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Targeted Assessment and Context-Tailored Implementation of Change Strategies (TACTICS) to increase evidence based psychotherapy in military behavioral health clinics: Design of a cluster-randomized stepped-wedge implementation study

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Abbreviations: BH, behavioral health; BHDP, Behavioral Health Data Platform; CFIR, Consolidated Framework for Implementation Research; DHA, Defense Health Agency; *DSM-5*, *Diagnostic and Statistical Manual of Mental Disorders, 5th Edition*; DoD, U.S. Department of Defense; EBPs, evidence-based psychotherapies; EHR, electronic health record; ERIC, Expert Recommendations for Implementing Change project; FTP, file transfer protocol; GAD-7, Generalized Anxiety Disorder Screener – 7; GLMM, generalized linear mixed model; HIPAA, Health Insurance Portability and Accountability Act; ICD-9, International Classification of Diseases, Ninth Revision; ICS, Implementation Climate Scale; ILS, Implementation Leadership Scale – Leadership and Staff Versions; IRB, Institutional Review Board; MHS, Military Health System; MTFs, military treatment facilities; NLP, natural language processing; PCL-5, The PTSD Checklist for *DSM-5*; PE, Prolonged Exposure therapy; PHQ-9, Patient Health Questionnaire-9; ProQOL-5, Professional Quality of Life Scale – 5; PTSD, posttraumatic stress disorder; SDD, Defense Health Agency Solutions Delivery Division; Site PI, site principal investigator; TACTICS, Targeted Assessment and Context-Tailored Implementation of Change Strategies; U.S., United States of America; VA, U.S. Department of Veterans Affairs.

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ABSTRACT

Background: Despite efforts by the U.S. Department of Defense to train behavioral health (BH) providers in evidence-based psychotherapies (EBPs) for posttraumatic stress disorder (PTSD), numerous barriers limit EBP implementation. A context-tailored implementation approach called TACTICS (Targeted Assessment and Context-Tailored Implementation of Change Strategies) holds promise for increasing the use of EBPs such as prolonged exposure therapy (PE) in military treatment facilities. TACTICS combines a needs assessment, a rubric for selecting implementation strategies based on local barriers, an implementation toolkit, and external facilitation to support local champions and their implementation teams in enacting changes. This paper describes the rationale for and design of a study that will evaluate whether TACTICS can increase implementation of PE for PTSD and improve patient outcomes in military BH clinics relative to provider training in PE alone.
Methods: The study is a multi-site, cluster randomized, stepped-wedge trial, with the military treatment facility as the unit of analysis. Eight facilities undergo a provider-training phase, followed by 5 months of TACTICS implementation. The timing of TACTICS at each facility is randomly assigned to begin 9, 14, or 19 months after beginning the provider-training phase. Primary analyses will compare the proportion of PTSD patients receiving PE and patients' mean improvement in PTSD symptoms before and after the onset of TACTICS.
Discussion: TACTICS endeavors to balance standardization of empirically-supported implementation strategies with the flexibility of application necessary for success across varied clinical settings. If successful, TACTICS may represent a systematic and scalable method of promoting and supporting EBP implementation.
Trial registration: Clinicaltrials.gov Identifier: NCT03663452

1. Targeted Assessment and Context-Tailored Implementation of Change Strategies (TACTICS) in military behavioral health clinics: a randomized stepped-wedge implementation study

Clinical practice guidelines from the U.S. Department of Defense (DoD) and Department of Veterans Affairs (VA) [1] recommend trauma-focused psychotherapies as first-line treatments for posttraumatic stress disorder (PTSD) *throughout the entire military health system (MHS)*. However, the implementation of these treatments in military treatment facilities (MTFs; e.g. *hospitals and clinics at DoD military installations*) is limited [2–4]. To date, there have been two primary approaches to increasing evidence-based psychotherapy (EBP) implementation to treat PTSD in both *DoD and VA*: (a) broad policy statements supporting EBP implementation, and (b) provider training through didactic workshops and case consultation (*the consultation portion is optional in DoD and few military providers receive it*) [5,6].

Provider training, while necessary, is not sufficient to ensure routine EBP implementation with consistency and fidelity [2,3,7]. In particular, provider training does not address organizational or logistical barriers to EBP delivery, such as lack of dedicated provider time or difficulty scheduling weekly appointments [6,8]. Barriers to the use of EBPs for PTSD within the MHS are complex and traverse various levels of the organization, from the individual provider to higher headquarters' policies, directives, and guidelines [5]. Moreover, the barriers are likely to vary from one MTF to another based on: (a) the military mission of the installation; (b) characteristics of the active duty and beneficiary population; (c) staffing levels; (d) the provider mix of active duty military, government civilian, or contract staff; and (e) the available behavioral health (BH) resources in the local community to supplement care.

The best chance of increasing EBP use comes from an implementation approach that is tailored to the local context, leverages existing strengths, and ameliorates the most critical deficits [9]. However, the process for selecting implementation strategies [10–15] is often complex and far from transparent. Selection of specific change is often based on the facilitator's expert judgement or group consensus rather than a systematic process [16,17]. Therefore, more efficient, systematic, and scalable approaches to tailor implementation efforts are needed.

