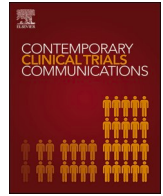


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Identifying suicidal subtypes and dynamic indicators of increasing and decreasing suicide risk in active duty military personnel: Study protocol

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ABSTRACT

Objectives: Several recent studies have demonstrated that posttraumatic stress disorder (PTSD) and insomnia treatments are associated with significant reductions in suicidal ideation (SI) among service members. However, few investigations have evaluated the manner in which suicide risk changes over time among military personnel

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Active duty military personnel
Posttraumatic stress disorder (PTSD)

receiving PTSD or insomnia treatments. This paper describes the study protocol for a project with these aims: (1) explore potential genetic, clinical, and demographic subtypes of suicide risk in a large cohort of deployed service members; (2) explore subtype change in SI as a result of evidence-based psychotherapies for PTSD and insomnia; (3) evaluate the speed of change in suicide risk; and (4) identify predictors of higher- and lower-risk for suicide. **Methods:** Active duty military personnel were recruited for four clinical trials (three for PTSD treatment and one for insomnia treatment) and a large prospective epidemiological study of deployed service members, all conducted through the South Texas Research Organizational Network Guiding Studies on Trauma and Resilience (STRONG STAR Consortium). Participants completed similar measures of demographic and clinical characteristics and subsets provided blood samples for genetic testing. The primary measures that we will analyze are the Beck Scale for Suicide Ideation, Beck Depression Inventory, and the PTSD Checklist for DSM-IV. **Discussion:** Results from this study will offer new insights into the presence of discrete subtypes of suicide risk among active duty personnel, changes in risk over time among those subtypes, and predictors of subtypes. Findings will inform treatment development for military service members at risk for suicide.

List of abbreviations

AUDIT	Alcohol Use Disorders Identification Test	PCL-S	PTSD Checklist – Stressor-Specific Version
BAI	Beck Anxiety Inventory	SSI	Beck Scale for Suicidal Ideation
BCT	Brigade Combat Team	LEC	Life Events Checklist
BDI-II	Beck Depression Inventory-II	PERI	Psychiatric Epidemiology Research Interview Life Events Scale
CBTi	Cognitive Behavioral Therapy for Insomnia	PHQ-15	Patient Health Questionnaire 15-Item Somatic Symptom Severity Scale
CERQ	Cognitive Emotional Regulation Questionnaire–Short	PCT	Present-Centered Therapy
CPT	Cognitive Processing Therapy	PI	principal investigator
C-SSRS	Columbia-Suicide Severity Rating Scale	PSS-I	Posttraumatic Symptom Scale–Interview Version
CTS2	Revised Conflict Tactics Scale	PTCI	Posttraumatic Cognitions Inventory
DRRI-ABE	Deployment Risk and Resilience Inventory Aftermath of Battle Experiences	PTSD	posttraumatic stress disorder
DRRI-CE	Deployment Response and Resilience Inventory Combat Exposure Scale	RCT	randomized controlled trial
DRRI-DE	Deployment Risk and Resilience Inventory Deployment Environment Scale	RSES	Response to Stressful Experiences Scale
DSM-IV-TR	<i>Diagnostic and Statistical Manual of Mental Disorders, 4th Edition, Text Revision</i>	SASS-Y	Self-Assessment of Sleep Survey–Split
ESS	Epworth Sleepiness Scale	SB	suicide behaviors
FON	Frequency of Nightmares	SI	suicide ideation
FVT	fluid vulnerability theory	SNP	single nucleotide polymorphism
HHI	History of Head Injury	S-PE	spaced Prolonged Exposure therapy
ICC	intraclass correlation	SSI	Beck Scale for Suicide Ideation
ISEL-12	Interpersonal Support Evaluation List – 12	STAXI-S	State Trait Anger Expression Inventory–State Version
ISI	Insomnia Severity Index	STRONG STAR	South Texas Regional Organizational Network Guiding Studies on Trauma and Resilience
MCC	minimal contact control	TRGI	Trauma-Related Guilt Inventory
M-PE	massed Prolonged Exposure therapy	US	United States of America
		VR-12	Veterans RAND 12-Item Health Survey
		WRAIR	Walter Reed Army Institute of Research

Suicide mortality rates in the military exceeded those of civilians from 2008 to 2015 [1]. Posttraumatic stress disorder (PTSD) and sleep disorders are risk factors for suicidal thoughts and behaviors among active duty military personnel [2]. Although suicide prevention strategies significantly reduce risk of suicide ideation (SI) and suicide behaviors (SB) for many individuals [3,4], these strategies are not universally efficacious. Treatment studies rarely unpack mean effect sizes to determine trajectories of change in suicide risk. For example, some service members may have periodic significant escalations in suicide risk, while others experience routine but not clinically significant variability. If the characteristics of the former group could be identified, prevention efforts with greater precision could be utilized.

