09)	0.40
0 to 6 months	19.3 (58)	13.4 (40)	1.55 (0.99, 2.40)	0.0510
0 to 12 months	25.0 (73)	17.0 (49)	1.62 (1.08, 2.43)	**0.0194**
≥50% Improvement, Depression				**0.014**
0 to 3 months	12.2[2] (38)	10.8 (33)	1.14[3] (0.70, 1.88)	0.60
0 to 6 months	21.3 (64)	13.8 (41)	1.70 (1.11, 2.61)	**0.0149**
0 to 12 months	29.7 (86)	20.6 (59)	1.65 (1.13, 2.42)	**0.0100**

[1] mean (SE)
[2] percent improved (number improved)
[3] odds ratio (95% confidence limits)
PDS=PTSD Diagnostic Scale
SCL-20=Hopkins Symptom Checklist, 20 item depression screen

- Aim 2: We also detected significant changes in several secondary outcomes as shown in

Table 4. The STEPS UP intervention arm was significantly associated with decreased physical symptom burden (as measured by the PHQ-15), improved mental health functioning (as measured by the SF-12 mental component), but no changes for alcohol consumption (as measured by the AUDIT-C), physical health function (as measured by the SF-12 physical component) or pain (intensity and interference) were observed.

Table 4. Changes in secondary outcomes among study patients from baseline to each follow-up assessment.

	CACT (n=332)	**Usual Care (n=334)**	**Measure (95% CI)**	**Overall P Value**
AUDIT-C, mean (SE)				0.24
0 to 3 months	-0.26 (0.12)	-0.29 (0.12)	-0.04 (-0.28, 0.36)	
0 to 6 months	-0.34 (0.13)	-0.33 (0.12)	-0.001 (-0.35, 0.35)	
0 to 12 months	-0.54 (0.14)	-0.20 (0.14)	-0.33 (-0.72, 0.06)	
PHQ-15, mean (SE)				**0.0252**
0 to 3 months	-1.12 (0.25)	-0.58 (0.25)	-0.53 (-1.22, 0.15)	
0 to 6 months	-1.56 (0.26)	-0.69 (0.29)	-0.88 (-1.64, -0.11)	
0 to 12 months	-2.29 (0.33)	-0.92 (0.31)	-1.37 (-2.26, -0.47)	
SF-12, mean (SE)				
Physical (PCS)				0.65
0 to 3 months	-1.02 (0.41)	-1.16 (0.44)	0.14 (-1.04, 1.31)	
0 to 6 months	-0.64 (0.45)	-1.10 (0.46)	0.46 (-0.80, 1.72)	
0 to 12 months	-1.11 (0.47)	-1.25 (0.55)	0.14 (-1.29, 1.57)	

Mental (MCS)				**0.014**
0 to 3 months	4.31 (0.65)	4.13 (0.65)	0.18 (-1.62, 1.98)	
0 to 6 months	5.78 (0.74)	3.51 (0.74)	2.28 (0.23, 4.33)	
0 to 12 months	8.10 (0.80)	4.93 (0.82)	3.17 (0.91, 5.42)	
Pain Intensity, mean (SE)				0.32
0 to 3 months	-0.17 (0.13)	0.02 (0.11)	-0.19 (-0.51, 0.14)	
0 to 6 months	-0.18 (0.13)	0.08 (0.13)	-0.26 (-0.61, 0.10)	
0 to 12 months	-0.25 (0.15)	0.08 (0.12)	-0.33 (-0.74, 0.07)	
Pain Interference, mean (SE)				0.36
0 to 3 months	0.09 (0.19)	0.27 (0.13)	-0.17 (-0.54, 0.20)	
0 to 6 months	-0.05 (0.15)	0.18 (0.14)	-0.23 (-0.63, 0.18)	
0 to 12 months	-0.19 (0.16)	0.20 (0.17)	-0.39 (-0.85, 0.07)	

AUDIT-C=Consumption items of the Alcohol Use Disorders Identification Test
PHQ-15=Patient Health Questionnaire somatic symptom severity score
MCS=SF-12 Mental Component Summary score
PCS=SF-12 Physical Component Summary score

- We also examined three symptoms of suicidality (for questions of "hopelessness about the future," "thoughts of death and dying," and "thoughts of ending one's life") that are part of the depression measure, and found that these were significantly reduced in the STEPS UP condition as well. Specifically, repeated measures analysis (treatment group, by time, and their interaction) revealed statistically significant reductions in suicide-related SCL-20 items in the STEPS UP arm (versus no change in usual care) for "hopelessness about the future" (p=0.04), "thoughts of death and dying" (p=0.003), and in "thoughts of ending

one's life (p=0.04).

- We further examined the development of the suicide risk management (SRM) protocol used within the STEPS UP study, and are preparing a manuscript to describe how suicide risk was managed in our large randomized trial, describe features of people who tripped our SRM system in our trial, and describe the potential role for this model for reducing suicide in general medical settings. The web-based STEPS UP data collection instrument included a component designed to review and alert appropriate project staff of concerns about a respondent's mental state. When a research participant endorsed suicidality at a clinically significant level while completing the screening or follow-up assessment, an on call study provider and site research staff were automatically alerted via de-identified email and page/text. After receiving the alert, the provider would electronically acknowledge receipt of the information and then attempt to contact the participant for further assessment and to make appropriate treatment recommendations. Based on the on call provider's assessment, appropriate next steps were taken (escort to ER, notify care manager and/or primary care provider, etc.). In this paper, we present challenges and successes with implementing a suicide risk management protocol as part of a large multi-site randomized effectiveness trial for service members with PTSD and depression in military primary care settings, and discuss this model's potential utility for use in routine clinical practice in suicide prevention within other large integrated healthcare

systems.

- To further understand the findings in Aims 1 and 2, we also examined the process of care. We found that the STEPS UP intervention was also significantly associated with more telephone contacts and more months on an appropriate PTSD and depression medication than the usual care group as noted in Table 5.

Table 5. Patient reported mental health service use by treatment group (mean, SE).

			Treatment Effect	
	CACT (n=332)	**Usual Care (n=334)**	**Measure (95% CI)**	**P****
Individual Therapy Visits				0.49
3 months prior to enrollment	2.66* (0.27)	2.68 (0.45)	-0.02 (-1.06, 1.01)	
0 to 3 months	2.94 (0.26)	2.86 (0.26)	0.08 (-0.62, 0.79)	
3 to 6 months	2.82 (0.29)	2.32 (0.24)	0.50 (-0.24, 1.24)	
6 to 12 months	3.66 (0.47)	3.55 (0.41)	0.11 (-1.11, 1.33)	
Telephone Contacts				**<0.0001**
3 months prior to enrollment	1.53 (0.14)	2.56 (0.63)	-1.03 (-2.30, 0.25)	
0 to 3 months	3.05 (0.22)	1.76 (0.13)	1.·29 (0.80, 1.79)	
3 to 6 months	2.72 (0.31)	1.46 (0.13)	1.26 (0.59, 1.92)	
6 to 12 months	3.30 (0.35)	1.99 (0.22)	1.31 (0.51, 2.12)	
Months of Depression Medication[1]				**0.0129**
3 months prior to enrollment	0.67 (0.06)	0.77 (0.06)	-0.10 (-0.26, 0.07)	
0 to 3 months	1.30 (0.07)	1.13 (0.08)	0.16 (-0.05, 0.37)	

3 to 6 months	1.37 (0.08)	1.22 (0.08)	0.15 (-0.07, 0.37)	
6 to 12 months	2.42 (0.16)	2.02 (0.16)	0.40 (-0.05, 0.84)	
Months of PTSD Medication[2]				**0.0122**
3 months prior to enrollment	0.47 (0.05)	0.51 (0.06)	-0.04 (-0.18, 0.11)	
0 to 3 months	1.05 (0.07)	0.85 (0.07)	0.20 (-0.003, 0.39)	
3 to 6 months	1.20 (0.08)	0.88 (0.08)	0.32 (0.10, 0.53)	
6 to 12 months	2.03 (0.16)	1.60 (0.15)	0.43 (0.003, 0.86)	

[1] Any antidepressant medication
[2] Any selective serotonin reuptake inhibitor or prazosin
* mean (standard error)
** p for treatment difference averaged over 3-, 6-, and 12-month assessments

- Additionally, we examined differences in mental health utilization patterns between patients in the STEPS UP arm relative to patients in the collaborative care as usual treatment arm (see Appendix D). Utilization data acquired from MHS administrative datasets were analyzed to determine mental health service use and patterns. Clinical complexity and patient characteristics were determined based on self-report questionnaires collected at baseline. Compared to the treatment as usual arm, STEPS-UP participants received significantly more mental health services ($p < .001$ for primary care encounters and $p = .012$ for specialty mental health encounters) and psychiatric medications ($p = .016$) across primary and specialty care settings during the year of their participation. Patterns of service use indicated that greater clinical complexity was associated with increased service use in the STEPS UP group, but not in the usual care group ($p = .027$). Results suggest that stepped, centrally-assisted collaborative care models

such as STEPS UP may increase the quantity of mental health services patients receive, while efficiently matching care based on the clinical complexity of patients.

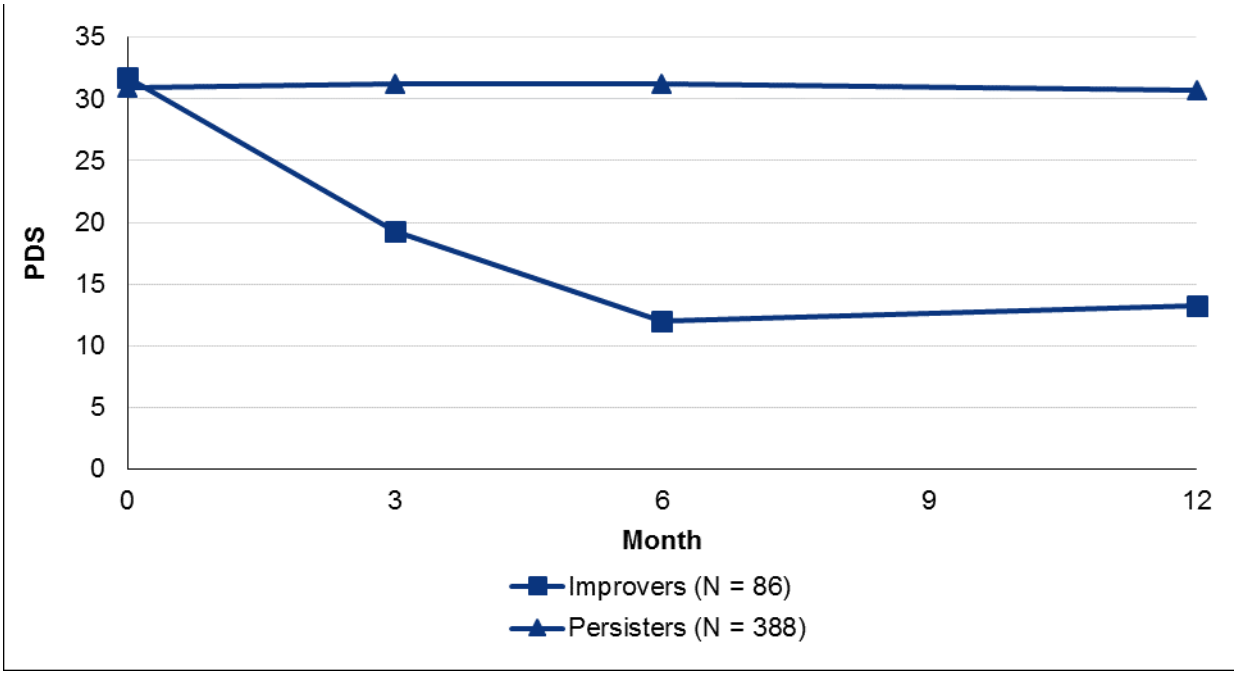
- We also examined the longitudinal course of primary-care patients with PTSD associated in the active-duty Army and identified prognostic indicators of PTSD severity (see Appendix E). To do this we conducted analysis on a subset of participants from the STEPS UP trial, specifically, 474 soldiers with PTSD defined as scoring ≥50 on the PTSD Checklist. Assessments were obtained at six US Army installations, at baseline with follow-ups at 3-months (93% response rate (RR)), 6-months (90% RR), and 12-months (86% RR). Combat exposure and seven validated indicators of baseline clinical status (alcohol misuse, depression, pain, somatic symptoms, low mental health function, low physical health function, mild traumatic brain injury) were used to predict PTSD symptom severity outcomes using the Posttraumatic Diagnostic Scale. Growth mixture modeling identified two trajectories of PTSD symptom change and multivariate logistic regression modeling identified baseline clinical predictors of symptom trajectories, controlling for demographics, installation, and treatment condition.

  Two PTSD symptom trajectories were identified as shown in Figure 3: (a) patients reporting persistent symptoms over 12 months (Persisters, 82%, n = 388), and (b) patients reporting improvements in symptoms (Improvers 18%, n = 86). Logistic regression showed that patients reporting moderate combat exposure adjusted OR = 0.441, 95% CI = 0.198 – 0.981) or high combat exposure (OR= 0.386, 95% CI = 0.171 – 0.872) were less likely to be Improvers. Other baseline clinical

problems were not related to subsequent symptom trajectories.

It is sobering that most primary care patients with military-related PTSD experienced persistent symptoms. Little is known about the most effective management strategies for patients with PTSD first diagnosed in primary care and the best methods and settings for effectively treating them. These findings highlight the importance of improving the effectiveness of their care. Most indicators of clinical status, while related to future PTSD outcomes, offered little prognostic information beyond the brief assessment of combat exposure.

Figure 3. Trajectories for PTSD Treatment Outcomes



- Additionally, we examined pain as a moderator of treatment effects in the study; a manuscript on this topic is being prepared. The prevalence of chronic pain in U.S. service members is 44%, with nearly half of these reporting chronic pain duration

in excess of one year. Additionally, those with posttraumatic stress disorder (PTSD) and major depressive disorder are significantly more likely to experience chronic pain. Several decades of research on the co-occurrence of pain and depression as well as pain and PTSD show that the relationship is bidirectional. The empirical collaborative care literature on the impact of chronic pain on the management of depression and anxiety including PTSD suggests that collaborative care is effective in patients with chronic pain, although the size of the effect may be lessened. The current study examined the degree to which pain severity moderates treatment effects for a collaborative care-based model of PTSD and depression treatment compared to treatment as usual. Pain was a significant moderator of the STEPS UP treatment effect ($b=-.07$, $p<.05$) among those with PTSD, and the coefficient indicated that as pain increased, the difference in change over time between the STEPS UP and TAU groups increased. Results for depression followed the same pattern as those for PTSD. These findings suggest that pain should be strongly considered in the treatment plans of active duty service members with PTSD and/or depression.

- We also examined whether changes in alcohol misuse status over the course of the STEPS UP study affected PTSD and depression treatment outcomes. Alcohol misuse, and PTSD and depression symptoms were assessed longitudinally over the course of the year in the STEPS UP trial. Results revealed significant changes in alcohol misuse status over the course of the study. Findings also revealed that trends in alcohol misuse status were associated with smaller reductions in PTSD and depression symptoms at long-term follow-up (6 months and 12 months).

Findings highlight the significance of considering alcohol misuse in the treatment of PTSD and depression in military primary care.

- Additionally, we evaluated alcohol misuse screening in the trial In the STEPS UP trial, both the STEPS UP and usual care interventions included routine symptoms screening by a care manager in primary care. Screening of alcohol misuse was encouraged, but not required in both conditions. We examined differences in screening rates between intervention conditions. The STEPS UP intervention had much higher rates of alcohol screening by care managers during the study year (74.4%), compared to the usual care intervention (5.7%). Components of the STEPS UP training that may have improved screening rates (e.g., engagement-focused staffing, motivational interviewing skills training and supervision) are discussed in this manuscript. We also examined adverse events. There were no participant deaths and no psychiatric emergencies or hospitalizations determined to be study related.
- Furthermore, we are evaluating overlapping symptoms of PTSD, depression, and mild traumatic brain injury (mTBI). Several studies have identified a strong association between mTBI, PTSD, and depression among combat veterans. The discourse surrounding the complex relationship of these conditions has at times been polarized. At one end of the continuum are those who might discount mTBI among service members as an interesting psychosomatic manifestation of war-related psychological injury. Still others, at the other extreme, have maintained the presence of a hidden epidemic of war-related mTBI among war veterans, suggesting perhaps that much of the "PTSD" observed after other combat

deployments was actually misdiagnosed mTBI.

This paper seeks to illustrate how this diagnostic overlap affects the practical assessment of PTSD and mTBI as well as the limits of that assessment from the perspective of the diagnostician. The clinical diagnoses of PTSD and of mTBI are both "symptom-based". That is, diagnoses are made based on characteristic symptom constellations. There is no known reliable or pathognomonic sign (an observable finding elicited on physical examination) and no definitive laboratory or imaging test that the clinician may use to establish either diagnosis.

We use data from a primary care sample of Army personnel meeting screening criteria for PTSD or depression, a large proportion of whom also report a history of one or more mTBI events to: (1) assess the clinical overlap between PTSD, depression, and mild TBI; and (2) to test the clinical capacity of characteristic symptoms to support the presence or absence of these three commonly comorbid syndromes. We then perform similar analyses in a larger population sample of soldiers to contrast the performance of characteristic symptoms in the population (non-clinical) context. At present, data analyses for the paper have been completed and a draft of the paper is in preparation.

- Also, we are evaluating the central assistance component of the STEPS UP intervention. Integrated healthcare models aim to improve access and continuity of mental health services for patients in general medical settings. Unlike specific treatment interventions targeting a particular disorder, collaborative care models aim to improve the care system for a targeted population through use of an

interdisciplinary team with pre-assigned roles and structured protocols, uniform screening and longitudinal measurement, the use of registries to support measure-guided treatment, and data-driven quality improvement. The centralized component of the STEPS UP intervention aimed to ensure greater fidelity to the collaborative care model, increase uptake of evidence based treatments, and improve treatment outcomes, as compared to the usual collaborative care group. The goal of this paper is evaluate multiple data sources to determine how effective this centrally-assisted intervention maintained fidelity to central collaborative care components over time, promoted evidence-based care for patients, and improved treatment outcomes across the entire symptomatic population of participants. We hypothesize that (1) STEPS UP will promote greater fidelity to collaborative care across time based on care contacts, symptom monitoring, and patient staffing; (2) patients in the STEPS UP arm will be more likely to receive evidence-based care as defined by a prescription for an SSRI/prazosin or eight mental health sessions by a mental health provider; and (3) patients in the STEPS UP arm will be more likely to be diagnosis-free by the end of the trial. Results will help inform healthcare delivery in the MHS.

- Additionally, we are examining the relation between work functioning, mental health, and alcohol use. The effectiveness of the military is dependent upon the productivity of its individuals and teams in carrying out both routine daily tasks as well as complex, coordinated operations, at home and around the world. The high level of operational tempo experienced since 9/11 has produced a generation of soldiers who are fatigued from multiple deployments, high levels of combat

exposure, and complex systems of care for physical and mental injuries upon return. These factors often deplete the resources of the individuals who face them, which may in turn jeopardize the individual's ability to perform to their full capacity at work. The end result is a negative impact to overall force readiness, work functioning, and productivity. Therefore, it is vital to understand and minimize factors contributing to diminished work functioning and subsequent productivity loss.

This paper seeks to examine the extent to which work functioning (conceptualized as presenteeism and absenteeism) is impacted and can be predicted by mental health (PTSD and depression) and alcohol use problems, and how changes in these factors over time correlate to changes in work functioning. We use longitudinal data from a randomized controlled behavioral trial of Army personnel meeting screening criteria for PTSD or depression. Analyses focus on (a) developing a path model to estimate the relationship of mental health and substance use to work functioning at a single time point, and (b) establishing estimates of change in work functioning from baseline to 12-month follow-up. Preliminary analyses indicate small improvements in work functioning over time, which, though statistically modest, from a practical standpoint translate into huge monetary savings at the organizational level. At present analyses are mostly complete but still in progress, and a draft of the manuscript is in preparation.

- We are also examining the placement of PTSD within a recently-proposed alternative to the traditional DSM arrangement of emotional disorders into the two broad categories of mood and anxiety disorder. The DSM approach to

determination of common and distinctive features of disorders has depended as much—if not more—on expert consensus as on solid empirical evidence concerning shared features. In contrast, the proposed reformulation of these conditions is based on actual, rather than perceived, similarities. From this new perspective, the structure of these disorders is better explained by a model that differentiates "distress" disorders from "fear" disorders. The feature common to distress disorders is the pervasive presence of general distress or dysphoria whereas the principle characteristic of fear disorders is the predominance of somatic hyperarousal. Thus, within this realignment, disorders epitomized by the presence of symptoms of subjective distress (e.g., worry, despair, restlessness, and loss of interest) are characterized as distress orders. By contrast, disorders typified by symptoms of somatic or anxious arousal (e.g., heart pounding, trembling, shortness of breath, and feeling light-headed or dizzy) are classified as fear disorders. Empirical data generally support this alternative hierarchical model of the mood and anxiety disorders. Specifically, panic disorder, agoraphobia, specific phobia, and social phobia appear best viewed as "fear" disorders whereas general anxiety disorder (GAD), major depression and dysthymia are best regarded as "distress" disorders. At present, however, the placement of PTSD within this system is unresolved. Although PTSD has historically been viewed as a disorder of fear, ample evidence indicates that symptoms characteristic of PTSD are shared with both major depression and GAD. Thus, it is not clear whether PTSD is best conceptualized as a fear disorder, a distress disorder or as some mixture.

Therefore, we will report the results of latent variable covariance structure modeling using data derived from three different studies (i.e., the STEPS UP intervention; a longitudinal study of veterans exposed to combat; and a longitudinal study of survivors of injuries requiring hospitalization). As revealed across seven different data sets from these three studies, results are consistent with placement of PTSD as a distress disorder sharing more in common with GAD and major depression than with the fear disorder of agoraphobia, panic disorder, specific phobia, and social phobia. Generally speaking, all PTSD symptom clusters are more strongly associated with external markers of general distress than with markers of anxious arousal. The clinical and research implications of these findings will be discussed.

- We are also examining the reciprocal relations among PTSD symptoms, depressive symptoms, and health-related quality of life (HRQOL) over the course of the STEPS UP trial. Although a considerable body of research has descriptively documented levels of HRQOL associated with depression and, to a lesser extent, PTSD, most research has been cross-sectional in nature. Little attention has been devoted to the impact of depression and PTSD on HRQOL over time. Moreover, to our knowledge, no research has examined simultaneously the impact of depression and PTSD on HRQOL. Conversely, investigations have seldom, if ever, studied the potential influence of HRQOL on either PTSD or depression.

  We are testing two hypotheses: (1) PTSD symptom severity and depression symptom severity are independently and significantly associated with

HRQOL such that high levels of PTSD symptom severity and high levels of depression symptom severity predict decreases in HRQOL across time; and (2) HRQOL is predictive of changes in both PTSD and depressive symptoms over time. This paper will address these hypotheses in the context of cross-lagged panel modeling of data drawn from the STEPS UP clinical trial. In this modeling framework, depressive symptom severity, PTSD symptom severity, and HRQOL scores will be examined as both antecedents and consequences of each other over time. Findings will be discussed with respect to clinical implications and future research directions.

- Aim 3: Collaborative care can be an effective treatment for PTSD and depression, but the cost-effectiveness of this approach is understudied. To evaluate the cost effectiveness of stepped, collaborative care (STEPS UP) compared with optimized usual care (OUC) for PTSD and depression in the military health system (MHS), quality of life, depressive and PTSD symptoms were measured at baseline, 3, 6 and 12-months. Quality adjusted life years (QALYs) derived from military health records and claims data were used to estimate costs of medical care from a societal perspective. 629 patients (320 STEPS-UP; 309 OUC) who received the intervention and had both cost and health outcome follow-up data were included in the analysis. STEPS UP patients gained approximately 0.02 QALYs (95% CI: -0.001, 0.03) relative to OUC patients. STEPS UP had $1754 significantly higher intervention costs over a 12-month period, but total costs were only $987 (95% CI: -$3056, $5030) higher versus OUC. STEPS UP is estimated to cost $49,346 per QALY gained compared to OUC over 12-months. There is a 58% probability that STEPS UP is cost-effective at a $100,000/QALY threshold. The STEPS

UP collaborative care intervention appears to be a cost-effective strategy for managing PTSD and depression in the MHS.

- Aim 4: Qualitative Study Results

    - One manuscript published in *Psychiatric Services* examines patient and provider perspectives on the STEPS UP intervention (see Appendix C). Specifically, the study included patients recruited for the study, health care providers working within site clinics, and the care managers employed within the study to implement the intervention protocol.

      Results of the qualitative analysis raised a number of issues, which fell into two main categories: structural factors associated with the system itself and institutional attitudes and cultural issues across the U.S. military. Structural issues included concerns about the existing capacity of the system, for example whether there were enough providers available to address the populations' needs and the constraints on clinic hours and scheduling practices. The institutional attitude and cultural issues fell into two main areas: attitudes and perceptions among the leadership and the concern that those attitudes could result in negative career repercussions for those who access care.

      The findings reveal that despite these significant efforts, stakeholders within the Army medical system still perceive significant barriers to care. Efforts to ensure adequate, timely, and quality access to mental health care for service members will need to appropriately respond to capacity constraints and organizational and institutional culture.

- A second qualitative paper currently under review examines stakeholder experiences with collaborative care (see Appendix F). The STEPS UP study was designed to leverage the effective components of collaborative care models to improve care for soldiers with PTSD and depression in military health settings. Insights from stakeholder experiences with collaborative care models may improve implementation of these approaches in the future. This paper examines providers, care facilitators, and patients' perceptions of integrating behavioral health care in primary care settings, the use of care facilitation to improve treatment, and the specific therapeutic tools used within the study. Stakeholders included patients recruited for the study (n=38), health care providers working within site clinics (n=31), and the care managers employed within the study to implement the intervention protocol (n=7). We conducted a series of qualitative interviews with study stakeholders within the context of a large randomized controlled trial being conducted across 18 Army primary care clinics. Most stakeholders concerns clustered around the need to improve collaborative care tools and care managers and providers' comfort and abilities to treat behavioral health issues in the primary care setting. While stakeholders recognize the value of collaborative care in overcoming barriers to care, perspectives among stakeholders about the value and utility of different tools varied. The extent to which the collaborative care mechanisms are well-understood, navigated and implemented by providers, care facilitators, and patients is critical to the success of the model. Improving web-based therapy tools as well as additional training for primary care providers on screening and treatment for PTSD and depression

and the collaborative care model's structure, processes, and offerings may improve stakeholder perceptions and utilization of collaborative care.

REPORTABLE OUTCOMES:

Published Manuscripts:

Belsher BE, Jaycox LH, Freed MC, et al. Mental health utilization patterns during a stepped, collaborative care effectiveness trial for PTSD and depression in the military health system. *Med Care*. 2016; Epub ahead of print.

Engel CC, Bray RM, Jaycox L, et al. Implementing collaborative primary care for depression and posttraumatic stress disorder: Design and sample for a randomized trial in the U.S. military health system. *Contemp Clin Trials*. 2014;39(2):310-319. doi: 10.1016/j.cct.2014.10.002.

Ramchand R, Rudavsky R, Grant S, Tanielian T, Jaycox L. Prevalence of, risk factors for, and consequences of posttraumatic stress disorder and other mental health problems in military populations deployed to Iraq and Afghanistan. *Curr Psychiatry Rep*. 2015; published online 16 April 2015. doi: 10.1007/s11920-015-0575-z. Available at: http://rd.springer.com/article/10.1007/s11920-015-0575-z.

Tanielian TL, Woldetsadik M, Jaycox LH, et al. Barriers to engaging service members in mental health care within the U.S. military health system. *Psychiatr Serv*. 2016;Epub ahead of print.

Accepted Manuscripts:

Bray RM, Engel CC, Williams J, et al. Posttraumatic stress disorder in military primary care: Trajectories and predictors of one-year prognosis. *J Trauma Stress.* In press.

Engel CC, Jaycox L, Freed MC, et al. Centrally assisted collaborative telecare for posttraumatic stress disorder and depression among military personnel attending primary care: A randomized controlled trial. *JAMA Intern Med*. In press.

Freed MC, Novak LA, Killgore WDS, et al. IRB and research regulatory delays within the military healthcare setting: Do they really matter? And if so, why and for whom? *Am J Bioeth*. In press.

Submitted Manuscripts:

Batka C, Tanielian T, Woldetsadik MA, Farmer C, Jaycox LH. Stakeholder experiences in stepped collaborative care study within US Army clinics. Under review.

Manuscripts in Preparation:

Belsher BE, et al. Centralized, collaborative care framework for managing mental health disorders in the military health system. In progress.

Bray RM, et al. Challenges diagnosing PTSD, depression, and mTBI from overlapping symptoms. In progress.

Evatt DP, et al. Association between alcohol misuse and PTSD and depression treatment. In progress.

Evatt DP, et al. Effects of enhanced collaborative care on alcohol misuse screening in primary care. In progress.

Freed MC, et al. At the crossroads of research and practice: Challenges and successes implementing a suicide risk management protocol as part of a multi-site randomized effectiveness trial for the management and treatment of PTSD and depression in military primary care. In progress.

Lane ME, et al. Improving work functioning among U.S. soldiers in collaborative care. In progress.

Lavelle T, et al. The cost-effectiveness of a collaborative care approach to treating depression and post-traumatic stress disorder in military personnel. Under review.

Marshall G, et al. Temporal associations among PTSD symptom severity, depression symptom severity, and health-related quality of life in treatment-receiving military personnel. In progress.

Marshall G, et al. The association of PTSD symptom clusters with general distress and

anxious arousal: Implications for an alternative structure of mood and anxiety disorders. In progress.

Rae Olmsted K, Bray RM, Morgan J, Williams J, Engel CC. Pain as a moderator of collaborative care treatment effects for PTSD and depression. In progress.

Planned Presentations:

Belsher BE, Engel CE, Novak LA, et al. Population-based impact of an enhanced collaborative care intervention in the military health system (MHS). Part of ISTSS Symposium: Evaluating the Population Impact of an Enhanced Collaborative Care Intervention for PTSD and Depression: Examining Reach, Effectiveness, and Cost Effectiveness across the Military Health System (MHS). Belsher, BE. (chair). Abstract submitted for presentation at: 32nd Annual Meeting of the International Society for Traumatic Stress Studies; November 2016; Dallas, TX.