To address this gap, we developed TACTICS (Targeted Assessment and Context-Tailored Implementation of Change Strategies), an implementation strategy matching process [18]. TACTICS combines local needs assessment, a rubric for linking barriers with implementation strategies, an implementation toolkit, and external facilitation. Using a randomized, stepped-wedge design, the current study will evaluate whether TACTICS can increase implementation of prolonged exposure therapy (PE), an EBP for PTSD, in MTFs relative to provider training in PE alone.

2. Design and methods

2.1. Stepped-wedge design

The study will utilize a cluster-randomized, stepped-wedge design, which has the following advantages: (a) it accounts for clustering of providers within sites; (b) it requires a substantially smaller sample size than most alternate designs; (c) it enables us to model the temporal effect of our strategy; (d) it will allow us to provide the intervention to all sites, which increases the benefit of participation to study sites. All sites (i.e., MTFs) will undergo time periods in which they are “unexposed” to the TACTICS intervention followed by time periods during which they are “exposed” [19]. During the “unexposed” period, MTFs receive provider workshop training in PE with optional clinical consultation (i.e. delivery of DoD training as usual), with no additional implementation support. Sites are randomized to one of three cohorts, whose exposure to TACTICS will begin 9, 14, or 19 months after the start of the study (see Fig. 1 below). Each cohort will be “exposed” to 5 months of TACTICS implementation support, starting with a needs assessment and tailored implementation plan, followed by coaching calls between the local implementation champion and the TACTICS consultant.

2.2. Study aims

Study aims address the reach and effectiveness of TACTICS to increase implementation of PE for PTSD, as well as provider satisfaction with the TACTICS process.

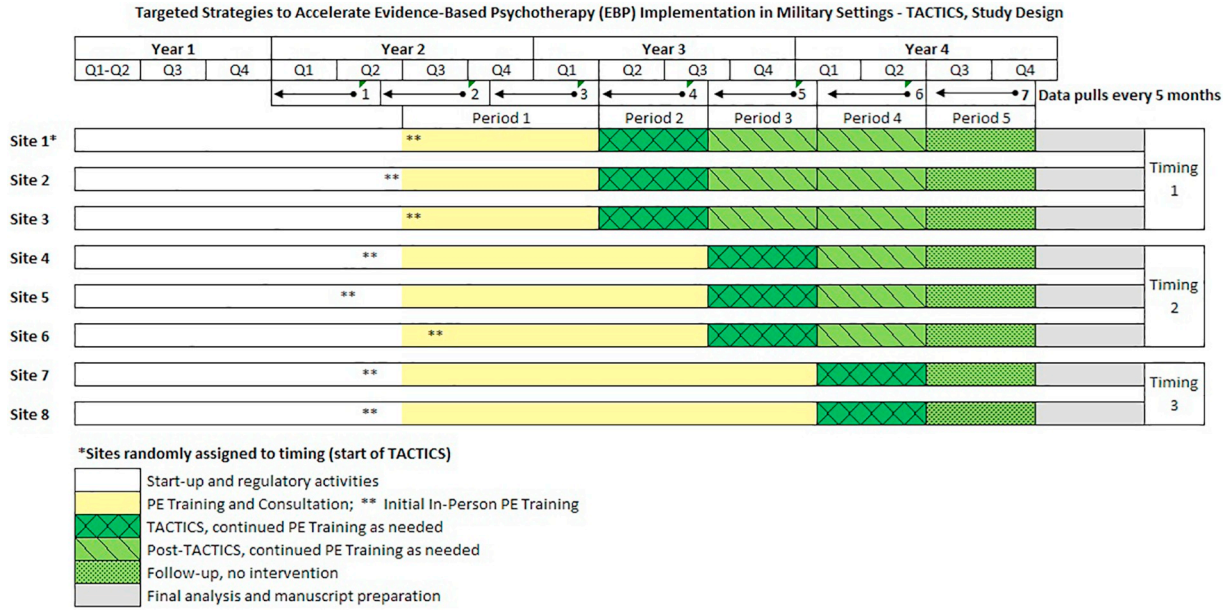

Fig. 1. Notes. PE = prolonged exposure therapy; Q1, Q2, etc. = Quarter; TACTICS = Targeted Assessment and Context-Tailored Implementation of Change Strategies. The Center for Deployment Psychology provides an initial in-person training, and then offers quarterly online training in PE thereafter. Participating clinics may opt to send providers to one of these online trainings if 1) the provider could not attend the initial in-person training, 2) the provider joined the clinic after the initial in-person training, or 3) the provider would like refresher training. Additional details about the TACTICS study timing can be found in the TACTICS section below.

2.3. Primary aim

2.3.1. Study aim 1 (reach)

To examine the impact of a multi-modal, tailored implementation approach (TACTICS) over and above conventional PE training on the proportion of PTSD patients who receive PE for PTSD, as measured by natural language processing (NLP) of psychotherapy encounter notes (primary measure) and provider-identified psychotherapy modality (secondary measure).

