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PREPARED FOR: U.S. Army Medical Research and Materiel Command
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14. ABSTRACT Over the course of the last year, The RTI Institutional Review Board (IRB) has reviewed and approved the study protocol, consent form, and related study materials. RTI finalized the listing and ordering of items to be included on the baseline questionnaire instrument. A survey methodologist review and evaluate items to be included in the baseline instrument for methodological considerations such as usability, item placement, and response considerations. Web programming of the baseline instrument is nearing completion. The web programming incorporates the study instrumentation (currently baseline only), randomization scheme, emergency response protocol, data security protocol, data collection and other study reports, and other functions. In preparation for study launch, the STEPS UP team has conducted three site visits at Joint Base Lewis-McChord, Fort Bliss, and Fort Carson to initiate intervention awareness and training for primary care and behavioral health providers, clinic nurses and clerical staff, and RESPECT-Mil personnel. We have developed job descriptions and timelines to hire study support personnel. RTI has conducted recruiting, interviewing, and hiring activities for research coordinators and assistants for Joint Base Lewis-McChord, WA (coordinator hired) and Fort Bliss, TX (candidates identified).					
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INTRODUCTION:

The purpose of the STEPS UP (**ST**epped **E**nhancement of **PTSD** **S**ervices **U**sing **P**rietary **C**are) trial is to compare centralized telephonic care management with preference-based stepped posttraumatic stress disorder (PTSD) and depression care to optimized usual care. We hypothesize that the STEPS UP intervention will 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 hypothesize that qualitative data will show (4) patients, their family members, and participating clinicians find that the STEPS UP intervention is an acceptable, effective, and satisfying approach to deliver and receive PTSD and depression care

STEPS UP is a six-site, two-parallel arm (N = 1,500) 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 will include web-based cognitive behavioral self-management, telephone cognitive-behavioral therapy, continuous nurse care management, and computer-automated care management support. Both arms can refer patients for mental health specialty care as needed, preferred and available. The study will use sites currently running RESPECT-Mil, the Initiating PI's 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 effective, we expect that STEPS UP will increase the percentage of military personnel with unmet PTSD- and depression-related health care needs who get timely, effective, and efficient PTSD and depression care. Our real-world primary care effectiveness emphasis will prevent the Institute of Medicine's so called "15 year science to service gap." If successful, STEPS UP could roll out immediately, reinforcing and facilitating pathways to PTSD and depression recovery.

BODY:

The study is currently in the regulatory review and approval phase. The RTI Institutional Review Board (IRB) has reviewed and approved the study protocol, consent form, and related study materials (20 appendices including data collection materials, manuals, impact statements, advertisements, and study personnel scripts). Additionally, the RTI IRB approved protocol was submitted to the Human Research Protection Office (HRPO) for review.

During the second year of the project, we finalized the listing and ordering of items to be included on the baseline questionnaire instrument. Completion of the baseline instrument required a great deal of coordination to ensure that all team members were in agreement about scales and items to be included, as well as item ordering and transition text. As an extra check

on our approach we had a survey methodologist review and evaluate items to be included in the baseline instrument for methodological considerations such as usability, item placement, and response considerations. A list of variables and web programming specifications was created and approved by the RTI team.

Web programming of the baseline instrument is nearing completion. The web programming incorporates the study instrumentation (currently baseline only), randomization scheme, emergency response protocol, data security protocol, data collection and other study reports, and other functions. The RTI team has extensively tested the web instrument for issues of usability, text and item flow, skip logic, scoring algorithms, and other key factors. RTI has also designed the data collection and monitoring system for tracking data and generating automated reports. We have held numerous discussions with the RTI IRB and data security representatives regarding emergency contact issues should a participant indicate a high risk of suicide on one of the study's web instruments. Our programmers have installed the data collection portion of the study website in our Enhanced Security Network (ESN) to ensure security of study data, including personal identifying information (PII) and protected health information (PHI). Finally, RTI has begun work on the follow-up instrument to be administered at 3, 6, and 12 months post-enrollment. We have also made additional refinements to the study website to give it full functionality for the data collection aspect of the study and for maximum usability for the entire STEPS UP team.

RTI has held weekly meetings with the full STEPS UP team, as well as weekly calls with the Deployment Health Clinical Center (DHCC) to address planning and anticipated logistical issues associated with data collection. We also held internal (RTI only) weekly meetings to address the development of the RTI IRB protocol, baseline instrument, website development and programming, and data collection planning activities.

In preparation for study launch, the STEPS UP team has conducted three site visits at Joint Base Lewis-McChord, Fort Bliss, and Fort Carson to initiate intervention awareness and training for primary care and behavioral health providers, clinic nurses and clerical staff, and RESPECT-Mil personnel. We expect to complete site visits to the remaining three sites in the next six months.

We have developed job descriptions and timelines to hire study support personnel. RTI has conducted recruiting, interviewing, and hiring activities for research coordinators and assistants for Joint Base Lewis-McChord, WA (coordinator hired) and Fort Bliss, TX (candidates identified). During the second year of the project, we conducted training and logistics planning activities with the research coordinator at Joint Base Lewis-McChord, as well as securing office resources (e.g. computer equipment, cell phones and usage plans) for research coordinators and assistants for all participating sites.

KEY RESEARCH ACCOMPLISHMENTS:

There are not yet any clear scientific findings resulting from this research as data collection efforts have not yet commenced. Results are expected in June 2015.