Evatt DP, Belsher BE, Beech EH, et al. Alcohol misuse and co-occurring PTSD in military primary care: Identification and population impact. Part of ISTSS Symposium: Evaluating the Population Impact of an Enhanced Collaborative Care Intervention for PTSD and Depression: Examining Reach, Effectiveness, and Cost Effectiveness across the Military Health System (MHS). Belsher, BE. (chair). Abstract submitted for presentation at: 32nd Annual Meeting of the International Society for Traumatic Stress Studies; November 2016; Dallas, TX.

Lavelle T, Engel, C, Freed, M, Kommareddi M, Belsher, B, Jaycox L.H. The cost-effectiveness of a collaborative care approach to treating depression and post-traumatic stress disorder in military personnel. AcademyHealth Annual Research Meeting, June 2016, Boston, MA.

Lavelle T, Jaycox LH, Kommareddi M, et al. The cost-effectiveness of a collaborative care approach to treating depression and post-traumatic stress disorder in military personnel. Part of ISTSS Symposium: Evaluating the Population Impact of an Enhanced Collaborative Care Intervention for PTSD and Depression: Examining Reach, Effectiveness, and Cost Effectiveness across the Military Health System (MHS). Belsher, BE. (chair). Abstract submitted for presentation at: 32nd Annual Meeting of the International Society for Traumatic Stress Studies; November 2016; Dallas, TX.

Novak LA, Belsher BE, Evatt DP, et al. Improving retention rates in military research: Lessons from a randomized treatment trial for PTSD and depression among active-duty service members. Abstract submitted for poster presentation at: Military Health System Research Symposium (MHSRS); August 2016; Kissimmee, FL.

<u>Completed Presentations:</u>

Freed MC. A randomized trial of centrally assisted collaborative telecare management for PTSD and depression in military primary care. Part of ISTSS Symposium: Trauma Informed Practice: A Tale of Two Collaborative Primary Care Treatment Trials. Green, B. (chair). Presented at: 31st Annual Meeting of the International Society for Traumatic Stress Studies; November 2015; New Orleans, LA.

Freed M, Belsher B, Novak L, et al. Suicide risk and PTSD in military primary care populations: From epidemiology to practice. Part of ISTSS Symposium: A Translational Approach to Posttraumatic Risk Behaviors across Trauma Exposed Patient Populations. Zatzick, D. (chair). Presented at: 31st Annual Meeting of the International Society for Traumatic Stress Studies; November 2015; New Orleans, LA.

Belsher B, Jaycox L, Evatt D, et al. Bridging the health system: Evaluating patterns of behavioral health utilization among active duty soldiers with trauma symptoms in a stepped, collaborative care intervention. Poster presented at: 31st Annual Meeting of the International Society for Traumatic Stress Studies; November 2015; New Orleans, LA.

Evatt D, Belsher B, Jaycox L, et al. Relationship between alcohol misuse, alcohol screening, and treatment outcomes in STEPS-UP. Poster presented at: 31st Annual Meeting of the International Society for Traumatic Stress Studies; November 2015; New Orleans, LA.

Bray RM, Engel CC, Williams J, Jaycox L, Lane ME, Freed MC. PTSD trajectories in collaborative care treatment among U.S. soldiers. Presented at: 57th International Military Testing Association Conference; September 2015; Stockholm, Sweden.

Lane ME, Bray RM, Williams J, Engel CC, Freed MC, Jaycox L. Improvements in work functioning among U.S. soldiers in collaborative care. Presented at: 57th International Military Testing Association Conference; September 2015; Stockholm, Sweden.

Engel CC, Freed MC, Tanielian T. Evidence and implementation: Collaborative primary care for PTSD and depression in the U.S. military. Presented at: Defense Centers of Excellence for Psychological Health and Traumatic Brain Injury Summit: Continuum of Care and Care Transitions in the Military Health System; September 2015; Falls Church, VA.

Zatzick D, Galea S, Engel CC. Implementing collaborative primary care for behavioral health conditions: What, when, why, and how. Presented at: Defense Centers of Excellence for Psychological Health and Traumatic Brain Injury Summit: Continuum of Care and Care Transitions in the Military Health System; September 2015; Falls Church, VA.

Belsher B, Jaycox L, Evatt D, et al. Health care utilization patterns in a stepped, collaborative care effectiveness trial: Examining the relationship between symptom severity and treatment engagement. Poster presented at: Military Health System Research Symposium (MHSRS); August 2015; Ft. Lauderdale, FL.

Evatt D, Belsher B, Jaycox L, et al. Alcohol misuse in the STEPS UP clinical trial: Relationship between alcohol misuse, alcohol screening, and co-occurring PTSD and depression. Poster presented at: Military Health System Research Symposium (MHSRS); August 2015; Ft. Lauderdale, FL.

Freed MC, Engel CC, Jaycox LH, et al. DoD STEPS UP: Main findings from a real-world randomized effectiveness trial of centrally assisted collaborative care for PTSD and depression in

military primary care. Presentation at: Military Health System Research Symposium (MHSRS); August 2015; Ft. Lauderdale, FL.

Tanielian T. Patient and provider perspectives of collaborative primary care in the U.S. military health system. Part of APA Symposium: Implementation and Evidence: Collaborative Primary Care for PTSD and Depression in the U.S. Military. Engel CC (chair). Presented at: American Psychiatric Association 168th Annual Meeting; May 2015; Toronto, ON.

Freed MC. Randomized effectiveness trial of collaborative care in the U.S. military: Effects on PTSD, depression, functioning, and service use. Part of APA Symposium: Implementation and Evidence: Collaborative Primary Care for PTSD and Depression in the U.S. Military. Engel CC (chair). Presented at: American Psychiatric Association 168th Annual Meeting; May 2015; Toronto, ON.

Engel CC. Scalable, centrally implemented collaborative primary care treatment package for PTSD and depression in the U.S. military. Part of APA Symposium: Implementation and Evidence: Collaborative Primary Care for PTSD and Depression in the U.S. Military. Engel CC (chair). Presented at: American Psychiatric Association 168th Annual Meeting; May 2015; Toronto, ON.

Unutzer J. Collaborative care for anxiety and depression: An opportunity for the U.S. military health system. Part of APA Symposium: Implementation and Evidence: Collaborative Primary Care for PTSD and Depression in the U.S. Military. Engel CC (chair). Presented at:

American Psychiatric Association 168th Annual Meeting; May 2015; Toronto, ON.

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Freed MC, Engel CC, Belsher B, et al. Suicide risk and correlates to PTSD, depression, and alcohol misuse in military primary care populations. Part of ISTSS Symposium: Implementing Traumatic Stress Services in Military Primary Care: Treatment & Trials. Engel CC (chair). Presented at: 30th Annual Meeting of the International Society for Traumatic Stress Studies (ISTSS); November 2014; Miami, FL.

Curry J. RESPECT-Mil: Implementation of a systems-level approach to mental health in military primary care settings. Part of ISTSS Symposium: Implementing Traumatic Stress

Services in Military Primary Care: Treatment & Trials. Engel CC (chair). Presented at: 30th Annual Meeting of the International Society for Traumatic Stress Studies (ISTSS); November 2014; Miami, FL.

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Bray RM, Lane ME, Williams J Engel CC, Jaycox L, Freed MC. Predicting changes in PTSD and depression among U.S. Soldiers: Initial findings for control participants. Paper presented at: 56th International Military Testing Association Conference; October 2014; Hamburg, Germany.

Lane ME, Bray RM, Williams J, Engel CC, Jaycox L, Freed MC. Mental health and substance use predictors of work functioning among U.S. soldiers. Paper presented at: 56th International Military Testing Association Conference; October 2014; Hamburg, Germany.

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Freed M, Engel C, Bray R, et al. Collaborative primary care for depression and PTSD in the

U.S. military health system: Design and early findings from STEPS UP, a multisite randomized effectiveness trial. Presented at: Military Health System Research Symposium (MHSRS); August 2014; Ft. Lauderdale, FL.

Engel CC, Freed MC, Lane B, et al. DoD STEPS-UP: Design, roll-out and early lessons from a randomized effectiveness trial of collaborative PTSD care in Army primary care. Part of ISTSS Symposium: Interventions for PTSD in Primary Care Medical Settings: Implementation and Early Effectiveness Outcomes. Meredith L (chair) & Zatzick D (discussant). Presented at: 29th Annual Meeting of the International Society for Traumatic Stress Studies (ISTSS); November 2013; Philadelphia, PA.

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Engel CC, Freed MC, Jaycox L, et al. PART I: Re-engineering healthcare integration programs (REHIP): Blending embedded behavioral health providers (BHPs) and care managers (CM) in triservice primary care (PC) clinics. PART II: Stepped enhancement of PTSD services using primary care (STEPS UP). Presented at: Armed Forces Public Health Conference (AFPHC); March 2011; Hampton Roads, VA.

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Annual Meeting of the International Society for Traumatic Stress Studies (ISTSS); November 2010; Montreal, Quebec, Canada.

Engel CC, Bray RM, Jaycox L, et al. A randomized effectiveness trial of a systems-level approach to stepped care for war-related PTSD. Poster presented at: USUHS Research Week; May 2009; Bethesda, MD.

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CONCLUSION:

This is the first randomized trial to assess collaborative care for active component military personnel and one of few trials to assess collaborative primary care for PTSD. Results showed that the centrally assisted collaborative care model with stepped psychosocial and pharmacologic management (STEPS UP intervention) improved outcomes of PTSD and depression in military personnel within primary care. The qualitative study component helped identify patient and provider perceptions of barriers to accessing mental health care in the MHS and helped evaluate acceptability of the intervention across stakeholder groups. The cost-effectiveness analyses will help measure and understand the value of the intervention. If

eventually implemented, given our positive findings, we expect that STEPS UP will increase the likelihood that military personnel with unmet PTSD- and depression-related health care needs will get timely, effective, and efficient PTSD and depression care. STEPS UP is available to roll out immediately, reinforcing and facilitating pathways to PTSD and depression recovery within the MHS. Overall, the STEPS UP intervention enhancements are feasible and implementable within the MHS. Results from the trial have the potential to inform decisions about providing mental health care within the MHS and improving the lives of service members.

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targeting posttraumatic stress disorder and related comorbidities after acute trauma. Gen Hosp Psychiatry. 2011;33:123-134.

LIST OF APPENDICES:

Appendix A: Design Manuscript (Published)

Engel CC, Bray RM, Jaycox L, et al. Implementing collaborative primary care for depression and posttraumatic stress disorder: Design and sample for a randomized trial in the U.S. military health system. *Contemp Clin Trials*. 2014;39(2):310-319. doi: 10.1016/j.cct.2014.10.002

Appendix B: Main Outcomes Manuscript (In press)

Engel CC, Jaycox L, Freed MC, et al. Centrally assisted collaborative telecare for posttraumatic stress disorder and depression among military personnel attending primary care: A randomized controlled trial. *JAMA Intern Med*. In press.

Appendix C: Qualitative Study Manuscript on Barriers to Care (Published)

Tanielian TL, Jaycox LH, Farmer C, Woldetsadik M, Moen S, Epley C. Barriers to engaging service members in mental health care within the military health system. *Psychiatr Serv*. 2016;Epub ahead of print.

Appendix D: Utilization Manuscript (Published)

Belsher BE, Jaycox LH, Freed MC, et al. Mental health utilization patterns during a stepped, collaborative care effectiveness trial for PTSD and depression in the military health system. *Med Care*. 2016;Epub ahead of print.

Appendix E: Modeling Trajectories of PTSD Symptoms and Predictors of One-year Prognosis (In press)

Bray RM, Engel CC, Williams J, et al. Posttraumatic stress disorder in military primary care: Trajectories and predictors of one-year prognosis. *J Trauma Stress.* In press.

Appendix F: Qualitative Study Manuscript on Stakeholder Perceptions (Under review)

Batka C, Tanielian T, Woldetsadik MA, Farmer C, Jaycox LH. Stakeholder experiences in stepped collaborative care study within US Army clinics. Under review.

Appendix A

Design Manuscript

Contemporary Clinical Trials 39 (2014) 310–319

Contents lists available at ScienceDirect

Contemporary Clinical Trials

journal homepage: www.elsevier.com/locate/conclintrial

Implementing collaborative primary care for depression and posttraumatic stress disorder: Design and sample for a randomized trial in the U.S. military health system ☆

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ARTICLE INFO

Article history:
Received 3 July 2014
Received in revised form 28 September 2014
Accepted 2 October 2014
Available online 12 October 2014

Keywords:
PTSD
Depression
Collaborative care
Primary care
Implementation
Military

ABSTRACT

Background: War-related trauma, posttraumatic stress disorder (PTSD), depression and suicide are common in US military members. Often, those affected do not seek treatment due to stigma and barriers to care. When care is sought, it often fails to meet quality standards. A randomized trial is assessing whether collaborative primary care improves quality and outcomes of PTSD and depression care in the US military health system.
Objective: The aim of this study is to describe the design and sample for a randomized effectiveness trial of collaborative care for PTSD and depression in military members attending primary care.
Methods: The STEPS-UP Trial (STepped Enhancement of PTSD Services Using Primary Care) is a 6 installation (18 clinic) randomized effectiveness trial in the US military health system. Study rationale, design, enrollment and sample characteristics are summarized.
Findings: Military members attending primary care with suspected PTSD, depression or both were referred to care management and recruited for the trial (2592), and 1041 gave permission to contact for research participation. Of those, 666 (64%) met eligibility criteria, completed baseline assessments, and were randomized to 12 months of usual collaborative primary care versus STEPS-UP collaborative care. Implementation was locally managed for usual collaborative care and centrally managed for STEPS-UP. Research reassessments occurred at 3-, 6-, and 12-months. Baseline characteristics were similar across the two intervention groups.
Conclusions: STEPS-UP will be the first large scale randomized effectiveness trial completed in the US military health system, assessing how an implementation model affects collaborative care impact on mental health outcomes. It promises lessons for health system change.

1. Introduction

The 2014 Institute of Medicine report, "Treatment for Posttraumatic Stress Disorder in Military and Veteran

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http://dx.doi.org/10.1016/j.cct.2014.10.002
1551-7144/

Populations: Final Assessment" [1] emphasized an urgent need to expand Department of Defense (DoD) and Department of Veterans Affairs (VA) capacity for integrated, coordinated, and evidence-based PTSD care. The prevalence of PTSD and depression in the U.S. military is estimated at 13%–18% after deployment to Iraq and Afghanistan, with 28% reporting serious symptoms of PTSD, anxiety, or depression [2,3]. These problems are significant contributors to military attrition, absenteeism, misconduct, and sick call visits [4–6]. However, less than half of U.S. military members with PTSD receive mental health treatment [2,3,5,7], and only half of those getting treatment receive minimally adequate care [3].

Mental health care in the military is unusual in some ways. Typically, both providers and patients work for the military—sometimes even for the same commanding officer. Providers consistently experience clear and competing obligations to military and patient interests. Perhaps not surprisingly, underuse of military mental health care is associated with military member concerns about the potential for treatment to harm to their career, mistrust of military mental health providers, and fears of negative reactions from leaders and peers [2,3]. While the U.S. military health system offers challenges, delays and barriers to PTSD care are a national problem, with one study estimating a 12-year median time from PTSD onset to first treatment [8]. The average term of U.S. military enlistment hovers near five years, and therefore a comparable delay in military mental health treatment is simply too long.

Systems-level "collaborative care" is an established method of increasing the reach, quality and outcomes of mental health care in a variety of settings [9]. Large, well-conducted randomized trials indicate that collaborative care improves outcomes for patients with depression and anxiety [10–12], depression and related suicidal ideation [13,14], depression and chronic health conditions (e.g., diabetes, asthma) [15], panic disorder [16], persistent physical symptoms such as chronic pain [17–19] and analgesic management [20]. Cost-effectiveness analyses suggest that costs associated with collaborative care-related improvements are within a range considered acceptable for public health improvements [21]. For PTSD, however, there has only been one randomized trial of collaborative primary care, a negative trial completed in VA [22].

Since 2007, the Army has implemented collaborative care worldwide using the same model tested in the VA trial [23,24], but insufficient access to and quality of military mental health care remain a recurrent concern [3,7,25–27]. Despite implications for current and future wartime health system response, there have been no controlled trials of collaborative care completed in the military health system, a service system with the mission of providing health care for over 9 million beneficiaries including active duty military personnel and their families at a rising annual cost of $52 billion in 2012 [28].

A large multisite randomized effectiveness trial is underway comparing a scalable, centrally managed primary care treatment package using collaborative care for PTSD and depression (STEPS-UP, STepped Enhancement of PTSD Services Using Primary Care) versus a widely practiced and locally implemented primary care collaborative care model used in the U.S. Army health system (UCPC, Usual Collaborative Primary Care). This paper describes the design and methods employed in this trial, a six military installation (18 primary care clinic) randomized effectiveness trial comparing the impact of 12-months of clinical intervention (STEPS-UP versus UCPC). The randomized design will offer a valid assessment of benefit for new versus current health system practice. The effectiveness design, aimed to equip leaders and policy makers with evidence to guide decision-making, is expected to yield maximally generalizable findings, relevant cost-effectiveness information, and qualitative assessments of related clinician and beneficiary views of their care. In short, if STEPS-UP demonstrates superior clinical and cost effectiveness and is acceptable to patients and providers, it will be immediately ready for rapid scaling and implementation.

2. Study design

2.1. Interventions

Both intervention arms involve elements of collaborative care. Collaborative care is a service delivery package that accommodates empirically validated psychotherapies and evidence-based pharmacologic approaches. Collaborative care is not a type of psychotherapy per se. Three or four basic strategies are used to increase consistent delivery of effective, guideline-concordant care [29,30]. Oxman et al. [31] summarize these in a "Three Component Model": (1) prepared primary care practice using clinical tools for screening, diagnosing, and measurement-based symptom assessment; (2) care management to help clinical teams track treatment response, insure follow-up and continuity of care, and to help patients adhere to treatment and know their treatment options; and (3) enhanced mental health specialty care interface to insure optimal and efficient expert consultation wherein care managers meet weekly with a specialist to review their caseload and convey recommendations to the primary care team. Four additional aspects of collaborative care include (4) telephonic treatment and communications for efficiency and to reduce patient and provider burden; (5) real time registries for tracking indicators of patient treatment response; (6) stepped treatment sequencing strategies that maximize patient choice and match treatment intensity to illness severity and trajectory; and (7) centralized implementation to monitor performance across sites, reduce variation and enhance scalability [30,32–38].

Table 1 uses these 7 collaborative care elements for a comparative view of study treatment (STEPS-UP) and comparison (Usual Collaborative Primary Care, UCPC) interventions.

2.2. Comparison intervention: Usual Collaborative Primary Care (UCPC)

In 2007 Army primary care clinics began to implement a collaborative care approach called "RESPECT-Mil" (Re-Engineering Primary Care Treatment of PTSD and Depression in the Military) based on a sustainable version of the previously described Three Component Model [31,34]. Dietrich et al. found that the model significantly improved depression care quality, treatment response and depression remission [34]. In other studies the model showed sustainability, and high fidelity was associated with better treatment response [39]. RESPECT-Mil adapted the model to the military and successfully tested for military primary care feasibility [23]. Added to the original Three

Table 1
Intervention components—STEPS-UP versus Usual Collaborative Primary Care (UCPC).

Component	Steps-up	UCPC
1. Prepared practice		
Patient screening:	Depression (PHQ-2), PTSD (PC-PTSD), self-harm (PHQ-9i)	Depression (PHQ-2), PTSD (PC-PTSD), Self-Harm (PHQ-9i)
Diagnostic aids:	Depression (PHQ-9), PTSD (PCL-C)	Depression (PHQ-9), PTSD (PCL-C)
2. Nurse care management		
Nurse visit schedule	Within 2 weeks of referral and minimum every 4 weeks after	Within 2 weeks of referral and minimum every 4 weeks after
Patient screening:	Alcohol Misuse (AUDIT-C), mania (MDQ)	None
Symptom severity tracking:	Depression (PHQ-9), PTSD (PCL-C), suicide risk assessment	Depression (PHQ-9), PTSD (PCL-C), suicide risk assessment
Continuity monitoring:	Primary care, specialty care, military care (including deployments and field exercises), and civilian care (TRICARE, VA, other)	Restricted to military primary care practice
Nurse skills training:	Motivational interviewing, behavioral activation, problem solving, and web-based decision support training	Web-based decision support training
3. Specialty interface	Site-level and central enhancements	Site-level enhancements only
Clinic-based specialist:	Present and fully model integrated	No model integration if present
Case-level reviews:	Central and site specialists (weekly)	Site specialist only (weekly)
4. Stepped care	Psychopharmacologic and Psychotherapeutic Options	Pharmacologic Options only
Self-management:	Web-based PTSD and depression self-management options	None
Phone therapies:	Phone CBT for PTSD and depression	None
Face-to-face therapies:	Phone CBT for PTSD and depression	None
5. Telephone use	Phone CBT, local and central phone care management, phone-based training and team meetings	Local phone care management
6. Registries	Reports covering patient-level treatment response and aggregate caseload analysis	Individual patient tracking only
7. Implementation	Centrally managed	Site managed
Clinical implementation:	Central phone therapists, central case management, centrally run case and caseload reviews, and centrally moderated peer-supported learning	Case-based review
Continuing education:	Centrally moderated and led	Site dependent

Component Model were routine primary care screening for PTSD and depression, primary care diagnostic assessments for those screening positive (PTSD Checklist, or PCL-C, for PTSD; 9 item Patient Health Questionnaire, or PHQ-9, for depression), and care management for PTSD.

When the STEPS-UP trial started, all 18 participating primary care clinics (6 Continental U.S. installations) and 88 total Army primary care clinics (37 worldwide installations) practiced RESPECT-Mil, hereafter referenced as UCPC. Each installation had a "primary care champion" overseeing that installation's program and a "behavioral health champion", usually a psychiatrist, that meet with all installation care managers once weekly to review their caseload and provide feedback to primary care with care manager assistance. Patients in UCPC were assigned an onsite care manager. Care managers were instructed to contact patients within two weeks of program referral and then every four weeks thereafter. They were to assess PTSD and depression severity and monitor adherence to primary care provider (PCP) prescribed psychoactive medications at each care manager contact. Patients followed in mental health specialty care were discharged from the program. The only controlled trial of this model was a negative VA study [22].

2.3. Test Intervention: STEPS-UP Collaborative Care

STEPS-UP was designed as second-generation collaborative primary care for PTSD and depression in the military. The goal is to reduce PTSD and depression through reliable implementation of evidence-based psychotherapy and pharmacotherapy practices. Central implementation ensures that the package is delivered feasibly and with fidelity across sites and settings (military, civilian, primary care, and specialty mental health) and facilitates scalability during changing military and population needs.

STEPS-UP builds on existing UCPC infrastructure by: (1) enhancing care management, (2) adding stepped psychotherapeutic options, (3) using clinical registries to guide treatment; and (4) centralizing implementation coordination (see Table 1).

2.3.1. Care management enhancements

Care managers received added patient engagement training (behavioral activation, problem solving, and motivational interviewing). These skills helped care managers to provide patient support, to keep patients active and engaged in their care, and to help patients examine treatment options and develop preferences. Care managers reviewed treatment options using one-page guides with patients, helping them consider medications, psychotherapies, or both.

Care management was expanded beyond primary care to other service delivery sectors and contexts (e.g., mental health clinics, TRICARE, VA, other civilian medical care, deployments, field exercises, change of station, departing military service). Remote care management was available by phone for patients following location changes or as a substitute for local care managers when unavailable.

2.3.2. Stepped psychotherapies

To enhance patient access to psychotherapies beyond basic support from the care manager, patients were afforded stepped psychotherapy options. These included web-based cognitive behavioral self-management [40,41], psychologist-delivered telephone CBT [42], and face-to-face specialist delivered psychotherapy. Care managers discussed with patients their preferences for web, phone, or face-to-face therapy repeatedly over time. Central STEPS-UP team psychologists delivered phone CBT using a flexible, modularized protocol.

2.3.3. Clinical registries

A web-based decision support tool was used to track patients' PTSD and depression symptom severity, to drive treatment changes, to create registries for STEPS-UP team review, and to populate site-level performance tracking reports. Care managers enter data online during phone conversations with patients. The online platform guides the care manager through visits and insures appropriate questions are covered. Data entered include depression (PHQ-9) [43] and PTSD (PCL-C) [44–46] symptom severity, symptom-related difficulty, medication and psychotherapy adherence, suicide risk, behavioral activation strategies and goals, alcohol use (AUDIT-C) [47] and bipolar disorder (MDQ) [48] screening, and military transitions.

2.3.4. Centrally coordinated implementation

Psychiatric consultation and review were centralized in STEPS-UP. STEPS-UP at each site was coordinated and overseen by a central mental health team comprised of a psychiatrist, psychologist, care manager and administrative support. Care manager specific registries were centrally disseminated, and flags were generated for patients with (1) symptoms that had not shown improvement (less than 5 point improvement in the 8 weeks since the last treatment change or 50% overall improvement on PCL-C and PHQ-9); (2) recent missed care manager follow-up contacts; and (3) impending health care or military transitions (e.g., specialty care referral, deployment).

The central team and care managers met weekly for two types of phone conferences. One involved individual care managers to review patient specific data. Management recommendations were developed for patients' primary care providers and care manager engagement strategies reformulated for patients transitioning or at risk of dropping out of care. New and acute patients were reviewed first, followed by unimproved patients, and then patients in transition. The central STEPS-UP psychiatrist insured patients on medication received therapeutic doses and treatment duration or changed treatment if unimproved after six to eight weeks or if side effects occurred. Remaining time was used to discuss patients in web or phone therapy or to discuss site-level service system problems. Care managers conveyed STEPS-UP team recommendations to primary care providers and STEPS-UP team members charted notes for the electronic health record.

The central team and care managers weekly for a second phone conference. In this meeting, site performance metrics were reviewed, discussed and lessons learned; didactic training was delivered; and peer-support and lessons were shared among care managers to improve their care management skills. When system-level problems emerged at a site, the central team would consult with relevant site leaders seeking resolution.

2.4. Participants

Participants were active duty military members attending one of the 18 participating primary care clinics who were referred by their primary care provider for care management within UCPC. All primary care visits routinely involved initial depression and PTSD screening (PHQ-2, PC-PTSD). PHQ-2 and PC-PTSD items were dichotomous (yes/no) questions. Either or both PHQ-2 items endorsed 'yes' is a positive depression screen. Two or more of the four PC-PTSD items endorsed 'yes' is a positive PTSD screen. Patients with positive screens routinely then receive the PCL-C and PHQ-9 to as "diagnostic aids", tools that the providers use to guide assessment, diagnosis, and treatment planning. Involving the care manager is a clinical decision left to the discretion of the provider and patient. Patients referred to care management were contacted within a week by a UCPC care manager. After insuring the patient (1) had private access to computer and Internet and (2) anticipated residing nearby for at least six months, the UCPC care manager would ask if the patient would like to be contacted regarding "research studies related to ongoing efforts to improve the quality" of UCPC. If the patient assented to contact, a STEPS-UP trial research site coordinator would contact them for a second level screen, research informed consent, and eligibility assessment. Any patient declining to participate in or excluded from the trial was continued in UCPC with their previously assigned care manager.

2.5. Inclusion and exclusion criteria

For inclusion participants (1) were on active duty at enrollment; (2) met DSM-IV-TR criteria for PTSD using the PCL-C or depression using the PHQ-9 (explained below); (3) reported computer, Internet, and e-mail access; and (4) provided informed consent to participation. At first deployment since 2001 was required for inclusion but was dropped after the first month. The rationale for dropping this inclusion criterion was that participants with PTSD and depression could benefit from collaborative care whether or not symptoms followed deployment. Furthermore, assuming effectiveness, benefits summed over a larger proportion of patients would yield more favorable cost–benefit calculation given the system-level intervention.

Military members meeting inclusion criteria were excluded if they had (1) recently participated in UCPC; (2) active alcohol dependence; (3) active, unstable suicidal ideation or an attempt within the prior month; or (4) anticipated deployment, demobilization, change of station, or separation from military service within six months. Initially, those undergoing medical retirement proceedings ("medical board") were excluded. The exclusion was dropped in the first month of recruitment because it was frequent and inclusiveness was important for sample generalizability. Instead the plan is to eventually assess this as a potential modifier of intervention effect.

2.6. Eligibility screening and informed consent

A web-based research reporting system was used to administer research assessments and establish trial eligibility. Following informed consent, simple eligibility items and demographics, the following instruments establish study suitability:

(1) the PTSD Checklist-Civilian Version (PCL-C) where PTSD was operationalized as a "moderate" or greater severity level on 1 re-experiencing, 3 avoidance, and 2 hyperarousal symptoms, consistent with the DSM-IV-TR criteria (Civilian Version of the PCL was used rather than the Military Version because the latter is used in UCPC and because enrollment for PTSD due to any trauma (not solely military trauma) was the focus [44–46]; (2) the Patient Health Questionnaire-9 (PHQ-9) where depression was operationalized as endorsement of at least 5 of the 9 symptoms experienced "more than half the days" and at least one of those symptoms including either "little interest or pleasure in doing things" or "feeling down, depressed or hopeless, consistent with DSM-IR-TR criteria [43]; (3) the Mini International Neuropsychiatric Interview (MINI)-Plus—Suicidality Module (C1–C6) where individuals scoring greater than 9, regarding suicidal ideation during the past 2 months, were excluded from the participation (details below) [49]; and (4) the Alcohol Use Disorders Identification Test (AUDIT) where individuals scoring ≥15 were excluded consistent with ICD-10 definitions of potential alcohol dependence symptoms [47]. Research site coordinators oversaw eligibility assessment in their offices. UCPC care managers were informed for ineligibles and acute care was obtained as indicated to those with active suicide risk or alcohol dependence. A study mental health specialist was on call at all times for psychiatric emergencies.

2.7. Randomization and research follow-up procedures

In most cases once the site coordinator informed participants that they were eligible, they continued directly into the questionnaire (some finished later or from home). On completing the baseline assessment, the automated system randomized participants (stratified by site) to STEPS-UP or UCPC. Participants were told that their care manager would contact them within a week and reminded of future study team contacts for the 3-, 6-, and 12-month research assessments. The latter were completed using direct computer entry over the Internet from a location of their choice, eliminating the need for blinded assessors.