2.4. Secondary aims

2.4.1. Study aim 2 (effectiveness)

To examine the impact of TACTICS over and above provider training alone on mean improvement in MTF patients' scores on the PTSD Checklist for *DSM-5* (PCL-5) [20].

2.4.2. Study aim 3 (satisfaction)

To evaluate the usability of and overall satisfaction with TACTICS among senior leaders, site leaders, and providers, as assessed by qualitative data obtained from the post-TACTICS feedback interviews. As part of this effort, we also aim to identify TACTICS components that were (a) seen as most useful by participants and appear to contribute to implementation success; (b) potentially helpful but require modifications; and (c) potentially unnecessary and do not appear to contribute to implementation success.

2.5. Exploratory aims

2.5.1. Study aim 4

To assess the impact of TACTICS (over and above training alone) on provider and site-level factors theorized to facilitate implementation in the Consolidated Framework for Implementation Research (CFIR) [14]. These proximal factors include changes in provider knowledge/beliefs about PE, provider self-efficacy, burnout, implementation climate, and leadership engagement, as assessed through online surveys.

2.5.2. Study aim 5

To explore whether changes in CFIR-theorized provider- and site-level factors (based on emergent themes in qualitative needs assessment interviews and exit interviews) are associated with greater improvements in reach (greater number of patients receiving PE) and effectiveness (greater improvement in PTSD symptoms as measured by the PCL-5).

2.5.3. Study aim 6a

To examine the TACTICS implementation strategies employed at each site in connection with increased use of PE, to determine which strategies were more or less efficacious in increasing PE use.

2.5.4. Study aim 6b

To evaluate the impact of TACTICS over and above training alone on self-reported levels of PE fidelity, as measured by NLP data of psychotherapy progress notes.

2.5.5. Study aim 6c

To examine patient characteristics (e.g., depression, generalized anxiety, recent hospitalizations, other psychiatric diagnoses) that may be associated with PE receipt. This aim will be examined at the patient level within clusters.

2.6. Quality improvement and research components

This project includes two quality improvement components: PE training and the TACTICS intervention. The study also includes four research components that evaluate the impact of the quality improvement efforts: (a) online surveys assessing site staff knowledge, attitudes, and behaviors every 10 weeks; (b) rate of PE-use based on analysis of encounter note text; (c) changes in PTSD symptoms assessed via routine outcomes monitoring; and (d) qualitative post-implementation feedback interviews from BH staff at participating sites. A visual depiction of the process improvement and research activities timelines can be found in Fig. 2 below.