REPORTABLE OUTCOMES:

In November 2010, RTI staff were co-authors of a symposium presentation at the International Society of Traumatic Stress Studies (ISTSS) annual meeting held in Montreal (see Appendix 1). In March 2011, we co-authored a presentation at the Armed Forces Public Health Conference in Hampton Roads, VA (see Appendix 2). Additionally, the team presented a poster at the 2011 Uniformed Services University of the Health Sciences (USUHS) Research Week in May 2011 (see Appendix 3).

CONCLUSION:

There are no conclusions to report at this time, as the study has not been opened for enrollment.

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APPENDICES:

Appendix 1- Abstract for the presentation entitled *Improving primary care for US troops with PTSD and depression in military primary care clinics: RESPECT-Mil and STEPS-UP*, presented at the November 2010 meeting of the International Society of Traumatic Stress Studies.

Appendix 2- Abstract for the presentation entitled *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 the March 2011 Armed Forces Public Health Conference.

Appendix 3- Abstract for the poster presentation entitled *Stepped Enhancement of PTSD Services Using Primary Care (STEPS UP): Design and Methods of a DoD Funded Randomized Effectiveness Trial*, presented at the May 2011 USUHS Research Week.

SUPPORTING DATA:

N/A

APPENDIX 1

Improving primary care for US troops with PTSD and depression in military primary care clinics: RESPECT-Mil and STEPS-UP

Charles Engel, Lisa Jaycox, Robert Bray, Michael Freed; Brett Litz; Terri Tanielian, Doug Zatzick, Jürgen Unützer, Wayne Katon.

PTSD and depression are a serious problem for roughly 15% of U.S. military personnel returning from the conflicts in Iraq and Afghanistan. Stigma, fear of harm to career, and institutional barriers to mental health care in the military health system prevent many from seeking care. In 2007 the Army initiated RESPECT-Mil, a collaborative care approach to improving primary care recognition, treatment, and continuity of care for these conditions. RESPECT-Mil was rolled out to 15 Army sites (42 primary care clinics) and is now adding another 19 sites (53 clinics). In this presentation we will (1) describe the RESPECT-Mil model, (2) present data on program use to date, (3) outline feedback from implementers and providers, (4) discuss implementation logistics, barriers, and challenges, and (5) show how lessons to date are being used to develop and test a second generation model called “STEPS-UP.” STEPS-UP incorporates new care manager strategies for engaging and motivating patients and helping determine treatment preferences; adopts a more comprehensive stepped treatment paradigm, adding a continuum of psychosocial management options; and uses distance modalities (Web, telephone) to maximize participation. A new multisite controlled trial will evaluate STEPS-UP versus RESPECT-Mil to determine whether STEPS-UP benefits will outweigh its unintended effects.

APPENDIX 2

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)

COL Charles C. Engel, MD, MPH, MC, USA; Michael C. Freed, PhD, EMT-B; Lisa Jaycox, PhD; Robert M. Bray, PhD; Douglas Zatzick, MD; Brett Litz, PhD, MA; Jürgen Unützer, MD, MPH; Wayne Katon, MD; Terri Tanielian, MA; Donald Brambilla, PhD; Christine Eibner, PhD; Phoebe Kuesters, MPH; Laura Novak, BA; Julie Cooper, MPH; Eileen Delaney, PhD; Kristine Rae Olmsted, MSPH; Jennifer Weil, PhD; Kristie L. Gore, PhD

ABSTRACT: PART I: REHIP blends two integrated-collaborative primary care (PC) approaches (embedded behavioral health providers and care managers), achieving an evidence-based synergy that surpasses either approach alone. Combining the two "team medicine" models will lead to improved detection, rapid specialist access, continuous accountable patient monitoring, timely, as needed treatment changes for patients not responding to treatment, and useful PC provider management advice and treatment assistance for the widest range of PH issues. PART II: STEPS UP (Stepped Enhancement to PTSD Services Using Primary Care) will enhance RESPECT-Mil in two important ways: 1) the implementation of efficacious distance and in-person psychosocial therapies for PTSD and depression and 2) the option for centralized care management. In this randomized multisite trial, we hypothesize that STEPS UP is a cost-effective solution that will lead to greater symptom reduction and more improvement in quality of life than optimized usual care, which includes RESPECT-Mil.

APPENDIX 3

Stepped Enhancement of PTSD Services Using Primary Care (STEPS UP): Design and Methods of a DoD Funded Randomized Effectiveness Trial

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Background: Approximately 1/6th of returning servicemembers from the wars in Iraq and Afghanistan report clinically significant symptoms of PTSD and/or depression. Many are referred for specialty mental healthcare, but less than half actually follow through with the referral. The collaborative care model, a systems-level intervention which combines regular screening, on-site care management, and psychiatric consultation, all within primary care, is effective for treating and managing depression and other mental health problems in the civilian sector. This model is also becoming the standard of care in the Army for PTSD and depression, through a program called RESPECT-Mil. STEPS UP enhances RESPECT-Mil in two important ways: 1) efficacious in-person, telephone-, and web-based psychosocial therapies for PTSD and depression and 2) telephone and on-site care management. Patients will be offered STEPS UP interventions based on their preference and symptom severity. Methods: 1500 active duty servicemembers at 6 Army posts (18 primary care clinics) will be randomized to STEPS UP or usual care (which may include RESPECT-Mil) and followed for 12-months. Costs of health services will be assessed, and a subset of patients and providers will be interviewed to assess perceptions of care quality, satisfaction, and acceptability. Hypotheses: Participants randomized to STEPS will report lower depression and PTSD symptoms. STEPS UP will be an acceptable and cost-effective strategy, relative to usual care. Conclusions: If effective, STEPS UP will improve the 1) availability and diversity of treatments 2) technological infrastructure to manage patients and provide ongoing supervision and coaching to providers.