Research follow-up assessment reminders began 30 days prior to the 3-, 6-, and 12-month mark and continued for 60 days past that mark. Thus, participants were in each follow-up window for a total of 90 days. Initial contact was made via automated emails generated from the project control system. The emails linked to the project website and encouraged participants to log on and complete the follow-up assessment. If there was no response to the original notification email, the following additional notification methods were used on a predetermined schedule: (1) reminder telephone calls by site coordinators, (2) reminder emails from the automated system, (3) contacts by a telephone interviewer, (4) reminder texts from site coordinators, and (5) mailing of a paper and pencil questionnaire.

2.8. Research and clinical intervention assessments

This trial compares two interventions, each featuring measurement-based care. It was anticipated that administration rates of clinical status assessments would differ across the interventions during the 12-month follow-up period. The differential impact of STEPS-UP versus UCPC was assessed with different research status assessments than the ones STEPS-UP and UCPC used to track patients' clinical status. This was done to reduce the possibility that learning effects due to differential rates of repeated clinical assessment administration across study arms would confound research trial results, In the clinical setting, the PCL-C and PHQ-9 were used to track symptoms over time, the same measures used to determine intervention eligibility (as described earlier).

The following measures were used to examine primary outcomes across the two arms of the trial:

Posttraumatic Diagnostic Scale (PDS). The PDS is a self-report measure that assesses both severity of PTSD symptoms related to a single identified traumatic event and probable diagnosis of PTSD [50]. In this study, the first section of the PDS was replaced with the other two trauma checklists (see Table 2). Respondents were asked to identify the trauma that currently bothering them the most and the frequency of 17 PTSD symptoms was assessed. The PDS shows high sensitivity (.89) and specificity (.75) as compared to the SCID-IV interview for PTSD, with a high degree of concordance in diagnosis (kappa = .65). It also shows high internal consistency (.92) and also high correlations with other related constructs and test-retest reliability over 2–3 weeks (.78–.84 for each symptom cluster) [51].

Depression Symptom Severity: Hopkins Symptom Checklist Depression Scale-20 Item Version (HSCL-20). The HSCL-20 is a self-report scale comprising the 13 items of the Hopkins Symptom Checklist Depression Scale plus 7 additional items from the Hopkins Symptom Checklist-90-Revised. The additional 7 items were added to better represent all diagnostic symptoms of major depression and improve the instrument's sensitivity to clinical change [52].

Several other secondary outcomes and descriptive variables were assessed as described in Table 2. In addition administrative data on service utilization were obtained for cost analysis and qualitative interviews performed to understand the process of care (see Sections 2.11 and 2.12 below).

2.9. Target and revised sample size

Given uncertainty regarding final data distributions, the a priori approach to sample size calculation was conservative. Specifically, the sample size required to compare 12-month changes in the outcomes was determined, ignoring the intervening time points and the correlation between repeated measurements on the same subjects. The treatment difference was defined to be $D = (\overline{X}_{22} - \overline{X}_{21}) - (\overline{X}_{12} - \overline{X}_{11})$ where $\overline{X}_{ij}$ is mean PDS or HSCL-20 score in treatment arm i at time j (j = 0, 12). If the sample size, N, and standard deviation, σ, are the same in both treatment arms at both time points, then the standard error of D is $2\sigma/\sqrt{N}$.

Dietrich et al. [34] and Dobscha et al. [61] obtained standard deviations of 0.65–0.80 for the HSCL-20 at the various time points in their prospective studies. This is the standard deviation for the average score on the 20 items on the HSCL-20; the corresponding standard deviations for the sum of the 20 scores

Table 2
List of research assessment constructs, the research measures used to assess them, and research measurement time points at which they were assessed.

Research construct	Research measure(s)	Time points
Demographics	Adapted versions of previously tested questions to assess basic demographics, military and deployment history, branch of service, and beneficiary status	BL[a] only
Military traumatic stressors	Deployment Risk and Resilience Inventory [53]—Unit Support and Post-Deployment Life Events scales	BL only
PTSD criterion a trauma exposures	DoD Survey of Health Related Behaviors Among Active Duty Military Personnel Survey—Combat Exposure Scale [54] National Comorbidity Survey—Revised—PTSD Traumatic Events Scale [55]	BL only
Social support	Medical Outcomes Study Social Support Survey Items [56]	BL only
Traumatic brain injury (TBI)	TBI items from Land Combat Study [2]	BL only
Primary outcome		
PTSD symptom severity	Posttraumatic Diagnostic Scale (PDS) [50]	BL, 3-, 6-, and 12 months
Depressive symptoms	HSCL-20 [52]	BL, 3-, 6-, and 12 months
Secondary outcomes		
Somatic symptoms	PHQ-15 [57]	BL, 3-, 6-, and 12 months
Alcohol abuse	AUDIT-C [47] — Bush K, Kivlahan D, McDonell M, Fihn S, Bradley K. The AUDIT alcohol consumption questions (AUDIT-C): an effective brief screening test for problem drinking. Ambulatory Care Quality Improvement Project (ACQUIP). Alcohol Use Disorders Identification Test. Archives Of Internal Medicine [serial online]. September 14, 1998;158(16):1789-1795.	BL, 3-, 6-, and 12 months
Health-related functioning	SF-12 [58]	BL, 3-, 6-, and 12 months
Work presenteeism and absenteeism	WHO Health & Work Performance Questionnaire (HPQ) Short Form [59]	BL, 3-, 6-, and 12 months
Pain	Adapted Numeric Rating Scale for Pain [60]	BL, 3-, 6-, and 12 months
Health service use	Adapted versions of previously used questionnaires to assess formal and informal health service use frequency and type	BL, 3-, 6-, and 12 months

[a] BL = baseline.

were 13–16. Assuming that the item variances and covariances for the HSCL-20 and PDS are similar, 13–16 is the upper limit for the standard deviation on the PDS; i.e., the sum of 17 items should be less variable than the sum of 20 similar items.

With 2 endpoints of equal interest, a Type I error rate of 0.025 was assumed for the sample size calculations. Using this information, a target sample size of 600 subjects per arm was proposed, inflating this to 750 per arm on the assumption that 20% of subjects would fail to provide follow-up data. If $\sigma = 16$, then the study will have power = 0.80 to detect a difference of D = 5.7 between average 12-month changes in PDS scores in the two treatment arms. At $\sigma = 0.8$, power = 0.80 is anticipated to detect a difference of D = 0.29 on the HSCL-20.

As the study progressed baseline and follow-up data were obtained, allowing a re-examination of the assumptions underlying these early sample size calculations. Interim analysis indicated that the standard deviations at all time points were substantially less than those used in the original calculations. It was also found that the correlation between repeated measurements was approximately 0.5. Therefore, the sample size required to have power = 0.80 to detect the treatment differences above was determined to be substantially less than the originally planned total of 600 subjects with complete data. A sample size of 200 subjects per arm with complete data would provide power of approximately 0.90 to detect the treatment effects described above. The reduction in the sample size from the initial target was due to our ability to use less conservative assumptions about the within-group standard deviations and correlations.

2.10. Analysis plan

Two approaches to data analysis are under consideration. If a parametric model can be identified that accurately describes the relationship between outcome score and time on study, then this model will be used to evaluate the treatment effect. If such a model cannot be identified, then repeated measures analysis will be employed. Under the repeated measures approach, time is treated as an ordinal categorical variable. Under both approaches, the treatment effect is evaluated by adding an indicator for treatment group and the interaction between treatment group and time to the model. The interaction provides a test for a difference between rates of change in outcome score in the two treatment arms. If the interaction is not statistically significant, then it will be dropped from the model. The indicator for treatment effect will then provide a test for differences in outcome score, averaged over time points, between treatment arms. Because statistical power to detect interactions is more limited than power to detect main effects, this step may identify a treatment effect that is missed in the first part of the analysis. Because the two outcomes, PDS and HSCL-20, are of equal interest, a critical p-value of 0.025 will be used to evaluate the treatment effect for each one.

The effects of baseline characteristics on treatment responses will be evaluated by adding these characteristics to the model in secondary analyses. The three-way interaction among time, treatment arm and a baseline trait provides a test for variation in the treatment effect among levels of the baseline characteristic.

2.11. Cost analyses

In addition to assessing the impact of the program on patient outcomes, this study includes cost-effectiveness analysis (CEA) completed from health system perspective. CEA is a method that compares the economic desirability of alternative health interventions by calculating the marginal cost of a unit of improved health [62,63]. Our measure of cost-effectiveness will be the incremental cost-effectiveness ratio (ICER), defined as the difference in the per capita cost of the treatment and comparison groups divided by the difference in the average effectiveness of the interventions. Measurement of costs will account for all treatment costs (e.g. medications, nurse and physician salaries, building rents and maintenance, equipment costs) as well as personal costs that accrue to intervention participants. At each wave of follow-up research assessment, automated and self-report data on health care use will be used to understand the process of care, including number and type of medical and mental health services, telephone care, and use of Internet resources. Analyzing these data will allow a test of whether patients randomized to STEPS-UP care will have significantly lower direct and indirect care costs and more favorable cost-effectiveness ratio compared to participants randomized to UCPC.

2.12. Qualitative analyses

To assess patient, clinician, and care manager perceptions of collaborative care interventions, qualitative interviews were conducted and analyzed.

To assess acceptability, satisfaction, and effectiveness of interventions from the patient perspective, patients were randomly selected from the enrolled sample so as to include 6 from each site—3 from STEPS-UP and 3 from UCPC. They were selected early, mid-way, and late into the enrollment period at each site to account for any maturation of the interventions within site over time. To understand experience with services over time, interviews were attempted 3 times per patient, once after enrollment, 3-months later and 6-months later. Specifically, patients were interviewed about their satisfaction with their health care, the various services offered to them and used, adherence to services, any barriers or challenges to receiving care, and their recommendations for how to improve the system.

To understand the perceived effectiveness of the interventions from the provider perspective, interviews were conducted mid-way through the trial with 5–7 randomly selected primary care providers from each site. Interviews included their views on managing PTSD and depression in primary care, their training regarding these conditions, challenges within their system, and their direct experience with the two interventions, including facilitators and barriers hours spent on each program, and their perceptions of patient views of the interventions.

Finally, each site-located and centralized care manager was interviewed twice—once early in implementation and a second time towards the end of the study. Interviews focused on their perceptions of the various elements of the STEPS-UP intervention (engaging patients, coordination of care, use of telephone therapy and on-line intervention tools), comfort level with the role, and challenges in their roles. As part of the second interview, chart-assisted review of 5 randomly chosen patients the care manager had followed during the trial was discussed. The focus was on how the intervention went for these specific patients.

3. Results (sample characteristics)

Fig. 1 displays the number and flow of potential study participants into the study. Specific reasons for ineligibility or not entering the study are noted. Recruitment was conducted at six large military installations located nationwide. At the end of the enrollment period (August 31, 2013), UCPC care managers reported receiving 2592 collaborative care referrals. Of those, 1320 (51%) gave permission for research team contact, had Internet access, and anticipated remaining in the area for at least six months. After research team contact for informed consent and first level inclusion screen, 1041 of potential participants remained (40% collaborative care referrals across the six sites). Of the 60% of UCPC referrals (1551) excluded before the eligibility assessment, 922 (59%) declined research participation and 355 (23%) anticipated moving from the area in six months or less, the latter figure highlighting the mobility of the active duty population and a major challenge to providing them with sound health services.

Of the 1041 consenting participants, 666 (64%) met eligibility criteria and were enrolled and randomized, 332 to STEPS-UP and 334 to UCPC. Among the 375 (36%) that were excluded, the large majority (236, 63%) did not meet the trial's inclusive clinical definition for either PTSD or depression. Another large portion (107, 29%) were essentially too severe, meeting criteria for active suicidal ideation or alcohol dependence. Compared to those randomized, those excluded were similar with regard to gender (18% female versus 19%; $p = 0.78$), younger in age (30% less than 25 versus 22%; $p = 0.03$), lower in rank (56% junior enlisted versus 46%; $p = 0.002$), and less likely to have deployed (73% versus 83%; $p = 0.005$). Clinically, compared to those randomized, those excluded were less likely to meet study diagnostic criteria for PTSD (40% versus 90%; $p < 0.0001$), depression (23% versus 65%; $p < 0.0001$), or both (29% versus 59%; $p < 0.0001$) and reported higher mean AUDIT-C scores (3.5 ± 2.9 versus 2.9 ± 2.4; $p = 0.02$).

Table 3 presents basic information about the sociodemographic and military characteristics of the study participants along with data for selected screening and baseline assessment measures for the overall sample and for those randomized to STEPS-UP and UCPC. As shown and expected, the sociodemographic and military characteristics of the participants were highly similar in the two study arms.

Of the 666 enrolled in the study, 629 (94%) screened positive on the PC-PTSD scale. Those 629 were then asked the PCL-C items and 90% of them ($n = 566$) met criteria for PTSD (1 or more items were met for Criterion A, 3 or more for Criterion B, and 2 or more for Criterion C). For the PHQ-9, 432 (65%) participants met criteria for depression. Of the 629 participants who answered both the PCL-C and the PHQ-9, 370 (59%) met criteria for both PTSD and depression. Participants in the STEPS-UP arm of the study were somewhat more likely to meet criteria for PTSD and depression on the PCL-C and PHQ-9 than those in UCPC, though differences were not statistically significant.

Table 3 also shows average scores from the baseline assessment for three outcome measures: (a) PTSD measured by the PDS scale, (b) depression measured by the Hopkins

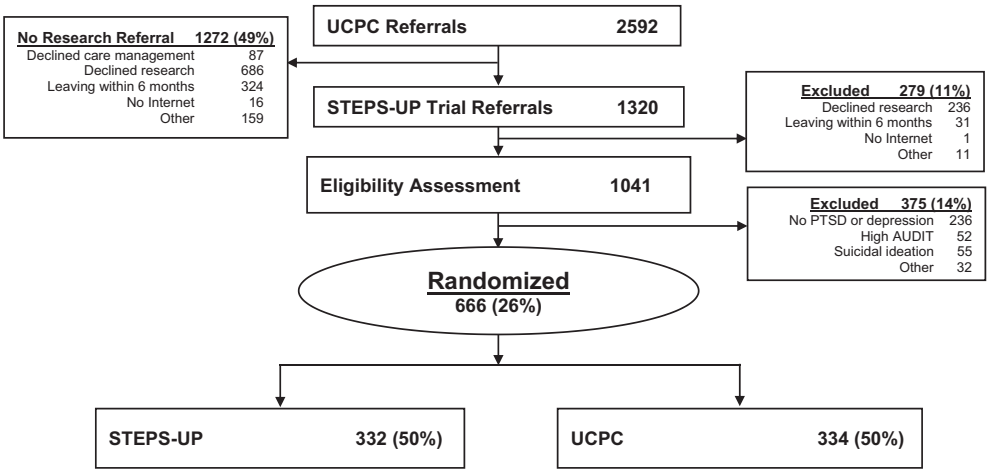

Fig. 1. CONSORT flow diagram for STEPS-UP Trial through the baseline assessment.

Symptom Checklist (HSCL-20), and (c) severity of somatic symptoms measured by the PHQ-15 [50,52,57]. For the PDS, the mean score of 29.2 indicated that on average participants had moderate to severe levels of PTSD. For the Hopkins Symptom Checklist (HSCL-20), average baseline scores were 2.1 out of a possible 4.0 suggesting that participants had

Table 3
Characteristics, screening, and assessment measures of STEPS-UP participants.*

Characteristic		Total $N = 666$ n (%) or mean (SD)	STEPS-UP $N = 332$ n (%) or mean (SD)	UCPC $N = 334$ n (%) or mean (SD)	P
Gender	Female	127 (19%)	68 (20%)	59 (18%)	0.35
Age	18–24	138 (22%)	73 (24%)	65 (21%)	0.74
	25–34	272 (44%)	135 (44%)	137 (45%)	
	≥35	205 (33%)	100 (32%)	105 (34%)	
Rank	E1–E4	306 (46%)	151 (46%)	155 (47%)	0.091
	E5–E6	274 (41%)	146 (44%)	128 (39%)	
	E7–O5	81 (12%)	32 (10%)	49 (15%)	
Installation	A	126 (19%)	63 (19%)	63 (19%)	>0.99
	B	26 (4%)	13 (4%)	13 (4%)	
	C	200 (30%)	100 (30%)	100 (30%)	
	D	18 (3%)	9 (3%)	9 (3%)	
	E	250 (38%)	124 (37%)	126 (38%)	
	F	46 (7%)	23 (7%)	23 (7%)	
Marital status	Married	446 (67%)	222 (67%)	224 (67%)	>0.99
Education	High school	203 (30%)	99 (30%)	104 (31%)	0.51
	Some college	325 (49%)	169 (51%)	156 (47%)	
	College degree	138 (21%)	64 (19%)	74 (22%)	
Race/ethnicity	White	318 (48%)	158 (48%)	160 (48%)	0.97
	Black	160 (24%)	82 (25%)	78 (23%)	
	Hispanic	117 (18%)	57 (17%)	60 (18%)	
	Other	70 (11%)	34 (10%)	36 (11%)	
Clinical indicators					
PC-PTSD	≥2	629 (94%)	310 (93%)	319 (96%)	0.23
PCL-C	DSM-IV	566 (90%)	285 (86%)	281 (84%)	0.54
PHQ-9	DSM-IV	432 (65%)	224 (67%)	208 (62%)	0.16
PTSD and depression	+PCL-C and PHQ-9	370 (59%)	193 (62%)	177 (55%)	0.18
AUDIT-C	score	2.8 (2.4)	3.0 (2.5)	2.7 (2.3)	0.15
Deployments after 2001	0	114 (17%)	59 (18%)	55 (16%)	0.89
	1	209 (31%)	102 (31%)	107 (32%)	
	2	159 (24%)	82 (25%)	77 (23%)	
	≥3	184 (28%)	89 (27%)	95 (28%)	
Research assessments					
PDS	Range, 0–51	29.2 (9.2)	29.4 (9.4)	28.9 (8.9)	0.55
HSCL-20 (range, 0–4)	Range, 0–4	2.1 (0.6)	2.1 (0.6)	2.0 (0.7)	0.0094
PHQ-15 (range, 0–30)	Range, 0–30	13.7 (4.8)	14.1 (4.7)	13.4 (4.8)	0.086
High combat exposure	CES score ≥ 10	452 (68%)	224 (67%)	228 (68%)	0.83

* Table includes completed data only. Missing items were rare, but result here in missing observations. Missing data imputation and intent-to treat analyses are planned for longitudinal data analyses.

moderate levels of depression. For the PHQ-15, the average score of 13.7 indicates medium somatic symptom severity.

4. Discussion

The STEPS-UP Trial is the first randomized effectiveness trial of mental health services conducted in the US Military Health System and represents a potentially important shift in the way new clinical programs are developed, tested and implemented for its 9 million beneficiaries to include military members, retirees, and their families. The design and baseline sample from this 6 installation randomized effectiveness trial was described, comparing the impact of collaborative care implementation on PTSD and depression outcomes across 18 military health system clinics.

A total of 666 participants were assigned to one of two arms and followed for 12 months. The comparison group received "usual collaborative primary care" as it has been widely practiced in US Army clinics since 2007, collaborative care in which implementation is managed largely at the installation level. STEPS-UP intervention participants received collaborative care using a centrally managed implementation process. STEPS-UP included central oversight of care managers trained in patient engagement techniques, availability of remote care managers for service members in transition, and stepped provision of both psychotherapeutic (web-based CBT self-management, telephone CBT from a central psychologist, and site-based face-to-face options) and pharmacologic treatment options. Of note, the most common reason for exclusion besides declining to participate in research was the expectation of relocating from the site within six months. The geographic mobility of military members with mental health needs underlines the important need to implement military health system strategies that enhance patient engagement and deliver safe and confidential services to remote and highly mobile patients.

The STEPS-UP Trial may eventually serve as a model for future scientific assessments of system change on clinical outcomes in military and veteran service systems. Key by-products of the trial for posterity will be program manuals (primary care, mental health specialist, care manager, phone therapy, and central program monitoring and operations), a web-based clinical decision support tool, patient education tools, and other tools that will enhance the scalability of the intervention. If the STEPS-UP intervention proves effective, these tools may play an instrumental future role, given the virtual certainty that large numbers of the U.S. military will once again step into harm's way.

Acknowledgments

The authors would like to thank the following additional individuals for their support of the STEPS-UP Trial:

Care Managers: Donna Buckmore (JBLM), Giovanna Buford (Fort Campbell), David Bynum (Fort Stewart), John Dempsey (Fort Bragg), Mary Hull (Fort Stewart), Lori Peterson (Fort Carson), Koby Ritter (Central), Tina Robertson (Fort Campbell), and Debbie Rosales (Fort Bliss). Psychiatrist: Brian Crowley (Central). Site Coordinators: Sandra Bozik-Lyman (Fort Bragg), Tahlia Bragg (Fort Carson), Alison Campbell (Fort Stewart), Emily Clark (JBLM), Jessie Gallaher (Fort Stewart), Christian Geye (JBLM), Sarah Nelson (Fort Campbell), Lucille Pittard (Fort Bliss), Carol Sheff (Fort Bragg), Laura Sweet (Fort Campbell), and Laura Whitton-Bonnett (Fort Bliss). Site Principal Investigators: Fort Bliss—Melissa Molina, MD, Stanley Harmon, RN, MSN, FNP; Fort Bragg—Lillie Walker, MPAS, PA-C, Andrew Fletcher, MD, LTC, MC, Thurman Saunders, MSN, FNP-C, MAJ, AN; Fort Campbell—Lisa Ford, LTC, AN, FNP-BC, Vlatka Plymale, DO, CPT, MC, Jason Dailey, MD, MAJ, MC; Fort Carson—Nicholas Piantanida, MD, COL, MC, Robert Price, MD, LTC, MC; Fort Stewart—Allen Swan, MD; JBLM—Kris Peterson, MD, Burton Kerr, PhD, Amy H. Park, PhD, CAPT, USPHS. Associate Investigators: Fort Campbell—Neel Shah, MD, CPT, MC; JBLM—Marc Bernson. MPAS PA-C. Research Assistants: Alexa Hays, Elizabeth Low.

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Appendix B

Main Outcomes Manuscript

Appendix B - Main Outcomes Manuscript

Text Word Count: 2800

Centrally assisted collaborative telecare for posttraumatic stress disorder and depression among military personnel attending primary care: A randomized controlled trial

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Key words: PTSD, depression, primary care, telemedicine, collaborative care, military, clinical trial

REVISED ABSTRACT

Importance: It is often difficult for members of the US military to access high quality care for posttraumatic stress disorder (PTSD) and depression.

Objective: To determine effectiveness of a centrally assisted collaborative telecare (CACT) for PTSD and depression in military primary care.

Design, Setting, and Participants: The STEPS-UP study (STepped Enhancement of PTSD Services Using Primary care) is a randomized trial comparing CACT to usual integrated mental health care for PTSD or depression. Patients, mostly men in their twenties, were enrolled from 18 primary care clinics at six military installations from February 2012 to August 2013 with 12-month follow-up completed in September 2014.

Interventions: Randomization was to CACT (n = 332) or usual care (n = 334). CACT patients received 12 months of stepped psychosocial and pharmacologic treatment with nurse telecare management of caseloads, symptoms, and treatment.

Main Outcomes and Measures: Primary outcomes were severity scores on the PTSD Diagnostic Scale (PDS; scored 0-51) and Symptom Checklist depression items (SCL-20; scored 0-4). Secondary outcomes were somatic symptoms, pain severity, health-related function, and mental health service use.

Results: CACT and usual care patients had similar baseline PDS PTSD (29.4±9.4 vs. 28.9 ±8.9) and SCL-20 depression (2.1± 0.6 vs. 2.0±0.7) scores. Compared to usual care, CACT patients reported significantly greater 12-month decrease in PDS PTSD scores (-2.53; 95% CI=0.59-4.47) and SCL-20 depression scores (-0.26; 95% CI=0.11-0.41). Fifty percent improvements were significantly greater at 12-months for CACT than usual care for both PTSD (25.0% vs. 17.0%; RR=1.6; 95% CI, 1.1-2.4) and depression (29.7% vs. 20.6%; RR=1.7; 95% CI, 1.1-2.4), with a number needed to treat for a 50% improvement of 12.5 (95% CI, 6.9-71.9) and 11.1 (95% CI, 6.2-50.5) respectively. CACT patients had significantly greater improvements in somatic symptoms and mental health-related functioning and increases in phone health contacts and

appropriate medication use.

Conclusions and Relevance: Central assistance for collaborative telecare with stepped psychosocial management modestly improves outcomes of PTSD and depression among military personnel attending primary care.

Trial Registration: NCT01492348

Introduction

Mental health care in the military is an international priority, and the Institute of Medicine has described a need for the US Departments of Defense (DoD) and Veterans Affairs (VA) to implement integrated, guideline concordant PTSD care.[1] PTSD prevalence after military deployment is an estimated 13%–18%, with severe PTSD, anxiety, or depression in 28%.[2,3] These problems cause suffering and impairment and contribute to military attrition, absenteeism, misconduct, and sick call visits.[4,5] Fewer than half of affected serving military personnel receive military mental health services and often services are not timely or adequate.[2,3]

Collaborative care is an empirically supported method of extending the reach, quality and outcomes of care for common mental disorders in medical settings.[6,7] Randomized trials of collaborative care have demonstrated improved outcomes among patients with depression and anxiety,[7-9] depression related suicidal ideation,[10] depression and chronic health conditions (e.g., diabetes, asthma),[11] and chronic pain.[12,13] For PTSD, however, we are aware of only three published randomized trials, one demonstrating improvements in PTSD[14] and two that do not.[15,16] Hence, the need for additional study of collaborative care for PTSD.

Recent military efforts to address mental health services have sought to better integrate them into primary care, and the first U.S. Army integration approach began in 2007.[17,18] However, no controlled trials of military integration efforts have been completed. Meanwhile, access to and quality of mental health services for military personnel has remained a recurring public policy concern.[1,19] We report the results of a multisite randomized trial of centrally assisted collaborative telecare (CACT) for PTSD and depression among military personnel attending primary care. The STEPS-UP Trial (STepped Enhancement of PTSD Services Using Primary Care) compares CACT to the Army's preexisting program integrating behavioral health in primary care.

Methods

Design

The study design is published elsewhere.[20] The study was reviewed and approved by institutional research review boards at Walter Reed National Military Medical Center (primary), six participating Army installations (i.e., military base/post, each of which may hosted multiple participating clinics), RTI International, RAND Corporation, University of Washington, and Boston VA, and the Human Research Protection Office, U.S. Army Medical Research Command. All participants provided written informed consent before enrollment.

A two parallel arm randomized design was used to evaluate the effectiveness of a 12-month primary care program for military personnel with PTSD and/or depression. An effectiveness design was chosen to enhance the generalizability of findings.[20] The primary hypothesis was that CACT is superior to usual integrated mental health care for improving PTSD and depression in primary care.

Intervention

Usual Care. In 2007 Army primary care clinics began an integrated mental health approach called RESPECT-Mil[18,21] based on a "three component model."[22] This program constituted usual care. This model for PTSD and depression (1) equipped and trained clinics to screen each visit and use symptom severity tools for diagnosis and assessment; (2) used nurse care managers to contact patients monthly and provide symptom status to primary care clinicians; and (3) increased access to non-primary care clinic based mental health specialists. All 18 participating primary care clinics at six Army installations (and 97 worldwide clinics at 39 Army installations) used this model. Installation "champions" oversaw model implementation.

Centrally Assisted Collaborative Telecare (CACT). The components of CACT are described in the text box.

Participants and Data Collection

From February 2012 through September 2013, 666 patients were randomized at 18 troop medical clinics at six large Army installations: Joint Base Lewis-McChord Washington; Fort Bliss Texas, Fort Hood Texas, Fort Stewart Georgia, Fort Campbell Kentucky, and Fort Carson Colorado. Primary care clinicians referred appropriate patients to nurse care managers per usual care. Research assistants assessed eligibility and obtained informed consent. Eligible patients (a) were on active duty; (b) met study criteria for probable PTSD (≥1 intrusion symptom, ≥3 avoidance symptoms, and ≥2 hyperarousal symptoms at ≥moderate level on the PCL-C) or depression (≥5 PHQ-9 symptoms – thoughts of self harm ≥"several days" or other symptoms ≥"more than half the days"); and (c) reported access to Internet and e-mail. Study assessments were done online or, in a few cases, by phone or paper questionnaire.

Exclusions were (a) current alcohol dependence (Alcohol Use Disorders Identification Test, AUDIT≥15);[30] (b) active suicidal ideation in the prior two months (Mini International Neuropsychiatric Interview (MINI)-Plus Suicidality Module score >9);[31] (c) major geographic relocation in the next six months (e.g., change of station, deployment, demobilization, separation); or (d) current duties in a participating clinic.

Randomization

After baseline assessment, participants were randomized in real time centrally to CACT or usual care by a computer-automated system that sent results to patients and care managers. Stratification was by site. Automated emails prompted follow-up research assessments. In the absence of response to initial emails, added methods were used on a predetermined schedule: (a) reminder phone calls, (b) reminder emails, (c) phone interviewer contacts, (d) reminder texts, and (e) paper questionnaire mailing. Research assessments were by direct computer entry at baseline, three, six, and 12 months.

Outcomes

Primary. Primary outcomes were the Posttraumatic Diagnostic Scale (PDS)[32,33] for PTSD symptoms and the Symptom Checklist Depression Scale (SCL-20) for depressive symptoms.[34] PDS (17 items) assesses severity of PTSD symptoms over the prior four weeks with high internal consistency and test-retest reliability;[33] scores are summed and range from 0 to 51; scores ≤10 are mild, 11 to 20 moderate, 21 to 35 moderate to severe, and ≥36 severe. SCL-20 is comprised of 13 Hopkins Symptom Checklist Depression Scale items plus seven additional depression items from the Symptom Checklist-90-Revised. The latter items better covered all diagnostic symptoms of depression and improve sensitivity to clinical change. Scores are a mean of item scores and range from 0 to 3.[34]

Secondary. Secondary outcomes were suicidality, physical symptoms, pain intensity and interference, alcohol misuse, and physical and mental health related quality of life. Suicidality was assessed with three items (hopelessness, thoughts of death, and thoughts of suicide) from the SCL-20.[34] Physical symptom severity was assessed with the PHQ-15, a 15-item scale scored from 0 to 30.[35] Health related quality of life was assessed on the Short Form-12 (SF-12) subscales measuring physical health and mental health related functioning.[36] Subscales are normed for the general population so that mean and standard deviation are approximately 50 and 10 respectively.[37] Pain intensity and interference were assessed with the Adapted Numeric Rating Scale for Pain;[38] each item is rated on a 0 to10 Likert scale. Alcohol misuse was measured using the three AUDIT consumption questions (AUDIT-C) that sum to scores of 0 to 12.[39] Patients reported amount and type of health care and medication use at each assessment. Counts of key intervention components were derived: number of individual patient visits with a mental health specialist and number of telephone contacts with a health care provider such as a care manager or other telephone assistance (e.g., crisis or helpline). Psychoactive medications were coded for type and duration, and used to derive a count of months on a guideline

concordant depression medication (i.e., antidepressant) or PTSD medication (i.e., SSRI, prazosin).