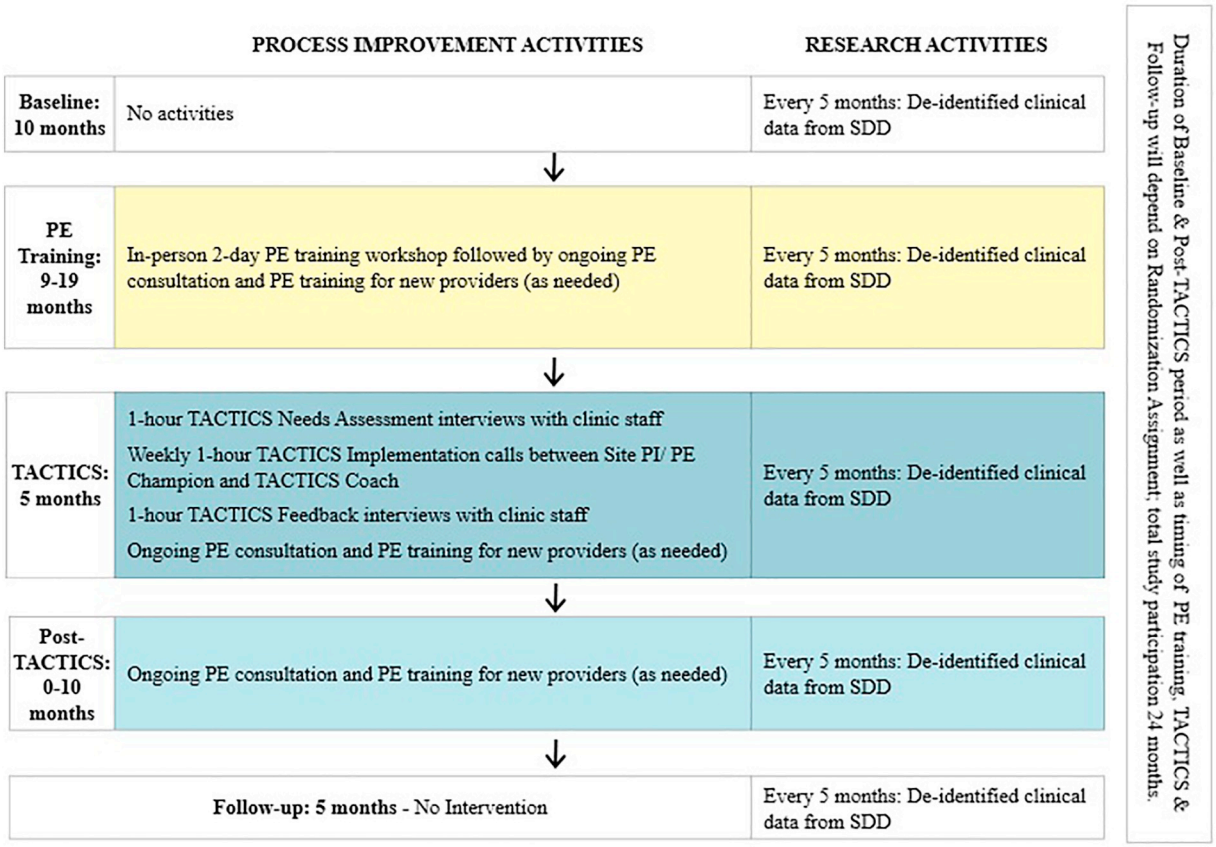

Fig. 2. Overview of TACTICS Study Flow and Project Activities. Note. PE = prolonged exposure therapy; site PI = site principal investigator; SDD = Defense Health Agency Solutions Delivery Division; TACTICS = Targeted Assessment and Context-Tailored Implementation of Change Strategies. The roles of the PE champion and the TACTICS coach are described in the "TACTICS" section below.

2.7. Site selection and recruitment

Participating sites meet the following criteria: (a) the site sees at least 25 new PTSD cases per year according to Defense Health Agency (DHA) administrative reports; (b) the site staff includes at least 8 BH providers; and (c) the site is not involved in another study targeting PTSD treatment.

Many of the policies and guidelines that affect BH sites are dictated from a higher headquarters level, such as the DHA. Prior to site recruitment, the study team conducted interviews with BH leadership with the Army, Navy, and Air Force to better understand administrative factors that may impact the ability of the MTF hospital leadership and local site to implement changes. An understanding of these policies was essential to informing the TACTICS approach.

Potential sites were identified through the study team's network of military contacts, as well as through data and contacts provided by the DHA. The process of site recruitment involved e-mail and phone communication with BH leadership at potential sites, as well as a site visit to finalize each facility's commitment to participate. The final decision to participate was made by BH leadership at all sites prior to randomization.

Site recruitment took place between November 1, 2017, and February 1, 2019. Four Army sites, three Air Force sites, and one Navy site agreed to participate. De-identified data will be collected over 5-month increments during the 35 months of the study from all patients receiving care at the participating sites who have a diagnosis of PTSD and who have a psychotherapy procedure code linked to that diagnosis (approximately 100 PTSD patients per site). During that period, we expect to analyze data from approximately 5600 PTSD treatment sessions provided by at least 80 providers (eight sites X approximately 10 providers per site). The baseline rate of PE use for PTSD treatment is estimated to be 10% to 20% for each site [21]. The study was powered based on an anticipated increase in the use of PE to treat PTSD by 10% following TACTICS. Based on these assumptions, power for eight sites was estimated at > 0.9 using the PASS 15.02 software for sample size estimation. For the stepped-wedge design, sites are randomized to cohorts using a SAS software random number generator code using a simple randomization without replacement technique, with the first and second cohorts consisting of three sites each, and two sites assigned to the final cohort.

2.8. Participants

As quality improvement activities are carried out at the cluster level, all providers at a participating site may be engaged in the tailored TACTICS implementation plan. The extent of their involvement will be determined by site leadership (providers are not consented for process improvement participation). In contrast, providers are not required to participate in the research activities of this project; they are invited to complete the surveys and to participate in post-TACTICS feedback interviews. Both of these activities meet the federal and DoD definition of human subjects research (32CFR219; 45CFR46; DoDI 3216.02) requiring informed consent.

Given staff rotation and related attrition during the study period, an estimated 80 to 300 behavioral health providers and leaders from participating sites will be invited to complete online surveys. To be eligible for the study, providers must (a) work in a participating site at least 1 day per week and (b) provide individual adult psychotherapy to a panel of patients, with at least some of those patients reporting significant PTSD symptoms, or (c) *supervise clinicians who fit criteria a and*

b. Providers are not eligible to participate if they have definite plans either to terminate their position or relocate within 5 months of the start of their site's study participation.

2.9. Data collection procedures and measures: de-identified patient data

Under waivers of informed consent and Health Insurance Portability and Accountability Act (HIPAA) authorization and with the support of the DHA Solutions Delivery Division (SDD), data from patients with an International Classification of Diseases, Ninth Revision (ICD-9) diagnosis of PTSD linked with a psychotherapy procedure code at participating sites will be extracted from the DoD's Behavioral Health Data Platform (BHDP) and the electronic health record (EHR). Under an approved Data Sharing Agreement, SDD will de-identify the data and transfer it to the study team using a secure file transfer protocol (FTP) site. EHR and PCL-5 data will be extracted over a 35-month period (10 months prior to the in-person PE training and 25 months thereafter) and divided into 5-month increments for analysis. The number of five-month periods occurring before and after TACTICS will depend on a site's position in the stepped-wedge design (see Fig. 1). Sites randomized to timing 1 will have 15 months (periods 1–3) of data prior to TACTICS and 20 months (periods 4–7) after the onset of TACTICS, whereas sites randomized to timing 3 will have 25 months of data (periods 1–5) prior to TACTICS and 10 months (periods 6–7) after the start of TACTICS. See Table 1 for a schedule of data collection activities.