According to the fluid vulnerability theory (FVT) of suicide [5], suicide risk entails both dynamic and stable properties. This theory posits that individuals with lower risk profiles gravitate toward a single stable state: low risk. In contrast, individuals with high risk profiles gravitate toward two opposing stable states: one characterized by lower risk and one characterized by higher risk. However, it is likely that there are more complex subtypes. For example, a recent study identified three

subtypes of suicide risk, namely: SI without SB, SB without SI, and both SI and SB [6]. FVT also hypothesizes that suicide risk follows a discontinuous, nonlinear process [7]. Different types of nonlinear processes may characterize different risk states [8]. If so, improved understanding of these change processes could improve assessment and treatment.

Identifying subtypes of individuals at high risk may involve not only important environmental stressors but also inherited biological vulnerability. Genetic factors account for approximately 50% of the risk of both suicidal behaviors [9] and death [10,11]. However, a recent large study indicated suicide attempts were associated with polygenic risks also associated with psychiatric conditions and behavioral traits [12].

Consistent with the FVT, we will use novel data analytic methods to examine change processes associated with lower and higher suicide risk states among active duty service members who participated in either clinical trials of PTSD treatments or a pre-to post-deployment epidemiological study [13–17]. We have four hypotheses. First, we hypothesize that three subgroups will be significantly differentiated by serotonin- and cortisol-related genes, demographic variables, and clinical variables, namely those reporting SI without SB, those reporting SB with

highly variable SI prior to attempts, and those reporting SB with discontinuous pathways to attempts. Prior research suggests that individuals who endorse SI without SB tend to have different clinical characteristics than individuals with both SI and SB, who also have different clinical characteristics than individuals with a history of SB but no SI [19]. However, because of the likelihood of multiple genetic subtypes, we expect that additional subtypes may be found through a more comprehensive genome-wide analysis. Second, we hypothesize that change over time associated with higher suicide risk will be characterized by greater stability (faster return to the original set-point, or typical level, similar to a point of homeostasis), whereas lower suicide risk will be characterized by weaker stability (slower return to the original set-point). Third, movement from lower to higher suicide risk states will be characterized by more sudden change patterns in SI and risk factors, compared to movement from higher to lower suicide risk states. Finally, we hypothesize that change in depression and PTSD symptoms over time will differentiate higher and lower risk states.

1. Methods

1.1. Participants

In all four randomized controlled trials (RCTs), participants were active duty US military personnel, activated Reservist, or activated National Guard members who had deployed in support of operations in and around Afghanistan and Iraq named Operation Enduring Freedom (OEF)/Operation Iraqi Freedom (OIF)/Operation New Dawn. Participants provided consent for each study and to have their data stored in the STRONG STAR Consortium data repository.

Inclusion Criteria. Inclusion criteria were similar across all four studies: (1) active duty service members or activated Reservist or National Guard who had at least one deployment, (2) at least 18 years of age (and younger than 65 years old in study by Foa and colleagues [13]), and (3) able to speak and read English. In addition to these inclusion criteria, all 3 PTSD clinical trials required a current (i.e., past month) diagnosis of PTSD according to the *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Text Revision* (DSM-IV-TR; American Psychiatric Association [18]). Diagnosis was established via the PTSD Symptom Scale-Interview Version (PSS-I [20]) which was administered by trained evaluators who were monitored for fidelity. Exposure to a combat trauma or other type of trauma during deployment was required. For the study by Taylor and colleagues [14], participation required a diagnosis of chronic insomnia, stabilization on continuous positive airway pressure therapy for at least 4 weeks, if relevant, less than 85% sleep efficiency on a sleep diary, and correct use an actigraphy device and sleep diary. To maximize generalizability, exclusion criteria across all four studies were minimal. Individuals were ineligible if they were incapable of providing informed consent due to a psychiatric or medical condition (e.g., mania, or psychosis; traumatic brain injury resulting in severe cognitive impairment) or if they had alcohol dependence (only in Foa and colleagues) [13], or suicidal ideation warranting immediate attention.

Exclusion based on imminent suicide risk warranting immediate attention. Supplemental file 1 outlines the decision tree used for determining whether a participant should be considered for exclusion on the basis of imminent suicide risk. In Taylor and colleagues [14], nine participants were excluded on the basis of suicide risk, whereas zero were excluded from Foa and colleagues [13], and one was excluded from each of the two Resick and colleagues RCTs [15,16]. In Resick and colleagues [15], participants were required to have been stabilized on psychiatric medications for 6 weeks prior to study entry, and they were requested not to change their medications during study participation; Taylor and colleagues [14] required medication stabilization for 4 weeks. Participants were excluded if it had been less than 3 months since their return from deployment or if they were pregnant, chronically sleep-deprived, reporting hypersomnia, reporting circadian rhythm

disorders, working rotating shifts, or working in a shift earlier than 6:00 a.m. In all studies, support was obtained from the service member's commander to participate in the study during normal duty hours.