Safety and Adverse Events. Serious adverse events were defined as participant death from any cause; or psychiatric emergency or hospitalization related to study participation. The study data and safety monitoring board (DSMB) chair and site-specific independent study monitors reviewed all adverse event reports to insure safe study implementation.

Statistical analyses

For the sample size calculations, we focused on the effect size, Δ/σ, for 12-month changes in scores in the two treatment groups, where Δ is the expected value of the difference between mean 12-month changes and σ is the within-group standard deviation at each time point. Initially, we assumed, conservatively, zero correlation between repeated measurements on the same subject reflecting that a study with 600 subjects per arm (750 assuming 20% attrition) and a Type I error rate of 0.025 to account for two endpoints of interest would have power=0.80 to detect an effect size of Δ/σ=0.252. We reevaluated the sample size calculations after 129 subjects completed 12-month assessments. Correlations between repeated measurements were nearly all >0.50. A correlation of 0.50 reduced the required sample size for the same power and effect size to 300 subjects per treatment group.

Analysis of scores on the PDS and SCL-20 was based on an exponential model of score vs time: $s_{ijk} = \beta_{j1} + b_{ij} + \beta_{j2}e^{-\beta_{j3}t_{ijk}} + d_{ijk}$ where s_{ijk} is score (PDS or SCL-20) for subject i in treatment arm j (j=1,2) at assessment k (k=1,..,4), β_{j1}, β_{j2} and β_{j3} are fixed parameters, b_{ij} is a normally distributed random parameter with mean zero, t_{ijk} is time on study at assessment k and d_{ijk} is a normally distributed error term with mean zero. This model accurately described changes both in mean scores and the variance of scores at each assessment. Under this model, $\Delta = \left(\beta_{12}e^{-12\beta_{13}} - \beta_{12}\right) - \left(\beta_{22}e^{-12\beta_{23}} - \beta_{22}\right)$ under the null hypothesis that Δ=0, $\Delta/\mathrm{SE}(\Delta)$ has approximately a standard normal distribution.

To assess clinical significance, we compared the proportions of participants achieving >50% score reduction at the three follow-ups using a generalized linear model with GEE to account for correlations between repeated observations on the same subjects.

Changes in the secondary endpoints were compared using repeated measures linear models (the exponential model did not fit the data). Predictors included treatment group, time and the interaction of time and group, with the interaction included to provide a test for differences between time trends in the two groups. Health care use was compared using Poisson regression with GEE and baseline use as a covariate. Other predictors included treatment group, an ordinal categorical variable for time and their interaction.

For PDS and SCL-20 scores, we tested differences between changes in the treatment arms over the first three months and the first 6 months to see if differences identified over 12 months were apparent earlier. We repeated this for the proportion with >50% reduction in score. We performed overall tests over 12 months when comparing treatment arms for secondary endpoints or health care use.

The main analysis was done at the end of the trial and included all randomized participants with usable outcome data according to the intention-to-treat principle. Number needed to treat for a binary outcome was one divided by the absolute difference between groups. Analyses were conducted using SAS/STAT software Version 9.3 of the SAS System for Windows.

Results

Sample

Figure 1 presents the study flow diagram. Follow-up assessments were completed by 93% of patients at 3 months, 90% at 6 months, and 86% at 12 months. Of 666 randomized patients, 332 were assigned to CACT and 334 to usual care. Complete follow-up data were obtained for 273 (82.2%) CACT and 280 (83.8%) usual care participants. Only 9 (2.7%) CACT participants and 21 (6.3%) usual care participants were missing all but baseline data. CACT and

usual care groups were balanced on baseline characteristics (Table 1). Subjects were mostly men in their twenties. Mean PDS PTSD score was 29.2 indicating moderate to severe PTSD and mean SCL-20 depression score was 2.1, indicating moderate depression severity.

PTSD and Depression Outcomes

Compared with usual care, patients in CACT reported significantly greater reductions in PTSD and depression symptoms over 12-months of follow-up (Table 2). CACT patients reported significantly greater 12-month decrease in PDS PTSD scores (-2.53; 95% CI=0.59-4.47) and SCL-20 depression scores (-0.26; 95% CI=0.11-0.41). Fifty percent improvements were significantly greater at 12-months for CACT than usual care for both PTSD (25.0% vs. 17.0%; RR=1.6; 95% CI, 1.1-2.4) and depression (29.7% vs. 20.6%; RR=1.7; 95% CI, 1.1-2.4), with a number needed to treat for a 50% improvement of 12.5 (95% CI, 6.9-71.9) and 11.1 (95% CI, 6.2-50.5) respectively. Differences in effects were significant at 12-months for PTSD and at six and 12 months for depression. Adjusting for site had very little impact on the difference between 12-month changes in scores in the two treatment groups or in the standard error of the difference.

Secondary Health Outcomes

Significant improvements in CACT versus usual care were noted for physical symptoms (PHQ-15) and mental health functioning (SF-12 mental component), but not alcohol consumption (AUDIT-C), physical health function (SF-12 physical component) or pain intensity/ interference (Table 3). Of note, repeated measures analysis (treatment group, by time, and their interaction) revealed significant reductions in suicide-related SCL-20 items in the CACT arm (versus no change in usual care) for “hopelessness about the future” (p=0.037), “thoughts of death and dying” (p=0.0034), and in “thoughts of ending one’s life (p=0.040).

Process of Care

We examined four key aspects of the process of care expected to differ between CACT and usual care: individual psychotherapy, telephone contacts with the care manager, and use of

appropriate PTSD or depression medications (Table 4). No treatment by time interactions were detected on these measures, but CACT participants reported significantly more telephone contacts and more months on an appropriate PTSD and depression medication. No differences were detected on the number of individual visits with a mental health specialist.

Adverse Events

There were no study related deaths, psychiatric emergencies, or hospitalizations.

Discussion

In a randomized controlled trial, military personnel attending primary care with PTSD or depression who were referred to 12 months of centrally assisted telecare with stepped psychosocial and pharmacologic management (CACT) reported significant improvements in PTSD and depression severity, physical symptom severity, and mental health function compared to those referred to usual integrated mental health care. Differences between the two groups were small to modest in size, with numbers needed to treat for 50% improvement of PTSD and depression of 12.5 and 11.1 respectively. However, improvements increased over time, and an effective primary care program may reduce treatment delays and extend the reach of treatment. Our findings are noteworthy because most service members with PTSD have received no or inadequate treatment in the past year,[2,3,40] and in the most recent available estimates, the median time from onset to first PTSD treatment nationally was an estimated 12 years.[41]

Modest CACT effects may have been related to several factors. First, to maximize generalizability, patients with a variety of medical and psychiatric comorbidities were included (e.g., mild traumatic brain injury, anxiety disorders, problem alcohol consumption). Indeed, 14% were undergoing medical retirement at randomization. Second, usual care was a long-standing program of mental health integration using routine screening, care management and measurement-based assessment.[18] Pre-post effects, however, were also modest for both groups. Third, military personnel are difficult to engage in mental health treatment, and the

276 military context is challenging. Service members are highly mobile, many left the military during
277 study follow-up, and confidentiality concerns[41] may erode trust and confidence in mental health
278 services. Fourth, in contrast to previous collaborative care trials, participants were mainly men in
279 their twenties, a demographic group that is unlikely to seek mental health care. Fifth, guideline
280 concordant psychotherapies for PTSD were difficult to obtain, even though clinics were staffed
281 with specialists. Telephone contacts were greater in CACT than in usual care, but
282 corresponding increases in medication and psychotherapy use were small.

283 Delayed PTSD improvement compared to improvement in depression is perhaps a
284 function of the greater complexity and comorbidity associated with PTSD, and fewer and less
285 efficacious pharmacologic options for PTSD. In qualitative research completed during the trial,
286 many primary care clinicians expressed discomfort treating PTSD.[18] We did not find significant
287 improvements in alcohol misuse or in pain outcomes; however we observed significant
288 improvements in mental health related function and overall physical symptom severity,
289 suggesting the impact of the intervention went beyond the targeted disorders. Of note, CACT
290 was associated with reductions in suicidal ideation, findings consistent with previous studies of
291 collaborative care for depression.[10]

292 Three collaborative care trials have reported on PTSD outcomes. Two trials[15,16] found no
293 benefit associated with models that mainly relied on psychiatrist-supervised care managers,
294 measurement-based symptom severity assessments, and stepped pharmacologic
295 management. Fortney and colleagues[14] found improved PTSD outcomes using a collaborative
296 care approach to PTSD designed to extend the reach and increase the use of cognitive
297 processing therapy. CACT also offered stepped telemental health support; although more
298 research is needed, remote psychotherapeutic approaches may be an important aspect of
299 collaborative care for PTSD.

300 Several study limitations should be considered. First, we randomized a multicomponent
301 treatment approach aiming to increase guideline concordant care, and this pragmatic design did

not allow randomized comparisons of individual treatment components. Second, we used self-report utilization data because participants in both groups often left the military and its health system, limiting analyses of the impact of care processes on treatment effect. Third, we have yet to report information about the cost and cost-effectiveness of this intervention or its acceptability to service members and military clinicians. Nonetheless, there is potential for central assistance to create economies of scale that allow support for small, rural, remote, or under-resourced primary care clinics where specialists are usually not available.

We conclude that greater central telecare assistance for collaborative care and the addition of stepped psychosocial management modestly improves primary care outcomes of PTSD and depression among affected military personnel and may hold promise for other groups of people with similar conditions.

Acknowledgments.

Dr. Engel had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis

The STEPS-UP Trial investigators acknowledge the recent loss of our coauthor, friend and mentor, Dr. Wayne J. Katon and dedicate this article to him. Dr. Katon provided a steady guiding hand throughout the project, and he spawned a generation of researchers and ideas toward improving mental and physical health care for primary care patients. Dear Wayne: Thank You. We miss you.

We also wish to thank the many devoted care managers, research site investigators, site coordinators, primary care clinicians, clinic staff, and mental health specialists who supported the study and provided essential assistance to service members every day.

Funding:

This study was supported by a U.S. Department of Defense Deployment Related Medical Research Program award (Grant DR080409). The award was a joint award to the Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc. (award W81XWH-09-2-0077), Research Triangle Institute (award W81XWH-09-2-0078), and RAND Corporation (award W81XWH-09-2-0079). The sponsor had no role in study design; in the collection, analysis and interpretation of data; in the writing of the report; or in the decision to submit the article for publication. The views expressed in this article are those of the authors and do not necessarily

represent the views of the Department of Veterans Affairs, the Department of Defense, the National Institutes of Health[*] or any US government agency.

[*] Dr. Freed is currently at the National Institute of Mental Health, National Institutes of Health, Bethesda, Maryland. His affiliations on the cover page reflect those at the time the work was completed.

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466 **Table 1.** Baseline characteristics of 666 randomized study patients.
467

Characteristic		CACT N=332 n (%) or mean (SD)	Usual Care N=334 n (%) or mean (SD)
Demographic	***Group(s)***		
Gender	Male	264 (80%)	275 (82%)
Age	Years	28.7 (10.9)	28.9 (11.4)
Rank	E1-E6	297 (89%)	283 (85%)
Marital Status	Married	222 (67%)	224 (67%)
Education	≥ High School	233 (70%)	230 (69%)
Race/Ethnicity	White, non-Hispanic	158 (48%)	160 (48%)
	Other, non-Hispanic	116 (35%)	114 (34%)
	Hispanic	57 (17%)	60 (18%)
Deployments after 2001	0	59 (18%)	55 (16%)
	1	102 (31%)	107 (32%)
	2	82 (25%)	77 (23%)
	≥ 3	89 (27%)	95 (28%)
Baseline Clinical Status			
High Combat Exposure[1]		224 (67%)	228 (68%)
PTSD	DSM-IV/PCL-C[2]	285 (86%)	281 (84%)
Depression	DSM –IV/PHQ-9[3]	224 (67%)	208 (62%)
PTSD and Depression		193 (58%)	177 (53%)

Characteristic		CACT N=332 n (%) or mean (SD)	Usual Care N=334 n (%) or mean (SD)
PTSD Severity	PDS	29.4 (9.4)	28.9 (8.9)
	PCL-C	58.5 (11.1)	57.7 (10.8)
Depression Severity	SCL-20	2.1 (0.6)	2.0 (0.7)
	PHQ-9	15.3 (4.6)	14.6 (4.5)
Alcohol Consumption	AUDIT-C	3.0 (2.5)	2.7 (2.3)
Somatic Symptoms	PHQ-15	14.1 (4.7)	13.4 (4.8)
Physical Health Function	SF-12, PCS	37.7 (10.0)	36.8 (10.6)
Mental Health Function	SF-12, MCS	32.7 (9.6)	34.4 (10.9)
Pain Intensity	BPI	5.7 (2.3)	5.7 (2.4)
Pain Interference	BPI	5.0 (2.6)	5.0 (2.7)

[1] High combat exposure = 10+ points on Combat Exposure Scale.

[2] Meets PCL-C criteria if 1 or more items are endorsed for Criterion A, 3 or more for Criterion B, and 2 or more for Criterion C. A total of 37 participants were not asked the PCL because they did not meet criteria on the PC-PTSD and were assumed not to meet PTSD criteria

[3] Meets PHQ-9 criteria if 5 or more items were endorsed for “more than half the days” and one of those items was “little interest or pleasure in doing things” or “feeling down, depressed or hopeless”.

AUDIT-C=Consumption items of the Alcohol Use Disorders Identification Test

PCL-C=PTSD Checklist, Civilian Version

PDS=PTSD Diagnostic Scale

PHQ-9=Patient Health Questionnaire depression severity score

PHQ-15=Patient Health Questionnaire somatic symptom severity score

SCL-20=Hopkins Symptom Checklist, 20 item depression screen

SF-12, MCS=SF-12 Mental Component Summary score

SF-12, PCS=SF-12 Physical Component Summary score

484 **Table 2.** PTSD and depression related outcomes among study patients.

Outcome	CACT (n=332)	Usual Care (n=334)	Measure (95% CI)	p-value
PTSD (PDS) Severity				
0 to 3 months	-2.95[1] (0.53)	-2.73 (0.54)	-0.23 (-1.72,1.26)	0.59
0 to 6 months	-4.86 (0.61)	-3.42 (0.60)	-1.43 (-3.11, 0.25)	**0.057**
0 to 12 months	-6.07 (0.68)	-3.54 (0.72)	-2.53 (-4.47,-0.59)	**0.003**
Depression (SCL-20)				
0 to 3 months	-0.29[1] (0.04)	-0.20 (0.04)	-0.08 (-0.19, 0.03)	0.062
0 to 6 months	-0.44 (0.05)	-0.25 (0.05)	-0.19 (-0.32, -0.06)	**<0.001**
0 to 12 months	-0.56 (0.05)	-0.31 (0.05)	-0.26 (-0.41, -0.11)	**<0.001**
≥50% Improvement, PTSD				**0.023**
0 to 3 months	11.5[2] (36)	9.5 (29)	1.25[3] (0.74, 2.09)	0.40
0 to 6 months	19.3 (58)	13.4 (40)	1.55 (0.99, 2.40)	0.051
0 to 12 months	25.0 (73)	17.0 (49)	1.62 (1.08, 2.43)	**0.019**
≥50% Improvement, Depression				**0.014**
0 to 3 months	12.2[2] (38)	10.8 (33)	1.14[3] (0.70, 1.88)	0.60
0 to 6 months	21.3 (64)	13.8 (41)	1.70 (1.11, 2.61)	**0.015**
0 to 12 months	29.7 (86)	20.6 (59)	1.65 (1.13, 2.42)	**0.010**

[1] mean (SE)

[2] percent improved (number improved)

[3] odds ratio (95% confidence limits)

PDS=PTSD Diagnostic Scale

SCL-20=Hopkins Symptom Checklist, 20 item depression screen

485

Table 3. Changes in secondary outcomes among study patients from baseline to each follow-up assessment.

	CACT (n=332)	Usual Care (n=334)	Measure (95% CI)	Overall P Value
AUDIT-C, mean (SE)				0.24
0 to 3 months	-0.26 (0.12)	-0.29 (0.12)	-0.04 (-0.28, 0.36)	
0 to 6 months	-0.34 (0.13)	-0.33 (0.12)	-0.001 (-0.35, 0.35)	
0 to 12 months	-0.54 (0.14)	-0.20 (0.14)	-0.33 (-0.72, 0.06)	
PHQ-15, mean (SE)				**0.025**
0 to 3 months	-1.12 (0.25)	-0.58 (0.25)	-0.53 (-1.22, 0.15)	
0 to 6 months	-1.56 (0.26)	-0.69 (0.29)	-0.88 (-1.64, -0.11)	
0 to 12 months	-2.29 (0.33)	-0.92 (0.31)	-1.37 (-2.26, -0.47)	
SF-12, mean (SE)				
Physical (PCS)				0.65
0 to 3 months	-1.02 (0.41)	-1.16 (0.44)	0.14 (-1.04, 1.31)	
0 to 6 months	-0.64 (0.45)	-1.10 (0.46)	0.46 (-0.80, 1.72)	
0 to 12 months	-1.11 (0.47)	-1.25 (0.55)	0.14 (-1.29, 1.57)	
Mental (MCS)				**0.014**
0 to 3 months	4.31 (0.65)	4.13 (0.65)	0.18 (-1.62, 1.98)	
0 to 6 months	5.78 (0.74)	3.51 (0.74)	2.28 (0.23, 4.33)	
0 to 12 months	8.10 (0.80)	4.93 (0.82)	3.17 (0.91, 5.42)	
Pain Intensity, mean (SE)				0.32
0 to 3 months	-0.17 (0.13)	0.02 (0.11)	-0.19 (-0.51, 0.14)	
0 to 6 months	-0.18 (0.13)	0.08 (0.13)	-0.26 (-0.61, 0.10)	

0 to 12 months	-0.25 (0.15)	0.08 (0.12)	-0.33 (-0.74, 0.07)	
Pain Interference, mean (SE)				0.36
0 to 3 months	0.09 (0.19)	0.27 (0.13)	-0.17 (-0.54, 0.20)	
0 to 6 months	-0.05 (0.15)	0.18 (0.14)	-0.23 (-0.63, 0.18)	
0 to 12 months	-0.19 (0.16)	0.20 (0.17)	-0.39 (-0.85, 0.07)	

489 AUDIT-C=Consumption items of the Alcohol Use Disorders Identification Test

490 PHQ-15=Patient Health Questionnaire somatic symptom severity score

491 MCS=SF-12 Mental Component Summary score

492 PCS=SF-12 Physical Component Summary score

493

494 **Table 4.** Patient reported mental health service use by treatment group (mean, SE).
495

			Treatment Effect	
	CACT (n=332)	**Usual Care (n=334)**	**Measure (95% CI)**	**P****
Individual Therapy Visits				0.49
3 months prior to enrollment	2.66* (0.27)	2.68 (0.45)	-0.02 (-1.06, 1.01)	
0 to 3 months	2.94 (0.26)	2.86 (0.26)	0.08 (-0.62, 0.79)	
3 to 6 months	2.82 (0.29)	2.32 (0.24)	0.50 (-0.24, 1.24)	
6 to 12 months	3.66 (0.47)	3.55 (0.41)	0.11 (-1.11, 1.33)	
Telephone Contacts				**<0.001**
3 months prior to enrollment	1.53 (0.14)	2.56 (0.63)	-1.03 (-2.30, 0.25)	
0 to 3 months	3.05 (0.22)	1.76 (0.13)	1.·29 (0.80, 1.79)	
3 to 6 months	2.72 (0.31)	1.46 (0.13)	1.26 (0.59, 1.92)	
6 to 12 months	3.30 (0.35)	1.99 (0.22)	1.31 (0.51, 2.12)	
Months of Depression Medication[1]				**0.013**
3 months prior to enrollment	0.67 (0.06)	0.77 (0.06)	-0.10 (-0.26, 0.07)	
0 to 3 months	1.30 (0.07)	1.13 (0.08)	0.16 (-0.05, 0.37)	
3 to 6 months	1.37 (0.08)	1.22 (0.08)	0.15 (-0.07, 0.37)	
6 to 12 months	2.42 (0.16)	2.02 (0.16)	0.40 (-0.05, 0.84)	
Months of PTSD Medication[2]				**0.012**
3 months prior to enrollment	0.47 (0.05)	0.51 (0.06)	-0.04 (-0.18, 0.11)	
0 to 3 months	1.05 (0.07)	0.85 (0.07)	0.20 (-0.003, 0.39)	
3 to 6 months	1.20 (0.08)	0.88 (0.08)	0.32 (0.10, 0.53)	
6 to 12 months	2.03 (0.16)	1.60 (0.15)	0.43 (0.003, 0.86)	

496 [1] Any antidepressant medication

[2] Any selective serotonin reuptake inhibitor or prazosin

* mean (standard error)

** p for treatment difference averaged over 3-, 6-, and 12-month assessments

Text Box. Centrally Assisted Collaborative Telecare (CACT).

CACT added to usual integrated mental health in primary care in four ways:

(1) Care Manager Patient Engagement Training: Both CACT and usual care used nurse care managers. In CACT, care facilitators were trained and telecoached weekly in behavioral activation, problem solving, and motivational interviewing. Care managers used these skills to help CACT patients make evidence-based treatment decisions, provide basic psychosocial support, monitor/encourage adherence to medication and psychotherapy, and connect to needed specialty services.

(2) Stepped Psychosocial Treatment Options: Both CACT and usual care offered stepped pharmacologic treatment and specialty mental health services. In CACT, care managers assisted patients with online cognitive-behavioral self-management[23,24] and a psychologist delivered telephonic cognitive behavioral therapy using a modularized, flexible, problem-based protocol;[25] and site therapists offered face-to-face psychotherapy in a primary care or specialty setting.

(3) Electronic Symptom Registry: Care managers for both CACT and usual care were trained to use an online interface for measurement-based assessments [including severity of depression (PHQ-9)[26] and PTSD (PTSD Checklist, Civilian Version; PCL-C).[27] In CACT, a central symptom registry was derived from assessments and used to identify patients in need of treatment change (i.e., suicidal behavior; <5 point improvement in PCL-C and PHQ-9 since the last treatment change; PCL >30 or PHQ-9 >10; >4 weeks from last care manager contact). The registry was also used to monitor care manager performance.[28,29]

(4) Central Telepsychiatry, Telepsychology and Telecare Manager Assistance*:* For CACT, a central psychiatrist, psychologist, and nurse care manager remotely assisted sites. The psychiatrist used the electronic registry for weekly care manager caseload reviews, suggesting treatment changes to primary care via electronic medical record. The psychologist delivered

526 tele-CBT for selected patients and engagement training/coaching for care managers. The care
527 manager helped to follow mobile patients and backed care managers remotely.
528

Appendix C

Qualitative Manuscript: Barriers to Engagement

Appendix C - Qualitative Manuscript : Barriers to Engagement

Barriers to Engaging Service Members in Mental Health Care Within the U.S. Military Health System

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Objective: Over the past decade, there has been growing recognition of the mental health consequences associated with deployment and service by military service personnel. This study examined potential barriers to mental health care faced by members of the military in accessing needed services.

Methods: This qualitative study of stakeholders was conducted across six large military installations, encompassing 18 Army primary care clinics, within the context of a large randomized controlled trial. Stakeholders included patients recruited for the study (N=38), health care providers working within site clinics (N=31), and the care managers employed to implement the intervention protocol (N=7).

Results: Issues raised across stakeholder groups fell into two main categories: structural factors associated with the Army medical system and institutional attitudes and cultural issues across the U.S. military. Structural issues included concerns about the existing capacity of the system, for example, the number of providers available to address the population's needs and the constraints on clinic hours and scheduling practices. The institutional attitude and cultural issues fell into two main areas: attitudes and perceptions by the leadership and the concern that those attitudes could have negative career repercussions for those who access care.

Conclusions: Although there have been significant efforts to improve access to mental health care, stakeholders within the military health system still perceive significant barriers to care. Efforts to ensure adequate and timely access to high-quality mental health care for service members will need to appropriately respond to capacity constraints and organizational and institutional culture.

Psychiatric Services in Advance (doi: 10.1176/appi.ps.201500237)

There is growing recognition of the mental health consequences associated with deployment and service among military service personnel (1). Several studies document the prevalence of mental health problems in the military (2–5) and highlight the potential barriers that members of the military may face in accessing mental health services (6–8). As the primary source of health care for service members, the military health system (MHS) bears special responsibility in addressing these issues. With 9.6 million beneficiaries, 56 medical centers, and 360 ambulatory care clinics, the MHS represents one of the largest health systems in the United States.

Primary care has been referred to as the de facto mental health system (9–11). Over the past two decades, multiple efforts have been implemented in health systems to integrate behavioral health into primary care settings. Often referred to as "collaborative care," the goal of these initiatives is to integrate and improve the mental health services that are delivered in primary care. Common components of these models include efforts to prepare the practice setting by training providers in behavioral health issues; use of a team approach, most often involving a care manager for engaging patients, improving their adherence to treatment, and assessing treatment response; and use of strategies to enhance the interface between specialists and primary care (12).

In the MHS, service members have an average of three encounters per year in primary care (13). There have been several attempts to integrate behavioral health services into primary care settings and line units in the MHS. In 2007, the Army began integrating mental health services into all of its primary care clinics, including the colocation of mental health specialists and the use of nurse care managers (14,15). In 2013, it expanded the assignment of trained behavioral health clinicians to line units and troop medical clinics. These efforts were intended to expand access to behavioral health specialty providers and reduce soldier concerns with seeking help. Despite these efforts, concerns about access to and quality of mental health treatment within the MHS persist (1,16).

This qualitative study was designed to understand stakeholder experiences regarding treatment of posttraumatic stress disorder (PTSD) and depression in Army primary care clinics

(17). Specifically, we gathered information about participants' experiences with barriers to accessing and utilizing mental health care within the U.S. Army. In addition to gathering insights regarding obstacles and barriers, we asked stakeholders for recommendations to increase help seeking among soldiers with mental health problems.

METHODS

We conducted a series of one-on-one interviews with stakeholders within the context of a large randomized controlled trial testing the effectiveness of a centrally assisted, stepped-care model of collaborative care for PTSD and depression. The model was compared with the standard version of collaborative care offered throughout the MHS. The study was conducted across six large military installations from which service members deployed and to which they returned; together these installations housed 18 primary care clinics (17). Stakeholder groups included patients of the primary care clinics who were recruited for the study, care providers in clinics at each installation, and care managers implementing the study intervention. Patient participants were drawn from both intervention arms in the study. Procedures were approved by all relevant institutional review boards. All stakeholders who were interviewed provided oral consent for participation.

Patients

We randomly selected patients within each site to participate in up to three 30-minute interviews. We randomly drew patients' names and contact information on a rolling basis across the one-year study enrollment period. At each site, we attempted to recruit six patients, two from each of the intervention conditions, for a total of 36 patients across the study. After sending an introductory e-mail, we contacted patients by phone to ascertain willingness to participate and schedule an interview. Of the 60 soldiers invited to participate, we were unable to reach 14, three declined participation, and five were no-shows.

Once recruited, each patient was asked to participate in up to three interviews across the one-year time span. Each of the three interviews followed the same protocol in an attempt to assess how experiences and responses evolved over time. Interviews were scheduled to occur at three time points: within approximately one to two months, four to five months, and seven to eight months of the soldier's entrance into the study. For some patients, delays in scheduling interviews increased the interval between appointments.

All interviews were conducted over the phone by trained qualitative interviewers assisted by a notetaker. Using a semistructured interview guide, the interviewer asked about expectations regarding study participation; experiences getting care and working with their assigned care manager; use of mental health services, including barriers to or facilitators of mental health services that they experienced personally; and use of study tools and resources, for example, Web-based self-management resources, and recommendations for improving the delivery of mental health care to soldiers with PTSD or depression. Interviews were recorded and transcribed, and they lasted less than 30 minutes. Once transcripts were verified, recordings were deleted. Patients received a $25 gift card following each interview, for a potential total remuneration of $75 for participating in all three interviews.

Providers

Given the absence of centralized rosters of providers, the study site coordinators generated lists of all health care providers working within the installations' clinics, by setting and specialty type. From these lists, the qualitative study team recruited a similar number of general medicine providers (physicians, physician assistants, and nurse practitioners) and mental health specialty providers (psychiatrists, psychologists, and social workers). For the mental health providers, we sought providers working in the primary care clinic as well as the behavioral health clinics and operational units on the installation, given that patients in the study could be receiving care in these locations as well, and they could be interacting with the care manager. The study team randomly recruited five providers per site from the lists of providers until it reached its target of 30 providers. The study team contacted 100 providers across the six sites, and interviewed 31. Providers were asked to participate in one 15- to 30-minute interview about their experiences addressing soldiers' mental health needs; delivering behavioral health care within the MHS, including barriers to or challenges in treating soldiers with PTSD or depression in their clinic; and any specific experience related to the study. At the end of each interview, providers were asked if they had any additional thoughts they wanted to share about addressing the mental health needs of soldiers. Participating providers were given a $35 gift card for participating.