2.9.1. Receipt of PE

The proportion of PTSD psychotherapy patients who receive PE is our primary outcome measure for Aim 1. During each 5-month period, we will first identify all psychotherapy encounters with a PTSD diagnosis in each site. For each of the selected psychotherapy sessions, NLP will determine whether PE was used during the session and which aspect(s) of PE were used. SDD will use computerized searches of encounter notes to identify key words and phrases indicative of PE-use. The target search terms were informed by NLP algorithms from two prior studies of VA progress notes and machine learning [22,23]. In those prior studies, automated searches produced recall (sensitivity) of 0.98 and 0.85 and precision (specificity) of 0.97 and 0.96 relative to experts' coding of progress notes for the presence or absence of PE. For our measure of PE reach, the denominator will be the number of unique patients who have one or more psychotherapy visits linked with a PTSD diagnosis, and the numerator will be the number of those patients who have one or more encounter notes containing text indicative of PE.

2.9.2. PTSD checklist for DSM-5 (PCL-5)

Our primary outcome for Aim 2 is mean improvement in PTSD symptoms among all patients with one or more PTSD psychotherapy visits. PTSD symptoms are assessed using the PCL-5 [20], a 20-item self-report measure designed to assess PTSD symptoms as defined by the *Diagnostic and Statistical Manual of Mental Disorders, 5th Edition* (*DSM-5*). The PCL-5 evaluates PTSD symptom severity on a 5-point scale ranging from 0 (“not at all”) to 4 (“extremely”). The PCL-5 has strong internal consistency ($\alpha = 0.94$) and test-retest reliability ($r = 0.82$) [20]. As part of routine care, patients who endorse symptoms on a PTSD screen are asked to complete this measure online at least once per month before a BH visit using the BHDP. Scores on the Patient Health Questionnaire-9 (PHQ-9) [24] and Generalized Anxiety Disorder Screener – 7 (GAD-7) [25] will also be collected from BHDP.

2.9.3. Demographic, military, clinical characteristics, and symptoms

Data on patient age, gender, ethnicity, race, military grade, and branch, will be collected from the EHR. Data on Warrior Transition Unit status, psychiatric diagnoses, number of BH encounters, number of hospitalizations in the past 5 months, and suicide risk will be collected from the EHR, and treatment modality for each BH session will be collected from the BHDP. These data will be used to control for variance in the statistical model, as well as to examine potential differences between characteristics of patients who do and do not receive PE at the individual patient level (exploratory Aim 6c).

2.10. Data collection procedures and measures: staff surveys and interviews

Providers who consent to participate will complete online surveys (taking approximately 15 to 20 min per administration) every 10 weeks, beginning prior to the TACTICS phase and continuing throughout the data collection period, for a total of nine administrations. Each of the measures listed below are included in these staff surveys. These surveys will be analyzed at the cluster level to address exploratory Aim 4.

2.10.1. Demographics and military service

Information on provider gender identity, age, race, ethnicity, education, employment status, professional status, professional experience, site role, workload, theoretical orientation, and prior training in PE will be collected during the baseline period. Providers' panel size, demand, number of scheduled appointments, and discrepancy between scheduled appointments and demand will also be collected from the Military Health System Data Repository for use as covariates. This data will be

Table 1
Study aims, corresponding data sources, and data collection schedule.

Data source	Corresponding aims	Collection schedule
• Coded EHR data (NLP)	Aim 1: PE receipt before and after TACTICS Aim 5: Association between CFIR factors and improved reach and effectiveness of PE at site Aim 6b: Impact of TACTICS over and above provider training on PE fidelity Aim 6c: Patient characteristics associated with PE receipt	• Seven 5-month periods o One prior to baseline training (pre-baseline) o Two to four during training (baseline) o Two to four after the start of TACTICS
• PCL-5 scores from BHDP	Aim 2: Change in PTSD symptomatology before and after TACTICS. Aim 5: Association between CFIR factors and improved reach and effectiveness	• Seven 5-month periods o One prior to baseline training (pre-baseline) o Two to four during training (baseline) o Two to four after the start of TACTICS
• Post-TACTICS feedback interviews	Aim 3: Provider and leadership satisfaction with TACTICS	• Once, within 2 weeks of completing the intervention
• Provider surveys	Aim 4: Impact of TACTICS on site-level implementation factors	• Nine repetitions, once every 10 weeks
• TACTICS implementation strategy fidelity tracking	Aim 6a: Strategies used at sites where PE receipt increased versus sites with neutral/negative impact Aim 6b: Impact of TACTICS over and above provider training on PE fidelity	• About 20 repetitions, once per week, every week during the 5-month TACTICS intervention period

Notes. BHDP = Behavioral Health Data Platform; CFIR = Consolidated Framework for Implementation Research; EHR = electronic health record; PCL-5 = Posttraumatic Stress Disorder Checklist for *DSM-5*; PE = prolonged exposure therapy; TACTICS = Targeted Assessment and Context-Tailored Implementation of Change Strategies. Provider surveys include the measures mentioned in the provider survey section.

used to control for variance in the cluster level model, as well as in analyzing provider level aims.