Sample Size. Sample sizes of all four RCTs for the intent-to-treat sample were as follows: Foa and colleagues [13]: spaced Prolonged Exposure (S-PE) $n = 109$, massed PE (M-PE) $n = 110$, Present-Centered Therapy (PCT) $n = 107$, minimal contact control (MCC) $n = 40$; Resick and colleagues [16]: group Cognitive Processing Therapy-Cognitive Only (CPT) $n = 56$, group PCT $n = 52$; Resick and colleagues [15]: group CPT $n = 133$, individual CPT $n = 135$; Taylor and colleagues [14]: in-person Cognitive Behavioral Therapy for Insomnia (CBTi) $n = 33$, internet-delivered CBTi $n = 34$, MCC $n = 33$.

The fifth study, by Williamson and colleagues ($n = 4,119$), was a large prospective cohort epidemiological study of PTSD in active duty service members who were assessed pre- and post-deployment. Inclusion criteria were as follows: (1) English-speaking; (2) active duty, activated Reserve, or activated National Guard service members of any branch of the US military; and (3) scheduled for deployment in support of OEF/OIF. About half of the participants ($n = 2,192$) completed the post-deployment assessment.

1.2. Research design

Three of the studies were RCTs (NCT01286415, NCT01049516, and NCT02173561) in which active duty service members with PTSD were recruited, and one study was an RCT with active duty service members with chronic insomnia (NCT01549899). The fifth study was a naturalistic observation study in which military service members were assessed at pre- and post-deployment, in which nonsuicidal individuals will serve as controls for genetic analyses. One design consideration was to only focus on secondary data analyses from the RCTs. However, because the STRONG STAR Consortium uses Common Data Elements to assess key constructs across all our studies and because of the large sample size in our pre-post deployment epidemiology cohort, we thought it would be of considerable interest to include the pre-post deployment study as well.

1.3. Sampling, eligibility, and recruitment

Similar recruitment strategies were used across the four RCTs that were all conducted at the Fort Hood US Army installation in Killeen, Texas. In all studies, direct advertising to service members was conducted, and study staff also received referrals from military providers. For the epidemiological study, service members were recruited from units deploying from Fort Hood to either Iraq or Afghanistan between November 2010 and May 2011. Service members were recruited from the 1st Brigade Combat Team (BCT), 2nd BCT, 3rd BCT, the 1st Air Cavalry Brigade of the 1st Cavalry Division, or from the 504th Military Intelligence Brigade. The only requirement to be included in the study was deployment during the next month and informed consent.

1.4. Therapeutic interventions

Foa and colleagues' [13] RCT included four conditions: M-PE, S-PE, PCT and MCC. PE includes psychoeducation, breathing retraining, and imaginal exposure (repeated recounting of a traumatic memory), followed by processing thoughts and feelings related to the imaginal experience, and in-vivo exposure (approaching trauma-related situations). The therapy also includes daily homework practice, such as listening to audio recordings of the imaginal exposure and in-vivo exposure practice. For M-PE, sessions were administered on 10 consecutive weekdays over 2 weeks, and for S-PE, sessions were delivered over 8 weeks: six sessions were delivered once weekly, and two were delivered twice weekly during the first and last weeks. PCT is a non-trauma-focused, manualized treatment that controls for nonspecific therapeutic factors. Ten 90-minute sessions were scheduled similarly to

S-PE and focused on current life problems. MCC consisted of 10- to 15-minute therapist telephone calls once weekly for 4 weeks in which participants were asked about their well-being and were offered support as needed.

Resick and colleagues' [16] RCT included two conditions: group CPT and group PCT, each administered in twelve 90-minute, twice-weekly sessions. Prior to starting therapy, participants met individually with therapists to confirm their index trauma. CPT is a cognitive therapy focused on beliefs about the causes and consequences of a trauma, on differentiating thoughts from facts, and on labeling thoughts, events, and emotions using Socratic questioning and worksheets. For group PCT, the group selected a theme for discussion at each session (e.g., isolation, going into crowds) and generated and evaluated possible solutions to practice. Any discussion of the trauma was redirected back to the present time. Exposure to feared situations, if generated as a strategy by patients, was not forbidden. Participants were dropped from treatment if they missed four sessions. Randomization occurred when 16 to 20 participants were enrolled, with eight to 10 participants per group (two groups running concurrently, six total cohorts).

Resick and colleagues' [15] RCT included two treatment conditions:

group CPT and individual CPT. Both conditions included 12 sessions, and the content was identical to Resick and colleagues' [16] prior group CPT protocol (described above). Groups met twice weekly for twelve 90-minute sessions, whereas individual sessions were twice weekly for twelve 60-minute sessions.

Taylor and colleagues' [14] RCT included three conditions: individual CBTi; unguided, internet-delivered CBTi; and MCC. Both CBTi conditions included six, weekly, 60-minute sessions focused on stimulus control, sleep restriction, sleep hygiene, relaxation training, problem solving and cognitive restructuring. Content was kept as similar as possible across the two CBTi conditions, and the internet-delivered CBTi included interactive components based on participants' responses and sleep diary information. For MCC, participants received three 5-minute check-in calls every other week for 6 weeks. The internet-delivered CBTi group also had biweekly check-in calls with the project coordinator.