Care Managers

The seven study care managers (licensed nurses responsible for managing care of specific patients) included six who were located at a specific site and one who was centrally located and provided backup or overflow care management; six of the seven were female. They were asked to participate in two one-hour interviews about their experiences with study patients and providers. The timing of interviews was based on the study's life cycle: one took place in the first three months of the site's study enrollment period and one occurred in the last month of the study. The early and late interview discussion guide covered a range of topics, including experiences engaging patients into care (for example, working with the patient to set treatment goals and schedule appointments), including any barriers they have encountered in delivering services, sharing information with providers both on- and off-site, and perceptions of the specific study tools and resources they were provided—and any other comments they might have about addressing soldiers'

TABLE 1. Characteristics of patients in a randomized controlled trial of enhanced stepped collaborative care for PTSD and depression at six military installations[a]

Characteristic	Enhanced care (N=19)		Usual care (N=19)		Total (N=38)	
	N	%[a]	N	%[a]	N	%[a]
Male	13	68	12	63	25	66
Age (M±SD)	32±6.9		29±6.7		30±6.9	
Rank						
Enlisted	10	53	9	47	19	50
Officer	8	42	8	42	16	42
Missing data	1	5	2	11	3	8
Marital status						
Single	9	47	11	58	20	53
Married or living with partner	4	21	3	16	7	18
Separated, divorced, or widowed	5	26	3	16	8	21
Missing data	1	5	2	11	3	8

[a] Percentages may not add to 100% because of rounding.

mental health needs. During the final interview, we also used a medical record–assisted recall approach to foster feedback on their experiences with five specific patients whose care they managed. For the assisted-recall methods, we randomly chose patients who participated in the intervention at each site, and their names were provided to the care manager at the time of the interview. All interviews were recorded and transcribed. Once transcripts were verified, recordings were deleted. Care managers were offered a $75 gift card for participating.

Analysis

All transcripts were coded by using ATLAS.ti qualitative data analysis software. A coding scheme was drafted, used to code five transcripts, checked by the analytic team, and refined and expanded. To ensure interrater reliability, another member of the team reviewed a random selection of each set of transcripts to ensure consistent application of theme categorizations. Review of interview transcripts of the same participants across their three interviews suggested that patients did not perceive changes in barriers to treatment over time but rather gradually became more engaged in care.

RESULTS

A total of 76 stakeholders (38 patients, 31 providers, and seven study care managers) were interviewed between July 2012 and June 2014 about their experiences with receiving or delivering mental health care within the MHS. Table 1 displays demographic characteristics of the 38 patients who participated in the initial interviews; 31 (82%) completed at least two interviews, and 27 (71%) completed all three. Table 2 displays information about the 31 providers who were interviewed.

TABLE 2. Characteristics of 31 providers at six military installations

Characteristic	N	%
Male	17	55
Setting		
Primary care clinic	22	71
Specialty clinic	4	13
Embedded in operational unit	5	16
Provider type		
Behavioral health (psychologists, social workers, and psychiatrists)	18	58
Primary care (physician assistants, nurse practitioners, and medical doctors)	13	42

During these discussions, 99% (N=75) of stakeholders discussed a number of issues that they perceived as inhibiting timely access to and receipt of high-quality mental health care. Issues raised across stakeholder groups fell into two main categories: structural factors associated with the system itself and institutional attitudes and cultural issues across the U.S. military.

Structural Issues

Timely receipt of mental health care is dependent not only on identifying the need for care and reaching out for help but also on whether care is available where and when it is needed. When asked about the types of challenges that got in the way of getting help or delivering services to soldiers with mental health problems, 47% (N=36) of stakeholders raised issues about the structure of the military health care system as potential barriers to delivering care. These issues included concerns about the capacity of the system, for example whether there were enough providers available to meet patients' needs (noted by 15 [20%] stakeholders). Both patients and providers raised this issue, particularly with respect to ensuring timely access to appointments. Table 3 contains illustrative quotes of stakeholder perceptions of structural barriers to care.

A second structural concern included constraints on clinic hours and scheduling practices. Thirty-nine percent (N=12) of providers and 57% (N=4) of care managers spoke of the limited time available during each visit to tend to the patient's full range of concerns. At the same time, many providers (particularly those engaged in trying to do follow-up telephone care) and care managers mentioned concerns about the overlap between their work hours and those of their patients, which made it nearly impossible to reach patients by phone during the day. In the MHS, care is such that appointments are offered only during duty hours, requiring that service members obtain permission from their supervisors or commanders to be absent from work in order to attend the appointment. As a result, their health care is subject to the varying knowledge, attitudes, beliefs, and will of their commanders, a subject that also arises below in the discussion of institutional attitudes and culture. Indeed,

TABLE 3. Perceptions by stakeholders of structural barriers to receipt of mental health care in the military health system

Perception	Patients[a] (N=38) N	Patients[a] (N=38) %[b]	Providers (N=31) N	Providers (N=31) %[b]	Care managers (N=7) N	Care managers (N=7) %[b]	Examples
Limited provider capacity restricts timely access to appointments	6	16	4	13	5	71	"The workload is very high. I am new and the population of clients coming through the door is nonstop." [BH provider] "Capacity to serve the high need for care is an issue. . . . I am running out of places to send my patients. I don't have any place to send acute patients. We need more capacity." [PC provider] "Patients are unable to get appointments, which disrupts continuity of care." [BH provider] "What we're having is not enough appointments for the soldiers, they're only booked once a month, so they feel like they're not getting enough care, as much as they need." [care manager] "I just want to know what's going on. When you're told you may have a problem . . . I want some answers sooner than three weeks away." [enhanced collaborative care patient] "My next appointment should be in the next week, and I have an appointment every 2–3 weeks or so. If I feel like it needs to be more—they talked about referring me off-post." [usual care patient] "One month I could go to this particular care provider, and then not even a week later, I'm speaking with someone else. And it's one of those things where the turnover rate or whatever was like super high." [usual care patient] "Some of the appointment wait times are 2–3 weeks." [BH provider] "Most PTSD clinics or Wounded Warrior clinics are full and the wait times are long." [PC provider] "Some of the challenges might be availability. We don't have enough staff to see people on a weekly basis. We have struggled to see suicidal patients weekly. [We have seen] 800 patients last monthly 3 weeks. We have three full-time therapists and two part-time therapists." [BH provider]
There are constraints on provider's time for appointments and follow-up	0	—	12	39	4	57	"Another part of the issue is my time. If I had the time to make phone calls and do virtual follow [follow-up by phone or email], I would do it." [PC provider] "I have had a hard time contacting service members who work the same hours that I do." [care manager] "And every time I called back it was, 'Oh, call back next week. Call back next week.' Sometimes one of the big things is just the feeling I get is . . . especially if you're trying to get the information over the phone . . . is you get the feeling that it's not really their priority to get you." [usual care patient] "Limitations make it tough to treat PTSD. Providers have limitations in terms of duration of time and numbers of appointments. I am supposed to limit visits to four per problem. This is not set in stone. My appointments are also limited to 30 minutes." [BH provider] "In terms of appointment time, an 8- to 15-minute allotment is not enough time." [PC provider] "In addition to the large patient load and the short appointment times, the overall complexity of PTSD is the issue." [PC provider] "I think the main issue is time. The therapies are supposed to be 90 minutes long, but we don't have time for that. Most appointments are 60 minutes. So we don't follow that guidance." [BH provider] "We do use those evidence-based practice (EBP) skills, but we need to modify them because of the constraints of 30-minute appointments that are short-term. I modify the EBPs to help the patient." [BH provider] "As an embedded provider, we are limited in time—so we can't spend as much time or have as many visits as we would have had we been in traditional behavioral health settings. You can request additional visits, but must get authorizations after significant justification for the 'extra' time. We are limited to 30–40 minute sessions." [BH provider]

continued

TABLE 3, *continued*

Perception	Patients[a] (N=38)		Providers (N=31)		Care managers (N=7)		Examples
	N	%[b]	N	%[b]	N	%[b]	
Work hours conflict with clinic hours	12	32	0	—	0	—	And that's why I didn't go to like that support group that I was recommended, because it's hard to get off work during the day and then be gone without having to make up a lie about why I'm leaving." [usual care patient] "That is a lot of it because like our unit, they don't like us—like Mondays, Wednesdays, and Fridays have pretty much [been] deemed out, you know, you can't have appointments on these days unless they're after hours. And, you know, just having Tuesdays and Wednesdays or, you know, trying to make an appointment on an evening, a lot of times you can't, you know." [usual care patient] "Well since I have to now keep appointments for my assessments to get out of the Army, half the time I don't tell them if it's a medical appointment or one of those. So they just assume it's one of the med board assessments, and I'm able to get off work. So I don't really tell them what the appointment is for, and I'm able to go to it easier." [enhanced collaborative-care patient]

[a] Patients were enrolled in a randomized controlled trial of enhanced collaborative care for PTSD and depression at six military installations. Abbreviations: BH, behavioral health; PC, primary care
[b] Percentages reflect stakeholders who identified a structural barrier to mental health care.

32% (N=12) of patients reported inability to take time off as a barrier to care.

Institutional Attitudes and Culture

The attitudes and culture of the Army as an institution and workplace setting were among the issues identified as affecting access to care. The military ethos values "toughing it out" and espouses that persons with problems are weak. These attitudes, sometimes defined as "public stigma," are perceived to be a major impediment to care seeking among military personnel. Stakeholders commonly cited these issues when asked about barriers to care that they had experienced. These issues broadly fell into two main areas: attitudes and perceptions of the unit (or line) leadership toward soldiers who seek mental health care and the possibility of negative career repercussions for persons who access care. Thirty-nine percent (N=15) of patients, 10% (N=3) of providers, and 86% (N=6) of care managers voiced concerns about attitudes among leaders and their willingness to allow soldiers to schedule appointments. Indeed, 39% (N=15) of patients were concerned that requesting time off for mental health visits and attending such visits would have an adverse impact on their careers, either through fewer promotion opportunities or even separation from the military. Table 4 summarizes stakeholder perceptions of institutional barriers to treatment that were related to attitudes and culture.

Recommendations for Improving Access and Receipt of Care

During each interview, we asked for suggestions on how to improve access to mental health care for soldiers. All patients, all care facilitators, and one-quarter of providers offered at least one suggestion. Among the 52 stakeholders who made a recommendation, 75% (N=39) called for expanding access for soldiers and their families to resources available off the installation. Soldiers mentioned not only that community resources were available but also that such resources were often preferred because they were perceived to offer a greater likelihood of confidentiality and because they were available outside work hours. Other suggestions included addressing the attitudes of leadership directly through targeted training programs—25% (N=13) of stakeholders commented that military leaders needed to become more aware of mental health challenges and issues facing soldiers and to be taught how to be more empathic and to facilitate soldiers' receipt of care. Others mentioned a need to encourage providers to communicate directly with command when there was a lack of support for service members in keeping their appointments. Table 5 lists recommendations for encouraging help seeking.

DISCUSSION

Ensuring access to mental health services for U.S. service members has been the focus of several national efforts,

TABLE 4. Perceptions by stakeholders of military attitudes and culture that serve as barriers to receipt of mental health services

Perception	Patients[a] (N=38)		Providers (N=31)		Care managers (N=7)		Examples
	N	%[b]	N	%[b]	N	%[b]	
Perceived leadership attitudes and perceptions influence soldiers' willingness to access care	15	39	12	39	6	86	"My chain of command does not believe me either. I guess they don't think anything is wrong with me . . . so they're really giving me a hard time." [enhanced collaborative care patient] "The major challenge we face is really being able to ensure the soldier can get time off to attend visits and get the needed care. They have difficulty getting chain of command to allow them time off or getting excused from the field." [PC provider] "They [chain of command] give me a hard time for going to appointments. They say I always have appointments and they always want me to bring a note in, bring a note after I'm done." [usual care patient] "The command is not very willing to release patients for therapy. When soldiers are in the field, they cannot leave." [BH provider] "Sometimes I don't think they understand the challenges that I'm facing, and there isn't a lot of empathy for—and I guess they don't understand the need for me to have an appointment during the work day. So it makes it very difficult. . . . I have like three appointments a month, I already get a lot of flak for that, and I'm definitely looked down upon." [enhanced collaborative care patient] "As much as they talk about getting help if you need it, they still have this tendency to portray that it's weakness. The sergeant major in my unit has told people to stop making appointments or they can't have any more appointments for now and to stop making appointments to get out of work." [enhanced collaborative care patient] "I have to go to [name of supervisor] all the time, and it doesn't do anything. I just want to get out because I can't do anything with that Army anymore." [enhanced collaborative care patient] "Availability is an issue. Command support for time away is another issue. Command support of behavioral health could be improved. It is variable from person to person." [BH provider] "Follow-up is good. We have good relationships with the chain of command. Our physician assistants can also follow up well." [BH provider]
Accessing care may have a negative career impact	15	39	0	—	6	86	"They're petrified, a lot of them, that if they tell you what's going on, that they will be kicked out of the service, even though they're told they're not going to, that stigma is still there for a lot of soldiers." [care manager] "That's why most of the time they just don't say anything. Because they're afraid that, because of the downsizing, that they'll be—end up getting chaptered out." [care manager] "And you don't want to tell your boss that you have an appointment for something behavioral health. You like to hide those problems. I feel that I look inferior if I, you know—I just like to tell them, hey, I have this issue and I'm dealing with it. But if I, you know, have to bring it up every couple weeks to say I have an appointment—I have to go here for this–you don't want it that visible. You want to look like you can always do your job, no matter what." [enhanced collaborative-care patient] "I can't receive the treatment that I need because of my job. So it comes down to a point where I can choose my professional career and what supports my family or what I actually need. And it's sad that it's like that." [usual care patient]

continued

TABLE 4, *continued*

Perception	Patients[a] (N=38)		Providers (N=31)		Care managers (N=7)		Examples
	N	%[b]	N	%[b]	N	%[b]	
							"I don't want to tell my boss that, 'Hey, I got a counseling appointment.' You just always want to appear that you can do everything and you don't need help. I think maybe they just wouldn't look at me the same. It's one thing to say—because I had to tell my boss that I have a problem going into the OR. I got a little PTSD stuff going on with that. And it's one thing to tell her that and, 'Hey, I'm trying to work on it; I'm getting a little counseling.' It's another to go up every week or two and say, 'Hey, I got to go for an appointment. I'm leaving a few hours early.' I think you just don't look quite as competent, not as self-sufficient, you know?" [enhanced collaborative care patient]

[a] Patients were enrolled in a randomized controlled trial of enhanced collaborative care for PTSD and depression at six military installations. Abbreviations: BH, behavioral health; PC, primary care

[b] Percentages reflect stakeholders who identified a structural barrier to mental health care.

including a presidential executive order (18). The Department of Defense and each of the military services have implemented many programs designed to raise awareness about the mental health issues associated with deployment, promote help seeking, and expand workforce capacity to meet demand for mental health services (19). Our findings reveal that despite these efforts, many stakeholders still perceive and experience significant barriers to care. Our study found significant overlap among patients seeking access to mental health care within the Army medical system and those responsible for providing or facilitating such care with respect to the obstacles and challenges faced by soldiers when trying to get help for mental health concerns.

Prior studies of barriers to mental health care among civilian populations often identify concerns about affordability and effectiveness of care (8). Many studies have suggested that the greatest barrier to receiving and remaining in care for military personnel was related to stigma among soldiers (5,8,20,21), and we found evidence of this issue among all of our stakeholders. However, even more frequently, stakeholders raised concerns about structural aspects of the Army medical system as well as about the institutional culture of the Army (8). Structural issues may be easier to change than cultural attitudes, yet they persist in spite of many efforts to facilitate access to mental health services and support (19). All of the service members in our study had a mental health problem and were assigned to a care manager to help them navigate care and obtain needed appointments. Yet these stakeholders noted significant structural and organizational barriers to securing timely care.

Both patients and providers perceived a shortage of professionals and expressed frustration over the resulting long wait times for appointments. Providers also noted that the short visit times limited their ability to attend to all of the patient's concerns, including those related to mental health. Addressing these concerns will involve considering structural changes to improve the systems of mental health service delivery, such as hiring more mental health providers, expanding access to off-post mental health providers, lengthening the time allotted for primary care sessions, and expanding clinic hours to offer appointments during evenings and weekends.

Both patients and providers also noted that attitudes among Army leaders toward help seeking, particularly attitudes that discourage getting help and promote the "tough it out" ethos, were a significant barrier for soldiers who needed or wanted help. A handful of other studies have also documented the influence of poor leadership not only on the experience of postdeployment mental health problems (22) but also on stigma and soldier help seeking (5,8,20,21). Britt and others (23) found that leaders who engaged in negative behaviors, such as embarrassing unit members in front of others, were more likely to create work environments conducive to higher levels of stigma concerning mental health care among their soldiers. Our stakeholders reported that getting approval to leave work and attend appointments may

TABLE 5. Recommendations by stakeholders for encouraging mental health help seeking among soldiers

Recommendation	Patients[a] (N=38) N	Patients[a] (N=38) %[b]	Providers (N=7) N	Providers (N=7) %[b]	Care managers (N=7) N	Care managers (N=7) %[b]	Examples
Expand access to off-post resources	31	82	2	29	6	86	"The only thing I'd think of is if there would be a way that they could either contract out to civilian doctors off-post or something like that. That way they would be able to lower the caseload and not have to wait a month, month-and-a-half, for your next appointment." [enhanced collaborative care patient] "I think it'd be easier to have more stuff [we] can do outside of work . . . as well as having places that you can go outside of work . . . so having an option to go to after duty hours or on weekends or something like that would be nice." [enhanced collaborative care patient] "[Off-post provider] has been a lot better and talking to [my care manager] on the phone has been good enough. I don't think he [off-post provider] comes from [a perspective of] defending the military and telling me that it's OK what they are doing to me. He's not like the lady I was seeing who was military. He listens to how I feel and helps me cope with it better. He's not telling me how they [the military] see it or trying to make me change my opinion. I can tell him exactly what's on my mind and how I feel without him telling me that I knew that when I joined or that's how it is." [enhanced collaborative care patient] "I would say the only thing would be to work on not having it [be] so difficult to go to a civilian provider. The process of having to go on-post for X amount of visits before you can get a referral to go see somebody else is kind of ridiculous, because if you have somebody like me—like if I could have I would have gone off-post immediately because I don't want to have anything to do with the on-post counselors because of the generalization and the 'stigmatism' that carries. I would have gone off post originally. But a lot of times that isn't a very easy option." [usual care patient] "It's worlds different. I think the thing with on-post is they just, in their mind, they already have an agenda and they already think they know what you're going to say. So I felt like they anticipate because they already have it all figured out what you're going to say and what their prognosis or diagnosis of you is and what they think about you. They already have all that planned out before you even start talking to them." [usual care patient]
Provide better training for leadership	9	24	3	43	1	14	"The leaders need more training on how to deal with us. They need more training on how not to call us out about our issues or call[ing] us weak. I think they need training because the ones saying these things need help themselves. I think training the leaders is the first step and then training the soldiers with the families is important too." [enhanced collaborative care patient] "Educate commands to encourage their soldiers to go get help. Or even bring in—I know when I was in my first tour, we had somebody come in one day when the whole group was there and just kind of give us an overall kind of class on, you know, different things that could have been going on and just kind of a gateway to, OK, well, that's going on in my life. Maybe I should set up an appointment." [enhanced collaborative care patient] "It has to start from the top. It has to be something from way high up to come down to say, 'Hey, this is [name of superior]'—you know, they—pretty much they have to figure out how to make the units—at the highest level, make the lowest level [unit leaders] understand that something's got to be done in certain situations or [telling them that] needing help is OK." [usual care patient] "The better the chain of command is with their support, the easier it is for the soldiers to make them want to go to it—or not make them—encourage them to go to these services that the Army has available." [enhanced collaborative care patient]

continued

TABLE 5, *continued*

Recommendation	Patients[a] (N=38)		Providers (N=7)		Care managers (N=7)		Examples
	N	%[b]	N	%[b]	N	%[b]	
Encourage communication between providers and command	4	11	3	43	1	14	"I feel like—like if I had an appointment tomorrow and I feel like one of the people, providers should have one of these nurses or somebody send out an e-mail to my chain of command, be like [name of soldier] has an appointment tomorrow. Please allow [the soldier] to come, or something like that." [usual care patient] "Maybe send a letter out to them [leadership or command] explaining what the program is about and stuff like that because I don't think anybody really knows about [this program] unless you go through [the medical clinic] and stuff like that. Like all they know about is behavioral health. They don't have any idea about STEPS-UP." [enhanced collaborative care patient]

[a] Patients were enrolled in a randomized controlled trial of enhanced collaborative care for PTSD and depression at six military installations (STEPS-UP).
[b] Percentages reflect stakeholders who identified a structural barrier to mental health care.

be intimidating, and many feared that there could be adverse career repercussions if they did so. Britt and colleagues (23) also observed that leaders who engaged in more positive behaviors were more likely to make accommodations for individuals who sought treatment. In a 2013 study of active duty soldiers, Zinzow and colleagues (8) noted that leadership attitudes and behaviors were critical as both potential barriers to and facilitators of treatment seeking.

Taken together, these findings suggest that improving military leaders' attitudes about mental health may be important for facilitating help seeking. Given the multiple levels of leadership within the military, these efforts need to include senior, mid-grade, and junior officers to ensure that they reach all of the microcultures within the overall military command climate. Within the first-responder community, other agencies have implemented Psychological First Aid for Leaders to change how leaders understand and respond to individuals who experience mental health issues (www.phe.gov/abc). This course may serve as a model for the Department of Defense as it continues to address barriers to mental health treatment among service members and promote more supportive work environments.

A few study limitations should be noted. Specifically, our data were collected from patients who had successfully overcome some of the barriers and who sought care at relatively large installations with robust care systems. As such, their concerns may underrepresent the magnitude and scope of barriers facing service members in other settings, including those at smaller military installations. Furthermore, these data were collected from within Army clinics, and it is unclear to what extent the same issues would be identified among patients in clinics managed by other service branches. However, we expect that regulatory tensions between the military unit and persons seeking military medical care are likely to remain qualitatively similar across branches of service. Finally, few study participants sought care outside the MHS and, therefore, did not discuss barriers they might face in the civilian service sector. There has also been a proliferation of civilian provider networks that serve service members, veterans, and their families. As such, whether service members face similar barriers within those systems has yet to be evaluated.

CONCLUSIONS

Military service, particularly during a period of active combat, is arguably one of the most stressful occupations. Given added concerns about trauma exposures, both before and after service and deployment, there is sound basis to enhance access to mental health services for service members. The issues and concerns regarding the role of the leadership and commanders in influencing service members' willingness and ability to seek such care are of significant concern. Commanders are often regarded as members of the care team, and they have unusual access to medical records (24). These factors suggest a need to reexamine commanders' roles around mental health service

delivery and to ensure that they are facilitators of and not barriers to the mental health care needed by their troops.

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This study was supported by a Department of Defense Deployment Related Medical Research Program award (grant DR080409; award W81XWH-09-2-0079). The sponsor of this study had no role in study design; in the collection, analysis, and interpretation of data; in the writing of the report; or in the decision to submit the article for publication. The views expressed in this article are those of the authors and do not necessarily represent the views of the U.S. Department of Veterans Affairs, the Department of Defense, or a U.S. government agency.

The authors report no financial relationships with commercial interests.

Received June 15, 2015; revision received September 14, 2015; accepted November 16, 2015; published online March 15, 2016.

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Appendix D

Utilization Manuscript

Mental Health Utilization Patterns During a Stepped, Collaborative Care Effectiveness Trial for PTSD and Depression in the Military Health System

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Background: Integrated health care models aim to improve access and continuity of mental health services in general medical settings. STEPS-UP is a stepped, centrally assisted collaborative care model designed to improve posttraumatic stress disorder (PTSD) and depression care by providing the appropriate intensity and type of care based on patient characteristics and clinical complexity. STEPS-UP demonstrated improved PTSD and depression outcomes in a large effectiveness trial conducted in the Military Health System. The objective of this study was to examine differences in mental health utilization patterns between patients in the stepped, centrally assisted collaborative care model relative to patients in the collaborative care as usual-treatment arm.

Methods: Patients with probable PTSD and/or depression were recruited at 6 large military treatment facilities, and 666 patients were enrolled and randomized to STEPS-UP or usual collaborative care. Utilization data acquired from Military Health System administrative datasets were analyzed to determine mental health service use and patterns. Clinical complexity and patient characteristics were based on self-report questionnaires collected at baseline.

Results: Compared with the treatment as usual arm, STEPS-UP participants received significantly more mental health services and psychiatric medications across primary and specialty care settings during the year of their participation. Patterns of service use indicated that greater clinical complexity was associated with increased service use in the STEPS-UP group, but not in the usual-care group.

Conclusions: Results suggest that stepped, centrally assisted collaborative care models may increase the quantity of mental health services patients receive, while efficiently matching care on the basis of the clinical complexity of patients.

Key Words: service utilization, collaborative care, stepped-care, mental health

(*Med Care* 2016;00: 000–000)

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Supported by a US Department of Defense Deployment Related Medical Research Program award (Grant DR080409). The award was a joint award to the Henry M. Jackson Foundation for the Advancement of Military Medicine Inc. (award W81XWH-09-2-0077), Research Triangle Institute (award W81XWH-09-2-0078), and RAND Corporation (award W81XWH-09-2-0079). The sponsor had no role in study design; in the collection, analysis and interpretation of data; in the writing of the report; or in the decision to submit the article for publication. The views expressed in this article are those of the authors and do not necessarily represent the views of the Department of Defense, the US Government, or any other organization or agency, public or private.

The preliminary findings from this research were presented in a poster presentation at the 2015 Military Health System Research Symposium (MHSRS) on 18 August 2015 in Ft. Lauderdale, FL.

The authors declare no conflict of interest.

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ISSN: 0025-7079/16/000-000

Integrating mental health care into general medical settings is a national priority of health care reform initiatives.[1–3] The collaborative care model[4] is one of the most widely supported integrated approaches to mental health care in the primary care settings, which consists of (1) a prepared practice that defines specific team member roles and responsibilities; (2) use of a care facilitator; (3) health informatics systems to track symptoms and support clinical decisions; and (4) enhanced mental health specialist integration.[5,6] Over 70 randomized controlled trials have demonstrated that collaborative care approaches are effective in treating common mental health disorders, are cost-effective, and are sustainable across diverse settings and populations.[7–9] Prominent policy-guiding organizations, including the Institute of Medicine[10] and the Community Preventive Services Task Force,[11] recommend a collaborative care approach for the effective management of mental illness.

In light of the evidence supporting the collaborative care model, the US Departments of Defense and the Veterans Health Administration, which operate 2 of the largest health care systems in the nation, have led major initiatives to implement collaborative care models.[12,13] Despite these

efforts, however, care access and treatment quality issues remain major concerns, complicated by a growing population of mental health consumers and overburdened specialty mental health clinics.[3,14,15]

To address health-system issues surrounding poor access and limited resources, stepped-care approaches have been proposed as a potential strategy to improve care efficiency.[16] Although stepped-care is a component of collaborative care, the stepped-care approach is often described as a distinct care model.[17] Bower and Gilbody[16] note 2 basic features of stepped-care. First, treatment recommendations start with the least intensive treatment that is still likely to provide significant health gain. Second, stepped-care is self-correcting, meaning that patient progress is monitored and treatment decisions are reassessed as patients' clinical status evolves. Thus, stepped-care seeks to treat patients at the lowest appropriate intensity of care, monitor clinical progress longitudinally, and reserve more intensive treatments for those patients who do not benefit from first-line treatments or for those with more complex clinical presentations.[16] Whereas stepped-care approaches are increasingly favored for depression and anxiety, support for the approach is largely conceptual and there remains little direct empirical support for its general effectiveness.[18]

Recently, the first large, randomized effectiveness trial on collaborative care for posttraumatic stress disorder (PTSD) and depression in the Military Health System (MHS) was conducted.[19] Of particular importance to this paper, both treatment arms received collaborative care interventions in primary care settings, but the interventions differed in important ways. Specifically, STepped Enhancement of PTSD Services Using Primary Care (STEPS-UP) incorporated a central assistance team and placed greater emphasis on bolstering the stepped components of the model. The trial demonstrated that the enhanced care model resulted in improved PTSD and depression outcomes above the traditional collaborative care model.[20] The STEPS-UP trial offers a unique opportunity to compare 2 collaborative care models to examine whether these collaborative care enhancements influence health care utilization patterns. With greater pressures being placed on large health care systems to provide integrated, cost-efficient, and evidence-based services across large patient populations, evaluating the service utilization patterns of innovative health care delivery models is particularly relevant.

The current research draws on the administrative health care data from patients enrolled in this large, multisite randomized effectiveness trial. The aims of this effort were to (1) determine whether STEPS-UP participants received a greater quantity of mental health services and psychiatric medications across the primary and specialty care settings, and (2) explore whether mental health care use was moderated by clinical complexity, based on the quantity and location of care received.

METHODS

Design

Full details on the design and main outcomes of the randomized trial are available.[19,20] Briefly, a 2-parallel arm randomized design was used to evaluate the effectiveness of an enhanced collaborative care model (STEPS-UP) as compared with the existing collaborative care model (usual care) for military members screening positive for probable PTSD or depression through primary care. The study was reviewed and approved by institutional review boards at Walter Reed National Military Medical Center (primary), 6 participating Army installations, RTI International, RAND Corporation, University of Washington, Boston VA, and the Human Research Protection Office, US Army Medical Research and Materiel Command.

Research Setting and Subjects

Participants (N = 666) were active-duty US military service members recruited at 6 large military treatment facilities from 18 primary care medical clinics. Eligible participants were serving on active duty at enrollment, met DSM IV-TR criteria for probable PTSD on the PTSD Checklist-Civilian Version (PCL-C; "moderate" or greater on 1 re-experiencing, 3 avoidance, and 2 hyperarousal symptoms)[21,22] and/or probable depression on the Patient Health Questionnaire-9 (PHQ-9; at least 5 of the 9 symptoms experienced "more than half the days" and at least 1 symptom included either anhedonia or depressed mood)[23] and reported having Internet and e-mail access. Participants were excluded for current alcohol dependence, active suicidal ideation in the prior 2 months, anticipated permanent geographic relocation over the next 6 months, or had current duties in a participating clinic.

Interventions

Usual Care

Patients assigned to the usual-care arm received a collaborative care approach for PTSD and depression used in Army primary care clinics since 2007 called RESPECT-Mil.[24] On the basis of a "3-component model,"[6] RESPECT-Mil is an integrated mental health approach based in primary care that includes (1) universal screening for PTSD and depression; (2) care management; and (3) increased access to a mental health specialist to assist primary care providers.[25]

STEPS-UP

The STEPS-UP intervention builds on the RESPECT-Mil model by incorporating 4 components: (1) enhanced care management; (2) stepped psychosocial treatment options; (3) centralized tracking, analyzing, and feedback of patient symptom trajectories derived from the electronic symptom registry; and (4) central assistance in developing and modifying treatment recommendations. The intervention team included care managers situated in primary care clinics who followed patients for the entire year of the study. The central assistance team provided ongoing support to nurse care managers through real-time monitoring and feedback on patient symptom trajectories, tailored treatment recommendations, and skills training for nurses to facilitate patient treatment engagement and adherence. The intervention promoted a stepped-care procedure to triage and treat symptomatic patients and included treatment options such as a web-based cognitive behavioral self-management tool,

telephonic psychotherapy, pharmacotherapy management in primary care, and referral to face-to-face psychotherapy and pharmacotherapy in specialty behavioral health care.