2.10.2. Attitudes towards PE

Attitudes toward PE will be assessed with a 38-item measure of current treatment practices, beliefs about the effectiveness of PE, self-confidence in delivering PE, and perceptions about patient factors that would influence providers' decision to use PE. This measure, developed by the study team, has been shown to predict both initial adoption [26] and sustained use of PE [6]. Attitudes toward PE will be measured as part of Aim 4 and Aim 5 (exploratory aims).

2.10.3. Professional quality of life scale – 5 (ProQOL-5)

Provider burnout will be assessed with this 30-item self-report, which measures the frequency with which providers have experienced compassion fatigue, burnout, and secondary traumatization within the past 30 days [27]. It is comprised of three subscales—secondary traumatic stress, compassion fatigue, and burnout—and uses a 5-point Likert scale ranging from 1 ("never") to 5 ("very often"). We will be using five items from the PRO-QOL-5 (items 2, 9, 12, 21, and 24; one item from the burnout scale, two from the compassion fatigue scale, and two from the secondary traumatic stress scale) selected based on their face validity to examine the impact of TACTICS on provider QOL.

2.10.4. Implementation climate scale (ICS)

The ICS is an 18-item scale measuring six dimensions of implementation climate: focus on EBP, educational support for EBP, recognition for EBP, rewards for EBP, selection of new staff members based on experience delivering the target EBP, and selection of new staff members based on adaptability [28]. Items are scored on a 5-point scale 0 ("not at all") to 4 ("very great extent"). We will be using 11 of the 18 items. Items were eliminated to reduce repetitiveness and further align the measure with the current study. This outcome measure pertains to both the cluster and provider levels.

2.10.5. Implementation leadership scale – leadership and staff versions (ILS)

The ILS is a 12-item measure of actual or perceived leadership support for an implementation intervention [29]. The leadership and staff versions of the scale are identical, except that questions in the leadership version are phrased in first-person (e.g., "I have developed a plan to facilitate the implementation of PE"). For each version of the scale, we will be using nine of the 12 items. Items were eliminated to reduce repetitiveness and further target the measure to the current study. This outcome measure pertains to both the cluster and provider levels.

2.10.6. Summative feedback interviews

Within 2 weeks of the conclusion of the 5-month TACTICS implementation period, hospital leadership, providers, and administrative staff will be invited to participate in a 1-h, individual feedback interview by telephone. The feedback interview is voluntary and will be audio-recorded unless the interviewee requests otherwise; the interviewer will also take notes on interviewee responses. Questions will address the interviewee's perception of the TACTICS program compared with training-as-usual, barriers and facilitators to implementing TACTICS, thoughts regarding future PE implementation at their site, as well as improvement of the TACTICS program. Responses will be coded thematically and analyzed at the cluster level to address Aim 3 and exploratory Aim 6a.

2.11. Dissemination/Implementation activities

In this study, dissemination and implementation activities include provider training as usual and the TACTICS implementation program.

2.11.1. PE training as usual

To evaluate the incremental effects of TACTICS over and above training as usual, providers at each site will be trained in PE prior to initiating TACTICS via a 2-day, in-person training workshop using the standard model employed across the MHS. After completing the training, providers will have access to weekly telephone consultation, as per usual training procedures. New providers who join site staff after the in-person training will be invited to complete an online training workshop in PE, which has been shown to be equally effective as a face-to-face workshop in increasing knowledge about PE, as well as self-perceived readiness and self-confidence in delivering PE [30].

2.11.2. TACTICS

The 5-month TACTICS phase of the project includes four components: (a) identification of a local champion and implementation team; (b) needs assessment; (c) collaborative selection of implementation targets; and (d) execution of the implementation plan with support from an external facilitator.

2.11.3. Development of TACTICS

TACTICS is an innovative barrier-to-solution tailoring framework that is designed to be flexibly applied at each of the eight sites and which leverages a partnership among implementation practitioners, researchers, and local site staff to accomplish changes in BH practices. The TACTICS rubric is based on prior practical experience from EBP implementation efforts at over 20 military installations. Through these prior efforts, the Center for Deployment Psychology developed a Lessons Learned Manual that identified common barriers to EBP implementation that may operate in MHS sites and that suggested strategies and tools to overcome those barriers [5]. In addition, the Center for Deployment Psychology developed a Clinic Optimization Program that uses local MTF data [31] to examine patterns of service utilization within individual BH sites to inform efforts to change current practices.

In developing the TACTICS rubric, the study team enriched the Center for Deployment Psychology's Lessons Learned Manual and Clinic Optimization Program by integrating additional strategies informed by implementation science, particularly the Expert Recommendations for Implementing Change (ERIC) project [13]. Additional strategies that were appropriate to both the military context and the relatively short timeframe for the TACTICS intervention were also selected. The result was the version of the TACTICS rubric that will be used in the study, which recommends 140 potential implementation strategies (proximal targets for change and strategies to enact those changes) to address 17 specific potential barriers. One purpose of the study is to further develop and refine the TACTICS rubric based on observations and lessons learned at each of the eight study sites in order to produce a final rubric for potential scale-up and dissemination as an implementation intervention.