1.5. Assessments

Common data elements [21] were assessed across each of the RCTs as well as study-specific assessments of particular interest. Assessments

Table 1
Common data elements across STRONG STAR consortium studies.

Measure	Variable Assessed	Williamson	Resick (2015)	Resick (2017)	Foa (2018)	Taylor (2017)
Suicide						
C-SSRS	Suicidal behaviors, suicide ideation	X	X	X	X	X
SSI	Suicidal behaviors, suicide ideation		X	X	X	X
BDI-II item 9	Suicide ideation	X	X	X	X	X
Environmental						
DRRI-CE	Trauma	X	X	X	X	X
DRRI-ABE	Trauma	X	X	X	X	X
DRRI-DE	Deployment environment	X	X	X	X	X
LEC	Trauma	X	X	X	X	X
PERI	Non-traumatic stress	X	X	X	X	X
Psychiatric						
BAI	Anxiety	X	X	X	X	X
BDI-II	Depression	X	X	X	X	X
PCL-S	PTSD	X	X	X	X	X
AUDIT	Alcohol use	X	X	X	X	X
STAXI-S	Anger expression	X	X	X	X	X
TRGI	Guilt		X	X	X	X
PTCI	Trauma-related cognitions		X	X	X	X
CERQ	Emotion regulation		X	X	X	X
Sleep						
ESS	Sleepiness			X	X	X
ISI	Insomnia	X		X	X	X
FON	Nightmares			X	X	X
SASS-Y	Sleep duration			X	X	X
Physical/Medical						
HHI	Head injury	X	X	X	X	X
VR-12	Physical/mental health function		X	X	X	X
PHQ-15	Somatic Symptoms	X	X	X	X	X
Other						
RSES	Coping	X	X	X	X	X
ISEL-12	Social support	X	X	X	X	X
CTS2	Psychological and physical partner violence		X	X	X	X
WRAIR	Social support	X	X	X	X	X
Biological variables						
	PAXgene RNA	X	X	X	X	X
	PAXgene DNA	X	X	X	X	X
	ACD plasma samples	X	X	X	X	X
	PsychArray GWAS	X	X	X	X	X

Note. C-SSRS = Columbia-Suicide Severity Rating Scale; SSI = Beck Scale for Suicide Ideation; BDI-II = Beck Depression Inventory-II; DRRI-CE = Deployment Response and Resilience Inventory Combat Exposure Scale; DRRI-ABE = Deployment Risk and Resilience Inventory Aftermath of Battle Experiences Scale; DRRI-DE = Deployment Risk and Resilience Inventory Deployment Environment Scale; LEC = Life Events Checklist; PERI = Psychiatric Epidemiology Research Interview Life Events Scale; BAI = Beck Anxiety Inventory; BDI-II = Beck Depression Index-II; PCL-S = PTSD Checklist–Stressor-Specific Version; AUDIT = Alcohol Use Disorders Identification Test; STAXI-S = State Trait Anger Expression Inventory–State Version; TRGI = Trauma-Related Guilt Inventory; PTCI = Posttraumatic Cognitions Inventory; CERQ = Cognitive Emotional Regulation Questionnaire-Short; ESS = Epworth Sleepiness Scale; ISI = Insomnia Severity Index; FON = Frequency of Nightmares; SASS-Y = Self-Assessment of Sleep Survey–Split; HHI = History of Head Injury; VR-12 = Veterans RAND 12-Item Health Survey; PHQ-15 = Patient Health Questionnaire 15-Item Somatic Symptom Severity Scale; RSES = Response to Stressful Experiences Scale; ISEL-12 = Interpersonal Support Evaluation List – 12; CTS2 = Revised Conflict Tactics Scale; WRAIR = Walter Reed Army Institute of Research Military Vertical & Horizontal Cohesion Scales; RNA = ribonucleic acid; DNA = deoxyribonucleic acid; ACD = anticoagulant citrate dextrose; GWAS = genome-wide association study.

were conducted and monitored through the STRONG STAR Consortium (see Table 1). Only assessments relevant to the goals of this project are discussed herein, but this is not intended to represent a comprehensive list.

1.6. Suicide measures

Columbia-Suicide Severity Rating Scale (C-SSRS). [22] The C-SSRS is a clinician-rated measure of suicide risk with three subscales: Suicidal Ideation, Intensity of Ideation and Suicidal Behavior. The Suicidal Ideation and Behavior subscales are comprised of binary items, whereas the Intensity of Ideation subscale is a Guttman scale reflecting increasing levels of intensity. The measure has strong psychometric properties, including high sensitivity and specificity for suicidal behavior classification and strong convergent and divergent validity with other measures. The C-SSRS is sensitive to change over time and is therefore ideally suited as a primary outcome measure. In all studies, the baseline assessment queried about the most severe lifetime episode of suicidal ideation or behavior, whereas the follow-up assessments measured the time since last assessment. While some recent psychometric research has demonstrated poor performance of the intensity of ideation subscale on the C-SSRS, the suicidal ideation and suicidal behavior subscales have stronger psychometric support and will therefore be used in this study, whereas the intensity of ideation subscale will not [23].