Measures

Demographics and Military History

Demographic variables, military history, and symptom measures were collected at baseline using validated survey items (Table 1).

Clinical Complexity

Entry into the study was determined using an inclusive screening threshold to improve the generalizability of trial results as described elsewhere.[19] For this study we opted for a more conservative (higher) cutoff point to enable and improve classification of clinical complexity. For the PHQ-9, a cutoff score of 15 was used to designate moderate to severe symptomatology.[23] A PCL-C cutoff score of 50, often used as a conservative cutoff point for identification of PTSD,[26] was used to designate moderate to severe PTSD symptoms. Clinical complexity was defined using these cutoff scores and participants were categorized as having (1) *subthreshold symptoms* (PHQ-9 and PCL-C were both below the identified cutoff scores), (2) a *single diagnosis* (either PHQ-9 or PCL-C was above the identified cutoff scores), or (3) a *comorbid diagnosis* (both PHQ-9 and PCL-C were above the identified cutoff scores). Clinical complexity, on the basis of this definition, was significantly related to lifetime trauma history ($F_{2,663} = 7.51$, $P < 0.001$),[27] mental health functioning ($F_{2,659} = 45.27$, $P < 0.001$),[28] and physical functioning ($F_{2,659} = 11.00$, $P < 0.001$).[28]

TABLE 1. Baseline Socioeconomic and Clinical Characteristics by Treatment Arm

	STEPS-UP (n = 332)	Usual Care (n = 334)	
Variables	**Mean (SD) or Percentage**		***P***
Socioeconomic			
Age	30.9 (7.6)	31.4 (7.8)	0.39
Male	79.5	82.3	0.36
White	47.6	47.6	0.99
Married	62.7	62.6	0.98
High school graduate	70.2	68.9	0.71
Prior deployment	82.2	83.5	0.66
Junior enlisted (E1- E6)	45.9	46.7	0.84
Medical board initiated	13.6	13.8	0.94
Clinical complexity*			
Subthreshold symptoms	19.6	19.5	0.97
Single diagnosis	31.6	37.1	0.14
Comorbid diagnosis	48.8	43.4	0.16
Ineligible for MHS care† (mo)			
0–3	0	0	
0–6	0	0	
0–9	3.0	3.3	0.84
0–12	8.4	9.0	0.80

*Subthreshold symptoms: PHQ-9 < 15 and PCL < 50; single diagnosis: PHQ-9 ≥ 15 or PCL ≥ 50 (but not both); comorbid diagnosis: PHQ-9 ≥ 15 and PCL ≥ 50.
†The participant is no longer eligible to receive services within the Military Health System.

Utilization Outcome Measures

Individual-level enrollment, claims, and encounter data were acquired directly from the Military Health System Data Repository (MDR) and the Fast Informatics Risk & Safety Tracker and Stepped Treatment Entry & Planning System (FIRST-STEPS). The MDR includes the official utilization records of all health care visits for both direct and purchased care for all service members. FIRST-STEPS is an electronic symptom registry that tracked care manager contacts across both arms of the study. In each case, data were extracted at the patient level for the 1-year period that participants were enrolled in the study. Some participants left the military and became ineligible for services before the end of the study, thus truncating their utilization data. However, loss of MHS services did not differ significantly between the 2 treatments arms (Table 1).

Primary care mental health encounters included any encounters that occurred in the primary care setting with a mental health provider, including telephonic contacts by care managers. The study-related telephone encounters used in both arms of the study were not recorded in the MDR dataset, but rather recorded separately by care managers in the FIRST-STEPS system. We extracted patients' telephonic encounter data from the FIRST-STEPS system and added them to their encounter sum. In addition, because all participants met with a care manager before their enrollment in the study, we increased participants' encounter sum by 1. Mental health specialty care encounters were tabulated on the basis of face-to-face encounters recorded in the mental health service line. These visits included scheduled visits, walk-in visits, and group appointments with any type of provider.

Psychiatric medication utilization was tabulated on the basis of pharmacy records. We examined use of antidepressants and prazosin, medications that would be recommended for the treatment of depression or PTSD.[29,30] For each participant, prescribed medication days for 1 or more of these medications was determined by calculating their total medication possession ratio (MPR) over the 365-day period. MPR is a commonly used metric calculated by dividing a patient's supply of dispensed medication by the specific time frame under consideration (365 d in this case) to determine the percentage of time a patient is in possession of medication.[31]

Statistical Analyses

Analyses examined whether participants in the STEPS-UP arm received more encounters of mental health care in primary and specialty settings, and if so, whether this finding was moderated by clinical complexity. Demographic and military factors were included in the models as control variables. Given our primary hypotheses on the global effect of treatment arm on utilization, we performed a sequential, step-up approach.[32] We first included only the treatment arm as the primary predictor (controlling for demographic and military factors) to test the effect of treatment on service

utilization; subsequently, we included clinical complexity as an additional covariate and its interaction with the treatment arm to explore whether clinical complexity moderated the effect of treatment arm on service utilization. The second analysis controlled only for variables that were statistically significant in the first step. Clinical complexity was specified as a classification variable with 3 levels as previously described. To test the interaction between treatment arm and clinical complexity on service utilization, the *comorbid diagnosis* level was used as the reference group.

For mental health specialty care, a considerable proportion of respondents reported no utilization so a 2-stage regression model was used to estimate group-wise predictions. A 2-stage regression model estimates 2 sequential events of the predictors on the outcome variables. We first performed a multiple logistic regression analysis to examine the likelihood of any utilization followed by a linear regression on the conditional density function on the amount of utilization among those with nonzero values. Duan's[33] retransformation method was applied to estimate the above 2-equation model. The overall prediction bias was accounted for by use of the retransformation method.[33–35]

All continuous data were log transformed to correct for significant outliers, address nonlinearity of the observed outcomes, and protect against censored data. Maximum likelihood was used to estimate the parameters. Although utilization data are often analyzed as counts with the Poisson regression, our examination of the data showed that use of a general linear model provided a more appropriate fit in this case. A sensitivity analysis using the Poisson model showed similar parameters to those presented here. Some patients in both arms became ineligible for care before the end of the study, so censoring might generate bias in the analytic results. We found that all of the participants were eligible for MHS care up to 6 months, 3% (n = 21) of participants became ineligible for care at 9 months, and 9% (n = 58) of participants were ineligible for care by the end of the trial period. A sensitivity analysis excluding individuals who became ineligible for care during the trial demonstrated that the parameter estimates did not change substantially.

RESULTS

Primary Care Mental Health Utilization

Unadjusted rates indicated that STEPS-UP participants received a median of 8.0 (range: 1.0–33.0) primary care mental health encounters and usual-care participants received a median of 4.0 (range: 1.0–23.0) encounters. Results of the regression on the log-transformed data are presented in Table 2A. There was a significant effect of treatment arm on primary care utilization, demonstrating that STEPS-UP participants received significantly more treatment relative to usual-care participants ($P < 0.001$). The interaction terms were not significant, indicating that clinical complexity did not moderate the relationship between treatment arm and primary care utilization. The model-predicted values of primary care mental health encounters are illustrated in Figure 1A.

Mental Health Specialty Care Utilization

Unadjusted rates of specialty care encounters indicated that 84.9% (n = 282) of STEPS-UP participants engaged in at least 1 mental health specialty care appointment, compared with 88.3% (n = 295) of usual-care participants. Table 3 (upper panel) lists the results of the first-stage logistic regression evaluating the probability of any specialty care engagement. The first step of the logistic regression did not demonstrate a significant effect of treatment arm on specialty care engagement. However, there was a significant interaction between treatment arm and clinical complexity status on specialty care engagement (odds ratio = 0.16; $P = 0.001$; 95% confidence interval: 0.05–0.55). The probability of engaging in any specialty care was similar between comorbid participants in both treatment arms; however, mental health engagement of participants with subthreshold symptoms was significantly lower for STEPS-UP participants relative to usual-care participants (Fig. 2A).

Median unadjusted encounters among patients who engaged in specialty care were 10.5 (range: 1.0–151.0) and 8.0 (range: 1.0–123.0) for STEPS-UP and usual care, respectively. Results of the second-stage linear regression on the log-transformed specialty care utilization are presented in Table 2B. Among participants with any specialty care mental health encounters, STEPS-UP was associated with a significantly greater amount of treatment relative to usual care ($P = 0.012$). The interaction term between treatment arm and clinical complexity in the second-stage model approached significance ($P = 0.08$). The predicted values of specialty care encounters based on the 2-stage model are illustrated in Figure 1B.

Psychiatric Medication Coverage

On the basis of unadjusted rates, 78.0% (n = 260) of STEPS-UP participants were dispensed a psychiatric medication compared with 68.0% (n = 226) of usual-care participants over the trial period. Results of the first-stage logistic regression (Table 3, lower panel) showed that STEPS-UP participants had a significantly greater probability of being prescribed a psychiatric medication than usual-care participants (odds ratio = 1.724; $P = 0.003$; 95% confidence interval: 1.21–2.46). The interaction was not significant, indicating that both groups experienced an increasing probability of psychiatric medication utilization with increasing clinical complexity (Fig. 2B).

The results of the second-stage linear regression on the log-transformed average MPR are listed in Table 2C. There was a significant effect of treatment arm on psychiatric medication coverage, with STEPS-UP participants prescribed a greater coverage of psychiatric medication relative to usual care participants ($P = 0.016$). The interaction term between treatment arm and clinical complexity was again not significant.

Total Mental Health Utilization Across Settings

The final model tested the effect of treatment arm and clinical complexity on total mental health utilization across the primary and specialty care settings. Unadjusted rates indicated that STEPS-UP participants received a median of

TABLE 2. Utilization for Patients Based on Treatment Arm (Step 1) and the Interaction of Treatment Arm and Clinical Complexity (Step 2) Across Different Utilization Outcomes

Outcome	Variable	B (SE)	95% CI
(A) Primary care mental health encounters			
	Step 1†		
	Intercept	1.30 (0.09)	
	Treatment	0.75 (0.05)***	0.65, 0.86
	Step 2‡		
	Intercept	1.27 (0.06)	
	Treatment	0.82 (0.08)***	0.67, 1.00
	Subthreshold symptoms	0.18 (0.10)	−0.02, 0.38
	Single diagnosis	0.10 (0.08)	−0.07, 0.26
	Treatment × subthreshold	−0.16 (0.14)	−0.44, 0.13
	Treatment × single diagnosis	−0.11 (0.12)	−0.35, 0.12
(B) Mental health specialty care encounters			
	Step 1†		
	Intercept	2.09 (0.17)	
	Treatment	0.23 (0.10)*	0.03, 0.44
	Step 2‡		
	Intercept	2.09 (0.11)	
	Treatment	0.32 (0.15)*	0.03, 0.61
	Subthreshold symptoms	−0.50 (0.19)**	−0.88, −0.13
	Single diagnosis	−0.03 (0.16)	−0.34, 0.28
	Treatment × subthreshold	−0.07 (0.28)	−0.62, 0.49
	Treatment × single diagnosis	−0.40 (0.23)	−0.84, 0.05
(C) Psychiatric medication coverage			
	Step 1†		
	Intercept	−0.54 (0.14)	
	Treatment	0.21 (0.08)*	0.04, 0.37
	Step 2‡		
	Intercept	−0.60 (0.10)	
	Treatment	0.26 (0.12)*	0.02, 0.49
	Subthreshold symptoms	−0.32 (0.17)	−0.66, 0.02
	Single diagnosis	−0.04 (0.14)	−0.31, 0.23
	Treatment × subthreshold	−0.04 (0.24)	−0.43, 0.51
	Treatment × single diagnosis	−0.14 (0.19)	−0.52, 0.23
(D) Total mental health encounters			
	Step 1†		
	Intercept	2.46 (0.07)	
	Treatment	0.40 (0.07)***	0.27, 0.53
	Step 2‡		
	Intercept	2.53 (0.08)	
	Treatment	0.55 (0.10)***	0.35, 0.75
	Subthreshold symptoms	−0.16 (0.13)	−0.41, 0.10
	Single diagnosis	0.03 (0.11)	−0.18, 0.24
	Treatment × subthreshold	−0.28 (0.18)	−0.62, 0.07
	Treatment × single diagnosis	−0.31 (0.15)*	−0.61, −0.02

†The first step of the analysis shows the main effect of treatment arm after controlling for: sex, race, age, education, marital status, previous deployment, medical board status, and installation. The second stage includes the interaction terms and only those terms that were significant in the first step.

‡Subthreshold symptoms: compares subthreshold symptoms group versus comorbid diagnosis group (ref group); Single diagnosis: compares single and comorbid diagnosis (ref) groups; Treatment × subthreshold: interaction term of treatment are differences between subthreshold symptoms group and comorbid diagnosis group; Treatment × single diagnosis: interaction term of treatment difference between single and comorbid diagnosis groups.

*$P < 0.05$.

**$P < 0.01$.

***$P < 0.001$.

CI indicates confidence interval.

19.0 (range: 3.0–165.0) mental health encounters and usual-care participants received a median of 14.0 (range: 1.0–130.0) encounters. Results of the regression analysis on the log-transformed total mental health encounters are presented in Table 2D. There was a significant interaction ($P = 0.027$) of treatment arm and clinical complexity on mental health utilization. Patients with a comorbid diagnosis showed an increase in utilization in the STEPS-UP arm, but no increase in utilization in the usual-care arm (Fig. 1C).

DISCUSSION

In this study, we examined mental health utilization differences between a treatment as usual collaborative care model and a centrally assisted, stepped-care collaborative care model. Our findings suggest that STEPS-UP was more effective at increasing the quantity of mental health care services received across primary care and mental health specialty care settings, as well as increasing psychiatric medication uptake and coverage.

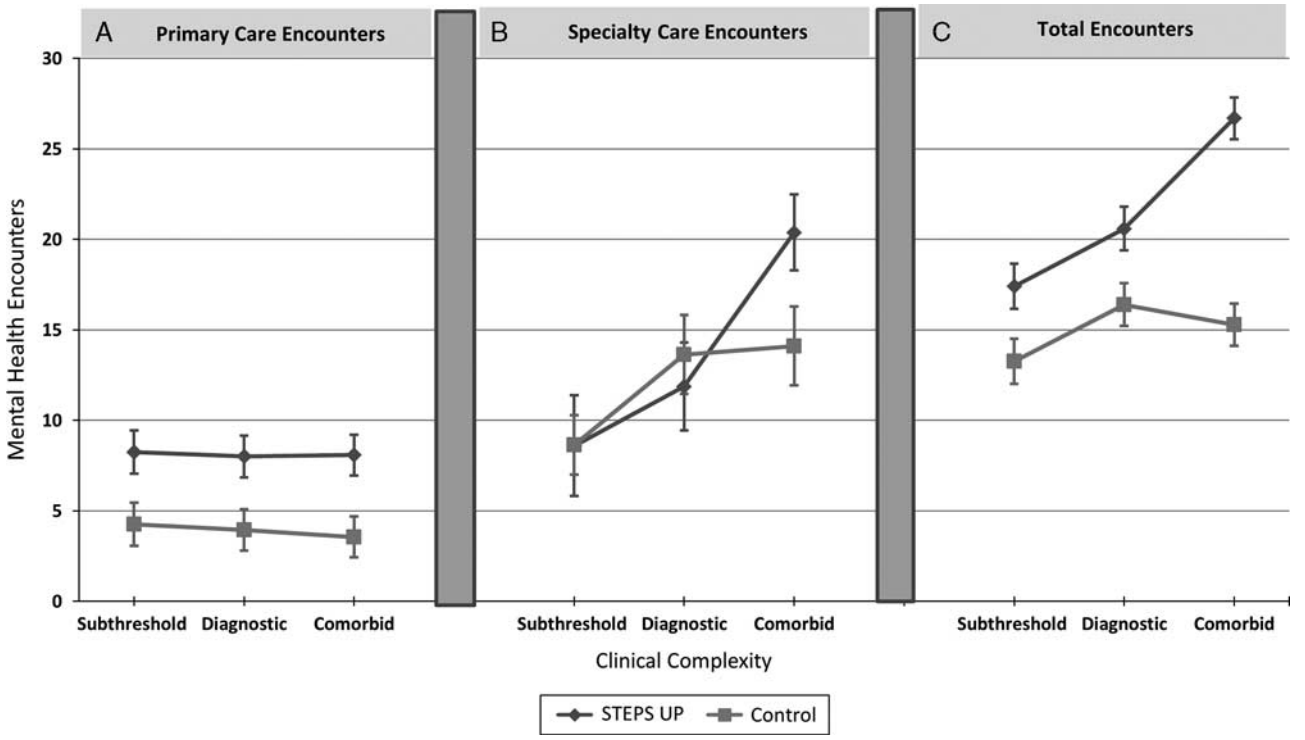

FIGURE 1. Predicted mental health encounters based on treatment arm and clinical complexity organized by (A) primary care–based mental health encounters, (B) specialty mental health encounters, and (C) total encounters. Subthreshold; PHQ-9 < 15 and PCL < 50; Diagnostic: PHQ-9 ≥ 15 or PCL ≥ 50 (but not both); Comorbid: PHQ-9 ≥ 15 and PCL ≥ 50.

In addition, we found that patterns of care differed on the basis of the clinical complexity of patients. STEPS-UP patients appeared to be triaged more carefully, such that those with a comorbid diagnosis were more likely to be sent to specialty care and receive a greater quantity of care relative to those with less clinical complexity. In contrast, patients in the usual-care arm were equally likely to be referred to specialty care regardless of their clinical complexity. Keeping the less symptomatic patients in the lower steps might be efficient, cost-effective, and increase specialty care access for more symptomatic patients. Increased primary care utilization among STEPS-UP participants was primarily due to the more intensive care management participants received in this arm. The pattern of specialty care referrals and increased specialty care utilization among STEPS-UP participants with greater clinical complexity may be attributable to the stepped-care central assistance with better monitoring of symptom trajectories, remote psychosocial treatment, ongoing specialist consultation, and facilitated engagement in mental health care. Thus, STEPS-UP appears to demonstrate an effect on mental health utilization patterns across settings, along with better outcomes (reported elsewhere).[20] Taken together, these studies suggest that it is possible to improve uptake and outcomes of collaborative care for PTSD and depression using central implementation assistance.

The findings from this research are relevant to concerns raised regarding the limited capacity of the MHS to ensure that adequate mental health resources are available to meet the needs of returning service members, as demonstrated by long wait times and infrequent appointments.[12,14,15,36] Further, the pattern of care demonstrated by the STEPS-UP intervention is in line with the national emphasis over the past decade on improving the efficiency of civilian and military health care systems.[1–3] Approaches that solely focus on increasing the identification and referral of symptomatic patients into specialty care may ultimately be a disservice given the finite resources available in many specialty mental health settings. From a system perspective, appropriate and timely treatment intensification and referral to specialty care is necessary.

Our findings on service utilization are partially consistent with other recent trials on collaborative care for PTSD and depression,[37,38] indicating that these interventions are associated with increased mental health service utilization,[37,38] greater receipt of psychiatric medications,[38] and tailored treatment matching that does not increase workload among specialty care providers.[39] Consistent with the Fortney et al[37] trial and in contrast with the Schnurr et al[38] trial, STEPS-UP demonstrated a significant effect on symptom outcomes compared with the usual-care arm.[20] These findings suggest that, although collaborative care interventions increase service utilization, the specific mechanisms of improving treatment outcomes may differ depending on the design and elements of the stepped-care components. More

TABLE 3. Logistic Regression Testing the Effect of Treatment Arm (Block 1) and the Interaction of Treatment Arm and Clinical Complexity (Block 2) on the Probability of Treatment Engagement and Psychiatric Medication

Outcome	Variable	OR (95% CI)
1 ≥ Mental health specialty care encounter		
	Block 1[†]	
	Treatment	1.36 (0.86, 2.15)
	Block[‡]	
	Treatment	1.66 (0.76, 3.61)
	Subthreshold Symptoms	1.10 (0.43, 2.80)
	Single Diagnosis	0.97 (0.46, 2.02)
	Treatment X Subthreshold	0.16 (0.05, 0.55)***
	Treatment X Single Diagnosis	0.40 (0.14, 1.17)
1 ≥ Psychiatric medication dispensed		
	Block 1[†]	
	Treatment	1.75 (1.23, 2.48)**
	Block 2[‡]	
	Treatment	2.12 (1.18, 3.78)*
	Subthreshold symptoms	0.54 (0.29, 1.02)
	Single diagnosis	0.58 (0.34, 0.98)*
	Treatment × subthreshold	0.49 (0.20, 1.24)
	Treatment × single diagnosis	0.88 (0.39, 2.01)

[†]The first block of the analysis shows the main effect of treatment arm after controlling for: sex, race, age, education, marital status, previous deployment, and medical board status. The second block includes the interaction terms and those terms (centered) that were significant in the first block.

[‡]Subthreshold symptoms: difference between participants with subthreshold symptoms and those with a comorbid diagnosis (ref group); Single diagnosis: difference between participants with single and comorbid diagnosis (ref); Treatment × subthreshold: interaction term of treatment differences between subthreshold symptoms to comorbid diagnosis groups; Treatment × single diagnosis: interaction term of treatment difference between single and comorbid diagnosis groups

*$P < 0.05$.

**$P < 0.01$.

***$P < 0.001$.

CI indicates confidence interval; OR, odds ratio.

research is needed to understand these specific components and ensure that efficacious interventions are delivered efficiently within collaborative care models.

The limitations of this research include the consolidation of service use across the entire 12-month period, which limited our ability to capture how effective the intervention was in stepping patients up or down on the basis of symptom severity at any given time point. Further, MPR was based on medication dispensed and is not a direct indicator of medication adherence. Another limitation may be our definition of clinical complexity. Although clinical complexity was based upon validated screening cutoff scores, there are alternative ways to define and measure it. In addition, the research was conducted in the MHS and the results may not be entirely generalizable to other health care systems. Nonetheless, as one of the largest integrated health care systems in the United States, the MHS may serve as a blueprint for other large integrated health care systems undergoing health care reforms. Finally, we did not assess the relationship between utilization, care quality, and treatment outcomes. However, the current findings suggest that collaborative care augmentation may promote improved care utilization patterns compared with usual collaborative care. Specific questions regarding optimal treatment matching will require further investigation.

In conclusion, this centrally assisted, stepped-care collaborative model appears to increase the quantity of mental health care delivered across health care settings while also effectively tailoring care on the basis of the available health care system resources. The results extend our understanding of how central-assistance and stepped-care components may augment traditional collaborative care models

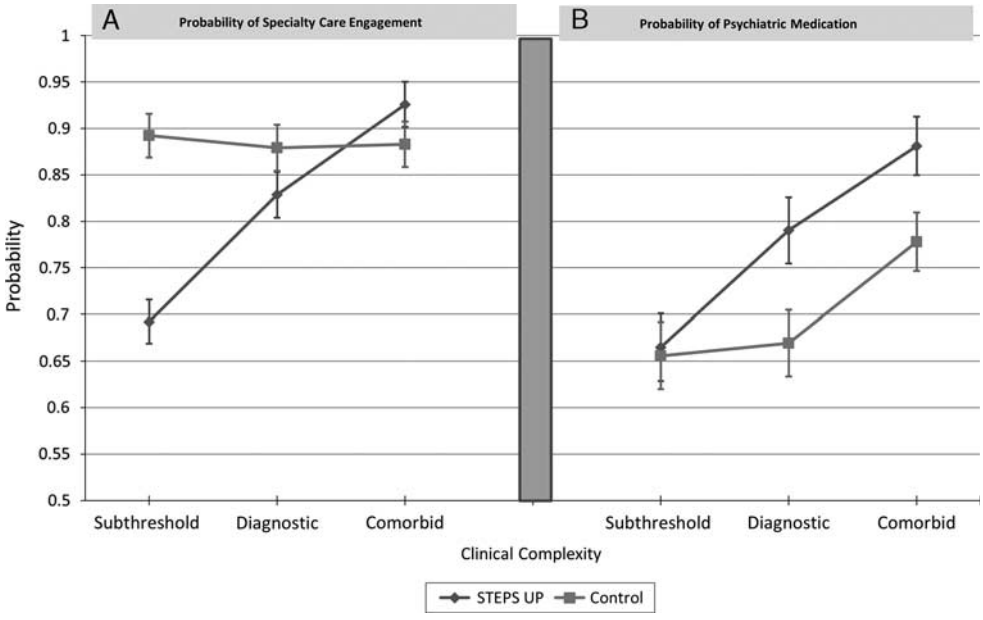

FIGURE 2. Probadility of (A) mental health specialty care engagement and (B) psychiatric medication based on treatment arm and clinical complexity. Subthreshold: PHQ-9 < 15 and PCL < 50; Diagnostic: PHQ ≥ 15 or PCL ≥ 50 (but not both); Comorbid: PHQ-9 ≥ 15 and PCL ≥ 50.

with regard to health care service delivery. These findings are particularly relevant in the face of health care reform efforts, with implications extending beyond the military to other settings in which a centrally assisted, stepped-care approach might facilitate more precision in the allocation of health care services.

ACKNOWLEDGMENTS

The authors thank Koby Ritter for her review and audit of clinical chart note and utilization records.

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Appendix E

Modeling Trajectories of PTSD Symptoms and Predictors of One-year Prognosis

Posttraumatic Stress Disorder in Military Primary Care: Trajectories and Predictors of One-year Prognosis

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Key words: PTSD, primary care, trajectories, collaborative care, military

Word Count: Text 5298, Tables and Figure 1000 = 6298

Acknowledgements

This study was supported by a U.S. Department of Defense Deployment Related Medical Research Program award (Grant DR080409). The award was a joint award to the Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc. (award W81XWH-09-2-0077), Research Triangle Institute (award W81XWH-09-2-0078), and RAND Corporation (award W81XWH-09-2-0079). The sponsor had no role in study design; in the collection, analysis and interpretation of data; in the writing of the report; or in the decision to submit the article for publication. The views expressed in this article are those of the authors and do not necessarily represent the views of the Departments of Department of Defense, Veterans Affairs, or any US government agency.

In Press, Journal of Traumatic Stress

Abstract

We examined the longitudinal course of primary-care patients with Posttraumatic Stress Disorder (PTSD) in the active-duty Army and identified prognostic indicators of PTSD severity. Data were drawn from a six-site randomized trial of collaborative primary care for PTSD/depression in the Military. Participants were 474 soldiers with PTSD (scores ≥ 50 on the PTSD Checklist). Four assessments were completed at US Army installations: baseline, with follow-ups at 3-months (93% response rate (RR)), 6-months (90% RR), and 12-months (86% RR). Combat exposure and seven validated indicators of baseline clinical status (alcohol misuse, depression, pain, somatic symptoms, low mental health functioning, low physical health functioning, mild traumatic brain injury) were used to predict PTSD symptom severity on the Posttraumatic Diagnostic Scale (Cronbach's $\alpha = 0.87, 0.92, 0.95, 0.95$ at assessments 1-4, respectively). Growth mixture modeling identified two PTSD symptom trajectories: patients reporting persistent symptoms (Persisters, 82%, n = 388), and patients reporting improved symptoms (Improvers 18%, n = 86). Logistic regression modeling examined baseline clinical predictors of symptom trajectories, controlling for demographics, installation, and treatment condition. Patients reporting moderate combat exposure (adjusted OR = 0.441, 95% CI = 0.198 – 0.981) or high (OR= 0.386, 95% CI = 0.171 – 0.872) were less likely to be Improvers. Other baseline clinical problems were not related to symptom trajectories. Findings suggest that most military primary-care patients with PTSD experience persistent symptoms, highlighting the importance of improving the effectiveness of their care. Most indicators of clinical status offered little prognostic information beyond the brief assessment of combat exposure.

The time from onset to initial treatment for posttraumatic stress disorder (PTSD) is an estimated 12 years (Wang et al., 2005). Only about two-thirds of individuals with PTSD report having received related treatment (Wang et al., 2005). The situation in the US military appears to mirror the larger societal problem, where large epidemiologic studies have found that less than half of individuals with PTSD have received any assistance in the past year (e.g., chaplain, primary care, specialty mental health care) and fewer than one fourth have received specialty mental health services. Still other research suggests that fewer than half of military service members receiving PTSD-related care receive minimally adequate care (Tanielian & Jaycox, 2008). While the reasons for inadequate treatment are undoubtedly complex and almost certainly vary by patient, recent evidence suggests that keeping those with mental health treatment needs engaged in appropriate services is difficult in both military and veteran health system settings (Hoge et al., 2014; Mott, Hundt, Sansgiry, Mignogna, & Cully, 2014). Hence, improving the treatment of PTSD and commonly co-occurring depressive and anxiety disorders will likely require efforts to (a) improve the reach of effective services (i.e., the extent that those affected can identify and access care), and (b) increase the duration and appropriateness of treatment among patients that access PTSD care.

Solving these challenges will require a prominent role for primary care, a setting long ago described as the de facto mental health service system (Regier, Goldberg, & Taube, 1978). Over half of mental health treatment is delivered in primary care settings, and yet little is known about the course and prognostic indicators of PTSD diagnosed in primary care. This information is critical for guiding primary-care clinicians' decisions regarding the appropriate management of affected patients (Regier et al., 1978; Regier et al., 1993; Wang et al., 2005).

The objective of the current study was to use one-year follow-up data from a pragmatic effectiveness trial of a primary care PTSD treatment approach to identify prognostic indicators of PTSD severity. Several recent studies have used growth mixture modeling (GMM) to assess common PTSD symptom severity trajectories in other samples (Andersen, Karstoft, Bertelsen, & Madsen, 2014; Orcutt, Erickson, & Wolfe, 2004; Pietrzak et al., 2014). GMM estimates differential rates of change over time in unobserved subgroups of participants. Categorical indicators of membership in distinct patterns of change can then be used in subsequent analyses as either predictors or outcomes, depending on the model. We used this technique to examine the longitudinal course of primary care military patients with PTSD.