Most strategies included in the rubric are accompanied by one or more tools in the implementation toolkit designed to assist MTFs in enacting change at their site to support implementation of the target EBP. While some barriers (and thus TACTICS strategies) relate to exposure therapy specifically, most of the rubric is comprised of barriers and strategies that could be used to increase the use of any EBP in BH care settings. Of note, although PTSD was the target diagnosis for the study, the DoD's request for proposals did not indicate which EBP would be the focus of the implementation study. DoD selected PE as the EBP to be implemented only after the contract was awarded.

2.11.4. Local champion

TACTICS will use a volunteer site champion to work with the TACTICS implementation coach – essentially an external facilitator – in the implementation of site-specific strategies selected during the needs assessment. That local champion is a provider or administrator who has support from local leadership to act as a change agent at the target site. The site champion will also be encouraged to identify additional key

personnel at their site who should be involved core members of an implementation team.

2.11.5. Needs assessment

TACTICS includes a targeted needs assessment, in which local stakeholders are interviewed to identify implementation barriers and potential facilitators. The needs assessment begins with generating a report on service utilization at the site through the Clinic Analyzer Tool, an MS Office-based program developed by the Center for Deployment Psychology, to better understand patient flow through the site. This is followed by a coordinated set of 1-h, semi-structured, needs assessment interviews with key MTF staff (site and team leaders, front-line providers, scheduling personnel) selected to represent a range of perspectives. The interviews are voluntary. Interviewers will take notes on interviewees' responses, and interviews will be audio-recorded unless the interviewee requests otherwise. See Table 2 for a sample list of questions included in the needs assessment and feedback interviews.

2.11.6. Implementation plan

The TACTICS team (on-site interviewers in consultation with implementation science experts and the PIs) will review results of the Clinic Analyzer Tool report and needs assessment interviews to identify the 3–5 most important barriers to implementation of PE. The team will then use the TACTICS rubric to identify potential actions (proximal targets for change and strategies to enact those changes) to address those barriers.

The TACTICS team will share their preliminary findings with leadership and will work collaboratively with leadership and the site champion to select one or more strategies to address each barrier and its identified cause(s). The site champion and leadership will also identify other stakeholders who need to be engaged to affect each change. See Table 3 for an example of the TACTICS rubric.

2.11.7. Execution of implementation plan

Over the course of the 5-month TACTICS phase, the TACTICS coach (external facilitator) will support the site champion in making the specific changes to accomplish the goals identified in the plan. The coach will conduct weekly calls with the champion to review progress and troubleshoot issues regarding implementation at the site. The coach will take structured notes and all calls will be audio recorded if attendees consent.

2.11.8. Fidelity and process monitoring

Fidelity monitors will use three sources of data to evaluate how TACTICS was implemented at each site: the initial report and recommended actions developed during the needs assessment, the TACTICS coaches' structured notes and call logs, and audio recordings of the coaching calls. These will each be analyzed to determine to how fully core elements of TACTICS were implemented. These elements include having a site champion who is engaged and has support from local leadership, establishment of a site implementation team, completion of needs assessment interviews, the TACTICS study team suggesting recommended actions to address specific barriers identified in the needs assessment, the coach and champion collaboratively selecting and prioritizing actions to be taken, occurrence of weekly telephone calls between the coach and site champion, and the extent to which coaching call content addresses progress on the actions and priorities outlined in the site's plan.

Table 2
Sample needs assessment interview and feedback interview questions.

Needs assessment interview questions
- How are patients assigned to therapists? (i.e., how do patients get assigned to you rather than to someone else?)
- How do you decide which treatment to provide to a patient with PTSD?
- Has PE worked well for the service members seen by your team?
  - o PROBE: Which patient characteristics might make someone a good or poor candidate for PE?

Feedback Interview Questions
- How effective do you think the TACTICS process was for your site?
- What challenges did you encounter in implementing the TACTICS program?
- How will your site implement prolonged exposure therapy moving forward?

Note. PE = prolonged exposure therapy; PTSD = posttraumatic stress disorder; TACTICS = Targeted Assessment and Context-Tailored Implementation of Change Strategies. The questions included in this table are samples and are representative of the content included in the needs assessment interview and feedback interviews. As each interview is semi-structured; probes may be included for each question.

2.12. Data analysis plan

Statistical modeling of data from a stepped-wedge design has been well described in the literature [19,32,33]. Statistical analyses will be conducted using both SAS 9.4 and the R statistical programming language [34,35]. Prior to developing statistical models, an examination of the univariate distribution of variables will be conducted. To account for nesting in the data structure (i.e., patients and providers nested in MTFs), mixed effect multi-level models will be developed where MTF is included as a random effect. Prior to building statistical models, we will compare patients in each MTF cluster with respect to patient, providers, and facility characteristics.

2.12.1. Statistical model for aim 1

The effect of TACTICS on the proportion of PTSD patients who receive PE will be examined through a Generalized Linear Mixed Model (GLMM) with random cluster (MTF) level effects. A binary, fixed effect for treatment exposure (1 = “exposed”, 0 = “not exposed”) will allow for the comparison of study results from exposed and unexposed observation periods [19]. Time will be included as a fixed effect to assess the added or reduced impact of TACTICS across time [33]. The statistical models will be fit with the LME4 package using R software or through SAS PROC GLIMMIX. Tests will use a 2-sided level of significance, $p = .05$.