Beck Scale for Suicide Ideation (SSI). [24] The SSI is a 21-item, self-report measure of suicidal ideation, suicide attempts, and suicide behavior more generally, rated on a 0- (least severe) to 2-point (most severe) Likert scale. Participants are given three statements describing types of suicidal ideation, ranging in severity, and are asked to rate which of the four statements provided describes how they felt in the past week. The SSI has high product-moment correlations with clinician ratings of SI (0.90) and high internal consistency ($\alpha = .93$) in outpatients and psychiatric inpatients [25]. This measure was administered at each session referencing suicidal ideation and behavior in the past week. For M-PE, the SSI was administered every other session.

Beck Depression Inventory-II (BDI-II). [26] The BDI-II is a 21-item, self-report measure of depression. The measure has strong psychometric properties, including test-retest reliability ranging from 0.73 to 0.96 and strong convergent and divergent validity [27]. Item 9 is a suicide item rated on Likert scale, ranging from 0 (“I don’t have any thoughts of killing myself”) to 3 (“I would kill myself if I had the chance”). The baseline and follow-up administrations reflected the prior 2 weeks, whereas administration at treatment sessions reflected “the time since we last saw you” or “in the past week.” In M-PE, the BDI-II was administered every other session.

1.7. Exposure to stressors

The following deployment exposure variables were collected: Deployment Risk and Resilience Inventory Combat Experiences (DRRI-CE) [28]; Deployment Risk and Resilience Inventory Aftermath of Battle Experiences (DRRI-ABE) [28]; Deployment Risk and Resilience Inventory Deployment Environment Scale (DRRI-DE) [28]. In addition, participants were administered the Life Events Checklist (LEC) [29] and the Psychiatric Epidemiology Research Interview (PERI) Life Events Scale [30].

1.8. Psychiatric Variables

The following psychiatric variables were collected: PTSD Checklist-Stressor-Specific Version (PCL-S) [31]; Beck Anxiety Inventory (BAI) [32]; Alcohol Use Disorders Identification Test (AUDIT) [33]; State Trait Anger Expression Inventory-State Version (STAXI-S) [34]; The Trauma-Related Guilt Inventory (TRGI) [35]; Posttraumatic Cognitions Inventory (PTCI) [36]; Cognitive Emotional Regulation

Questionnaire-Short (CERQ) [37]; Epworth Sleepiness Scale (ESS, except in Resick and colleagues [16]) [38]; Insomnia Severity Index (ISI, except in Resick and colleagues [16]) [39]; Frequency of Nightmares (FON, except in Resick and colleagues [16]) [40]; Self-Assessment of Sleep Survey-Split (SASS-Y, except in Resick and colleagues [16]) [41]; and Response to Stressful Experiences Scale (RSES) [42].

1.9. Physical health and functioning variables

The following physical and medical variables were collected: History of Head Injury (HHI) [43]; Veterans RAND 12-Item Health Survey (VR-12) [44,45]; Patient Health Questionnaire 15-Item Somatic Symptom Severity Scale (PHQ-15) [46].

1.10. Other variables

The following variables were also collected: Interpersonal Support Evaluation List-12 (ISEL-12) [47], to assess social support; the Revised Conflict Tactics Scale (CTS2) [48], to measure aggressive behaviors and the Walter Reed Army Institute of Research (WRAIR) Military Vertical & Horizontal Cohesion Scales [49] to measure current unit social climate.

1.11. Biological variables

Genotyping will be done using a highly informative, customizable, genome-wide array, the Illumina Global Screening Array (<https://www.illumina.com/products/by-type/microarray-kits/infinium-global-screening.html>). This array has multi-ethnic genome-wide content, maximizing our ability to detect variants across individuals of different ethnic backgrounds. It also contains selected variants with established disease associations, allowing potential immediate associations with disease-relevant functional variants. Finally, it is fully customizable, allowing comprehensive tests of the cortisol and serotonergic gene pathways. Genotyping quality control will be performed using single nucleotide polymorphism (SNP) clustering in the Illumina Genome Studio software (<https://www.illumina.com/techniques/microarrays/array-data-analysis-experimental-design/genomestudio.html> accessed 2/2019). SNPs will be retained if the GenTrain score is > 0.5 and the Cluster Separation score is > 0.4 . SNPs will then be converted to HG19 plus strand and subjected to additional generally accepted quality control tests (e.g., poorly performing SNPs, poorly performing samples, linkage disequilibrium, Hardy Weinberg equilibrium) using the PLINK software package [50]. Subsets with specific genetic ancestry will be determined using principal components analysis [51] matching to the 1000 Genomes genomic reference data [52]. Genetic subtypes can then be tested within and across ancestry groups.