Method

Design and Participants

Data for the present study were drawn from participants in a larger randomized clinical trial (RCT) that evaluated the effectiveness of a 12-month primary care treatment program for military personnel with PTSD and/or depression. The two-arm trial compared participants who received centrally assisted stepped collaborative telecare management with participants who received usual integrated collaborative mental health care in military primary care settings (Engel et al., 2014). The RCT was reviewed and approved by institutional research review boards at Walter Reed National Military Medical Center (primary), the six participating Army installations, RTI International, RAND Corporation, University of Washington, VA Boston Healthcare System, and the Human Research Protection Office of the US Army Medical Research and Materiel Command.

Patients were enrolled in the RCT from February 2012 through August 2013 at 18 troop medical clinics located at six large Army installations in the continental United States. Interested

service members were referred by their primary care clinicians to nurse care managers and then contacted by a research coordinator to assess eligibility and obtain informed consent. Patients eligible for the RCT (a) were serving on active duty at enrollment; (b) met DSM-IV-TR criteria for probable PTSD on the PTSD Checklist-Civilian Version (PCL-C) or probable depression on the Patient Health Questionnaire-9, or both; and (c) reported having Internet and e-mail access. Research assessments were completed at baseline, 3-, 6-, and 12-months, with follow up rates of 93%, 90%, and 86%, respectively. Assessments were Web-based with participant entry (in a few cases by phone interviewers or paper and pencil questionnaire).

Only patients with high symptoms of PTSD, defined as scoring 50 or higher on the PCL-C (N=475) were included in analyses for this study. One participant was excluded during trajectory modeling because of an erratic pattern on the PDS, resulting in a final analytic sample of 474 service members. Because participants in both RCT conditions received some form of collaborative care in a primary care setting, we combined participants across study arms (and controlled for treatment condition) to increase statistical power.

Measures

We used three types of measures in our analyses: PTSD measures (one for selecting participants and the other for assessing symptom outcomes); clinical predictors (combat exposure, comorbidities, trauma exposures); and control variables (demographic variables including age, race/ethnicity, and gender, along with installation where participants were stationed, and RCT treatment condition).

PTSD Selection and Outcome Measures

PTSD Screener Measure, PCL-C. The PTSD Checklist (Weathers, Litz, Huska, & Keane, 1994) was used to select participants with high symptoms of PTSD. The checklist is a 17-item

questionnaire that asks about experiences related to PTSD, has good sensitivity and specificity (Weathers et al., 1994), and is widely used in military studies (Bliese, Wright, Adler, Thomas, & Hoge, 2007; Dobie et al., 2002; Lang, Laffaye, Satz, Dresselhaus, & Stein, 2003). The civilian version (PCL-C) was used rather than the military version (PCL-M) in order to capture PTSD symptoms resulting from traumatic experiences prior to enrolling in the military. Respondents rated items on a 1–5 Likert scale which were then summed for a total score of 17–85. Persons scoring ≥ 50 were classified as screening positive for PTSD.

PTSD Outcome Measure, PDS. The PDS was used as our outcome measure to assess PTSD symptoms across time (Foa, 1995; Foa, Cashman, Jaycox, & Perry, 1997). The PDS is a self-report measure that assesses both severity of PTSD symptoms and probable diagnosis of PTSD (Foa, 1995). Respondents completed this scale after indicating exposure to 18 possible lifetime traumatic events (described below). They were asked to think about traumatic experiences like those in the 18 lifetime traumatic events and to indicate how often each of 17 trauma-related problems had bothered them in the past month (e.g., having upsetting thoughts about an event, bad dreams about the event, reliving the event, feeling distant or cut off from people, feeling emotionally numb, being jumpy). Responses were along a 4-point scale: (0) not at all or only one time, (1) once a week or less/once in a while, (2) 2 to 4 times a week/half the time, or (3) 5 or more times a week/almost always. Item scores were summed to yield a scale score ranging from 0 to 51. The PDS shows high sensitivity (.89) and specificity (.75) for PTSD, with a high degree of concordance in diagnosis (kappa = .65). Additionally, it shows high internal consistency (.92) and high correlations with other related constructs and test-retest reliability over 2–3 weeks (.78–.84 for each symptom cluster) (Foa et al, 1997). Cronbach's α in the sample for our study was 0.87 at baseline, 0.92 at 3 months, and 0.95 at 6 and 12 months.

Clinical Predictor Measures

Combat exposure. Exposure to combat was measured using a 17-item scale adapted for the Department of Defense Survey of Health Related Behaviors (Bray et al., 2009), from the Deployment Risk and Resilience Inventory (King, King, & Vogt, 2003), and the Land Combat study (Hoge et al., 2004). Items assess exposure to incoming fire, mines, and improvised explosive devices, as well as commonly experienced combat situations such as firing on the enemy, viewing dead bodies or human remains, and interacting with enemy prisoners of war. Items asked how many times respondents had been exposed with five categorical response options ranging from 0 (0 times) to 4 (51 or more times). Items were dichotomized as 0 (0 times) or 1 (1 or more times) and summed, giving a potential range of 0 to 17. This sum score was then used to create a categorical combat exposure measure, where a score equal to zero was considered "no exposure," a score from 1 to 7 was considered "low exposure," a score of 8 to 12 was considered "moderate exposure," and a score of 13 to 17 was considered "high exposure." The low, moderate, and high exposure categories were derived from tertiles of the total score.

Comorbidities. We formed a comorbidity index of seven mental health and physical functioning indicators shown previously to share comorbidity with PTSD. Each indicator was coded as a present/not present dichotomy, and a sum score was calculated as a measure of comorbidity. Dichotomization used the following cutoffs as indicators of the problems: problem alcohol use—AUDIT-C (Alcohol Use Disorders Identification Test; Babor, Higgins-Biddle, Saunders, & Monteiro, 2001) score of 4 or more for men (3 or more for women); depression—PHQ-9 greater than 9; pain—mean score of pain interference and pain intensity greater than 5 (scale midpoint); somatic symptoms—PHQ-15 greater than 9; mental health—SF12 mental health composite score one standard deviation or more below the mean; physical health—SF12

physical health composite score one standard deviation or more below the mean; mild traumatic brain injury (mTBI)—history of mTBI with loss of consciousness. The range of the comorbidity index was 0–7; we collapsed the 0–1 and the 6–7 categories for use in the multivariate analyses due to low numbers in these categories.

Trauma Exposures. We used the lifetime trauma burden scale adapted from the PDS (Foa et al., 1995) and the National Comorbidity Study Replication (Kessler et al., 2005) to measure trauma exposures. The scale included 17 trauma exposures ranging from life-threatening accidents and injuries to combat trauma to child sexual and physical abuse plus an item to capture any trauma not listed, for a total of 18 items. We excluded the combat exposure item to reduce overlap with the combat exposure scale, resulting in a 17-item scale. Each item was scored 0 (no trauma exposure) or 1 (trauma exposure) and summed to create a Lifetime Trauma Burden score with a possible range from 0 to 17.

Control Measures

We used several variables to adjust for potential confounding in the modeling analysis, focusing on variables that predated the episode of care and were not likely to change during the course of care. These included demographic characteristics of age (17–25, 26–34, 35 or older), race/ethnicity (white, black, Hispanic, other), and gender. The installation where participants were stationed (coded 1 to 6) was included to account for potential site differences. We also controlled for Treatment Condition to isolate differences in class membership due to the clinical predictors outlined above.

Statistical Analyses

GMM was used to investigate statistically distinct trajectories of change in PDS from baseline to the 12-month follow-up. GMM is a mixture model extension of common longitudinal

growth models and is used to explore unobserved groups of participants that share a similar pattern of change. The base model was curvilinear (quadratic) and included random effects for intercept and linear slope. The quadratic slope had insufficient variability for inclusion of its variance component. Time was centered at the midpoint of the timespan included in the data (6 months) so that the linear time estimate represented the overall linear decrease from baseline to 12 months. GMM models were estimated in Mplus version 7.2 (Muthén & Muthén) and extracted a varying number of classes, from 2 to 5 (the upper bound at which computation problems arose).

The optimal number of GMM classes that were retained was guided by comparative fit indices from models with a varying number of classes. Comparative fit was evaluated with the Bayesian Information Criterion (BIC), the Lo-Mendell-Rubin likelihood ratio test (LRT), the Vuong-Lo-Mendell-Rubin likelihood ratio test, (Lo, Mendell, & Rubin, 2001), and the parametric bootstrapped LRT. These indices, particularly BIC, have been shown to be adequate discriminators of classes in simulation studies (Nylund, Asparouhov, & Muthén, 2007). Preferred models minimize BIC and are those for which an additional class leads to a significant worsening of fit by the LRT. All models accounted for missing data from attrition using full information maximum likelihood estimation and all cases were retained.

Table 1 presents the fit indices for the GMM PTSD trajectory modeling. As shown, the BIC and both non-bootstrap LRT criteria suggested a two-class solution as an optimal representation of how PDS symptom scores changed over time. Models extracting five or more classes were not stable and were not examined. Although differences were not large across various model solutions, BIC was minimized in the two-class solution. Both the VLMR and LMR likelihood ratio tests detected nonsignificant improvement of model fit by adding a third

class, indicating that two classes were sufficient. The bootstrap LRT did not identify a best fitting solution for the model.

Following the determination of our solution of two classes (trajectories), each respondent's most likely class membership was then used as the dependent variable in a regression model. This model predicted membership in each trajectory as a function of treatment condition, demographics, combat exposure, installation, and the comorbidity index described above. Referent categories for categorical variables were chosen at endpoints for most items (e.g., the youngest age group, the non-deployed combat exposure group) except for the comorbidity index. There were very few cases at the endpoints of this measure and so we used the midpoint value of four as the referent for this item.

Results

Figure 1 presents results from the modeling analyses to identify treatment trajectories. As shown, patients with PTSD were classified into one of two trajectories: (a) those who showed improvement or reduced PTSD symptoms over time (Improvers), or (b) those who showed little change or no improvement in their symptoms during the year despite being involved in treatment (Persisters). Stated another way, some patients got better whereas others stayed about the same, but no class of participants was found to have worsening symptoms. The improver group had a significantly decreasing linear component (b= -5.04 (0.64), p<.001) as well as a significant quadratic component (b= 0.29 (0.05), $p<.001$) suggesting that there was notable decline or reduction in PDS symptoms that attenuated over time beginning around 6 months. The persister group showed nonsignificant change over time for both linear ((b= -0.28 (0.19), *ns*) and quadratic (b= 0.01 (0.01), *ns*) components.

Table 2 presents baseline characteristics of participants for our analyses overall and of Improvers and Persisters. Of interest, nearly 82% (n = 388) of patients were Persisters and 18% (n = 86) were Improvers. The average PCL-C score at baseline was similar for Improvers (61.4) and Persisters (62.9), as was the average PDS score at baseline (Improvers = 32.1, Persisters = 32.7).

Table 2 also shows that the large majority of participants in our analyses were male and less than age 35. This is consistent with the military medical context and in contrast to typical primary care samples that consist predominantly of women and older patients. Most were enlisted personnel of junior or midlevel rank E1–E4 (46.7%) or E5–E6 (39.7%); about two thirds were married; and more than half had some college education, followed by slightly less than a third with a high school degree only. Because we used tertiles to define the levels of combat exposure, roughly equal proportions of participants were in the low, moderate, and high exposure groups. Descriptively, compared to Persisters, Improvers were more likely to be of younger ages (17–34), of junior rank (E1–E4), and to be unmarried. They were also more likely to have had no combat exposure (had not deployed) or low combat exposure.

Table 3 presents the prevalence of the seven common mental health problems that are often comorbid with PTSD. Although there was notable variation in the prevalence of each problem overall and among Improvers and Persisters, there were no significant differences between Persisters or Improvers on any of the comorbidities. The mean number of comorbidities reported was 3.61 (*SD* = 1.20) across the entire sample.

Table 4 presents results of multiple logistic regression analyses predicting Improver trajectory status. The first analysis calculated unadjusted odds ratios (ORs) for each predictor in the model (similar to the bivariate analyses in *Table 2*), and the second analysis calculated

adjusted ORs controlling for all predictors in the model. The unadjusted ORs showed significant effects for age and combat exposure with older persons, and soldiers with high or moderate combat exposure being less likely to be Improvers, similar to results in Table 2. In contrast, after adjusting for all variables in the model, only high combat exposure (adjusted OR = 0.386, 95% CI = 0.171 – 0.872 and moderate combat exposure (adjusted OR=0.441, 95% CI = 0.198 – 0.981) were statistically significant. Patients reporting high or moderate combat exposure (that is, those more likely to have experienced combat trauma) were less likely to be in the improver group. We also expected that other pre-military traumas may be predictive of PTSD symptom severity, but this was not the case. Lifetime trauma burden did not differ between Persisters and Improvers. We conducted some more detailed analyses that included indicators for physical or sexual abuse separately in the models, but like the results for overall trauma burden, these also were not significant.

Discussion

The current study is the first to provide information about the one-year course of PTSD diagnosed in military primary care patients, including the key indicators of PTSD prognosis. Little is known about the trajectories of PTSD symptom severity in this group, as studies to date have largely concentrated on individuals who were not in treatment (Bonanno et al., 2012; Nash et al., 2015; Solomon, Horesh, Ein-Dor, & Ohry, 2012), or who were in residential treatment (Currier, Holland, & Drescher, 2014). These latter individuals may be farther along in the course of their PTSD compared to patients diagnosed in primary care.

Our study used participants from a large randomized trial of primary care patients in the military health system with PTSD. Findings from the controlled trial confirmed that collaborative care yielded significant improvements over time among service members with

PTSD (unpublished observations). However, the current analyses found that the majority of participants with PTSD showed a persistent course of symptoms, with little if any improvement observed over the year of follow-up. Only 18% of individuals fell into the Improver group.

The only other study to date examining trajectories of symptoms within a collaborative-care context was with patients admitted to a surgical trauma setting, and it identified four trajectories: resilient, recovery, relapsing/remitting, and chronic (Osenbach et al., 2014). In contrast, our study conducted with young military primary care patients also found a group that had chronic symptoms (called Persisters in this study). Our study did not differentiate between resilient/recovery, and instead had only one group of Improvers; our study also did not identify a class of relapsing/remitting participants. Differences between sample characteristics and other medical and physical problems between the studies likely account for the different trajectory patterns.

It is notable that we did not identify a class of patients who were worsening over time. Other studies indicate that PTSD among returnees from Afghanistan and Iraq showed worsening over time (Grieger et al., 2006; Milliken, Auchterlonie, & Hoge, 2007; Thomas et al., 2010), suggesting that as problems with daily functioning accrue, the symptoms may tend to worsen. Perhaps the collaborative care models utilized in this study were helpful in keeping symptoms stable over time or improving them, keeping patients off of a worsening trajectory.

In examination of predictors of PTSD symptom trajectory, we found several variables related to the trajectories in bivariate analyses, but only combat exposure was related in the multivariate models. Improvers were less likely to report having experienced a moderate or high degree of combat exposure when deployed as compared to Persisters, after controlling for comorbidities, intervention type, and demographic variables. Our findings were in some ways

consistent with earlier studies of improvement in collaborative care (e.g., alcohol use not predicting improvement status) but in other ways were not consistent in finding common comorbidities (e.g., depression) and demographics relating to improvements (Kelly, Jakubovski, & Bloch, 2015; Osenbach et al., 2014). One reason for these differences could be related to the samples in each, and the fact that our sample was relatively healthy, with low rates of injury as compared to the trajectories described for hospitalized patients (Osenbach et al., 2014) and all participants being employed and insured as compared to participants in both of the other studies (Kelly, Jakubovski & Bloch, 2015; Osenbach et al., 2014). Perhaps the main reason for these differences across studies may be related to the fact that combat exposure has been identified as the single best predictor for post-deployment PTSD and depressive disorders (Schell & Marshall, 2008). That is, combat exposure may be the single best marker for the development of other common contributing problems.

When evaluating findings of this study, consideration should be given both to its limitations and strengths. The first limitation is that all assessments were based on self-reported data without structured psychiatric interviews involving clinician verification. A second limitation is the lack of medical record or other direct indicator of physical illness severity. Physical illness is a potential consequence of combat exposure and may lead to poorer PTSD prognosis. However, we used patient assessments of their physical health-related functioning, pain, and physical symptoms, and these clinical indicators still failed to offer added value for prognostication over and above combat exposure itself. Finally, we did not present treatment utilization data, and it is possible that persistence was due to poorer treatment. However, we controlled for trial intervention group, and given the observational nature of the data, the sickest

patients with the most persistent course are likely to receive the most treatment, making it difficult to interpret the specific impact of treatment on PTSD symptom trajectory.

Several study strengths should also be noted. First, data collection was prospective, and the use of a secure, automated data collection interface essentially ensured the equivalent of blinded ratings. Second, the follow-up rate was 86% across the entire 12-month period, unusually high for a longitudinal study completed in a military context. Third, the study employed valid, clinically relevant assessments that are brief and feasibly completed in a busy health care delivery context. These pragmatic indicators provide a real world estimate of the accuracy of primary care PTSD prognostication. Fourth, study data are from a large, multisite study with broad inclusion criteria that aimed to maximize the generalizability of findings.

It is sobering that most military primary care patients with PTSD experienced persistent symptoms. Little is known about the most effective management strategies for patients with PTSD first diagnosed in primary care and the best methods and settings for effectively treating them. A preliminary study in the military showed feasibility and safety of home telehealth for behavioral activation for PTSD and depression (Luxton et al., 2015), and a recently completed randomized trial found that high fidelity cognitive processing teletherapy delivered remotely within collaborative care was an effective psychosocial intervention for patients with PTSD with otherwise limited access to mental health services (Fortney et al., 2015). Furthermore, our research found that the sort of brief clinical indicators that are feasibly assessed in busy primary care settings, while related to future PTSD outcomes, offer little prognostic information beyond the simple assessment of combat exposure. This finding points to the need for future research into the predictors of primary care PTSD prognosis, so that intensive but scarce treatment resources may be better directed toward those patients who are most likely to benefit.

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Table 1

Growth Mixture Model Comparative Fit Indices

No of classes	BIC	VLMR	LMR	BootLRT
1	12463.47	na	na	na
2	12384.23	0.0005	0.0006	<.0001
3	12388.36	0.0668	0.0727	0.0128
4	12395.69	0.0025	0.0031	<.0001

Note. Na = not applicable. BIC = Bayesian Information Criterion. VLMR = Vuong, Lo, Mendell, Rubin likelihood ratio test. LMR = Lo, Mendel, Rubin adjusted likelihood ratio test. BootLRT = parametric bootstrapped likelihood ratio test.

Table 2

Baseline Characteristics of Participants

Characteristic	Improvers N = 86 n (%) or Mean (SD)	Persisters N = 388 n (%) or Mean (SD)	Total N = 474 n (%) or Mean (SD)
Gender			
Male	64 (74.4%)	322 (83.0%)	386 (81.4%)
Female	22 (25.6%)	66 (13.9%)	88 (18.6%)
Age*			
17-25	33 (38.4%)	104 (26.8%)	137 (28.9%)
26-34	36 (41.9%)	141 (36.3%)	177 (37.3%)
≥ 35	17 (19.8%)	143 (36.9%)	160 (33.8%)
Rank*			
E1-E4	53 (61.6%)	167 (43.4%)	220 (46.7%)
E5-E6	25 (29.1%)	162 (42.1%)	187 (39.7%)
E7-O5	8 (9.3%)	56 (14.6%)	64 (13.6%)
Marital status*			
Married	46 (53.5%)	271 (69.9%)	317 (66.9%)
Not married	40 (46.5%)	117 (30.2%)	157 (33.1%)
Education			
High school	36 (41.9%)	110 (28.4%)	146 (30.8%)
Some college	42 (48.8%)	226 (58.3%)	268 (56.5%)
College degree	8 (9.3%)	52 (13.4%)	60 (12.7%)
Race/ethnicity			
White	42 (48.8%)	177 (45.6%)	219 (46.2%)
Black	27 (31.4%)	91 (23.5%)	118 (24.9%)
Hispanic	11 (12.8%)	72 (18.6%)	83 (17.5%)
Other	6 (7.0%)	48 (12.4%)	54 (11.4%)
Combat exposure*			
Not deployed	24 (27.9%)	56 (14.5%)	80 (16.9%)
Low exposure	26 (30.2%)	101 (26.1%)	127 (26.9%)
Moderate exposure	18 (20.9%)	114 (29.5%)	132 (27.9%)

High exposure	18 (20.9%)	116 (30.0%)	134 (28.3%)
PTSD screener,			
PCL-C[a]	61.4 (8.3%)	62.9 (8.1%)	62.6 (8.2%)
PTSD outcome,			
PDS[b]	32.1 (7.6%)	32.7 (7.6%)	32.6 (7.6%)
Lifetime trauma burden (excluding Combat)	6.9 (2.9%)	6.5 (2.5%)	6.6 (2.6%)

[a]PTSD Checklist.

[b]PDS = Posttraumatic Diagnostic Scale.

* $p < .05$ by Wald chi-square test for bivariate distribution of class and demographic categories

Table 3

Relations of Common Comorbidities with PTSD among Improvers and Persisters

Characteristic	Improvers N = 86 n (%) or Mean (SD)	Persisters N = 388 n (%) or Mean (SD)	Total N = 474 n (%) or Mean (SD)
Alcohol use	27 (31.4%)	155 (40.0%)	182 (38.4%)
Depression	84 (97.7%)	365 (94.1%)	449 (94.7%)
Pain	59 (68.6%)	280 (72.2%)	339 (71.5%)
Somatic symptoms	72 (83.7%)	331 (85.3%)	403 (85.0%)
Mental health	18 (20.9%)	58 (15.0%)	76 (16.0%)
Physical health	15 (17.4%)	69 (17.8%)	84 (17.7%)
mTBI[a]	25 (29.1%)	150 (38.7%)	175 (36.9%)
No. of problems			
0	0 (0.0%)	2 (0.4%)	2 (0.4%)
1	5 (5.8%)	15 (3.2%)	20 (4.2%)
2	13 (15.1%)	45 (11.6%)	58 (12.2%)
3	22 (25.6%)	109 (28.1%)	131 (27.6%)
4	31 (36.1%)	128 (33.0%)	159 (33.5%)
5	11 (12.8%)	72 (18.6%)	83 (17.5%)
6	4 (4.7%)	15 (3.9%)	19 (4.0%)
7	0 (0.0%)	2 (0.4%)	2 (0.4%)
Mean # of comorbidities	3.48 (1.21)	3.62 (1.19)	3.61 (1.20)

Note. There were no significant differences by class for any row.

[a]mild traumatic brain injury.

Table 4

Odds Ratio (OR) Estimates Showing Likelihood of Being in the PTSD Improver Trajectory

Characteristic	Unadjusted OR	95% Wald Confidence Limits		Adjusted OR	95% Wald Confidence Limits	
Treatment arm (STEPS UP)	1.415	0.884	2.264	0.711	0.432	1.172
Age						
17-25	ref			ref		
26-34	0.805	0.471	1.375	0.997	0.548	1.813
≥ 35	0.375*	0.198	0.709	0.486	0.240	0.987
Male	0.596	0.343	1.036	0.901	0.467	1.738
Race/ethnicity						
White	ref			ref		
Black	1.250	0.725	2.158	1.107	0.600	2.042
Hispanic	0.644	0.314	1.320	0.622	0.290	1.337
Other	0.527	0.211	1.313	0.545	0.208	1.428
Combat exposure						
High exposure	0.362*	0.182	0.721	0.386*	0.171	0.872
Moderate exposure	0.368*	0.185	0.734	0.441*	0.198	0.981
Low exposure	0.601	0.316	1.143	0.576	0.279	1.190
Not deployed	ref			ref		
Lifetime trauma burden (excluding combat)	1.056	0.967	1.155	1.072	0.971	1.184
Comorbidity						
0-1 problem	1.214	0.416	3.546	1.101	0.350	3.470

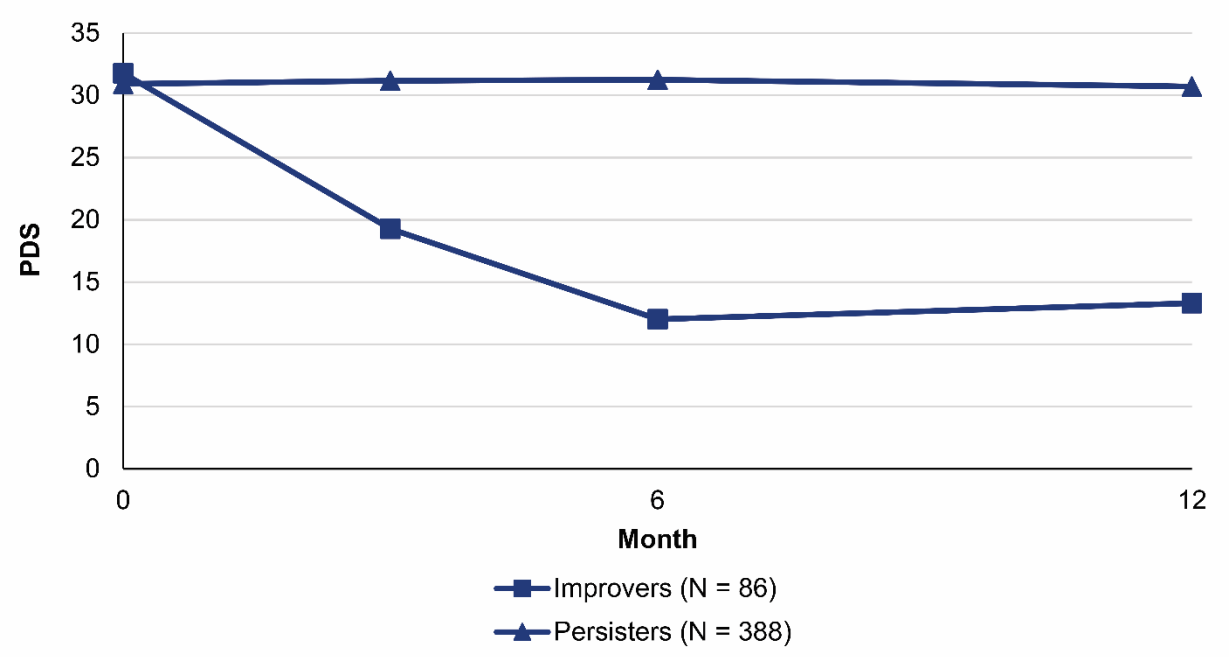
2 problems	1.193	0.574	2.478	1.208	0.550	2.650
3 problems	0.833	0.456	1.523	0.744	0.387	1.428
4 problems	ref			ref		
5 problems	0.631	0.299	1.330	0.680	0.307	1.505
6-7 problems	0.972	0.305	3.092	0.813	0.241	2.744

Note: Unadjusted models include single predictor variables. Adjusted estimates are from a multiple regression model including all predictors. The multiple regression model also controlled for Installation which showed no significant effects (ORs omitted from table).

*p<.05

Figure 1

Trajectories for PTSD Treatment Outcomes



Appendix F

Qualitative Manuscript: Stakeholder Experiences

Appendix F - Qualitative Manuscript - Stakeholder Experiences

Stakeholder Experiences in Stepped Collaborative Care Study within US Army Clinics

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Abstract word count: 288

Article text word count: 3,974

Number of tables: 5

Number of references: 13

Keywords: Mental health, primary care, deployment health, stakeholder engagement

Abstract

Background: The Army's Stepped Treatment Enhanced PTSD Services Using Primary Care (STEPS UP) study was designed to leverage the effective components of collaborative care models to improve treatment for soldiers with PTSD and depression in military health settings.

Objective: This paper examines providers, care facilitators, and patients' perceptions of integrating behavioral health care in primary care settings, the use of care facilitation to improve treatment, and the specific therapeutic tools used within the study.

Design**:** This is a qualitative study of stakeholders within the context of a large randomized controlled trial conducted across 6 military installations.

Participants: Stakeholders included patients recruited for the study (n=38), health care providers working within site clinics (n=31), and the care facilitators employed within the study to implement the intervention protocol (n=7).

Approach: We conducted a series of qualitative interviews with study stakeholders within the context of a large randomized controlled trial being conducted across 18 Army primary care clinics.

Key Results**:** Most of stakeholders' concerns clustered around the need to improve collaborative care tools and care facilitators and providers' comfort and abilities to treat behavioral health issues in the primary care setting.

Conclusions: While stakeholders generally recognize the value of collaborative care in overcoming barriers to care, their perspectives about the utility of different tools varied. The extent to which collaborative care mechanisms are well-understood, navigated, and implemented

by providers, care facilitators, and patients is critical to the success of the model. Improving the design of the web-based therapy tools, increasing the frequency of team meetings and case presentations, and expanding training for primary care providers on screening and treatment for PTSD and depression and the collaborative care model's structure, processes, and offerings may improve stakeholder perceptions and utilization of collaborative care.

Stakeholder Experiences in Stepped Collaborative Care Study within US Army Clinics

Caroline Batka, Terri Tanielian, Mahlet A. Woldetsadik, Carrie Farmer, and Lisa H. Jaycox

Introduction

Collaborative care models integrate behavioral health into primary care and other health care settings. These models generally include an interdisciplinary team of providers working with patients within primary care settings to offer regular behavioral health screening, monitoring, and treatment for both behavioral and physical issues, care coordination, and referrals for patients needing alternative or specialty care treatment. Over 70 randomized control trials (RCTs) have demonstrated that collaborative care models are more effective and more cost effective than usual care approaches for treating common mental illnesses,[1] and research shows that compared with usual care, collaborative care offers significant improvement in depression and anxiety outcomes for adults.[2]

While the evidence base indicating the effectiveness of collaborative care for treating depression developed over the last 20 years,[3] research on the effectiveness of treating PTSD through collaborative care is still developing.[4] Two RCTs of collaborative care for PTSD showed no differences in symptoms or functioning between patients in usual care and those who were treated through the collaborative care approach,[5, 6] whereas another study showed positive effects as a result of increased psychotherapy uptake and completion.[7] Even before this evidence was available, interest in this model led the U.S. Army to initiate the Re-Engineering Systems of Primary Care for PTSD and Depression in the Military (RESPECT-Mil) program in 2007 at 15 Army military treatment facilities involving 43 primary care clinics.[8] RESPECT-Mil leverages the effective components of collaborative care models, such as enhanced access to mental health

specialists, care management, and integration with mental health services.[9] The program includes the five core principles of collaborative care: patient-centered teams, population-based care, measurement-based treatment to target outcomes, evidence-based care, and accountable care.[10] Based upon early positive feedback, the Army extended RESPECT-Mil to 37 Army installations and more than 90 clinics.[8,11] Preliminary studies of RESPECT-Mil found that patients in the program had significantly reduced PTSD symptoms during their participation.[12]

As policymakers seek to integrate the principles of collaborative care models into various health care settings, stakeholder experiences and perceptions about the model can improve acceptability and success of the approach. Insights regarding mental health and primary care providers' comfort with collaborative care treatment for depression and PTSD can enhance training and implementation of provider support tools. Furthermore, perceptions of telephone care facilitation and web-based therapy tools used in collaborative care can inform the development and use of such tools, and ultimately, their effectiveness.