2.12.2. Statistical model for aim 2

The impact of TACTICS over and above conventional EBP training on mean improvement in MTF patient's scores on the PCL-5 will be addressed with a General Linear Mixed Model where the outcome is the mean improvement in PCL-5 scores. The predictors in the base model will be identical to those for Aim 1. The specific structure of the models will be determined by examination of the distribution of change scores.

2.12.3. Content analysis for aim 3

To evaluate the usability of and stakeholder satisfaction with TACTICS, we will conduct a qualitative thematic content analysis of responses to the feedback interviews [36,37]. Transcribed data will be imported into an analytic software program, NVivo, to facilitate data analysis. To discern salient themes, data analysis will follow a series of iterative steps characteristic of qualitative methodology. Procedures to enhance rigor and credibility in qualitative analysis will be used including transparency of method, maximization of validity (attention to deviant cases), maximization of reliability, constant comparison within the data and within a case, and a reflexive approach to analysis [36,37].

2.12.4. Analysis of aims 4 and 5

To analyze the impact of site- and provider-level factors on implementation of PE, General and Generalized Linear Mixed Effects Repeated Measures models will be developed, with providers (a random effect) nested within site. Moderator analysis will assess whether contextual factors prior to TACTICS (e.g., staff workload, staff stress, leadership support for implementation) moderate the effect of TACTICS on implementation of PE. Mediational analyses will also be performed to assess whether changes in proximal variables (e.g., changes in clinician

Table 3
Example from the TACTICS Rubric.

Identified barrier	Causes	TACTICS Strategies
Too many patients in the system (not enough appointments)	Providers pulled away from patient care Not enough individual appointments	Reduce amount of time dedicated to nonclinical activities Expand group therapy offerings Limit influx of new cases, especially mild

Note. BHT = behavioral health technicians; TACTICS = Targeted Assessment and Context-Tailored Implementation of Change Strategies. Barriers, causes, and TACTICS strategies listed in the rubric are primarily derived from the Center for Deployment Psychology's Lessons Learned Manual, although additional barriers and strategies were added.

perceptions of PE; changes in leadership support for implementation) predict subsequent changes in use of PE. Finally, we will compare the proximal targets for change and the specific implementation strategies used at each site to determine whether any particular strategies appear to be associated with larger improvements in use of PE.

3. Discussion

Successful implementation of EBPs for PTSD will likely improve military readiness by increasing the number of service members who successfully return to duty with reduced PTSD symptomatology. Successful implementation of EBPs for PTSD may also improve patient flow through the behavioral healthcare system in the MHS. Further, successful treatment of service members prior to separation from the military may reduce the burden on VA healthcare and disability systems.

EBPs are complex interventions, and their implementation can be impeded by numerous factors at the patient, provider, and local organizational levels. Given the multiplicity of potential barriers to address, a key challenge is determining which barriers to target and what strategies to use at any given site. TACTICS endeavors to combine a field-based understanding of the barriers commonly encountered in military behavioral health settings with implementation science expertise on potential ways of addressing those barriers, with the aim of enabling a collaborative dialogue with local stakeholders to prioritize targets for change to increase EBP use. This effort aims to develop and validate a replicable and scalable process for collaboratively developing site-specific intervention plans and using external facilitation to enact that plan. The results of this study will help define the parameters of an evidence-informed implementation model that may be used across the MHS. Incorporating measures of implementation climate, leadership engagement, and staff perceptions of the TACTICS program will enable us to test (a) whether change strategies targeting these factors are effective and (b) whether changing these proximal factors results in greater EBP penetration and effectiveness.

Moreover, this study will contribute to the broader literature on matching implementation strategies to identified barriers. Having an explicit process for matching strategies to barriers provides a framework for evaluating whether change strategies had their intended effects on the identified barriers, enabling us to refine our strategy-matching procedures over time. By balancing the need for site-specific approaches to implementation with the standardization offered by the needs assessment and rubric, the TACTICS program intends to be scalable. If TACTICS proves effective, this approach could be used throughout the MHS and other healthcare systems to increase implementation of a broad range of evidence-based psychotherapies.

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Trial status

The study protocol was approved by the Stanford University Institutional Review Board (IRB of Record, Protocol # 45031) on May 15, 2019, in compliance with all applicable federal regulations governing the protection of human subjects. The study protocol is currently under review at the military IRBs overseeing research at each of the performance sites. All study staff, including investigators at military installations, have completed the requisite human subjects training preparatory to research. This paper outlining the methodology for conducting the study is an activity preparatory to research, not requiring IRB approval.

Availability of data and materials

The Lessons Learned Manual referenced in the creation of the TACTICS rubric is publicly available from https://deploymentpsych.org/system/files/member_resource/Lessons_Learned_Manual_0.pdf.

Competing interests

David Riggs reports investments in Johnson & Johnson and Procter & Gamble. All other authors declare that they have no competing interests.

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Disclaimer

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