1.12. Setting and personnel

Therapists and therapy training. Study therapists were either credentialed psychologists, credentialed social workers, or postdoctoral fellows. Depending on the standardized training procedures for each therapy, therapists attended a 2- to 4-day didactic and participatory workshop on the study protocol. In all four RCTs, therapists completed 2 supervised training cases. All therapy sessions were video-recorded for supervision and adherence monitoring, and all studies included weekly consultation calls to promote fidelity and supervision.

Evaluators and evaluator training. For all clinical interviews, assessors with either a master’s or doctoral degree in psychology completed an in-person training with a licensed clinical psychologist. All evaluations were audio-recorded. Evaluators were blinded to treatment condition in all studies. Evaluators were continuously monitored by the STRONG STAR Assessment Core for fidelity to reduce drift and improve interrater reliability.

Consent, safety, and adverse events. Institutional review board approval was received from each of the participating recruitment sites

and engaged universities. In all four RCTs, a similar procedure was used for documenting adverse events, which included clinically significant untoward changes in physical or mental health since the prior adverse event assessment, including changes in suicide risk [53].

Sample size and recruitment. As reported in Foa and colleagues [13], 526 were assessed for eligibility, of whom 156 (29.7%) were ineligible and 370 were randomized. Of participants randomized, 15 (13.6%) of those in M-PE, 27 (24.5%) of those in S-PE, 13 (11.8%) of those in PCT, and 0 (0%) of those in MCC either dropped out or did not receive the full intervention. As reported in Resick and colleagues [15], 147 participants consented to assessment, 39 (26.5%) individuals were ineligible, and 108 were randomized. Of those randomized to group CPT, 12 (21.4%) dropped out or had to leave the study and 3 (5.4%) never began treatment. Of those randomized to group PCT, 6 (11.5%) dropped out or had to leave the study and 1 (1.9%) never began treatment. As reported in Resick and colleagues [16], 427 consented for assessment, of whom 159 (37.2%) were ineligible, and 268 were randomized. For group CPT, 49 (36.8%) dropped out of treatment or had to leave the study, and an additional 11 (8.3%) never began treatment in group CPT. For individual CPT, 40 (29.6%) dropped out of treatment or had to leave the study, and an additional 13 (9.6%) never began treatment. As reported in Taylor and colleagues [14], 250 service members were assessed for eligibility, with 150 excluded for a variety of reasons and 100 randomized to the three conditions. Of those randomized, 4 (12%) did not complete in-person CBTi, 7 (20.5%) did not complete internet-delivered CBTi, and 4 (12%) did not complete MCC. For the Williamson study [17], 4,119 soldiers were recruited pre-deployment, completed a battery of self-report assessments, and had their blood drawn for genetic studies. A total of 2,192 (53.2%) soldiers were reassessed post-deployment, at which time they completed the same battery of self-report assessments and were interviewed with the C-SSRS and the Structured Clinical Interview for *DSM-IV* diagnoses to assess lifetime episodes of suicidal thoughts and behaviors, PTSD, and other psychiatric conditions.

Procedures. The STRONG STAR Consortium has standard operating procedures addressing the use of common data elements, data collection procedures, and data storage methods. Upon receiving institutional review board approval for the retrospective data analysis identifying suicidal subtypes, database managers at the University of Texas Health Science Center at San Antonio, the data repository custodians, will extract the required variables from the IRB-approved STRONG STAR Repository. Separate coded data files will be created for the studies. Data dictionaries will be assembled.

1.13. Data analysis

Power analyses. We hypothesize that temporal patterns would differ between those with increasing risk and those with decreasing risk. Although the sample sizes for some of the clinical trials appear small ranging from 185 to 360, most of these trials included 10 or more repeated assessments nested within individuals. The primary level of analysis will be suicide ideation scores (i.e., level 1). If we assume a large intraclass correlation ($ICC = 0.50$), the effective sample sizes range from $n = 185$ (Taylor study) to $n = 366$ (Foa study), yielding $> 85\%$ power to detect a small effect ($d = 0.11$). If we assume smaller ICC values, statistical power increases.

Planned analyses. To examine and describe temporal patterns that signal transitions in suicide risk states, we will conduct analyses using data collected from four clinical trials maintained in the STRONG STAR Consortium Data Repository. We will approach analyses informed by a dynamical systems framework to identify temporal patterns associated with the higher and the lower suicide risk states. To conduct these analyses, we will use data from the four clinical trials, all of which have three to 13 repeated assessments of the following scales: SSI, BDI-II, and PCL-S. In addition, all of the trials used the C-SSRS at baseline and all follow-up assessments to identify the occurrence of suicidal behavior.

Finally, a range of environmental, psychological, and medical variables at baseline and follow-up (see Table 1) will be used for secondary analyses.

We will focus our analyses on the SSI, BDI-II, and PCL-S for two primary reasons. First, these three scales were assessed with the highest frequency across all four trials (up to 13 times each). These three scales will therefore provide the greatest precision when modeling nonlinear change processes. Second, because the enrolled samples in the clinical trials were diagnosed with either PTSD or chronic insomnia and both of these conditions frequently co-occur with depression, these variables will enable us to determine if treatments that reduce PTSD, insomnia, depression, and other symptoms also mitigate suicide risk, thereby enabling us to address a priority research objective identified by the National Action Alliance for Suicide Prevention.