Our study

We conducted a qualitative study to understand stakeholder experiences with integrating treatment for PTSD and depression within primary care clinics in the U.S. Army.[9] We interviewed providers, care facilitators, and patients on their personal experiences with and opinions of the collaborative care approach.

Methods

We conducted stakeholder interviews within the context of a large RCT to assess the effectiveness of an enhanced collaborative care approach for patients with PTSD and/or depression in the U.S. Army. The Stepped Treatment Enhanced PTSD Services Using Primary

Care (STEPS UP) model extended the RESPECT-Mil design described above by offering enhanced, centralized clinical supervision for care facilitators who were also trained in behavioral activation techniques. STEPS UP also offered additional therapeutic options, including two web-based therapy tools and telephone-based psychotherapy (delivered by licensed psychologists). Soldiers with PTSD and/or depression were randomized to the enhanced stepped-collaborative care model (STEPS UP) or to the standard version of collaborative care offered by the Army health system (RESPECT-Mil). The RCT was conducted across 6 large Army installations from which soldiers deployed and returned, encompassing 18 primary care clinics.[12]

Stakeholder groups included soldier-patients recruited for the study, care providers in clinics at each installation, and care facilitators implementing the study intervention. Patients were drawn from both intervention arms in the study. Procedures were approved by all relevant Institutional Review Boards. All interviewed stakeholders provided oral consent for participation. Additional details about the methods of the qualitative study may also be found in Tanielian et al. (forthcoming, Psychiatric Services).[13]

Patients. We randomly selected patients within each site to participate in up to 3, 30-minute interviews, across the span of their study participation (one year). We invited a total of 61 patients into the qualitative study; we were unable to reach 14 through follow up emails or phone calls; 3 declined participation; and 5 consented to participate but did not attend their first scheduled interview or respond to attempts to reschedule.

Of the 38 patients who consented to participate in the interviews, 27 (71%) completed all 3 interviews. Table 1 displays the demographic characteristics of the patients interviewed.

{insert Table 1 about here}

Using a semi-structured interview guide, we asked about their experiences getting into care and working with their assigned care facilitator, their utilization of mental health care and resources, to include any barriers or facilitators that they experienced and their use of specific study tools (for those in the intervention arm). Patients received a $25 gift card following each completed interview.

Providers. To recruit providers, we relied upon site-generated lists of all health care providers working within the installation clinics, by setting and specialty type. We attempted to recruit roughly the same number of general medicine providers (physicians, physician assistants, nurse practitioners) and mental health specialty providers (psychiatrists, psychologists, social workers). We randomly chose five providers for recruitment per site until we reached our target at each location. Since randomization in the RCT occurred at the patient level, providers were working with patients in both intervention conditions and had varying degrees of familiarity with collaborative care. We contacted a total of 100 providers across the six sites, interviewing 31 providers in total. Once recruited, providers were asked to participate in one 15-30 minute interview about their experiences addressing the mental health needs of soldiers and using collaborative care. Providers who participated in the study were each given a $35 gift card as a token of appreciation.

{insert Table 2 about here}

Care Facilitators. The seven care facilitators working within the intervention arm of the study were asked to participate in two one-hour interviews about their experiences working with the patients and providers within the study. The first interview occurred within the first three

months of their study participation and the second occurred within the last month of the study. The semi-structured protocol queried about experiences engaging patients into care, sharing information with providers, and perceptions of the specific study tools and resources (training in motivational interviewing and behavioral activation, web-based therapy tools, and centralized supervision). Care facilitators were offered a $75 gift card for completing the final interview.

Analysis. All interviews were conducted by phone (by a trained facilitator who was assisted by a note-taker), tape-recorded, and transcribed. Once transcripts were verified, recordings were deleted. All transcripts were coded using ATLAS.ti qualitative data analysis software. A coding scheme was drafted, used to code five transcripts, checked by the analytic team and refined/expanded. To ensure interrater reliability, another member of the team reviewed a random selection of each set of transcripts to ensure consistent application of theme categorizations.

Results

A total of 76 stakeholders were interviewed between July 2012 and June 2014. We identified a number of themes regarding overall stakeholder perceptions of the provision of behavioral health care in primary care settings, the use of care facilitation and coordination as a model for improving access to treatment, and the specific intervention tools that were offered as part of the study.

Provider opinions about addressing behavioral health issues in primary care settings

We asked all participating providers their perspectives on and experience with addressing behavioral health issues in primary care settings. We inquired specifically about their level of comfort, prior training, and familiarity with identifying, treating, and managing behavioral health

issues in primary care settings. In general, participating provider opinions about the integration of mental health care into primary care settings fell into two categories: perceptions about competency and comfort among primary care providers for treating mental health issues and concerns about the relationships between primary and behavioral health providers. For illustrative quotes from stakeholders, please see Table 3.

Perceptions of competence / capabilities / capacity among health care staff

Providers reported varying experiences and insights regarding the competence and capabilities of health care staff providing behavioral health care in the primary care setting. We found that provider attitudes largely depended on the provider discipline, yielding some notable differences among primary care versus behavioral health providers. For example, most of the primary care providers (63%) interviewed reported that they were comfortable treating PTSD and depression in the primary care setting. Some primary care providers indicated this comfort came from their military experience treating patients with behavioral health issues while deployed. Both behavioral and primary care providers reported that some aspects of treating PTSD and depression in the primary care setting were improving through their acculturation and earlier experience with collaborative care models.

By and large, however, most behavioral health providers (80%) interviewed had negative perceptions of integrating behavioral health into primary care settings, based on their perceptions of primary care providers' capabilities. Behavioral health providers perceived issues with primary care providers' comfort and capability to treat both PTSD and depression, but they reported relatively more issues with PTSD. Only about a quarter of behavioral health providers indicated they believed primary care providers to be comfortable in treating depression in the

primary care setting, and only a fifth of behavioral health providers believed that primary care providers are comfortable treating PTSD in the primary care setting. In addition, about one in ten behavioral health providers indicated that they are not comfortable with PTSD being treated in the primary care setting because either they are not confident in primary care providers' capabilities or they believe some patients need the more intensive care offered in specialty settings.

Interviewed behavioral health and primary care providers described various reasons that primary care providers may be uncomfortable providing behavioral health care, including lack of experience and training, difficulty with differential diagnosis, and uncertainty in pharmacotherapy—especially for PTSD. In addition, some primary care providers reported that they were more comfortable when patients had been evaluated by specialists and when cases of depression and PTSD were mild or moderate.

In sharing these insights, several behavioral health and primary care providers referred to the potential benefits of the collaborative care implementation and staff, including increased communication and coordination regarding patient needs and enhanced preparedness to treat patients with mental health needs in primary care. On the other hand, behavioral health and primary care providers also reported negative experiences with mental health treatment in primary care. For example, providers discussed general capacity constraints in their settings leaving them with too few providers and not enough time to treat patients' mental health issues in primary care.

Difficult to create and maintain relationships between primary and specialty care providers

Behavioral health and primary care providers also expressed concern about the ability to develop and maintain meaningful relationships among primary and specialty providers. They also reported problematic relationships between primary care and behavioral health providers, naming issues like lack of trust and difficulty with care coordination. Some behavioral health and primary care providers indicated that they are concerned about the quality and continuity of care that patients may receive because of high turn-over among primary care providers in the military. Both behavioral health providers and primary care providers expressed hesitancy to refer patients out to others because they worried that the patient would be referred again or would otherwise slip through the cracks in the system of care. In theory, this is one area where the care facilitator could fill a gap– their role within the collaborative care models employed in the study was largely to facilitate communication between primary and special care providers about individual patients' care needs. However, some behavioral health and primary care providers discussed uncertainty about the role and purpose of care facilitators in their setting, describing their role and "duplicative" and "unnecessary," even noting that the manpower was needed in other places.

{Insert Table 3 about here}

Receptivity to Care Facilitation

We also asked providers, care facilitators, and patients about their experiences with care facilitation. In the RCT, care facilitators assigned to the STEPS UP arm were trained in the use of motivational interviewing (MI) and behavioral activation (BA). These skills were intended to enhance their ability to engage patients and work with them in setting and meeting treatment goals and overall symptom improvement. To maintain contact and engagement with the

patients, care facilitators in both arms of the study relied heavily upon the telephone and were encouraged to meet with each of their patients at least once per month by phone. Based on their location within the primary care clinic and frequent contact with the patients, care facilitators (in both arms of the study) were also in a position to help facilitate communication among providers and schedule follow up appointments or teleconsultations for specific patients with either primary care or behavioral health providers. Generally, stakeholders described favorable experiences working with the care facilitators, and patients in the STEPS UP arm in particular noted that interacting with the care facilitator regularly gave them the sense that someone cared about them and their well-being. Care facilitators themselves were grateful for the MI/BA training and perceived it helped them engage patients. Table 4 provides illustrative quotes with respect to stakeholder experiences with care facilitators, and below we describe some of these perspectives in more detail.

Interacting with the Care Facilitators

Most of the patients (80%) in the study (across both arms) reported at least one positive comment about either their assigned care facilitator or engaging in care management. Within the STEPS UP arm, patients reported that they liked the care facilitators' emphasis on specific issues like relaxation, sleep, and sobriety as opposed to bigger, multi-faceted issues like their PTSD. In addition, some patients felt that care facilitators listened to them better and were more invested in their care than military providers they encountered. Care facilitators also reported that discussing treatment plans and objectives with patients explicitly helped cultivate buy-in and treatment adherence.

Use of motivational interviewing and behavioral activation

All interviewed care facilitators conveyed positive attitudes toward the use of MI and BA, noting that the techniques generally helped them to more effectively engage and encourage their patients to initiate or remain in care. In particular, care facilitators underscored the importance of the techniques in promoting patients' motivation to get care and to improve.

While care the reception for MI and BA was mostly positive, some care facilitators felt that these methods took too long and involved too many questions. Sustaining motivation to engage in treatment plans was a noted challenge for care facilitators and patients. Some care facilitators reported having to reach out to patients from a number of different media (email, phone, text, and in-person) and invest a lot of effort to engage patients at least monthly. Despite these challenges, many of the care facilitators wanted additional training in MI and BA and to continue using these techniques after the study.

Reliance upon the telephone for patient engagement

Care facilitators' and patients' perception of telephone care management was mostly positive. In some cases, patients noted that they were intimidated to do in-person meetings, and talking on the phone was much easier. Other patients said that although they enjoyed the phone care management, they also appreciated face-to-face interactions. Some patients even preferred this to phone meetings. From participating care facilitators' perspective, patients generally liked phone meetings. Use of phones for care facilitation helped to overcome barriers to care, like accessing health care facilities, lack of time, and stigma associated with care-seeking. Texting was also a frequent mode of contact. Patients would frequently respond to texts from care facilitators even if they didn't answer their phone calls.

Although less frequent, some patients and care facilitators expressed concerns about telephone care management. One challenge was that care facilitators work the same hours as patients, so relying upon the telephone didn't resolve issues that patients had with carving out time for care. In other cases, care facilitators' efforts to call after work hours were still ineffective, since some patients had family commitments and other issues to deal with after work hours. A couple of care facilitators reported that obtaining phone numbers for patients and other individuals from the military was very difficult since numbers change and information is not publically available. In a few cases, care management was interrupted because calls kept dropping, and highly-motivated care facilitators and patients were able to overcome issues with phone management by arranging for patients to have access to land lines.

{insert Table 4 about here}

Perceptions of Intervention Tools for Depression and PTSD

For the RCT, several additional tools were available to patients in the STEPS UP arm. These included two web-based therapy tools, one for depression ("Beating the Blues") and one for PTSD ("DESTRESS-PC"). In addition to these web-based tools, patients in the STEPS UP arm were afforded the opportunity to receive telephone based psychotherapy from one of the study's centralized licensed psychologists. Experience with and perceptions of these tools are described in more detail below. Table 5 includes some illustrative quotes from care facilitators and patients about these tools.

Perceived advantages of web-based tools

Most patients did not know much about Beating the Blues or DESTRESS-PC. The few who were familiar with these approaches said their care facilitators encouraged them to use

either tool, but the use among these patients was minimal. This was mainly due to lack of interest, time, access to a computer, and preference for other forms of treatment, specifically in-person or phone therapy. Some patients had a negative impression of the online activities; they saw the exercises as homework that they didn't have the motivation to complete.

Care facilitators reported that the web-based tools worked very well for patients who were highly-motivated. Patients that reported using these tools said that videos and additional activities were helpful to their treatment. Several patients reported that they saw the benefits of using online programs—that they could access their tools from home, avoid the stigma of other soldiers seeing them seeking care, and they could fit the activities into their own schedules. However, we found that patients also reported that they didn't use the online programs because they perceived phone-based or in-person therapy was easier for working through specific issues, as noted in Table 5. Another potential barrier to using these tools mentioned by care facilitators was the amount of reading required, which may be too burdensome for some patients.

Attitudes toward phone-based psychotherapy

Generally, patients reported that they preferred in-person or phone therapy over using the web-based therapy tools. Care facilitators indicated that the phone therapy seemed to be well-received. Many noted the convenience of being able to schedule therapy sessions at convenient times, which afforded patients the ability to have therapy sessions in short time increments and in between their work and home responsibilities.

{Insert Table 5 about here}

Discussion

While perceptions of integrating behavioral health and employing stepped care techniques in a primary care setting varied by stakeholder type; providers, care facilitators, and patients generally reported that the collaborative care model was valuable in offering additional pathways to care. For patients who faced barriers to care such as fear of repercussions associated with treatment-seeking in the military, lack of transportation to appointments, long wait times for appointments, and issues with scheduling, the collaborative and stepped care models offered access to alternative and supplemental treatment options. In addition, integration of PTSD and depression screening and treatment into the primary care setting provided an opportunity to engage patients in behavioral health care during mandatory encounters that they have as part of active duty service, increasing access to care and awareness of treatment options.

Although stakeholders acknowledged the value of collaborative care, particularly in capacity constrained environments such as the military health system, differences in opinions about provider competency and comfort may be barriers to full, effective implementation. The relationships and communications among primary care providers, mental health providers, care facilitators, and patients are critical to functional collaboration. Stakeholders reported that there were issues with providers' comfort and competency levels, lack of trust, and confusion about the roles and systems within the collaborative care model. These issues could be ameliorated through robust and right-timed training on screening and treatment for PTSD and depression and the collaborative care model's structure, processes, and offerings. Improving stakeholder comfort treating PTSD and depression, trust, and understanding of systems is essential for cultivating investment in the collaborative care model. The individual components of the collaborative care model may be helpful in improving access and quality of care, but the full benefits of the model cannot be realized unless providers, care facilitators, and patients all buy

into the effectiveness of the model. More frequent team meetings and case presentations could reinforce collaboration and improve communication about patients within the collaborative care model.

The availability of additional tools for managing patients, including enhanced care facilitation using MI and BA techniques and web- and phone-based therapy options, may also improve access to and retention in care. Stakeholders' perceptions about difficulty reading and using the web-based tools suggest an opportunity for refinement of the tools themselves and their implementation. Improving the user-friendliness of them, or their use in conjunction with either in-person or telephone based therapy, may improve uptake.

In this study, the use of the phone for care management and psychotherapy seemed generally acceptable. While phone care management doesn't replace face-to-face engagement, it does provide an opportunity for quick check-ins and the provision of care in a manner that can improve access and continuity, particularly for busy individuals or clinics with limited in-person visit capacity. Phone therapy also offered patients access to care when traveling to the clinic was difficult or there were long wait times for appointments. Care facilitators had overwhelmingly positive perceptions of phone therapy, and patients who used it reported having good experiences. Offering both phone therapy and phone care management during non-work hours while ensuring that calls follow protocol may also improve their effectiveness.

The role of care facilitators within the collaborative care model is essential; however, we noted some confusion among providers about how to best use these professionals. Thus, better description and dissemination of their roles may improve health care providers' willingness to use collaborative care.

Lastly, efforts to improve the relationship between primary care and behavioral health providers may be needed. While some primary care providers noted a desire for more training to improve their comfort levels, most felt competent to address PTSD and depression in their clinic settings. However, most behavioral health providers didn't share the view that primary care providers were ready to fill this role. As collaborative care models continue to expand within primary care settings, emphasis on improving the awareness and comfort among specialty providers may also be needed to improve trust and relationships with their primary care partners.

The extent to which the collaborative care mechanisms are well-understood and navigated by providers, care facilitators, and patients is critical to the success of the model. Improving the design of specific collaborative care tools and the training on how to use them may improve stakeholders' perceptions and institutionalized utilization of collaborative care.

Limitations:

A few study limitations should be noted. Specifically, our data were collected from within Army clinics, and it is unclear whether the same issues would be identified among stakeholders in clinics managed by other Services or in other settings. In addition, stakeholder impressions of collaborative care may vary across the range of Army clinics in which the model was implemented. Since the clinics and stakeholders are varied, we recognize that key system factors like relationships among providers and care teams may differ from clinic to clinic. Despite the possibility for variation, we believe that the findings from our analysis can offer valuable insight into implementation of the collaborative care model across the Army.

Acknowledgements:

This study was supported by a Department of Defense Deployment Related Medical Research Program award (Grant DR080409; award W81XWH-09-2-0079). The sponsor had no role in study design; in the collection, analysis and interpretation of data; in the writing of the report; or in the decision to submit the article for publication. The views expressed in this article are those of the authors and do not necessarily represent the views of the Department of Veterans Affairs, the Department of Defense, or a U.S. government agency.

The findings described in this manuscript were also presented at the Annual Scientific Meeting of the American Psychiatric Association in Toronto, Ontario, Canada in May 2015.

Conflicts of Interest:

Caroline Batka: No conflicts of interest to disclose

Terri Tanielian: No conflicts of interest to disclose

Mahlet A. Woldetsadik: No conflicts of interest to disclose

Carrie Farmer: No conflicts of interest to disclose

Lisa H. Jaycox: No conflicts to interest to disclose

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Tables

Table 1. Participating Patient Characteristics

	Enhanced, Stepped Collaborative Care (N=19)		Usual Collaborative Care (N=19)		ALL (N=38)	
	N	%	N	%	N	%
Male	13	68	12	63	25	66
Mean Age (in years)	32		29		30	
Rank						
Enlisted	10	53	9	47	20	53
Officer	8	42	8	42	16	42
Missing	1	5	2	11	3	8
Marital Status						
Single	9	47	11	58	21	55
Married or Living with Partner	4	21	3	16	7	18
Separated/Divorced/Widowed	5	26	3	16	8	21
Missing	1	5	2	11	3	8

Note: percentages may not add to 100% due to rounding.

Table 2. Participating Provider Characteristics

	ALL (N=31)	
	N	%
Male	17	55
Primary Work Setting		
PC Clinic	22	71
Specialty Clinic	4	13
Embedded in Unit Clinic	5	16
Provider Type		
Behavioral Health (psychologist, social worker, psychiatrists)	18	58
Primary Care (Physician Assistants, Nurse Practitioners, Medical Doctors)	13	42

Table 3: Illustrative Quotes of Stakeholder Perceptions about Addressing Behavioral Health in Primary Care Settings

Nearly two-thirds of the primary care providers interviewed felt competent and confident addressing mental health issues in primary care	• "I am more comfortable with treating mental health issues in primary care than I was before participating in [the program], and now I am more willing and able to do something." –Primary Care Provider • "Primary care providers are comfortable with pharmacotherapy, and primary care providers are uncomfortable with psychotherapy." –Primary Care Provider • "For a long time as a line battalion physician assistant, I had to take care of [behavioral health issues in primary care] myself. In [overseas location], going to a psychologist would be a two-hour drive, which was very burdensome. To avoid this burden, we learned to do this ourselves. This is a long-winded way of saying I am very comfortable treating PTSD and depression." –Primary Care Provider • "I am comfortable identifying, treating and managing PTSD and depression in primary care settings. My experience and comfort comes from being exposed to the issues in the Army setting." –Primary Care Provider • "We work with such moderate behavioral health issues that the primary care setting makes sense. Our patient care is excellent." –Primary Care Provider • "I think the integration of behavioral health into primary care is inevitable. The Army has made such cuts that we cannot afford the specialty providers."—Primary Care Provider • "Most primary care providers like to refer to Behavioral Health initially. However, given capacity constraints, they end up managing the patients themselves because it would take too long to get the patients into specialty care." –Primary Care Provider
80% of behavioral health providers and some primary care providers were skeptical about integrating BH into PC	• "If it's something simple, then it's fine, but generally primary care providers don't have the experience or the comfort to prescribe or treat patients with complicated behavioral health needs." –Primary Care Provider • "I have experienced that many primary care managers don't want to offer behavioral health treatment. Primary care providers are supposed to do exercises to practice what to do in the case of a behavioral health casualty, but primary care providers aren't behavioral health-minded. They avoid behavioral health care." –Behavioral Health Provider • "We are not comfortable with prescribing [medications] for PTSD and depression because some drugs are quite addictive, and we are aware of that." –Primary Care Provider • "I don't think that many in the primary care setting feel qualified to treat PTSD and depression. I don't feel qualified."—Primary Care Provider • "Primary care providers do a poor job treating PTSD and depression. I don't think they understand the medications or the side effects. I don't think that the people who work in primary care do this a lot either. They are not trained and they shouldn't offer care in an area they don't know about."—Behavioral Health Provider • "I want to know my patient is being taken care of, and I'm not confident about that [when the patient is treated in primary care setting]." –Behavioral Health Provider • "We refer patients to primary care providers when patients just need straight forward medication management for depression. Some primary care providers are not comfortable so they send the soldiers back to us." –Behavioral Health Provider
Both primary care and behavioral health providers found it difficult to create and maintain relationships between primary and specialty care	• "If implemented well, the traditional consultation/liaison model would work nicely but there has been difficulty in engaging the primary care providers in development relationships, trusting working relationships with the behavioral health providers" –Behavioral Health Provider • "There is also a constant turnover in providers, so ensuring continuity of communication between providers is really difficult." –Primary Care Provider • "Primary care providers change frequently, and sometimes the soldier doesn't know who their provider is. Continuity of care, knowledge base, and trusted relationships are not maintained when providers constantly change." –Behavioral Health Provider

Table 4: Illustrative Quotes of Stakeholder Perceptions of Care Management and Use of Telephone

Patients and providers liked working with care facilitators	• "As far as [the program], [named care facilitator] is fabulous and very present in the clinic. We refer people to her. She refers people to us, and we constantly talk about the patients." – Behavioral Health Provider • "Having a behavioral health [provider] with close access to physician assistants works well." –Behavioral Health Provider • "I don't need someone to walk the soldier over to another office. The person [care facilitator] is an extra person that could be used somewhere else. It is unnecessary." – Behavioral Health Provider • "When talking to [named care facilitator], it was, you know, you could tell… she really did care and was paying attention. While talking to the military doctor, you know, the officer, it was just one of those like, 'Okay, soon as you're done here I got five more [patients] I got to see today.'" –Patient • "[Named primary care provider] has been a lot better and talking to [named care facilitator] on the phone has been good enough. I don't think he [primary care provider] comes from defending the military and telling me that it's okay what they are doing to me. [S/he] listens to how I feel and helps me cope with it better. [S/he's] not telling me how they [the military] see it or trying to make me change my opinion. I can tell [her/him] exactly what's on my mind and how I feel..." –Patient
Care facilitators valued the use of motivational interviewing and behavioral activation	• "Some [patients] will be started on medications or some are doing just counseling. Some are doing nothing. And then the part with the study patients that you can do is behavioral activation and motivational interviewing and give them food for thought when they walk out without any real treatment plan other than, 'If you're having problems, go to ER or go to behavioral health'. They kind of notice—they're more apt to recognize some of the things that we might talk about, and then voluntarily say, 'Okay, this isn't working.'" —Care Facilitator • "I pretty much tell them all …. 'What do you want to see happen with this, with the treatment plan?' And really getting them involved in it and letting them know that whatever it is they are willing to do at the beginning and what it is they want to see happen, that seems to get them more involved. They'll call me back. They'll call me, and then they seem to really understand." —Care Facilitator
Some patients and care facilitators were comfortable with use of the telephone to engage patients, while others still preferred face-to-face encounters	• "I mean I like—for me it's easier to talk over the phone to somebody than it is to talk face-to-face." –Patient • "I'm not a person to openly talk to people, so being one-on-one, face-to-face, is kind of intimidating to me at times. So being able to talk on the phone and being in an environment that I can be comfortable in, whether I'm sitting in my house or I'm outside or something like that, it allows me to open up a lot more." –Patient • "He [a soldier] said he was living off [-post] and the barracks were kind of far, and I don't know if it was his telephone at work that the calls would get dropped constantly, so he didn't think he was going to be able to do the telephone therapy because of that reason. So then through staffing, they said, 'Well offer him your landline and see if he'll do it that way.' And sure enough he came every week and he completed his telephone therapy, and he really liked it. Towards the end he told me, 'You know what, I'm glad I did this. I liked it.' And almost all of them that I have had done the telephone therapy, they engaged."— Care Facilitator • "I believe people need more face-to-face. I mean, I know they have a lot of programs like you're saying online and stuff like that. Those, you know, people will breeze through them and not pay attention. I'm more of a face-to-face type person. And maybe we'll get a realization of if somebody's actually telling you in a comfortable environment, like not a teaching, but just like a social thing. Like go meet somewhere and have lunch, and the next thing you know it's like a little conference thing where you're just talking. And let people vent out." – Usual Care Patient • "With the STEPS-UP, because I had a phone to text the patient, I think the texting helped a lot in engaging them. They were more responsive, a lot of them were--you

	know they wouldn't pick up but then they would text back." —Care Facilitator • "I have more frequent contact with STEPS UP patients, and I suppose that carries over into my RESPECT Mil patients also." —Care Facilitator
Care facilitators and patients had negative perceptions of use of telephone to engage and maintain contact with patients	• "I believe people need more face-to-face. I mean, I know they have a lot of programs like you're saying online and stuff like that. Those, you know, people will breeze through them and not pay attention. I'm more of a face-to-face type person. And maybe we'll get a realization of if somebody's actually telling you in a comfortable environment, like not a teaching, but just like a social thing. Like go meet somewhere and have lunch, and the next thing you know it's like a little conference thing where you're just talking. And let people vent out." – Usual Care Patient • "I really don't like, you know, I call my case manager over the phone. I definitely think it would be maybe more helpful if maybe, at least once a month, you know, [you] actually get to come in and see her face-to-face and talk to her. Because sometimes it's hard… and then even when I'm doing that, my symptoms and stuff like that, it's just like we're shooting through them and because I have to get off the phone because I'm doing you know, whatever for training so I really can't take that time to really think, I'm just shooting out answers and I'm just like, 'Ah!' So I think definitely, maybe once a month would be good, at a minimum, to just at least come in, say, 'Hey,' you know, 'I'm here.'" –Enhanced Collaborative Care Patient • "[Soldiers] see the phone ring, probably [with] my name on there, and they don't answer. So it's difficult. It's not easy to engage them."— Care Facilitator • "Well, it's been much easier to engage those who are here on site and who've established a relationship with me. You know, when you see each other face to face there's a rapport. They trust somebody that they know versus over the phone or email at the distant site." —Care Facilitator • "I notice that the patients that I do end up meeting face-to-face, they kind of engage a little bit better than the ones that I only do telephonically and they never get to meet me. I don't know if it's the connection there where they kind of put a face to the name and they feel a little bit more comfortable, because I do ask a lot of personal questions." –Care Facilitator • "For me I call during work hours and they're at work too, so I understand it's hard." —Care Facilitator

Table 5: Illustrative Quotes of Stakeholder Perceptions of New Tools for Treating Depression and PTSD

Some care facilitators and patients perceived advantages of web-based tools, but noted obstacles to using them	• "At the time that he [Care Facilitator] presented it [Beating the Blues], I didn't really feel the need to look for extra help. And so I just--when I had a crisis, it wasn't the first place my mind jumped to, I guess… I can't sit still for that. I prefer actually also just to talk to somebody. It's more helpful for me to talk to somebody than to look at a screen, I think." –Enhanced Collaborative Care Patient • "Beating the Blues with the embedded videos and the actual patients and stuff, I think is so much more engaging and we've had a lot more positive feedback from the patients on that one." –Care Facilitator • "DESTRESS-PC is a lot of work, and I don't think--I don't want to call my soldiers--especially on tape--I don't want to say this--they're not cognitive. I would say lots of times their grade level, reading levels, wouldn't go much past the sixth to the eighth grade at the most. And I think that if you take a look at DESTRESS-PC, sometimes it's a little over their heads. It's a little much. And there's a lot of work in DESTRESS." –Care Facilitator • "DESTRESS-PC has a lot of good information, but I think it's just a very long and wordy and a lot of reading, and most of the patients don't take time for that." –Care Facilitator • "They [soldiers who participated in DESTRESS-PC] enjoyed the videos and the mini homework assignments and the ability to see if they're improving and things like that." –Care Facilitator • I think that the soldiers with PTSD and stuff that DESTRESS-PC is a little intense. They would go into it and be, 'Okay, this is too much work.' I've put two or three patients on it, and they're not following through." –Care Facilitator • "It [DESTRESS-PC] was very helpful and it was easy to use. Well, one, the lady who helped me--the lady who guided me through it, she was very helpful. The program, after I left there, I felt a lot better. It was great." –Enhanced Collaborative Care Patient • "Soldiers tell me that they would prefer to [use online tools] because it's on their time and also the stigma's another thing. They don't want to go to Behavioral Health and sit there, or especially if they're higher rank, they don't want nobody seeing them walk in the building." –Care Facilitator
Those who used telephone therapy option liked it	• "From my perspective, [soldiers] were more receptive to the telephone therapy, and for the ones that did decide to engage in it, I did notice that they liked it."— Care Facilitator • "The phone therapy worked out well, and I like doing that." –Enhanced Collaborative Care Patient