Hypothesis 1. (Prediction of subgroups by genetic, clinical, and demographic information) analyses: We will use latent class analysis to characterize subgroups of suicide risk from the pre- and post-deployment study on the basis of a polygenic risk score (PRS), which is a quantitative score reflecting background genetic risk of a trait, as well as clinical variables and demographic variables. For the PRS, each p -value reflects an association of the genotype at that location to the trait in an external study [54]. These p -values are then applied to the genotypes in the current study to create score reflecting the background genetic risk of the trait. We anticipate that in our LCA analyses, one group will be characterized by greater risk, operationalized by more prior suicide attempts and a higher severity on the BSS than other groups. However, the LCA approach has the advantage of being data-driven, and thus these groups will be categorized based on the data as opposed to being categorized by a priori decisions about scores on certain items or measures.

Hypothesis 2. (Change over time and stability in risk) analyses: We will construct a multivariate latent change score model using structural equation modeling [55], with the difference between two consecutive scores calculated for the SSI. These change scores (from time t to time $t+1$) are predicted by the value of the SSI at time t . These changes occurred within each person over anywhere from 2 to 12-time steps (as depicted in Table 2). This results in three simultaneous change equations. Change in each variable is predicted by itself. These forms of equations have been shown to capture differences in overall levels of each variable, variability around these overall levels, and the predictive linkages between variables over time [56]. The differences in level correspond to the representation of being higher or lower overall in a time series while the variability around that level captures differences in

Table 2
Dataset time points.

Study	N	Study PI	Time points	Study type
Genetic and Environmental Predictors of Combat PTSD	4,119	Williamson	2	Naturalistic, prospective cohort
Group CPT vs. Group PCT	108	Resick (2015)	10	RCT
Individual CPT vs. Group CPT	268	Resick (2017)	10	RCT
S-PE vs. PCT; M-PE vs. MCC	366	Foa	3–13	RCT
In-person CBTi vs. internet-delivered CBTi vs. MCC	185	Taylor	3	RCT

Note. PI = principal investigator; PTSD = posttraumatic stress disorder; CPT = Cognitive Processing Therapy; PCT = present-centered therapy; S-PE = spaced Prolonged Exposure therapy; M-PE = massed Prolonged Exposure therapy; MCC = minimal contact control; CBTi = Cognitive Behavioral Therapy for Insomnia; RCT = randomized controlled trial.

the degree to which an individual moves up and down over time. With respect to stability, this approach will quantify homeostatic balance inherent within each variable over time (i.e., the tendency for variables to remain constant or resist change). With respect to dynamism, this approach will also determine how change in each variable is influenced by the other variables.

Hypothesis 3. (Movement from higher to lower risk states) and 4 (Change in depression and PTSD as predictors) analyses. These hypotheses implicate two distinct temporal patterns: one for higher suicide risk and another for lower suicide risk. To test the hypotheses, we will incorporate the above equations into a mixture modeling procedure. We will test coefficients within the model group together as a function of people and time increments. We will specify random effects to allow for variability in slope coefficients, intercepts, variances of the exogenous variables (SSI, BDI-II, and PCL-S at time t), and means of the exogenous variables. Using the coefficients from the mixture models, it will be possible to describe the paths taken by individuals transitioning from lower to higher risk states and vice versa.

A strength of our data analytic approach is that it provides a posterior probability of an individual being in a given group at any given time point. Posterior probabilities can be used to estimate the likelihood of a patient transitioning from one pattern to another at a given point. Such a model can be described as a form of Markov model, captured through a series of equations just like those described above, except now each equation entails the combination of posterior probabilities for each temporal pattern. For example, the posterior probability of a patient in the increasing risk group can be used to estimate the likelihood of him or her transitioning to the decreasing risk group at the next time point. Conversely, posterior probabilities can be used to estimate the likelihood that a given patient at a given time point will transition to the high-risk group at the next time point. This approach also allows for the inclusion of intervention as a predictor of posteriors.

2. Discussion

This study will characterize the classification of suicide risk subtypes and dynamic change in suicide risk over time analyzing data collected from four clinical trials and an epidemiological study, which all have a repeated measures (longitudinal) structure, among active duty military personnel. The goals of the study are to provide evidence about the following: (1) subtypes of suicide risk, (2) temporal change in suicide risk within those subtypes, (3) temporal change when moving from low- to high-risk states, and (4) the degree of association between PTSD, depression and suicide risk. Each of these areas of focus may have some degree of genetic control, which also will be explored. Whereas some studies have leveraged dynamic systems theory to understand suicide risk, this study will be the largest study to explore nonlinear change in suicide risk in active duty military personnel. This is important because of the elevated and rising rate of suicide among service members relative to civilians [1].

This study will improve knowledge in several areas identified by the National Action Alliance for Suicide Prevention Research Prioritization Task Force [57]. First, this study will advance our understanding of how people become suicidal because we will be able to develop and test risk models based on integrated data sources containing biological, psychological, health, and environmental variables. Second, this study will enable us to determine if processes that reduce two notable risk conditions, depression and PTSD, also reduce suicide risk, which could lead to the identification of secondary suicide-prevention strategies that could potentially mitigate or prevent the onset of suicidal ideation and behavior among high-risk subgroups. Third, this study will enable us to determine the value of using nonlinear dynamic modeling techniques for improving the detection and prediction of risk in clinical settings, especially among high-risk patient subgroups. This work stands in contrast to cross-sectional approaches with simplistic data analytic

frameworks.

Consistent with the fluid vulnerability theory of suicide [5,8,58], this study will explore both dynamic and stable properties of the change in suicide risk. For individuals with lower risk profiles, suicide risk is purported to demonstrate high stability because individuals with this profile gravitate toward a single stable state: low risk. In contrast, individuals with high risk profiles are theorized to gravitate toward two opposing stable states: one characterized by lower risk and one characterized by higher risk. Following a perturbation in suicide risk (for example, an increase in PTSD symptoms or insomnia), individuals with low risk profiles may quickly return to a low-risk state because they are drawn toward this source of stability. In contrast, individuals with high-risk profiles may take much longer to return to a low-risk state following perturbations in risk factors because these individuals are simultaneously drawn toward a low-risk and a high-risk state of stability. Under such circumstances, individuals with high-risk profiles would experience larger fluctuations in suicide risk, though this would also be expected in light of the greater suicide risk severity at the high-risk group's worst point. Furthermore, relatively small changes in clinical features (e.g., depression, insomnia, PTSD, etc.) could lead to disproportionately larger changes in suicide risk states in the high-risk group. Taken together, individuals with a lower risk profile may be drawn away from high-risk states, such that transitions to high-risk states in response to transient changes in risk factors endure for relatively brief periods of time. Individuals with a higher risk profile may instead be drawn toward high-risk states and may even cycle between low- and high-risk states. In this study, we will evaluate a variety of high- and low-risk subtypes to explore their stable and dynamic properties.

Several critical limitations of this study will require consideration. First, study results stemming from the clinical trials will only apply to active duty military personnel seeking treatment for PTSD or insomnia. While there is some diversity in gender, race, age, and branch of the military in the study, participants were mostly younger (mean age 35), male, and in the US Army, which also will limit generalizability. Second, participants in each of the randomized controlled trials received a behavioral intervention for either PTSD or insomnia. Therefore, we will need to account for the possibility of treatment differences in risk profiles over time, as well as unique predictors of risk profiles on the basis of treatment condition. Third, participants in the pre-deployment study were only measured at two time points, limiting the information that can be gleaned about the trajectory of change over time. Nevertheless, we anticipate that the results from this study will be essential to improving the understanding of the change in suicide risk over time. Fourth, dynamic systems analyses are complex and can be challenging for readers who are unfamiliar with this topic area to appreciate, which is a limitation of this approach. Wherever possible, we will attempt to present these analyses with interpretations that can be clinically useful. Fifth, dynamic systems analyses require multiple measures over time with the right timing to observe the phenomena's changes in a meaningful way. Therefore it is important to consider the timing of the data in the construction of the dynamic system to account for time differences. We will do this by entering the number of days between sessions, which varies across the studies into the analyses. This allows for notions akin to missing at random and missing completely at random from missing data theory as a way to think of our ability to recover key dynamic elements that occur over sessions. Finally, studies were conducted based on PTSD classification using the DSM-IV. Changes to the structure of PTSD in the DSM-5 may alter the interpretation of the findings, and this research should be replicated using measures from the DSM-5. STRONG STAR-CAP investigators have recently completed nine additional RCTs for the treatment of PTSD using the DSM-5 criteria. Although the primary outcome manuscripts for most of these studies have not yet been published, they will provide an opportunity in the future to compare the results from the present multi-study project using DSM-IV criteria to these other studies using DSM-5.

Study results will inform future projects aimed at reducing the

transition from lower-to higher-risk states. We will use the results from this study to identify which participants are likely to eventually become higher risk for suicide and to target prevention efforts toward those individuals in future studies. Fortunately, a variety of evidence-based treatments for suicide prevention exist, including brief treatment such as crisis response planning [3] and safety planning [53]. This study will reveal psychological and biological markers of service members who might be the most likely to benefit from brief interventions. In the future, we may be able to use information about suicidal subtypes to explore moderators of treatment response, such that some subtypes may demonstrate greater response to certain evidence-based treatments than others. Given that evidence-based treatments such as Safety Planning [59] and Crisis Response Planning [60] are associated with significant reductions in future suicidal behavior, it will important to eventually evaluate whether subgroups of participants have more favorable outcomes in these treatments. Finally, this study will improve our understanding of the effect of PTSD and insomnia treatment on suicide risk over time.

Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.conctc.2021.100752>.

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Disclaimer

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